

# WOULD PRICE TRANSPARENCY FOR GENERIC DRUGS LOWER COSTS FOR PAYERS AND PATIENTS?

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## ABSTRACT

In 2016, roughly 62,000 retail pharmacies filled over 4.4 billion drug prescriptions, costing almost \$400 billion and accounting for more than 10 percent of overall U.S. health care spending. Almost 9 of 10 retail prescriptions—4 billion—were for low-cost generic drugs, accounting for about \$100 billion in drug spending. The actual cost of the drug, or the ingredient cost, is a small fraction of what pharmacies are paid for generic drugs, where most of the payments support pharmacy dispensing costs and profits. In contrast, innovator (brand) drugs typically have much more expensive ingredients that account for most of the cost at retail pharmacies. Importantly, retail pharmacies find that selling generic prescriptions, which average \$26 per prescription, is more profitable than selling brand medicines, which average \$308 per prescription.

The U.S. system for selling prescription medicines involves multiple parties, differs markedly for generic and brand drugs, has complex, nontransparent financial arrangements, and limits available information in asymmetric ways that disadvantage third-party payers and patients. Health plans rely heavily on contracted pharmacy benefit managers (PBMs) to negotiate reimbursement terms on their behalf with retail pharmacies. However, PBMs also operate mail-order pharmacies, giving them knowledge of actual generic drug costs. To the extent that health plans pay similarly for retail and mail-order drugs, PBMs profit by keeping generic drug reimbursement generous. This disincentive to keep generic drug reimbursement low for their health plan clients poses an apparent conflict of interest for PBMs and increases health plan spending to the extent that a lack of information about actual generic drug costs leads to excessive reimbursement.

Along with providing background information on generic prescription drug pricing, this paper outlines a proposed policy to generate information on actual average prices paid by retail pharmacies to acquire generic drugs and discusses ways to minimize traditional antitrust concerns about greater transparency facilitating collusive pricing. We propose a strategy to make actual average generic drug price information selectively available to third-party payers and analyze the likely effects of limited price disclosure on competition and efficiency. If providing health plans with additional information leads to lower reimbursement to retail and mail-order pharmacies, health spending would decline by \$1 billion for every 1 percent reduction in the average reimbursement for a generic prescription, so a 4 percent reduction (equivalent to a \$1 reduction in the average price for a generic prescription) would save \$4 billion..

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# Introduction

The actual amounts paid to drug manufacturers for both branded and generic prescription medicines are secret. Actual or “net” drug prices reflect complicated arrangements among manufacturers, wholesalers, pharmacy benefit managers (PBMs), pharmacies, and health plans. Because they exclude rebates and other price concessions, the actual prices paid by end users—in this case pharmacies and health plans—are significantly lower than the public or “list” prices of most drugs. Contracts among the various players in the prescription drug market treat both negotiated reductions and net prices as confidential trade secrets. As a result, the amounts paid by a health plan and a patient for a prescription bear a tenuous relationship to publicly known prices and, for generic drugs, to what a pharmacy actually pays to acquire the medicine and what a manufacturer actually receives for that medicine.

In the retail market for generic drugs, providing payers with the average net prices pharmacies actually pay for generic drugs would shed light on how limitations on effective competition leads to health plans paying excessively more than pharmacy and wholesaler costs—known as windfalls or economic rents. We believe that selectively providing actual average drug pricing information to health plans could potentially lower generic drug spending while minimizing the risk of impairing competition by facilitating collusive pricing.

The paper begins with a discussion about shortcomings of published measures of prices paid by pharmacies and wholesalers to generic drug manufacturers. After summarizing the market for self-administered prescription drugs dispensed at retail stores and explaining different perspectives on prices, this paper assesses the likely economic effects of a limited approach to increase transparency of generic drug prices (see the Glossary on page 2 for a road map of terms used in the paper).

As in other concentrated markets, greater price transparency potentially can hamper competition and increase generic drug prices, so caution is needed. The paper discusses how the market for generic drugs differs from more typical retail markets and how accurate price information could be made available to payers to increase competition. We also outline a mechanism for efficiently collecting timely, accurate, and de-identified actual average amounts paid by retail pharmacies, net of all discounts and rebates, to manufacturers. The paper recommends a specific reform proposal but also identifies options for systematically altering the price information made available for generic drugs to allay antitrust concerns.

## Shortcomings of Reported Price Data for Generic Drug Ingredient Costs

Various companies, such as First Databank or Red Book, historically published “list” prices, such as the average wholesale price (AWP) and wholesale acquisition cost (WAC), of each of tens of thousands of products uniquely identified by an 11-digit national drug code (NDC). AWP or WAC provided the starting

point for establishing prices paid by health plans and other payers when pharmacies dispense medicines. However, these published prices omit discounts and rebates, a deficiency that in the case of federal health programs spurred dozens of False Claims Act lawsuits and creation of new indices attempting—but failing—to accurately reflect “actual acquisition costs” for pharmacies. Because actual prices generally vary significantly (but in complicated ways) from published prices, four additional perspectives can arise when assessing drug prices:

- When filling a prescription, what **total reimbursement** does a pharmacy receive from both a health plan (or its PBM) and a patient?
- What cost sharing does an **insured patient** pay for a prescription?
- What **ingredient cost** does a pharmacy actually pay to acquire a drug, net of all rebates?
- What **net revenue** does a manufacturer receive for producing and selling a drug, after reflecting the cost of all rebates?

Further complicating the picture, the economics of drug pricing diverge markedly for generic and brand medicines. The nature of competition and the related pricing issues in each market are distinct, requiring separate explanations. The rebates negotiated by brand manufacturers and PBMs (acting as agents for health plans) lower the net amount plans pay for prescriptions. As a result, rebates from a brand manufacturer lower the actual (net) costs paid by health plans, but they do not lower pharmacy ingredient costs. Because brand medicines tend to be expensive, ingredient costs for brand drugs account for the bulk of total health plan reimbursement to pharmacies. As a result, pharmacy retention—the amount retained by a pharmacy for dispensing costs and profit after deducting ingredient costs from total reimbursement—typically is a relatively small fraction of total reimbursement for brand drugs.

## GLOSSARY OF KEY TERMS

**Generic Drugs:** Approved by the FDA as “therapeutically equivalent” to the innovator (brand) product with the same clinical effect and safety profile.

**Rebates:** For ease of exposition in this paper, rebates refer to all on- and off-invoice price concessions, including rebates, discounts, chargebacks, and free goods. Rebates can occur substantially after the point of sale.

**Net Cost:** The actual price paid for a drug, including all rebates, which equals *net revenue* paid to a manufacturer.

**Ingredient Cost:** The actual amount paid by pharmacies to acquire medicines. For generic drugs, manufacturer rebates paid to pharmacies reduce ingredient cost.

