United States Government Accountability Office

Report to Congressional Requesters

August 2016

GENERIC DRUGS UNDER MEDICARE

Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases

GAO-16-706

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GAO Highlights

Highlights of GAO-16-706, a report to congressional requesters

Why GAO Did This Study

Medicare is the largest public payer for prescription drugs, representing 29 percent of total retail prescription drug spending in 2014. Generic prescription drugs have been a source of cost savings for the U.S. health care system due to their lower costs relative to brand-name drugs. However, recent price increases of certain generics may limit cost savings.

GAO was asked to examine price trends for generic drugs and the factors that affect prices. This report describes 1) how generic drug prices under Medicare Part D have changed over time; 2) the extent to which generic drugs under Medicare Part D experienced extraordinary price increases, the persistence of any increases, and their effect on benefit design; and 3) the factors stakeholders identified as contributing to price changes.

GAO analyzed Medicare Part D claims data from the first quarter of 2010 through the second quarter of 2015, the most recent data available. Based on the data, GAO created price indexes to show price trends; determined the number of drugs that had an extraordinary price increase of 100 percent or more; and tracked whether the increased price remained at 100 percent or more for an additional year. GAO also interviewed drug manufacturers, Medicare Part D plan sponsors, pharmacy benefit managers, relevant trade associations, and economics experts to identify factors contributing to generic drug price changes.

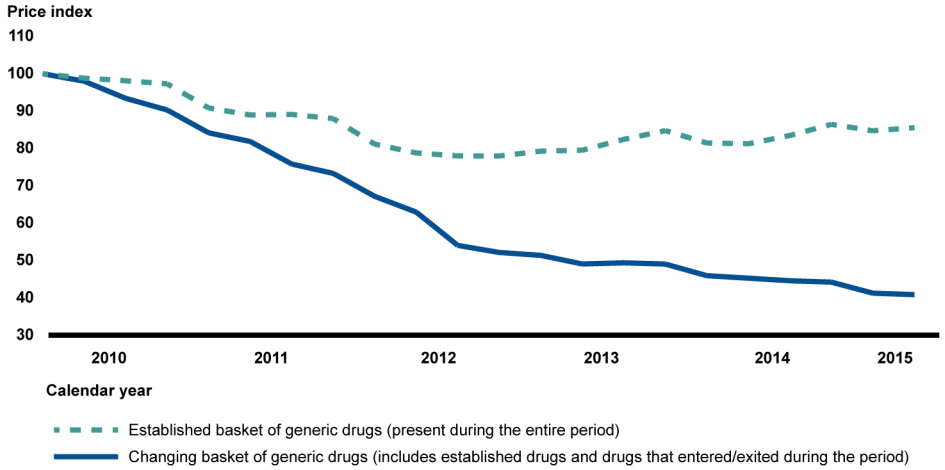
HHS reviewed a draft of this report and provided technical comments, which were incorporated as appropriate.

View GAO-16-706. For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

Generic drug prices declined overall under Medicare Part D—the voluntary outpatient prescription drug program administered by the Centers for Medicare & Medicaid Services within the Department of Health and Human Services (HHS)—since 2010. Specifically, generic drug prices fell 59 percent from the first quarter of 2010 through the second quarter of 2015. This decline reflects a changing basket of 2,378 unique generic drugs, including those that came into or exited the market during this period. GAO also analyzed an established basket of 1,441 generic drugs that were present during the entire period of analysis. Unlike the larger changing basket of drugs, prices of established generics decreased moderately and then increased slightly (see figure). The steeper price decrease for the changing basket of generic drugs is at least partially attributable to more rapid price declines among new generic drugs as they enter the market.

Medicare Part D Generic Drug Price Trends for All Generics and Established Generics, First Quarter 2010 to Second Quarter 2015



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

More than 300 of the 1,441 established generic drugs analyzed had at least one extraordinary price increase of 100 percent or more between first quarter 2010 and first quarter 2015. GAO found that drugs with extraordinary price increases moderated the overall decline in generic drug prices. Additionally, the extraordinary price increases generally persisted for at least 1 year and most had no downward movement after the extraordinary price increase. Given the low cost of generic drugs relative to their brand counterparts, stakeholders indicated limited changes to benefit design, including drug coverage.

Manufacturers reported that competition, determined by the price and availability of the same drug from other manufacturers, is the primary driver of generic drug prices, as less competition could drive prices higher. Stakeholders noted that the level of competition in the generic drug market is influenced by a variety of factors, including raw material shortages, production difficulties, consolidation among manufacturers, and a backlog of new generic drug applications awaiting federal review.

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Abbreviations

ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GDUFA	Generic Drug User Fee Amendments of 2012
HHS	Department of Health and Human Services
PBM	pharmacy benefit manager
PDE	prescription drug event

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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August 12, 2016

Congressional Requesters

In 2014, the United States spent about $297.7 billion on retail prescription drugs, which was approximately 12 percent of the estimated $2.6 trillion spent on overall personal health care services.[1] The use of generic drugs—that, on average have retail prices that are 75 to 90 percent lower than the retail prices of brand-name drugs—can provide significant cost savings to the U.S. health care system.[2] Generic drugs not only lower costs for individuals in the form of lower copayments and other out-of-pocket costs, but they also lower costs for third-party payers—including private health insurance plans and public programs. Medicare, which provides health care coverage for the elderly, certain persons with disabilities, and individuals with end-stage renal disease and is administered by the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS), is the largest public payer of prescription drugs, representing about 29 percent of total spending on retail prescription drugs in 2014. In that year, Medicare provided health coverage to nearly 54 million beneficiaries, of which more than 40 million were enrolled in Medicare's voluntary, outpatient drug benefit, known as Medicare Part D. Generic drugs are an

[1]Data are from the 2014 National Health Expenditure Accounts and provide estimates of total national spending on health care services by category. Retail prescription drug purchases include those that occur in pharmacies and drug stores (including both chain and independent), supermarkets and other grocery store pharmacies, mail-order and other direct-selling establishments, department stores, warehouse clubs and supercenters, and all other general mass-merchandising establishments. Personal health care services include spending for medical goods and services, including prescription drugs that are rendered to treat, or prevent, a specific disease or condition.

[2]A generic drug is chemically equivalent to its branded counterpart and is generally marketed by multiple manufacturers under a nonproprietary name; generic drugs can be introduced with the Food and Drug Administration's (FDA) approval after the patent for the branded counterpart has expired. The lower prices of generic drugs have been analyzed for older Americans by the Congressional Budget Office and AARP. See Congressional Budget Office, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending* (Washington, D.C.: September 2010) and Stephen W. Schondelmeyer and Leigh Purvis, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 2013*, AARP Public Policy Institute (Washington, D.C.: February 2016).

important component of Medicare Part D, as 84 percent of the prescriptions dispensed under Medicare Part D in 2013 were for generic drugs.

Recent increases in the price of certain generic drugs may limit the cost savings for third-party payers, including Medicare Part D, and the availability of these drugs to consumers under their plan benefits. Members of Congress have raised questions about these recent increases, as significant price increases of generic drugs can impose additional costs on beneficiaries and drive up the costs incurred by the federal government under Medicare Part D and other federal health programs.