**Cost Sharing:** Deductibles, coinsurance, or copayments paid by insured patients.

**Total Reimbursement:** For insured patients, the combined amount paid to pharmacies by health plans plus cost sharing; or the amount paid by uninsured patients.

**Pharmacy Retention:** The amount (also known as “gross profit”) retained by a pharmacy for dispensing prescriptions after deducting ingredient costs from total reimbursement. Retention includes both the cost of dispensing a prescription plus pharmacy profit.

**AWP, WAC, NADAC, ASP, and AMP:** Alternative measures of prices summarized in Table 1.

**Pharmacy Administrative Services Organization (PASO):** Generic drug group purchasing entity for pharmacies, run by a wholesaler or as a wholesaler-pharmacy joint-venture.

By contrast, generic manufacturers negotiate discounts and rebates either directly with pharmacies or with wholesalers, such as pharmacy administrative service organizations (PASOs) acting as pharmacies' purchasing agents. So, rebates negotiated by generic manufacturers flow to pharmacies, bypassing health plans. On average, the actual cost for a pharmacy to acquire a generic drug is a small fraction of the published price, but ingredient costs as a percent of WAC vary both by product and pharmacy. Unlike brand medicines, generic drugs tend to be relatively inexpensive commodities, with ingredient costs subject to strong price competition. Pharmacy ingredient costs average markedly less than half of generic prescription reimbursement, causing pharmacy retention—dispensing cost plus profit—for generic drugs to significantly exceed the actual price paid for the drug to generic manufacturers.

## The Market for Retail Prescription Drugs

### SIZE AND COMPOSITION

U.S. retail pharmacies dispensed 4.45 billion prescriptions in 2016, at a cost to third-party payers and patients of \$379 billion.<sup>1</sup> Annual drug spending has grown at an estimated 12.4 percent in 2014, 9.0 percent in 2015, and 5.0 percent in 2016; in 2016, retail prescription drugs constituted 10.1 percent of total U.S. health spending.<sup>2</sup> An estimated 89 percent of prescriptions, accounting for 27 percent of drug spending, were for multi-source generic drugs, at an average price of \$26 per prescription.<sup>3,4</sup> The remaining 73 percent of drug spending, associated with 11 percent of prescriptions, was for single-source innovator, or brand, drugs, at an average price of \$308 per prescription.<sup>5</sup>

About 62,000 retail pharmacies dispense prescription drugs in the United States, ranging from independent “mom and pop” pharmacies that only sell medicines and related medical supplies, to large stores selling both prescription drugs and a broad range of other goods. Over 40,000 retail pharmacies are part of drug store chains such as CVS or Walgreens, grocery chains such as Safeway, or “big box” stores such as Walmart; independent pharmacies total about 22,000.<sup>6</sup>

1 QuintilesIMS Institute. “Medicines Use and Spending in the U.S.: A review of 2016 and outlook to 2021.” (May 2017). Accessed June 5, 2017, at <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>; and Kaiser Family Foundation. “Total Number of Retail Prescriptions Filled at Pharmacies (2016).” Accessed May 25, 2017, at <http://kff.org/other/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>; and “Total Retail Sales for Prescription Drugs Filled at Pharmacies (2015).” Accessed May 25, 2017, at <http://kff.org/other/state-indicator/total-sales-for-retail-rx-drugs/?currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>.

2 Centers for Medicare and Medicaid Services. “National Health Expenditures: 2015 Highlights.” Accessed May 25, 2017, at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>.

3 The U.S. Food and Drug Administration (FDA) approves both brand and generic drugs. FDA approves drugs as generic only if they are “therapeutically equivalent” to the branded product and can be substituted for it with the full expectation that the substituted product will produce the same clinical effect and safety profile. For FDA to approve drug products as therapeutically equivalent, they must be both pharmaceutically equivalent (i.e., contains the same active ingredient(s), strength, dosage, and route of administration) and bioequivalent (i.e., performs in the same manner). <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm> See also *Orange Book Preface*, §1.2. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>; <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>.

4 Express Scripts. “2016 Drug Trend Report.” Accessed May 25, 2017, at <http://lab.express-scripts.com/lab/drug-trend-report/executive-summary>.

5 Generic Pharmaceutical Association. “2016 Generic Drug Savings & Access in the United States Report.” Accessed May 25, 2017, at <http://www.gphaonline.org/media/generic-drug-savings-2016/index.html>; and Express Scripts. “2016 Drug Trend Report.” Accessed May 25, 2017, at <http://lab.express-scripts.com/lab/drug-trend-report/executive-summary>.

6 National Community Pharmacists Association. “Independent Pharmacy Today.” Accessed May 25, 2017, at <http://www.ncpanet.org/home/independent-pharmacy-today>.

Third-party payers reimburse about 85 percent of annual spending for retail prescriptions dispensed for outpatient, self-administered drugs.<sup>7</sup> Health plans and self-insured employers typically contract with PBMs to administer prescription drug benefits for their insured enrollees.<sup>8</sup> PBMs not only process drug claims but also help health plans establish drug formularies and patient cost sharing schedules, conduct drug utilization management and review, and contract with networks of participating retail pharmacies. Acting on behalf of health plans, PBMs typically negotiate with pharmacies to set payment terms, which reimburse for drug ingredient costs, dispensing activities, and profit.

## PHARMACY REIMBURSEMENT FOR PRESCRIPTION DRUGS

Traditionally, pharmacies received separate fees for drug dispensing and ingredients. Pharmacies, however, focus on total reimbursement rather than payment of individual components. Pharmacy retention is the difference between total reimbursement and ingredient cost, which includes payments to wholesalers to acquire drugs.<sup>9</sup> Profit is the difference between retention and costs of dispensing prescriptions, such as pharmacist compensation, rent, etc. A key feature of the generic drug market is how little information most plans have about drug ingredient costs.

Estimates of and payment for dispensing costs differ significantly. Two studies report the average cost of dispensing at \$10.55 and \$11.65 per prescription in 2015, but most Medicaid agencies set substantially lower dispensing fees, which are supposed to reflect costs of dispensing. And median dispensing fees for brand and generic drugs paid to retail pharmacies by PBMs on behalf of plans averaged \$1.20 per prescription.<sup>10</sup> Several market developments are driving some reduction in pharmacy retention and calling into question the traditional expectation that reimbursement cover the cost of dispensing estimated by pharmacy groups. Many Medicare prescription drug plans have adopted narrower, or preferred, pharmacy networks as a strategy to increase plan bargaining leverage and negotiate better terms. Large retailers such as Walmart and Safeway now charge \$4 for a month's supply of some high-volume low-cost generic drugs, which in theory covers both their ingredient and dispensing costs, although some independent pharmacists allege that this is a "loss-leader" price that does not cover the full cost of the prescription. Nevertheless, the existence of prices that are substantially below the estimated cost of dispensing has tended to put pressure on pharmacy margins.

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7 CMS. "National Health Expenditure Data: Table 16: Retail Prescription Drug Expenditures; Levels, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years 1970-2015." Accessed May 25, 2017, at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

8 Third-party payers include employer coverage associated with either group insurance or self-insured plans, individual insurance (including Exchange coverage), and government financed coverage through Medicare, Medicaid, and the state Children's Health Insurance Program (CHIP). For ease of exposition, "plan" refers to any privately administered third-party payer, which includes coverage under Medicare Part D and Medicaid managed care organizations but excludes FFS coverage by Medicaid or Medicare.

9 Three large, national wholesalers (AmerisourceBergen Corp., Cardinal Health, Inc., and McKesson Corp.) account for 85 percent of drug distribution revenues. <http://www.mdm.com/2015-top-pharmaceuticals-distributors>. Wholesalers account for about 3 percent of prescription costs; CBO. "Medicaid's Reimbursements to Pharmacies for Prescription Drugs." (December 2004): 1. Accessed May 25, 2017, at <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/12-16-medicaid.pdf>.

10 Cost of dispensing studies are supposed to include a reasonable margin (profit). Medicaid agencies are supposed to set dispensing fees based on dispensing costs; currently 36 out of 51 Medicaid agencies have dispensing fees of less than \$5.00 (exceptions occur for certain medicines that are not oral solids). (CMS. "Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State." (March 2017). Accessed May 25, 2017, at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf>; National Community Pharmacists Association. "New NCPA, NACDS study finds \$10.55 cost of dispensing nationwide." (2015). Accessed June 2, 2017, at [http://www.ncpanet.org/newsroom/enews-weekly-archives/2015/10/26/new-ncpa-nacds-study-finds-\\$10.55-cost-of-dispensing-nationwide-enews-weekly-october-27-2015](http://www.ncpanet.org/newsroom/enews-weekly-archives/2015/10/26/new-ncpa-nacds-study-finds-$10.55-cost-of-dispensing-nationwide-enews-weekly-october-27-2015); Health Management Associates and Office of the Insurance Commissioner of Washington State. "Study of the Pharmacy Chain of Supply." (September 2015): 58, 60.



Increasingly for generic drugs, health plans and state Medicaid agencies rely on maximum allowable cost (MAC) limits rather than separate fees for ingredients and dispensing. MAC limits economically reward pharmacies for buying the least expensive generic product for drugs with multiple competing manufacturers. A form of reference pricing, plans pay a fixed amount for a generic medicine in lieu of a dispensing fee plus an ingredient fee that varies based on the differing published AWP or WACs set by competing manufacturers.<sup>11</sup> Savings from MAC limits depend critically on the appropriateness of the reference prices and their relationship to ingredient costs. PBM MAC limits typically substantially exceed the national average drug acquisition cost (NADAC), a measure that reflects only a subset of price concessions as discussed in Section IV.<sup>12</sup> As a result, plans using PBM-set MAC prices (as well as Medicaid MACs) pay significantly above ingredient cost.

In general, pharmacies have successfully negotiated with PBMs for total reimbursement from health plans that yield attractive margins for buying and dispensing generic drugs. Pharmacy retention tends to be largest when brand drugs must first compete with generic products, which occurs immediately after brand patent protection ends.<sup>13</sup>

Several factors have influenced why pharmacies receive favorable reimbursement terms from health plans. First, plans need to offer sufficiently attractive terms to maintain an adequate network of contracted pharmacies to provide enrollees with satisfactory access. Second, plans have rewarded pharmacies for filling prescriptions with generic instead of brand drugs because, given that generics cost substantially less than brand drugs, increasing generic substitution lowers plan costs. Third, the political influence of pharmacists with state legislatures also may constrain plan efforts to limit payments to pharmacies. Fourth, information asymmetry severely limits what health plans—but probably not PBMs—know about ingredient costs for generic drugs.

Payers have provided strong economic incentives for pharmacies to dispense generic rather than brand drugs for several decades, but “generic substitution” and “generic dispensing” have now both reached extremely high levels. The widespread consumer acceptance of generic products and strong health plan benefit design incentives to use generics has resulted in a generic substitution rate of 97.6 percent.<sup>14</sup> The almost universal dispensing of generic rather than brand drugs whenever possible, along with financial disincentives to substitute brand medicines, raises questions about the need to continue to reward

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11 Medicaid also sets “Federal Upper Limits” (FULs) for generic drugs with 3 or more manufacturers. Before a reform enacted in the Affordable Care Act (ACA, P.L. 111-148), FULs were nearly double state MACs. Post-ACA FULs averaged less than state MACs. (HHS/OIG. “Medicaid Drug Pricing in State Maximum Allowable Cost Programs, HHS/OIG OEI-03-11-00640.” (August 2013): 2. Accessed May 30, 2017, at <https://oig.hhs.gov/oei/reports/oei-03-11-00640.pdf>; and Academy of Managed Care Pharmacy. “Maximum Allowable Cost (MAC) Pricing.” (December 2013). Accessed May 30, 2017, at <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18734>; and Health Management Associates and Office of the Insurance Commissioner of Washington State. “Study of the Pharmacy Chain of Supply.” (2016). Accessed June 2, 2017, at <http://retailassociation.org/wp-content/uploads/2017/01/pharmacy-supply-chain-study.pdf>.

12 MAC prices generally ranged from WAC – 27 percent to WAC – 35 percent. Health Management Associates and Office of the Insurance Commissioner of Washington State. “Study of the Pharmacy Chain of Supply.” (September 2015): 39.

13 CBO. “Medicaid’s Reimbursements to Pharmacies for Prescription Drugs.” (December 2004): 1. Accessed May 25, 2017, at <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/12-16-medicaid.pdf>.

14 Generic substitution occurs when a different, usually generic, form of the same active substance is substituted for a prescribed branded drug. (Posner, J., and Griffin J.P. “Generic Substitution.” *British Journal of Clinical Pharmacology*. (2011) 72(5): 731-2. Accessed May 25, 2017, at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243006/pdf/bcp0072-0731.pdf>.) Generic dispensing refers to the ratio of the number of generic prescriptions dispensed divided by the total number of prescriptions. The rate of generic substitution has continued to increase over time. (Lieberman, J.N., and Roebuck M.C. “Prescription Drug Costs and the Generic Dispensing Ratio.” *Journal of Managed Care Pharmacy*. (Sept 2010). 16(7): 502-6. Accessed May 25, 2017, at <http://www.jmcp.org/doi/pdf/10.18553/jmcp.2010.16.7.502>.)

pharmacies by setting reimbursement to generate higher retention when dispensing generic rather than brand drugs. But for payers that seek to pay pharmacies less, lack of transparency about pharmacy drug ingredient costs may pose a barrier.