Given the widespread interest in generic drug prices, you asked us to look into generic drug price trends and the factors that affect the prices. This report examines

1. how generic drug prices have changed over time under Medicare Part D;
2. the extent to which generic drugs under Medicare Part D experienced extraordinary price increases, the persistence of any increases, characteristics of these drugs, and their effect on benefit design; and
3. the factors selected manufacturers and other stakeholders have identified as contributing to the change in generic drug prices.

To examine how generic drug prices have changed over time under Medicare Part D, we tracked generic drug prices using prescription drug event (PDE) data from CMS that contain pharmacy claims for all prescription drugs dispensed under Medicare Part D. We analyzed PDE data from the first quarter of 2010 through the second quarter of 2015, which was the most recent data available at the time we conducted our analysis.[3] We grouped claims with the same active ingredient, strength, dosage form, and route of administration to represent a generic drug.[4] For

[3]Due to data availability at the time we conducted our study, the second quarter of our 2015 Medicare Part D claims data is limited to data from April and May.

[4]The dosage form is the physical form in which a drug is produced and dispensed, such as a tablet or capsule; route of administration is the way of administering a drug to a site in a patient, such as taking a drug orally. To identify these characteristics, we used information from Red Book which is a compendium published by Truven Health Analytics.

each quarter, we calculated the price of each generic drug using the median per-unit ingredient cost—such as a dollar per tablet—among all claims for that drug.[5] To track the change in prices for generic drugs for our period of analysis, we created two price indexes. One index tracks the prices of a changing basket of drugs, which includes established drugs—that is, drugs that were billed under Medicare Part D for each quarter of our study—and drugs that were only billed for part of our time period, such as new generic drugs that became available or drugs that exited the market in the middle of our study period. The other index tracks the prices of only established drugs.[6] For a more detailed explanation of our methodology, see appendix I.

To determine the extent to which generic drugs under Medicare Part D experienced extraordinary price increases, we calculated the annual change in price for each established drug and identified the number of drugs that experienced an annual price change of 100 percent or more at any point during the period of our analysis.[7] Our analysis of extraordinary price increases was limited to established drugs to avoid including drugs that may have experienced large prices changes simply as a function of entering or exiting the market. We calculated the change in price for each drug between the first quarter of one year and the first quarter of the next year, for example the change between the first quarter of 2010 and the first quarter of 2011. To examine the persistence of any extraordinary price increases, we tracked whether the increased price remained at 100 percent or more above the original price for at least 1 additional year. We also examined characteristics of drugs that experienced an annual extraordinary price increase including route of administration, therapeutic

[5]The ingredient cost is the amount paid for the drug itself. This does not include other costs often associated with purchasing a drug, such as sales tax and a dispensing fee.

[6]To ensure drugs were not newly introduced immediately prior to when we begin tracking prices—in the first quarter of 2010—we required a drug to be billed in all four quarters of 2009 to be included in our basket of established drugs.

[7]Consistent with previous work, we defined an extraordinary price increase as an increase of 100 percent or more. See GAO, *Brand-Name Prescription Drug Pricing: Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases,* GAO-10-201 (Washington, D.C.: Dec. 22, 2009).

class, and drug utilization.[8] To understand the effect of generic drugs with extraordinary price increases on benefit design, such as changes to drug formularies, we interviewed Medicare Part D stakeholders, including six of the largest private insurers that sponsor Medicare Part D plans and the pharmacy benefit managers (PBM) that manage these plans' pharmacy benefits.[9] We selected the plan sponsors based on Medicare Part D enrollment data as of December 2014. In total, these Medicare Part D plans represent about 65 percent of all Medicare Part D beneficiaries as of December 2014.[10] We also conducted interviews with pharmacy trade associations and five academic economics experts to understand the impact of generic drug prices on benefit design and the economic factors influencing generic drug prices.

To examine the factors that contribute to changes in generic drug prices, we interviewed selected stakeholders involved in the manufacturing, distribution, and payment of generic drugs, including five generic drug manufacturers; various trade associations representing generic drug manufacturers, health insurance companies, PBMs, pharmacies, and drug wholesalers; and the Medicare Part D plan sponsors and PBMs we

[8]Therapeutic class represents groups of drugs that possess a similar chemical structure and similar therapeutic effects, such as ophthalmologic agents, and drug utilization represents the volume of Medicare Part D claims for that particular drug, such as low or high volume.

[9]A formulary is a list of the prescription drugs covered by an insurance plan.

[10]We interviewed representatives from UnitedHealth Group and its PBM, OptumRx, which also serves as a PBM for other health plans; Humana Inc., which operates its own PBM serving its own health plans; CVS Health Corporation, which operates a PBM for its health plans and other health plans; Express Scripts Holding Company, which operates a PBM for its health plans and others; WellCare Health Plans, Inc. which currently uses CVS Health Corporation as its PBM but previously used Optum; and Kaiser Foundation Health Plan, Inc. which operates its own pharmacies.

discuss above.[11] We also interviewed the five academic economics experts and reviewed relevant literature to inform our understanding of the generic drug industry.

Our findings on how generic drug prices have changed and those drugs that experienced an extraordinary price change are limited to Medicare Part D and not generalizable to all generic drugs. Additionally, our findings on the effects of generic drug price changes on benefit design and the factors contributing to generic prices are limited to the selected manufacturers and other stakeholders we interviewed. To ensure that the data used to produce this report were sufficiently reliable, we took several steps. Specifically, we interviewed CMS officials responsible for overseeing and collecting the Medicare PDE data about steps taken to assess reliability. For these data and the Medicare enrollment data used to select Medicare Part D plan sponsors to interview, we reviewed relevant documentation; examined the data for obvious errors, such as missing values and values outside of expected ranges; and compared the results to other published reports to ensure accuracy, when possible. We determined that all data sources were sufficiently reliable for the purposes of our reporting objectives.

We conducted this performance audit from June 2015 to August 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[11]We selected three of the manufacturers—Mylan, Sandoz, and Teva Pharmaceuticals—because they were among the manufacturers with the most claims and highest total ingredient costs in the Medicare Part D data in the first quarter of 2015. In order to obtain the opinion of smaller manufacturers, we selected two manufacturers—G&W Laboratories and Nephron Pharmaceuticals—that were not among those with the highest ingredient costs and claims, but had more than $1 million in ingredient costs and had more than 100,000 claims. The trade associations we interviewed were Generic Pharmaceutical Association, which represents generic drug manufacturers; America's Health Insurance Plans, which represents health insurance companies; Pharmaceutical Care Management Association, which represents PBMs; National Association of Chain Drug Stores and National Community Pharmacists Association, which represent chain and independent pharmacies; and Healthcare Distribution Management Association, which represents drug wholesalers.