Health plan payments for ingredients frequently exceed pharmacies' cost to buy a drug, with the excess retained by pharmacies. After paying for the actual cost of the products when dispensing drugs, pharmacies on average retained about 23 percent of the total payment, ranging from about 14 percent of brand drug reimbursement to 70 percent of generic drug reimbursement.<sup>15</sup> Despite average prices of \$308 for a brand prescription and \$26 for a generic prescription, “[d]ispensing generic drugs was more profitable than dispensing brand drugs” for retail pharmacies.<sup>16</sup>

PBMs that own mail-order pharmacies know the ingredient costs they incur, which provides access to granular, accurate information about actual generic drug costs for high-volume purchasers. Most health plans lack a comparable information source for generic ingredient costs. To the extent that plans link reimbursement for mail-order and retail pharmacies, PBMs directly benefit from generous generic reimbursement. However, the resulting boost in PBM profitability increases health plan drug spending. To illustrate the potential effect on national health spending, if asymmetric information about ingredient costs were to enable excess pharmacy retention of 4 percent—or \$1 per prescription—plans would incur \$4.0 billion in annual costs.<sup>17</sup>

## PATIENT COST SHARING

Health plans rely heavily on differential patient cost sharing to steer enrollees to low-cost generic alternatives rather than original innovator brand drugs, to preferred brand drugs and away from nonpreferred medicines, or to mail order.<sup>18</sup> Plans tier cost sharing, commonly charging lowest out-of-pocket costs for generics, somewhat higher out-of-pocket costs for preferred brand drugs, and highest out-of-pocket costs for nonpreferred and high-cost drugs. Cost sharing for generic drugs averages \$5.54,<sup>19</sup> but the widespread offering of many common, low-cost products at \$4 in total reimbursement raises the question of whether pharmacies are systematically overpaid, given that the claimed cost of dispensing exceeds \$4.<sup>20</sup>

## PUBLISHED DRUG PRICES AND REBATES

Selling either a generic or brand prescription drug to a patient generally requires three business-to-business transactions, which precede the business-to-consumer sale. The first two business-to-business

15 CBO. “Medicaid’s Reimbursements to Pharmacies for Prescription Drugs.” (December 2004). Accessed May 25, 2017, at <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/12-16-medicare.pdf>.

16 Health Management Associates and Office of the Insurance Commissioner of Washington State. “Study of the Pharmacy Chain of Supply.” (September 2015): 6; CBO reported that pharmacies retained approximately equal dollar amounts for brand and generic prescriptions in its 2004 study at 4, *ib id*. Express Scripts. “2016 Drug Trend Report: Executive Summary.” (February 2017): 6. Accessed June 2, 2017, at <http://lab.express-scripts.com/lab/drug-trend-report/executive-summary>. Pharmacy retention measured as a percentage of brand reimbursement has almost certainly declined significantly in the years since the CBO study due to the rapid growth in brand drug prices.

17 As noted on p. 3, QuintilesIMS reports 4.45 billion retail prescriptions in 2016; with 89 percent for generic drugs, generic prescriptions equal 4.0 billion.

18 For example, plans may charge beneficiaries cost sharing equal to two monthly prescriptions for a three-month supply to encourage mail order.

19 QuintilesIMS. “Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021.” (May 2017): 21. Accessed June 6, 2017, <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016-and-outlook-to-2021>.

20 *Ibid*, 2.

transactions are the same for generic and brand drugs, but the third transaction differs for generic and brand manufacturers. The first business-to-business transaction involves a wholesaler paying a manufacturer and taking possession of the medicine.<sup>21</sup> The second involves the wholesaler delivering the medicine to a pharmacy, and the pharmacy paying the wholesaler. For the third transaction, a generic manufacturer pays rebates to reward a pharmacy, but a brand manufacturer pays rebates to PBMs, which share rebates with health plans, as explained below.

As a general rule, manufacturers use after-sale rebates to discount their prices below WAC in return for a health plan or pharmacy influencing purchasing behavior to increase the amount sold of their drug product. Rebates may be paid directly to either a pharmacy or a health plan, or may more commonly flow through wholesalers (for generic drugs) and PBMs (for brand drugs) when they act as the agent for the pharmacy or the health plan, respectively.

The final step is the business-to-consumer sale, which is identical for both generic and brand drugs. In the sale to a consumer, a pharmacy dispenses product to a patient. At the point of sale, the PBM adjudicates the claim, paying the plan's share of the total reimbursement for the prescription to the pharmacy and communicating the amount of the applicable patient cost sharing, which the pharmacy collects from the patient.<sup>22</sup>

Prescription drug sales differ from standard consumer purchases in a number of important ways. Most fundamentally, consumer choice for medicines is quite different from other products. Accessing a drug requires a physician or other licensed clinician to prescribe the therapy, based on specialized expertise and licensure to write prescriptions. Plans create formularies that differentiate among similar products or therapeutic alternatives, further influencing consumer—and prescriber—choice. Because total reimbursement for a prescription includes both the plan share and patient cost sharing, the third-party payment itself causes the point-of-sale price paid by the consumer to differ significantly from the actual cost of the product. Cost sharing for a drug may be identical in multiple pharmacies within a plan's network, further masking price signals to consumers. In addition, the unique complexity and extent of regulation—involving physicians, third-party payers, patient cost sharing, PBMs, pharmacies, wholesalers, and manufacturers—further differentiates the prescription drug market from other markets.

Traditionally, health plans and PBMs reimbursed pharmacies based on a dispensing fee plus a cost of goods sold, calculated as a percentage discount off AWP, which is the price set by manufacturers purportedly for retail transactions. However, after more than a decade of litigation arguing that AWP is not a meaningful price, health plans are increasingly replacing pharmacy reimbursement linked to AWP with WAC, the price set by manufacturers for business-to-business sales.<sup>23</sup> The business-to-business

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21 In 2013, §202(23) of P.L. 113-54, the *Drug Quality and Security Act* defined a “Trading Partner” to include “a manufacturer, repackager, wholesale distributor, or dispenser”. <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf>. Manufacturers and pharmacies increasingly rely on wholesalers to distribute drugs. For ease of exposition, “wholesaler” in this paper refers to wholesalers, distributors, and repackagers.

22 The same steps apply when a patient fills a prescription through a retail or mail-order pharmacy. PBMs are the largest operators of mail-order pharmacies.