Background

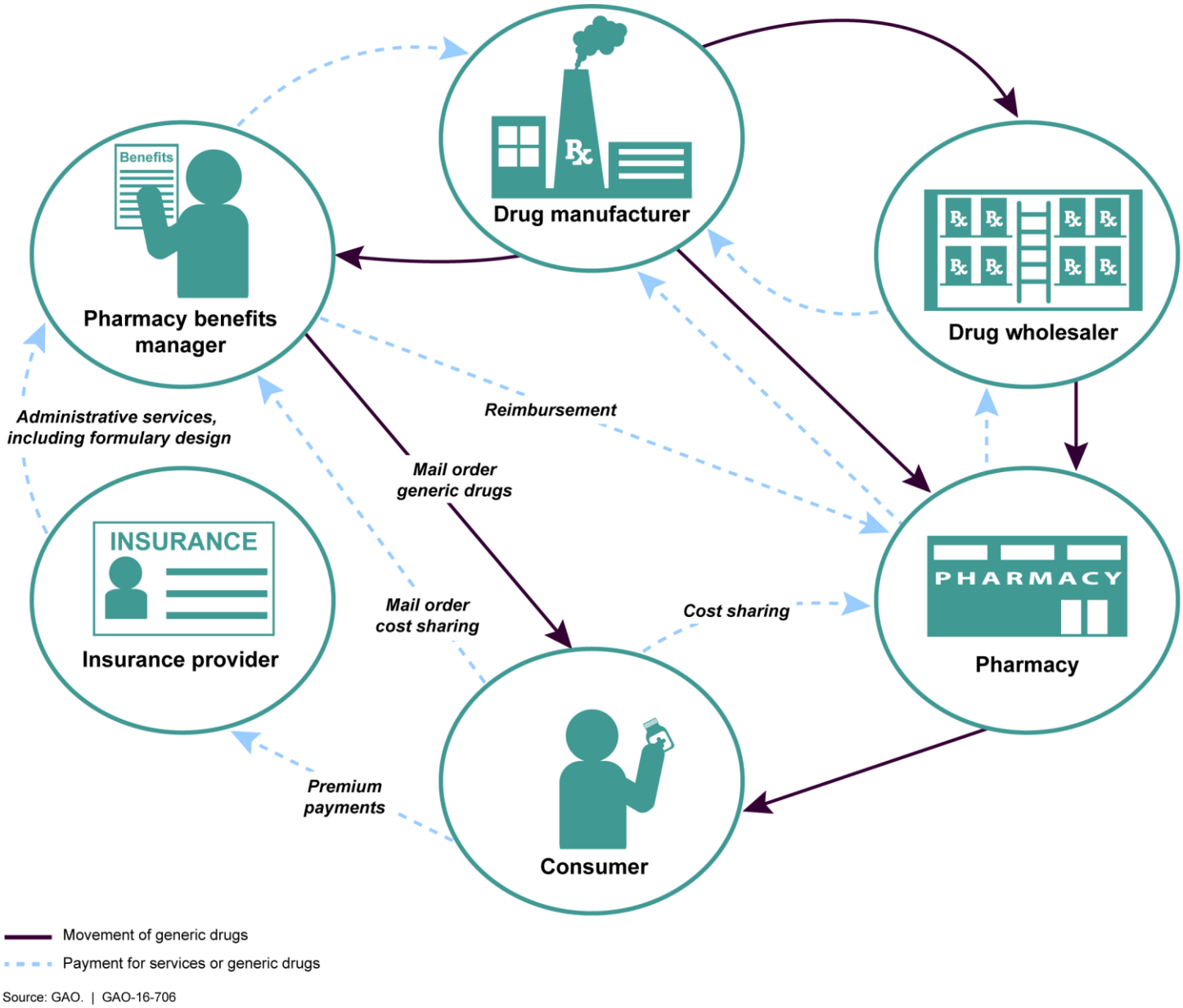
Distribution of and Payment for Generic Drugs

The distribution of and payment for prescription drugs dispensed by retail and mail order pharmacies, including generics, involves interactions among multiple commercial entities. These entities include drug manufacturers, wholesalers, retail pharmacies, and third-party payers that provide insurance coverage and their PBMs.

Drug manufacturers sell their drugs directly to pharmacies or to drug wholesalers, who in turn sell drugs to the pharmacies. Pharmacies dispense prescription drugs to consumers. Most consumers purchasing drugs pay a portion of the drug's price in the form of a copayment or coinsurance, with this cost sharing dictated by the consumers' insurance coverage. Consumers purchase insurance coverage from a third-party payer.

Third-party payers include private insurance plans, such as those offered by large corporations, and public health plans, such as those offered by the federal government through programs such as Medicare Part D. Third-party payers may use PBMs to help them manage their prescription drug benefits, including claims processing and assembling networks of retail pharmacies where the beneficiaries can fill prescriptions. PBMs may also operate mail-order pharmacies—highly automated facilities that fill prescriptions from a central location and deliver the prescription directly to the consumer. Contract terms and conditions between PBMs and pharmacies may include specifics about negotiated reimbursement rates (how much the pharmacy will be paid for dispensed drugs) and payment terms (e.g., the frequency with which the third-party payer or its PBM will reimburse the pharmacy for dispensed drugs), among other things. The reimbursement rate that third-party payers or their PBMs pay pharmacies affects pharmacy revenues. Retail pharmacies participating in a PBM's network are typically reimbursed for generic prescriptions according to the maximum allowable cost, which is set according to contract terms, and can vary between pharmacies. (See fig. 1, which shows the different entities involved in the distribution of and payment for generic drugs.)

Figure 1: Key Interactions and Stakeholders Involved in the Distribution of and Payment for Generic Drugs



Source: GAO. | GAO-16-706

Medicare Part D

Medicare Part D provides voluntary, outpatient prescription drug coverage for Medicare, the federally financed health insurance program for eligible individuals 65 years and older, certain individuals with disabilities, and individuals with end-stage renal disease and is administered by CMS.

Medicare Part D beneficiaries can enroll in stand-alone prescription drug plans, which add drug coverage to original fee-for-service Medicare and certain Medicare plans, or in Medicare Advantage prescription drug plans, which provide Medicare benefits and prescription drug coverage through a single privately managed plan. In 2014, federal spending on Medicare Part D totaled approximately $78 billion, or about 13 percent of total Medicare expenditures.[12] Medicare beneficiaries can obtain coverage for outpatient prescription drugs by choosing from multiple competing plans offered by third-party payers, known as plan sponsors—primarily private health insurers—that contract with CMS to offer the prescription drug benefit. These drug plans may differ in the monthly premiums charged to beneficiaries; beneficiary cost sharing, such as coinsurance or copayments; pharmacies available in-network and out-of-network for beneficiaries to fill prescriptions; and the drug prices negotiated with pharmacies. Each plan also has a formulary (a list of the prescription drugs that it covers) and plan sponsors select the coinsurance or copayment amount that beneficiaries must pay for each listed drug.[13] For drugs included on their formularies, plan sponsors may assign drugs to tiers that correspond to different levels of cost sharing. Plan sponsors submit formularies for their plans to CMS for review and approval on an annual basis. With certain exceptions, negative changes to a plan's formulary—such as a drug removal, which could restrict beneficiaries' access to drugs—require CMS's review and approval. Copayments for generic drugs under Medicare Part D ranged from $0 to $13 in 2016, depending on the plan and whether the generic drug is included as a preferred or nonpreferred generic on the plan sponsor's drug formulary.[14]

[12]Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2015 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (Washington, D.C.: July 22, 2015).

[13]Sponsors must adhere to a minimum set of formulary requirements. Sponsors generally must include at least two drugs within each therapeutic category and class of covered Medicare Part D drugs. Exceptions are allowed; for example, when there is only one drug in a particular category or class. In addition, CMS requires that formularies include "all or substantially all" drugs within six designated categories of clinical concern. See 42 U.S.C. § 1395w-104(b)(3)(C)(i); 42 C.F.R. § 423.120(b)(2)(2015); CMS, Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.2.5 (2016).

[14]A preferred drug is a drug for which beneficiary cost-sharing is lower (i.e., the drug has a preferred position), compared to a nonpreferred drug for which beneficiary cost-sharing is higher. Medicare Payment Advisory Commission, "Chapter 13: Status Report on Part D," *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 2016).

Plan sponsors also determine whether any utilization management practices apply for each listed drug, such as limits on the amount of drug that can be provided.[15]

Medicare Part D Generic Drug Prices Have Fallen Overall Since 2010 Due to the Modest Price Decline of Established Drugs and the Rapid Price Decline of New Generic Drugs

Prices under Medicare Part D fell rapidly from the first quarter of 2010 through the fourth quarter of 2012 and then declined moderately thereafter through the second quarter of 2015 for our changing basket of nearly 2,400 generic drugs—that is, drugs that were continuously billed under Medicare Part D and those that were only billed for part of our time period.[16] Overall, prices declined by 59 percent, or 4.2 percent per quarter on average, from the first quarter of 2010 through the second quarter of 2015. While the price for our changing basket of drugs continued to fall throughout our time period, the declines were faster earlier in our study period compared to the later years. For example, the average quarterly decline from the first quarter of 2010 through the fourth quarter of 2012 was 5.7 percent, while the average quarterly decline from the fourth quarter of 2012 through the second quarter of 2015 was 2.4 percent.

In contrast, prices decreased moderately from 2010 through 2012 then plateaued or increased slightly through second quarter 2015 for our basket of 1,441 established generic drugs—that is, drugs that were continuously billed under Medicare Part D for each quarter during our study period.[17] Overall, prices for this basket of drugs declined by 14 percent, or 0.7 percent per quarter on average, from the first quarter of 2010 through the second quarter of 2015, but trends varied over time.

[15]These utilization management practices can include (1) step therapy, which requires that a beneficiary try lower-cost drugs before a sponsor will cover a more costly drug; (2) prior authorization, which requires a beneficiary to obtain the sponsor's approval before a drug is covered for that individual; and (3) quantity limits, which restrict the dosage or number of units of a drug provided within a certain period of time. Utilization management practices are subject to CMS approval.

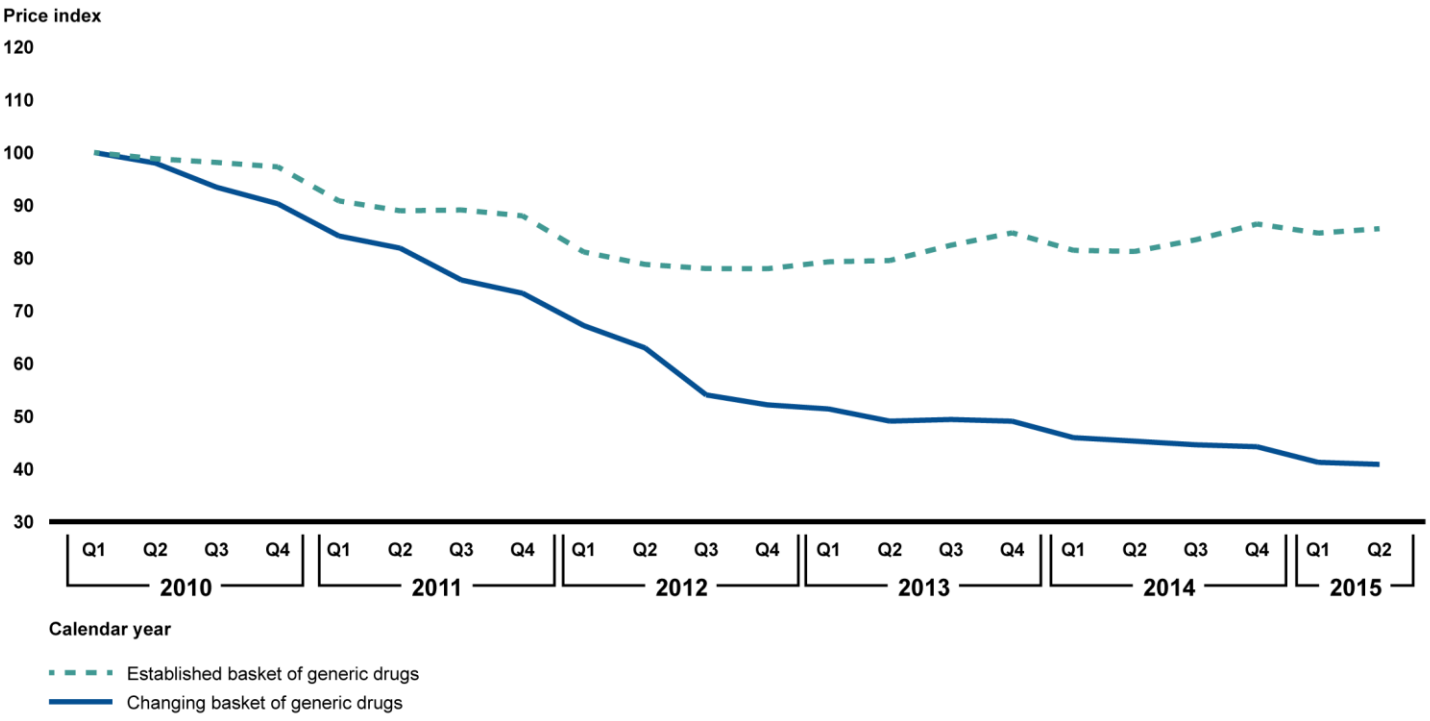
[16]For the changing basket of drugs, the number of drugs included in each period varies from 1,733 to 2,124. For example, the period from the first quarter of 2010 to the second quarter of 2010 has 1,733 drugs. A total of 2,378 unique drugs were included across our study period.

[17]The price trend among established generic drugs is driven by oral medications, such as tablets or capsules, because such drugs represent a large majority of the 1,441 established drugs in our analysis. However, we found different patterns for other types of drugs. For more information on these other patterns, see appendix II.

Specifically, we found that the price for this established basket of generic drugs decreased by 22 percent, or about 2.2 percent per quarter on average, from the first quarter of 2010 through the fourth quarter of 2012. From that point until the second quarter of 2015, however, the price of our established generic drug basket increased by 10 percent, or about 0.9 percent per quarter on average, which was four times the overall rate of general inflation of approximately 2.3 percent over the same time period.[18] (See fig. 2 for the price trends for the changing and established baskets of drugs.)