23 §1847A(b)(4)(B) of the Social Security Act defines WAC. AWP is not defined in federal statute. WAC was traditionally set at 80 percent of AWP (Social Security Administration. “compilation of the Social Security Laws: Use of average sales price payment methodology.” Accessed on June 2, 2017 at [https://www.ssa.gov/OP\\_Home/ssact/title18/1847A.htm](https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm)).

sales contracts between manufacturers and wholesalers and between wholesalers and pharmacies tie payment to WAC, but negotiated rebates frequently lower the actual price of a drug substantially below WAC. For the past several years, list prices have been rising faster than actual (net) prices as rebates have grown. Negotiated rebates vary significantly by product, as well as by health plan or pharmacy. Both the amount of the rebates and the resulting net prices are considered trade secrets and remain confidential.<sup>24</sup> Estimates suggest that pharmacy ingredient cost for generic drugs averages about 30 percent of WAC (i.e., WAC minus 70 percent), although the percentage varies widely by drug and pharmacy. For single-source brand drugs, pharmacy ingredient cost averages about 96 percent of WAC.<sup>25</sup>

By excluding rebates, published list prices like AWP and WAC neither reflect the actual net revenue paid to manufacturers nor the actual net prices paid by pharmacies (for generics) and health plans (for brands). Prices net of rebates vary significantly based on the degree of therapeutic competition and the ability of a pharmacy or plan to move market share, with smaller volume purchasers typically paying higher net prices than larger entities. In addition to being confidential, rebate amounts may not be known until well after a prescription has been dispensed, although drug claims are normally processed in real time at the point of sale. This occurs because rebate agreements frequently make payment contingent on actual performance during a specific period, such as volume sold in a quarter or year.

## REBATES AND GENERIC DRUGS

Because the FDA approves generic products as therapeutically equivalent to an innovator (brand) drug, state licensing laws authorize pharmacists to choose among competing products (manufacturers) without seeking physician approval. The presence of multiple manufacturers tends to make generic drugs commodities, with ingredient cost subject to strong competitive pressures. Once a physician has prescribed a multi-source product with a generic equivalent, pharmacists (or wholesalers or PASOs, acting as their purchasing agents) are the key decision makers controlling the volume of drugs purchased from a specific manufacturer. As explained previously, generic rebates dramatically reduce ingredient cost and bypass health plans, which typically give all generic versions of a drug the same position in their formularies.<sup>26</sup>

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<sup>24</sup> Unlike the rebates voluntarily negotiated in other businesses, federal law established the Medicaid drug rebate program requiring manufacturers to pay state Medicaid agencies statutory rebates on prescriptions dispensed to Medicaid beneficiaries.

<sup>25</sup> As noted earlier, MAC limits reflect substantially smaller discounts from WAC, with discounts generally in the WAC minus 27 to 35 percent range. CBO reported ingredient costs for independent pharmacies average 25 percent of AWP for generic drugs but 79 percent of AWP for single-source brand drugs, with WAC averaging 82 percent of AWP. We divided percentages of AWP by 82 percent to derive equivalent percentages of WAC. Transfer pricing distorted pharmacy acquisition costs for chain and food store pharmacies (which relied on their own “warehousing” function), but recent trends have increased reliance on wholesalers and diminished the role of warehousing and direct purchasing from generic manufacturers. CBO. “Prescription Drug Pricing in the Private Sector.” (January 2007): 14, 20. Accessed May 31, 2017, at <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf>.

<sup>26</sup> Wholesalers and PASOs increasingly function as group purchasing agents for pharmacies and negotiate rebates with generic drug manufacturers, bypassing health plans and PBMs (other than through their mail-order pharmacies). For example, Medicare Part D regulations require prescription drug plans to report all “direct and indirect remuneration” except generic rebates paid to pharmacies.

Three distinct factors further complicate determining average ingredient costs:

- Ingredient costs can vary significantly for different medicines or over time for the same medicine, which can occur in response to changes in the number of manufacturers making a product or the availability of raw materials.
- Specific purchasers can negotiate rebates that vary significantly from the average, which causes many pharmacies (typically with smaller volumes) to pay prices that are above the average, while large-volume entities typically pay less than the average ingredient cost.
- Rebates may not be determined until well after a prescription has been dispensed, despite drug claims, including any cost sharing, normally being processed in real time at the point of sale. Rebate agreements generally tie the amount of payment to actual performance on specified measures during a period, such as the volume of product purchased in a calendar quarter or year. The retrospective computation delays knowing the actual rebate payments—and the resulting net price—until weeks (if not months) after patients and health plans have paid for the prescriptions.

Secrecy, complexity, and variation in negotiated discounts mask the net amounts a specific pharmacy pays to a manufacturer to buy generic products. As a general rule for generic drugs, neither the average ingredient cost nor the net revenue paid to a manufacturer is publicly available information. Although PBMs know the ingredient costs paid by their mail-order pharmacies, most health plans do not have a similar information source for generic drug pharmacy rebates and ingredient costs.

## REBATES AND SINGLE-SOURCE DRUGS

Despite the net cost and revenue of both generic and brand drugs being masked by secrecy, complexity, and variation in rebates, single-source brand drugs differ fundamentally from multi-source (generic) drugs. Brand drugs are chemically unique products approved by the FDA that must be dispensed as prescribed by a physician. Unlike with multi-source drugs, only physicians—but not pharmacists— can substitute another product for a brand medicine. Thus, changing the volume of brand drug sales requires influencing the prescribing physician, which manufacturers do by contacting physicians directly through so-called detailing or influencing patient preferences through direct-to-consumer advertising or coupons that reduce enrollee cost sharing.<sup>27</sup> Health plans also can influence consumer preferences by assigning differing cost sharing levels (“tiers” or formulary positioning) to similar drugs (therapeutic substitution), making them key decision-makers affecting the volume of a brand product purchased from a specific manufacturer.

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27 Health plans have “pharmacy and therapeutics” (P&T) committees, which are typically comprised of doctors and pharmacists. A P&T committee organizes drugs intended to treat the same medical conditions into “therapeutic classes,” deciding which drugs are “preferred” versus “non-preferred” (or excluded outright from their “formulary”) based, in part, on the price concessions offered by manufacturers. A therapeutic class reflects a specific methodology for classifying drugs but generally refers to a set of medications that have similar chemical structures, the same mechanism of action (i.e., bind to the same biological target), a related mode of action, and/or are used to treat the same disease. American Society of Health-System Pharmacists. “ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System.” *American Journal of Health-System Pharmacists*. (2008)65:1272-83; <https://www.ashp.org/-/media/assets/pharmacy-practice/pharmacy-topics/preceptor-skills/formulary-guidelines-pt-committee-formulary-system.ashx?la=en>. See also [https://en.wikipedia.org/wiki/Drug\\_class](https://en.wikipedia.org/wiki/Drug_class).

# Need for a Meaningful Drug Price Average Actual Acquisition Cost Index

Despite reflecting list rather than actual prices, WAC provides a reasonable approximation of actual pharmacy acquisition costs for single-source brand drugs. However, as explained previously, WAC does not provide a reliable indication of ingredient costs for generic drugs. This section briefly reviews widely used measures of drug prices and their attributes, highlighting that none of the existing measures make actual average net prices for self-administered generic drugs publicly available.

Rebates reduce list prices, with the size of the negotiated rebates varying according to purchasers' characteristics. Under standard economic theory, price discrimination—selling the same product at different prices to different buyers—can maximize manufacturer sales and profits. But the confidentiality generally required to maintain vigorous price competition may play havoc with public reporting of actual drug prices. Without access to actual prices, plans do not know the net cost paid by pharmacies to acquire generic drugs, an information asymmetry that may contribute to economic rents—windfalls—that inflate societal costs for pharmaceuticals.