[18]To calculate the overall rate of general inflation, we analyzed data from the Bureau of Labor Statistics' May 2016 detailed CPI report. Specifically, we analyzed data for the historical chained consumer price index for all goods for urban consumers. We calculated the total growth rate from October 2012 through May 2015 since our 2015 Medicare Part D data ended in May.

Figure 2: Price Trends under Medicare Part D for the Changing Basket and Established Basket of Generic Drugs, First Quarter 2010 through the Second Quarter 2015



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

Note: For the changing basket of all generic drugs, the number of drugs included in each period varies from 1,733 to 2,124. For example, the period going from the first quarter of 2010 to the second quarter of 2010 has 1,733 drugs. A total of 2,378 unique drugs were included across our study period. To be considered an established drug, a drug had to be in the Medicare Part D claims data for each quarter from the first quarter of 2009 through the second quarter of 2015 and meet certain other data reliability standards. A total of 1,441 drugs met these criteria. Due to data availability at the time we conducted our study, the second quarter of our 2015 Medicare Part D claims data is limited to data from April and May.

The steeper price decrease experienced by our changing basket of generic drugs compared to our established basket is at least partially attributable to rapid price declines among new generic drugs, which are in our changing basket but not the established one. We found that prices declined much more rapidly for generic drugs newly billed under Medicare Part D relative to established generic drugs. For example, from the first quarter of 2010 through the first quarter of 2011, we found that the price

of our basket of newly billed generic drugs decreased by approximately 54 percent compared to a decline of less than 10 percent for established drugs.[19]

More Than 300 Established Generic Drugs under Medicare Part D Had an Extraordinary Price Increase, Most of Which Persisted, but Had a Limited Effect on Benefit Design

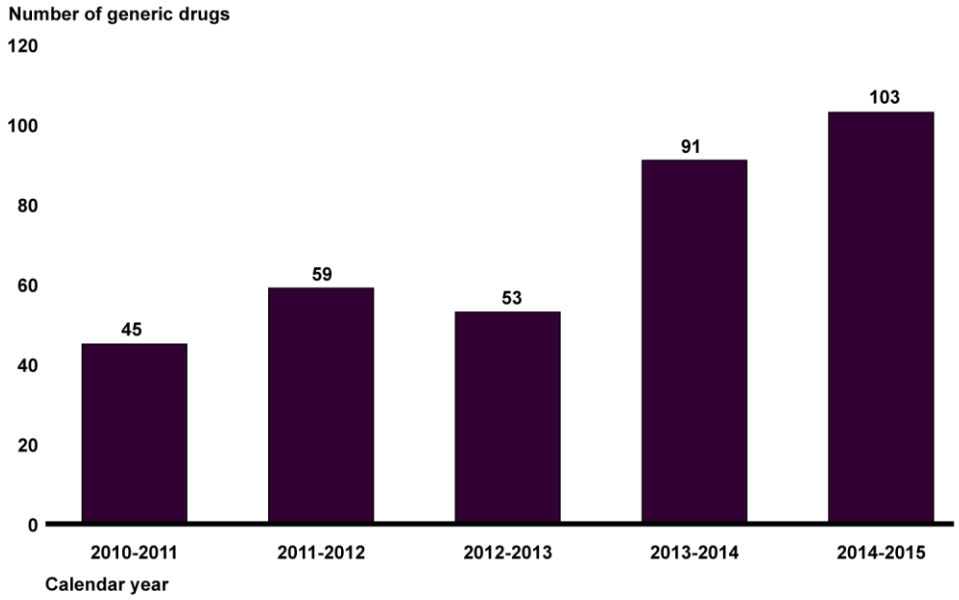
More Than 300 Established Generic Drugs Had an Extraordinary Price Increase from 2010 to 2015, and These Increases Have Moderated Generic Drug Price Declines

From first quarter 2010 to first quarter 2015, 315 of the 1,441 established drugs experienced an extraordinary price increase—a price increase of at least 100 percent—while many other generic drugs continued to decline in price. The number of established generic drugs that experienced an extraordinary price increase in a given year more than doubled over our study period from 45 drugs between the first quarter of 2010 to the first quarter of 2011 to 103 drugs between the first quarter of 2014 to the first quarter of 2015 (see fig. 3). In contrast, approximately 50 percent or more of all established generic drugs in each year (between 687 and 851)

[19]As a proxy to demonstrate the price effect of generic drugs that were introduced under Medicare Part D during the years of our analysis, we separately tracked these newly billed drugs and constructed a price index consisting only of those drugs. We then compared the price change for these drugs to the price change for established drugs.

experienced a price decrease from the previous year over our study period.[20]

Figure 3: The Number of Established Drugs under Medicare Part D That Experienced an Extraordinary Price Increase, First Quarter 2010 to First Quarter 2015



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

Note: A price increase of at least 100 percent from the first quarter of one year to the first quarter of the next is considered an extraordinary price increase. To be considered an established drug, a drug had to be in the Medicare Part D claims data for each quarter from the first quarter of 2009 through the second quarter of 2015 and meet certain other data reliability standards. A total of 1,441 drugs met these criteria.

Across our study period, the 315 established drugs experienced 351 extraordinary price increases.[21] Because we calculated an extraordinary

[20]In addition to those drugs that had an extraordinary price increase of 100 percent or more and those that declined in price, other drugs in our analysis remained flat or had an increase in price of less than 100 percent. Depending on the time period, the number of these drugs ranged from 499 to 701.