Americans filled over 4.0 billion prescriptions for inexpensive generic drugs in 2016. The high volume of low-cost generic medicines is only possible with a highly automated, low-cost system for distributing products and administering claims. The efficient distribution, sale, and claims processing of prescription drugs are predicated on having standard prices widely available for use in both business-to-business and business-to-consumer transactions. The first drug price index (AWP) was created half a century ago to facilitate automated pricing and reimbursement of prescriptions by establishing standard (list) prices. AWP's were set by drug manufacturers and quickly became widely adopted as the standard method for reimbursing pharmacies.<sup>28</sup>

Starting with a 1969 *Federal Register* notice, the federal government has repeatedly warned that AWP's were not actual transaction prices.<sup>29</sup> Nonetheless, since the mid-2000s, dozens of states (on behalf of their Medicaid agencies, often in conjunction with *qui tam* whistleblowers) have sued more than 70 generic and brand drug manufacturers, alleging violations of the federal False Claims Act and arguing that their Medicaid programs had relied on AWP to set pharmacy reimbursement on the assumption that the published prices represented “real” prices.

In addition, the publishers of drug pricing guides also have been sued, prompting them to agree to stop publishing AWP.<sup>30</sup> AWP was widely recognized as dramatically overstating actual (net) drug costs, prompting President Bill Clinton to devote a White House Saturday radio address to decrying wasteful

28 Pennebaker, G. “The Rest of the AWP Story.” *ComputerTalk*. (January/February 1998). 18(1):6-7. AWP has never been defined in federal statute or regulations.

29 *Federal Register*, Vol 34, 1969, 1244; and *Federal Register*, Vol. 39, No 230, Nov 27, 1974, 41480-81. Accessed May 25, 2017, at <https://cdn.loc.gov/service/ll/fedreg/fr039/fr039230/fr039230.pdf>.

30 Although sometimes renamed, AWP continues to be published and remains the basis for pharmacy reimbursement in many plans. (Swanson, B. “The Impact of AWP Litigation on Your PBM Contract.” *Milliman Health Perspectives*, (August 2009.) Accessed May 25, 2017, at [https://www.us.milliman.com/insight/Periodicals/health-perspectives/pdfs/Summer-2009/.](https://www.us.milliman.com/insight/Periodicals/health-perspectives/pdfs/Summer-2009/))

Medicare spending because reimbursement was based on AWP.<sup>31</sup> After years of failed attempts to end Medicare reimbursement for Part B drugs based on AWP, the Medicare Modernization Act of 2003 (MMA) shifted Part B reimbursement from AWP to a newly created average sales price (ASP) methodology, except for certain vaccines and a limited number of other medicines.<sup>32</sup>

For each drug, a manufacturer has established the WAC, which commonly equaled 80 percent of AWP. Originally intended to represent a wholesale price, WAC is typically the contractual starting point for business-to-business contracts involving manufacturers, wholesalers, and pharmacies, which comprise key participants in the pharmaceutical distribution system. The MMA defined WAC for the first time in federal statutes, specifying it as a list price that explicitly excludes discounts and rebates.

In addition to WAC, federal statutes define three other measures of drug prices. The Congress created average manufacturer price (AMP) in 1990 as part of the Medicaid drug rebate program, specifying that AMP was a net price that incorporated all discounts and rebates. As a condition of being able to sell their products to Medicaid enrollees, manufacturers must agree to reduce the cost of their drugs by paying rebates to Medicaid. Unless special circumstances have triggered another basis for determining manufacturer liability, rebates statutorily equal a specified percentage of AMP.<sup>33</sup> Basing rebates on these lower net (rather than list) prices has had the effect of tying rebate amounts to the revenues a manufacturer actually receives.

Participating manufacturers must report AMP for each 11-digit NDC, which constitutes the most granular level for identifying a prescription medicine. The Secretary of Health and Human Services (HHS) has issued detailed regulations and program guidance instructing manufacturers on how to report AMPs, which they report quarterly to CMS. Importantly, AMPs are legally treated as trade secrets, available only for administering the Medicaid rebate program, not publicly disclosed, and subject to strict confidentiality.

Years after creating the Medicaid drug rebate program defining AMP, the Congress established the average sales price (ASP) methodology in the 2003 MMA, which also defined WAC. Unlike WAC, ASP is a net price that includes discounts and rebates. CMS publicly reports ASPs on a quarterly basis but only for the limited subset of drugs covered by Medicare Part B.<sup>34</sup> ASPs are published at a relatively aggregated level, averaged across different strengths, package sizes, routes of administration, and, if applicable, manufacturers. As a result, each publicly reported ASP typically combines prices and rebates from multiple NDCs into a single average price reported at the Medicare billing (“J”) code level.

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31 “Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price, for drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price.” (President William Jefferson Clinton, The President’s Radio Address at the White House (Dec.13, 1997). the Weekly Compilation of Presidential Documents. (Dec. 22, 1997) 33(51): 2033-34. Accessed May 25, 2017, at <http://www.gpo.gov/fdsys/pkg/WCPD-1997-12-22/html/WCPD-1997-12-22-Pg2033-2.htm>.)

32 *The 21st Century Cures Act* (P.L. 114-255), enacted in 2016, moved many of the remaining Part B medicines reimbursed at AWP to ASP.

33 Congress has increased statutory Medicaid rebates over time; they currently equal 23.1 percent of AMP for brand drugs and 13 percent of AMP for generic drugs, with certain other drugs at 17.1 percent. Rebate liability may increase if a manufacturer has increased prices (since launch) faster than the consumer price index (CPI-U) or has created a lower “best price”. <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>.

34 Part B predates the Medicare prescription drug benefit created in 2003 (i.e., Part D). Part B only covers physician administration drugs, drugs treating cancer or certain vaccines, and infused or inhaled drugs. Reporting for both ASP and AMP reflects a two-quarter lag after sales have actually occurred.

In response to Congress calling for a measure of actual average pharmacy acquisition costs for Medicaid, CMS created the NADAC to report nationally representative prescription drug costs. NADAC reports the results of a monthly survey conducted by an accounting firm, Myers and Stauffer, of a limited number of NDCs at 2,000 to 2,500 pharmacies. Limitations of NADAC include pharmacies opting out of the voluntary survey and only reporting so-called on-invoice discounts, which omit significant off-invoice rebates.<sup>35</sup> These limitations undermine the accuracy of NADAC in reporting actual net prices. Another important NADAC deficiency is failure to account for the common practice of large purchasers that reflect all price concessions at a high-volume corporate point of intake (such as at a warehouse) and charge undiscounted prices to its retail pharmacies.<sup>36</sup>

As summarized in Table 1, none of the five main measures of drug prices publicly reports either ingredient cost or the average net amount paid to a manufacturer for a drug. AWP and WAC are list prices that exclude discounts and rebates. NADAC reports a hybrid of net and list prices that omit important off-invoice rebates and have other significant limitations. ASP reports net prices only for a limited set of drugs on an aggregated basis, combining prices and rebates from multiple NDCs into a single average price, with a two-quarter lag after sales have actually occurred. AMP includes all discounts and rebates and is reported at the 11-digit NDC level but is strictly confidential and not publicly reported.

**TABLE 1: KEY ATTRIBUTES OF 5 DRUG PRICE MEASURES<sup>37</sup>**

ATTRIBUTE	AVERAGE WHOLESAL PRICE (AWP)	WHOLESALE ACQUISITION COST (WAC)	NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC)	AVERAGE SALES PRICE (ASP)	AVERAGE MANUFACTURER PRICE (AMP)
List or Net Price	List	List	Hybrid	Net	Net
Confidential/ Public?	Public	Public	Public	Public	Confidential
Discounts/ Rebates	Excluded	Excluded	Off-Invoice/ Transfer Pricing Excluded	Included	Included
Applicable to	All NDCs	All NDCs	Sample of NDCs	Part B Drugs	All NDCs
Level of Reporting	11-digit NDC	11-digit NDC	Drug Group	J Code (NDCs Aggregated)	11-digit NDC
Source	Manufacturers; Publishers	Manufacturers; Publishers	CMS (voluntary data collection)	CMS (required reporting)	CMS (required reporting)
Timing	Daily	Daily	Weekly	Quarterly (2 Q Lag)	Quarterly (2 Q Lag)
Year Created	1969	1974	2012	2003	1990
Federal Statute	NA	42 USC 1395w-3a(c)(6)(B)	42 USC 1396r-8(f)	42 USC 1395w-3a(c)	42 USC 1396r-8k(1)

35 CMS. "Draft Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)." (June 28, 2012): Slides 11 and 12. Accessed June 2, 2017, at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/june28webinar508.pdf>.

36 NADAC permits this practice known as "transfer pricing". An example of this practice is reported by Myers and Stauffer. "Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky." (October 2003): 2, 26. Accessed June 2, 2017, at <http://chfs.ky.gov/NR/rdonlyres/93B0FC55-1E01-40F8-B755-BC58425C8559/0/dispensingacquisition.pdf>.

37 CMS. "Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs." (June 2012) Accessed May 25, 2017, at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-Pdrugs/downloads/narpdraftmethodology.pdf>.



# Using Actual Average Acquisition Costs: How to Collect Needed Data

The *Drug Quality and Security Act* (P.L. 113-54, enacted in 2013) requires licensing of all wholesalers either by states meeting federal requirements or, for nonapproved states, directly by HHS. We propose that the federal government require, as a condition of licensure, that wholesalers report to CMS in a standardized, electronic format, ingredient costs for all retail sales of multi-source (generic) drugs, capturing all rebates that flow among manufacturers, wholesalers, and retail pharmacies. Under this approach, each wholesaler would report to CMS its actual average net prescription drug price for each 11-digit NDC sold to retail pharmacies.<sup>38</sup> Data reported to CMS would be comprehensive, timely, and accurate, reflecting actual average retail prices for generic drugs, net of all on- and off-invoice price concessions to pharmacies. CMS would aggregate the highly granular data reported from each wholesaler to compile de-identified, composite average actual prices. As discussed in the next section, policymakers would have multiple options regarding the nature, granularity, and availability of data made available to payers and, potentially, the public.

As detailed in the Proposal Specifications on page 14, we propose to make timely, accurate data on actual average acquisition costs for generic drugs available to payers (but not others). Access to the average prices would require participating payers to comply with stringent nondisclosure requirements. The data would be reported at a national level that aggregates NDCs produced by multiple manufacturers and distributed in significant volume by at least two wholesalers.<sup>39</sup> The proposal would build on the sophisticated electronic systems used by wholesalers to have them report the ingredient cost data on a weekly or biweekly basis using a common format developed in consultation with the industry. CMS would maintain the reported data on a confidential basis, similar to AMP data. Unlike AMP data, CMS would report actual average acquisition costs for drugs to participating payers but any reported average would not permit re-identification of net prices associated with specific customers, which might require adopting different disclosure rules based on the characteristics associated with particular products.<sup>40</sup>

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38 The HHS Secretary would need to specify in regulations how to “smooth” reporting of estimated rebates where actual amounts are finalized outside of the reporting period, avoid duplicate counting of rebates, specify which sales should be included, assure that the reported prices would not permit re-identification of prices (i.e., by “reverse engineering” the information) to specific customers, and resolve other technical issues associated with implementation. Although pharmacies increasingly rely on wholesalers rather than buying directly from generic manufacturers, the proposal creates incentives for pharmacies to bypass wholesalers to avoid reporting actual ingredient costs. To forestall such an “end run”, we recommend giving the Secretary of HHS authority to require reporting of all rebates in the pharmacy distribution system.

39 Both Medi-Span and First Databank have systems for classifying active ingredients, Generic Product Identifier (GPI) and Generic Sequence Number (GSN), respectively. These two, widely used systems classify drugs based on having the same active ingredient, strength, route, and dosage form; they permit organizing products based on more or less stringent criteria, such as having the same active ingredient but differing package sizes. <http://phsrx.com/blog/gpi-vs-gsn>.

40 Statistical agencies such as the Census Bureau and the Bureau of Labor Statistics use a variety of techniques, such as “multiple noise masking” and limitations on disclosure (e.g., minimum number of observations) to prevent re-identification of survey respondents.

## PROPOSAL SPECIFICATIONS

1. As a condition of licensure, the proposal would require each wholesaler, for each NDC it sold in a biweekly reporting period, to electronically report to CMS data in a standard format that would reflect all price concessions associated with retail U.S. sales of multi-source prescription drugs.
2. CMS would collect, securely store, and analyze NDC-level data reported by wholesalers.
3. CMS would issue necessary rules and guidance. Examples of potential subjects include: clarifying how wholesalers should report interim estimates when final data are unavailable (e.g., rebates based on performance during a year); assuring that disclosed data would remain confidential and could not be “reverse engineered” in a manner that would permit re-identification of the prices associated with any particular manufacturer, wholesaler, or pharmacy; and creating special rules for concentrated market segments to preclude limiting competition, such as might occur for a particular medicine with only one manufacturer.
4. CMS would calculate reportable actual average acquisition costs by combining NDC data based on active ingredient, dosage, strength, and route of administration.
5. CMS would disclose computed actual average acquisition costs for generic drugs at retail pharmacies on a biweekly basis to authorized (plan) users. CMS would have the authority to specify the most appropriate approach for securely communicating the information, which might parallel how it currently communicates with health plans using secure internet portals for each participating plan.
6. CMS would charge participating plans a user fee to cover ongoing operating costs.