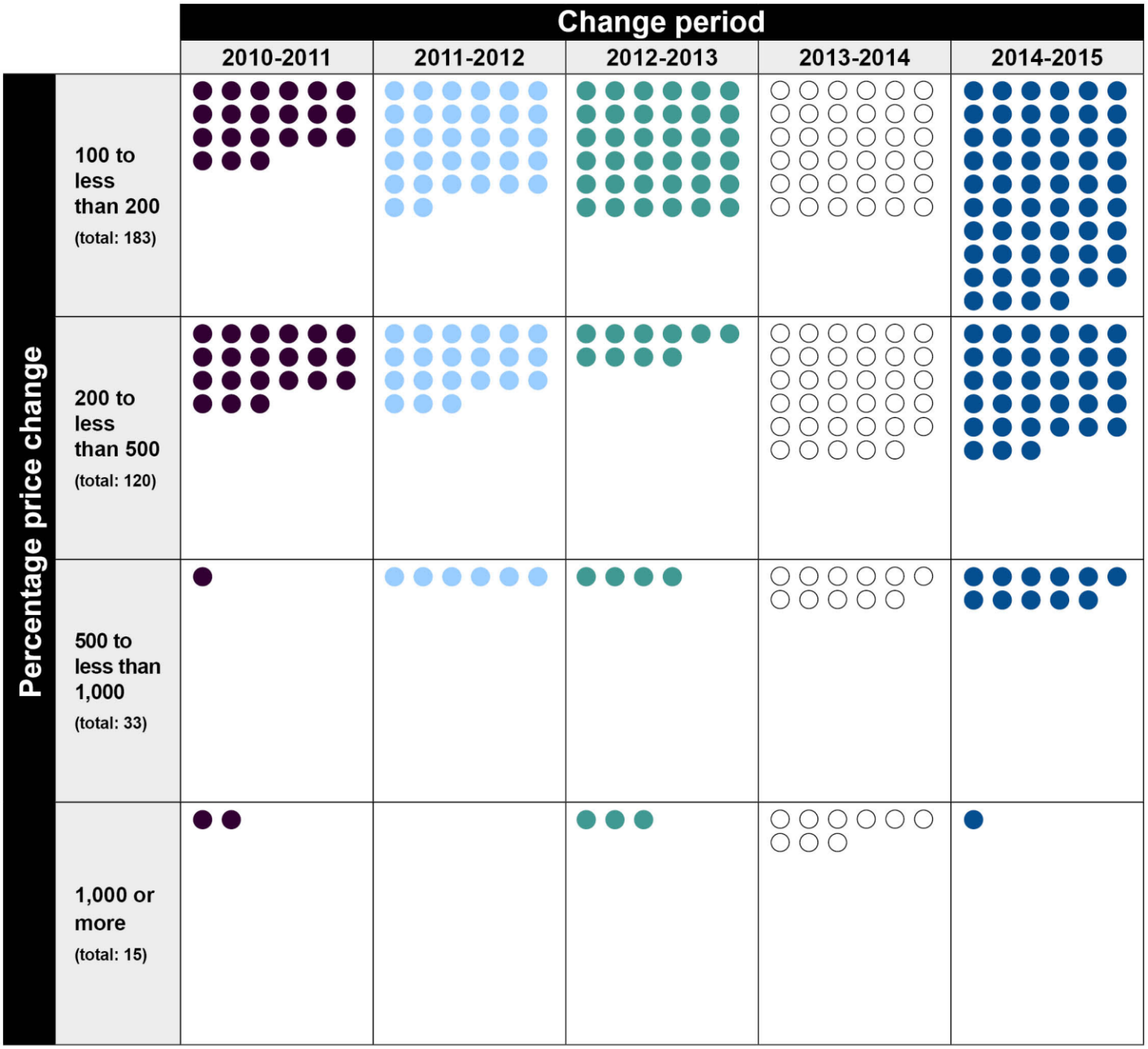
price increase as a 100 percent increase from the first quarter of one year to the next, a single drug could experience multiple price increases. (For a complete list of the drugs that experienced an extraordinary price increase and the year of the increases, see app. III.) From first quarter 2010 to first quarter 2015, 280 drugs experienced one extraordinary price increase, 34 drugs experienced two extraordinary price increases, and 1 drug experienced three extraordinary price increases. Specifically, the antibiotic drug, erythromycin/500mg/tablet/oral, had three separate price increases of at least 100 percent, with the price of the drug increasing from $0.24 per tablet in the first quarter of 2010 to $8.96 per tablet in the first quarter of 2015.[22]

While most extraordinary price increases were between 100 and 200 percent, a small number of the increases were substantially higher (see fig. 4). Specifically, out of the 351 extraordinary price increases, 48 were 500 percent or higher and 15 were 1,000 percent or higher. For example, the drug clomipramine HCL/50mg/capsule/oral, an antidepressant used to treat symptoms of obsessive-compulsive disorder, increased over 2,000 percent in 1 year, going from $0.34 per capsule in the first quarter of 2013 to $8.43 per capsule in the first quarter of 2014. In contrast, 183 out of the 351 extraordinary price increases were less than 200 percent. For example, the drug hydrocortisone/20mg/tablet/oral, a steroid, increased approximately 160 percent in 1 year, from $0.16 per tablet in the first quarter of 2012 to $0.41 per tablet in the first quarter of 2013. As this last example demonstrates, some extraordinary price increases still may not result in a very high price because the beginning price was relatively low.

[21]Because we define a generic drug at the active ingredient/strength/dosage form/route of administration level, several extraordinary price increases can be associated with one active ingredient. For example, phenobarbital is available in both a 30 mg tablet and a 60 mg tablet, among other strengths. In our analysis, these different strengths would be considered different generic drugs, even though they have the same active ingredient, phenobarbital. Across all years of our study, the 351 extraordinary price increases were associated with 157 unique active ingredients.

[22]The price of erythromycin/500mg/tablet/oral per tablet in the first quarter of each year was as follows: $0.24 in 2010, $0.89 in 2011, $1.40 in 2012, $3.00 in 2013, $4.39 in 2014, and $8.96 in 2015.

Figure 4: Distribution of Extraordinary Price Increases under Medicare Part D, by Year of Increases