# Analysis of Effects of Limited Generic Cost Disclosure on Competition and Efficiency

Limited public availability of generic ingredient average cost data potentially could lower generic drug prices at retail pharmacies for plans and their enrollees. Accurate data on generic drug ingredient costs would influence two distinct transactions—prices paid to manufacturers by pharmacies, typically through wholesalers, and prices paid to pharmacies by health plans but negotiated on the plan’s behalf by PBMs. Purchasers may have a good sense of their bargaining power with a supplier, but with only limited knowledge of the supplier’s cost structure, it is difficult to use that power effectively.

Although economists have done little research on the degree to which a buyer’s knowledge of a seller’s cost structure in a market where both sides are consolidated can lead to lower prices, some data support this. In collective bargaining, union knowledge of employer profitability influences the size of

wage increases.<sup>41</sup> In the retail purchasing of automobiles, consumer and other organizations provide to members information on net prices paid by dealers to manufacturers with the expectation that this will aid consumers in negotiating prices. Although we do not know the extent to which consumers with this information obtain lower prices, the persistence of these tools suggests such information sharing may work. In health care, a recent study shows that hospitals with access to information on what other hospitals paid for coronary stents were able to achieve significant savings. Twenty-six percent of the total potential savings from access to the price information were achieved.<sup>42</sup> Similarly, more knowledge of pharmacies' cost structure likely would lower costs to health plans.

PBMs are the entities actually negotiating reimbursement terms with pharmacies on behalf of plans. Since PBMs generally operate large-volume mail-order pharmacies, they have detailed information about the rebates they negotiate that reduce WAC to actual generic drug acquisition cost. But industry observers question how aggressively PBMs use this information to minimize pharmacy reimbursement for generic drugs. Negotiating the lowest possible prices with pharmacies would most likely lead to lower margins for PBM mail-order operations, which effectively "shadow price" retail reimbursement. So, more accurate cost information would affect market competitiveness not by informing PBMs but by informing their health plan clients. If these clients become better informed about the magnitude of margins generated in both retail and mail-order pharmacy, they likely could obtain better terms.

Antitrust authorities have long had concerns about how publication of prices in concentrated markets can have anti-competitive effects, with the Federal Trade Commission publishing guidelines about which types of price publication might be challenged.<sup>43</sup> Concerns center on the risk of price transparency fostering collusion and that sellers will be less motivated to selectively cut prices when competitors can learn about price changes quickly and match them.<sup>44</sup>

Industry-level data on concentration in the generic manufacturing sector have limited relevance because the markets are drug-specific. A generic manufacturer can have a 40 percent market share overall, but if it is one of ten manufacturers for a popular generic drug, it likely has little pricing power for that drug. Conversely, a manufacturer with only a 5 percent overall market share might be one of only two competitors manufacturing another generic drug. Because manufacturer concentration and the level of competition vary from drug to drug, the risk that transparency will lead to higher prices is important for some drugs but not others.

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41 Acemoglu D. "Asymmetric Information, Bargaining and Unemployment Fluctuations." *International Economic Review*. (November 1995). 36(4): 1003-1024.

42 Grennan, M, and Swanson A. "Transparency and Negotiated Prices: The Value of Information in Hospital-Supplier Bargaining." *NBER*. (February 2016). Accessed June 2, 2017, at <http://www.nber.org/papers/w22039>.

43 See for example, [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf).

44 Consider an example of a market with two hospitals and many insurers. Hospital A would like to gain market share from hospital B and is considering offering one of these insurers a larger discount if the insurer would in turn use its benefit design to steer more patients their way. But this strategy would not work for hospital A if its additional discount was immediately visible to hospital B. In this case, hospital B could match hospital A's discount and avoid the loss in market share, leaving hospital A with no gain in market share but reduced revenue. But in this situation, by knowing the rational response of its competitor, hospital A would not initiate the discount and would keep prices higher than they would be in the absence of transparency.

Thus, the reporting to participating health plans of net price data needs to be done with care. In our proposal, detailed data would be provided only to plans that have signed strict confidentiality agreements. Market averages would normally be reported at the active ingredient, dosage, strength, and route of administration, but reported data would be aggregated to higher levels if necessary to avoid potential re-identification of specific transactions or entities. Both because most pharmacies are part of national chains or purchasing organizations and ingredient costs generally do not significantly vary by region, only national data would be reported. Steps like these and others discussed below would reduce if not eliminate the risk that transparency could raise prices.

The degree of transparency could be adjusted by using different strategies for reporting average acquisition cost information. As an example, rather than reporting prices at an ingredient, dosage, strength, and route of administration level, more aggregated approaches could parallel Medicare Part B rules for reporting ASP. Commercial tools, such as those available from Medi-Span and First Databank, offer multiple options for categorizing generic drugs that could be used to produce more (or less) granular data. Another option is to restrict transparency for market segments with limited competition or that are otherwise heavily concentrated. Similarly, reporting could be more aggregated based on the potential for re-identification if reported at the normal level of specificity. Another option would be changing the frequency with which average prices are reported and/or disclosed.

An additional lever for calibrating transparency involves the rules for making average acquisition cost data available. For example, more entities could be permitted to have access to the data, confidentiality restrictions could be relaxed, or penalties for disclosure could be strengthened. Other options might include differentiating how data are made available, making more granular or more current information available only to participating plans on a confidential basis but making more aggregated or less current data more broadly available, or allowing researchers to have access either to selected data or under well-defined conditions.

Finally, it is possible to adopt an incremental approach, starting with limited disclosure of relatively aggregated data. Demonstration authority could be used to test more granular disclosure or other innovations for specific classes of drugs. Examples could include medicines that have many competing manufacturers or other products with attributes suited to greater transparency while not adversely affecting competition. Central to this approach would be rigorous evaluation of the results on competition and prices.

# Conclusion

The U.S. system for selling prescription medicines is complex, shrouded in secrecy, and likely results in higher than justifiable spending for retail generic prescription drugs. A major cause of limitations in competitive generic drug pricing appears to be third-party payers' lack of information about actual prices paid by retail pharmacies to wholesalers and manufacturers for generic ingredients. Complicating the situation, PBMs, which should be negotiating better retail generic drug prices from retail pharmacies for their health plan clients, have a perverse incentive to keep pharmacy reimbursements artificially high because their mail-order pharmacy operations benefit from the higher reimbursement.

Policymakers should take steps to increase competition by making actual generic drug pricing information selectively available to third-party payers through a thoughtful and well-designed program that will allay antitrust concerns that greater transparency could diminish rather than enhance competition. To the extent that providing health plans with additional information leads to lower reimbursement to retail and mail-order pharmacies, health spending would decline, with savings of \$4 billion for every \$1 reduction in the average reimbursement for a generic prescription.