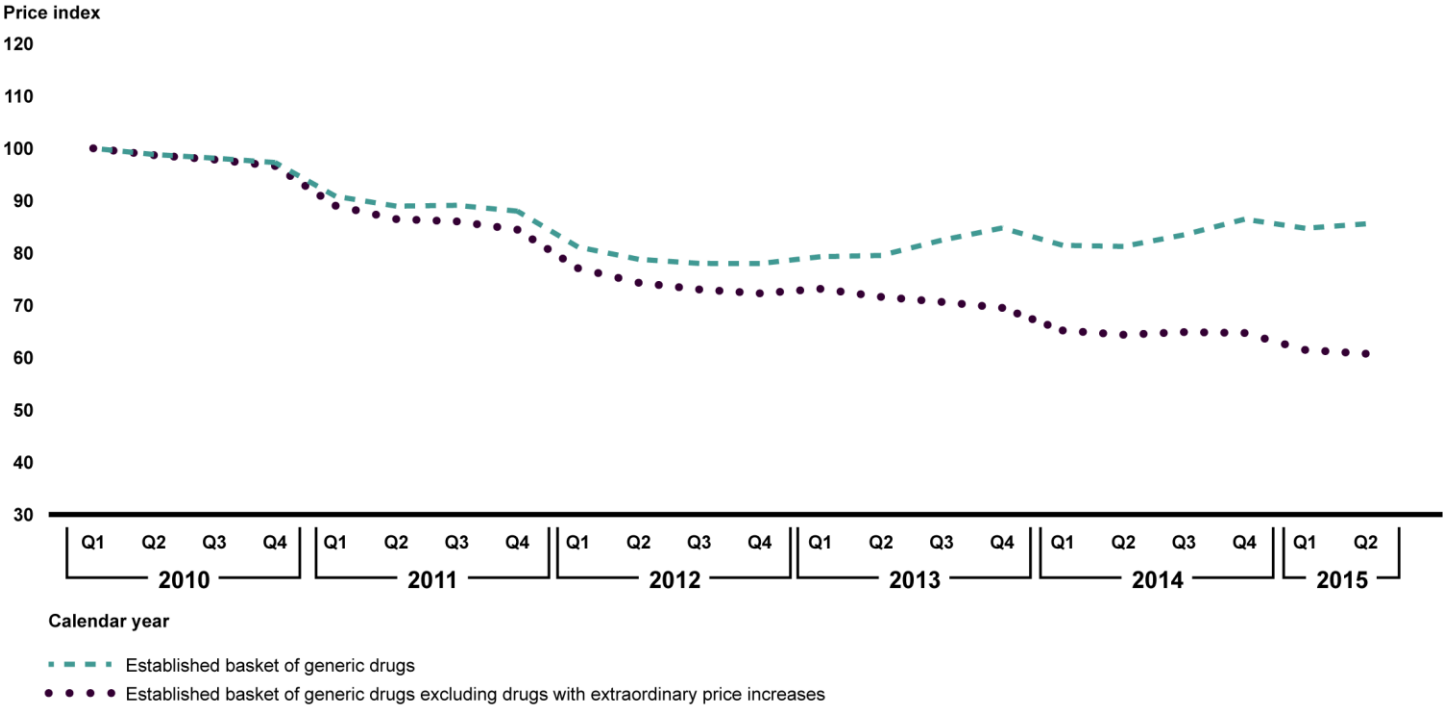


Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

Note: A price increase of at least 100 percent from the first quarter of one year to the first quarter of the next is considered an extraordinary price increase.

The 315 drugs that experienced an extraordinary price increase during our study period have moderated the decline in generic drug prices for our basket of 1,441 established drugs, despite only representing slightly more than one in five established generic drugs. To isolate the effect that drugs with extraordinary price increases had on the average price of our basket of 1,441 established drugs, we recalculated our established drug index after excluding the 315 drugs that experienced an extraordinary price increase at any point in our study and compared that to our full basket of established drugs. We found that these 315 drugs increased the average price of our established drug basket by 25 percentage points by the end of our study period. Specifically, by the second quarter of 2015, the average price for our basket of established generic drugs that excluded these 315 drugs fell by about 39 percent, while the average price for all 1,441 established drugs fell by only 14 percent (see fig. 5). These results suggest that the change in price for the established drug basket in the latter half of our study period is likely driven, at least in part, by the share of drugs experiencing large price increases.

Figure 5: Price Trends under Medicare Part D for All Established Drugs and Established Drugs without an Extraordinary Price Increase, First Quarter 2010 through the Second Quarter 2015



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

Note: To be considered an established drug, a drug had to be in the Medicare Part D claims data for each quarter from the first quarter of 2009 through the second quarter of 2015 and meet certain other data reliability standards. A total of 1,441 drugs met these criteria. A total of 1,126 drugs were included in the basket of drugs that did not experience an extraordinary price increase. Due to data availability at the time we conducted our study, the second quarter of our 2015 Medicare Part D claims data is limited to data from April and May.

Most Extraordinary Price Increases Persisted for at Least 1 Year, and Certain Drugs Were More Likely to Experience These Increases

Of the 351 annual extraordinary price increases that occurred from first quarter 2010 to first quarter 2015, we were able to track 248 of these annual increases for 1 or more additional years, and found that nearly all persisted at 100 percent or more above the original price for at least 1 year.[23] For example, tracking extraordinary price increases that occurred from the first quarter of 2010 to the first quarter of 2011, 44 of the 45 increases (98 percent) persisted at 100 percent or more above the original price as of the first quarter of 2012. In addition, for the 157 extraordinary price increases that we could track for longer periods of time, we found that these increases tended to persist at 100 percent or more above the original price longer than a year (see table 1). For example, the drug piroxicam/20mg/capsule/oral, a nonsteroidal anti-inflammatory drug that can be used to treat rheumatoid arthritis or osteoarthritis, increased by more than 2,000 percent, from $0.09 per capsule in first quarter 2010 to $1.94 per capsule in first quarter 2011. By first quarter 2015, the price of this drug had fallen to $1.82 per capsule, but that price remained over 1,900 percent above the original price.

[23]We were unable to track extraordinary price increases that occurred from the first quarter of 2014 to the first quarter of 2015 because data for the first quarter of 2016, 1 year after the price increase, were not available at the time we conducted our study.

Table 1: Number of Extraordinary Price Increases That Persisted at 100 Percent or More Above the Original Price for Generic Drugs under Medicare Part D, First Quarter 2010 to First Quarter 2015

Year of extraordinary price increase	Number of extraordinary price increases	Number of extraordinary price increases persisting after 1 year (percent)	Number of extraordinary price increases persisting after 2 years (percent)	Number of extraordinary price increases persisting after 3 years (percent)	Number of extraordinary price increases persisting after 4 year (percent)
2010-2011	45	44 (98%)	44 (98%)	44 (98%)	43 (96%)
2011-2012	59	59 (100%)	59 (100%)	58 (98%)	N/A
2012-2013	53	52 (98%)	50 (94%)	N/A	N/A
2013-2014	91	87 (96%)	N/A	N/A	N/A
2014-2015	103	N/A	N/A	N/A	N/A

Legend: N/A=not applicable

Source: GAO analysis of Medicare Part D prescription drug event data and Red Book. | GAO-16-706

Note: A price increase of at least 100 percent from the first quarter of one year to the first quarter of the next is considered an extraordinary price increase. Cells with "N/A" indicated that we were unable to track the prices of drugs beyond the period for which our data was available (that is, after the second quarter of 2015). For example, we were unable to track extraordinary price increases that occurred from the first quarter of 2014 to the first quarter of 2015 because data for the first quarter of 2016, one year after the price increase, were not available at the time we conducted our study.

Furthermore, we found that most extraordinary price increases had no downward movement in the subsequent years, with 184 of the 248 extraordinary price increases remaining at the same level or higher one year after the original increase. For example, one drug in our analysis used to treat glaucoma, methazolamide/50mg/tablet/oral, experienced a price increase of approximately 454 percent from about $0.33 per tablet in first quarter 2010 to $1.85 per tablet in first quarter 2011. By first quarter 2015, the drug's price had further increased and experienced an additional extraordinary price increase, ending at $5.47 per tablet, about 1,538 percent above the original price.

While the price increases for some drugs were extraordinary and persistent, our analysis found that generic drugs with extraordinary price increases were often not among the top 100 most utilized established generic drugs under Medicare Part D.[24] With the exception of the drugs that experienced extraordinary price increases from first quarter 2013 to

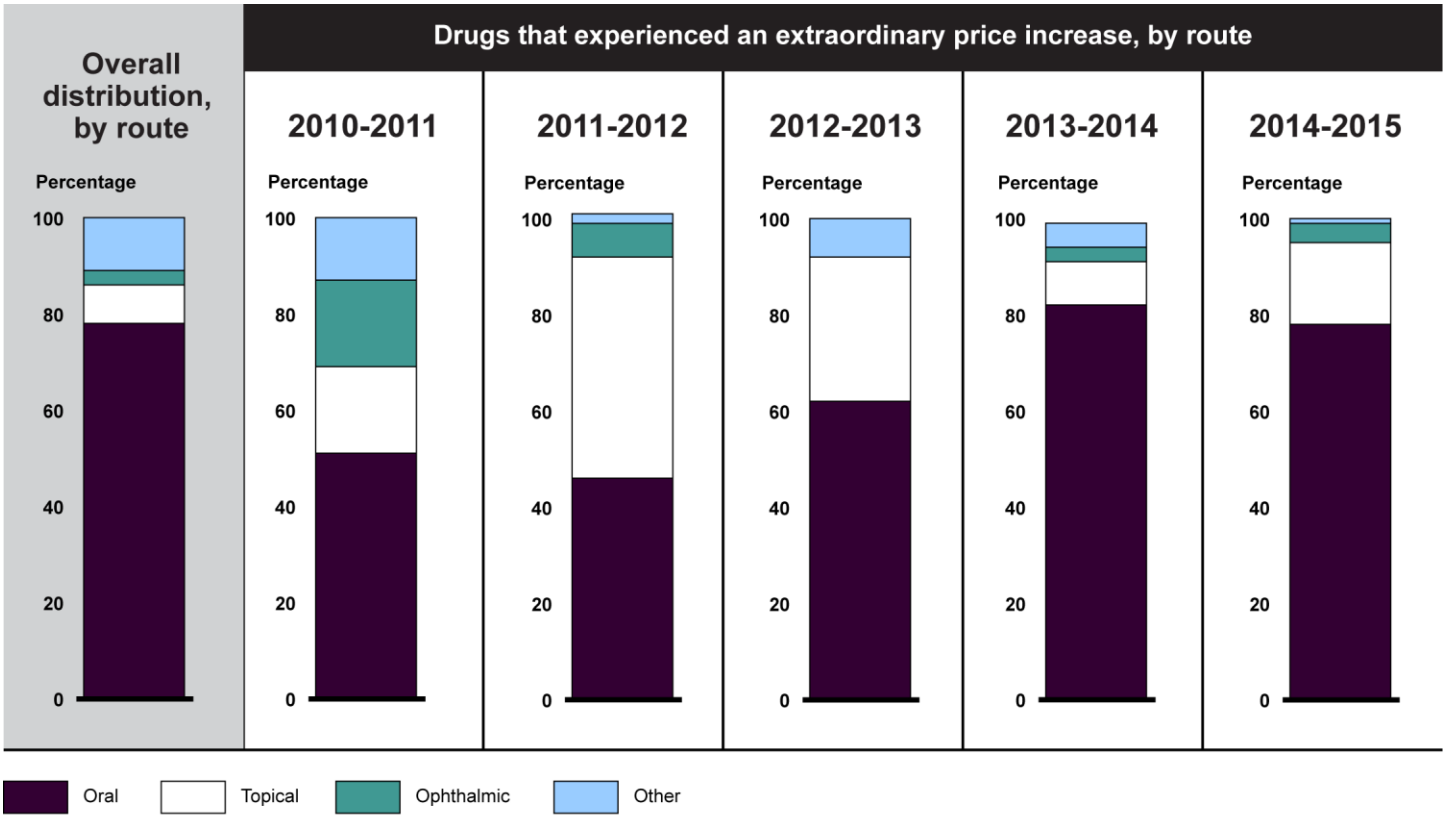
[24]The top 100 most utilized established generic drugs in each year of our analysis accounted for more than 60 percent of all Part D claims for established generic drugs, and the top 50 most utilized established generic drugs accounted for more than 40 percent of all claims each year.

first quarter 2014, no more than one of the drugs that experienced an extraordinary price increase in the years of our study period was among the top 100 most utilized established generic drugs in Medicare Part D. From first quarter 2013 to first quarter 2014, 4 of the 91 price increases were for drugs that were among the 100 most utilized, with 1 of them being the 24th most utilized.

In addition to examining the utilization of the drugs that experienced an extraordinary price increase, we looked at the route of administration for these 315 drugs. We found that, in the early years of our analysis, drugs with certain routes of administration were disproportionately likely to experience an extraordinary price increase. For example, ophthalmic drugs, such as eye solutions, which account for about 3 percent of all established drugs, represented 18 percent of all extraordinary price increases between 2010 and 2011, and topical drugs, such as creams and ointments, which account for 8 percent of all established drugs, represented 46 percent of all extraordinary price increases between 2011 and 2012. In contrast, oral drugs, which account for 78 percent of all established drugs, represented 51 percent of all extraordinary price increases from 2010 to 2011 and 46 percent of all extraordinary price increases from 2011 to 2012. In later years, drugs taken orally accounted for a roughly equal share of all established drugs and drugs that experienced an extraordinary price increase (see fig. 6).[25]

[25]Over all the years of our analysis, approximately 19 percent of oral drugs, 57 percent of topical drugs, 40 percent of ophthalmic drugs, and 11 percent of all other drugs experienced an extraordinary price increase.

Figure 6: Percent of Established Drugs That Experienced Extraordinary Price Increases under Medicare Part D from First Quarter 2010 to First Quarter 2015, by Route of Administration



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

Note: The overall distribution represents the distribution of the 1,441 established generic drugs across the years of our analysis. A price increase of at least 100 percent from the first quarter of one year to the first quarter of the next is considered an extraordinary price increase. Other routes of administration include categories such as intravenous, intramuscular, transdermal, otic, and nasal, among others.

With Generic Drugs Accounting for About 25 Percent of Part D Drug Costs, Stakeholders Reported That Increases in These Prices Have a Limited Effect on Drug Benefit Design

Despite some persistent and substantial price increases, stakeholders have reported limited impacts of these increases on drug benefit design. Some Medicare Part D plan sponsors and PBMs reported that generic drugs remain an important part of their prescription drug benefit given the low costs of generic drugs relative to their brand counterparts.[26] During the years of our analysis, the percent of generic drugs dispensed under Medicare Part D has increased from 71.9 percent in the first quarter of 2010 to 85.7 percent in the second quarter of 2015.[27] Despite the growth in the rate of generic drugs dispensed, the ingredient costs of generic drugs—that is, the amount paid for the drug itself—have remained relatively consistent, fluctuating between 22 and 28 percent of the total ingredient costs of all Medicare Part D drugs in a given quarter. Specifically, in the first quarter of 2010, generic drug ingredient costs were about 22 percent of the total of all ingredient costs paid for drugs dispensed under Medicare Part D, and, in the second quarter of 2015, they were 23 percent of all ingredient costs. Furthermore, ingredient costs of those generic drugs that experienced an extraordinary price increase have accounted for between 2 to 4 percent of the total ingredient costs paid under Medicare Part D during the years of our analysis.[28] Thus, generic drugs continue to bring value to Medicare Part D given their relatively high dispensing rate and low percentage of total drug ingredient costs.

However, plan sponsors and PBMs stated that generic drug price increases may be a factor when evaluating prescription drug benefit design changes for Medicare Part D plans and their other insurance offerings. Plan sponsors and their PBMs reported that, when possible, they may make some changes to their formulary design to minimize the effects of large increases in generic drug prices. Plan sponsors said they may increase beneficiary cost sharing for all insurance offerings by

[26]The increasing use of generic drugs, among other things, has contributed to lower than expected federal spending on Medicare Part D overall between 2006 and 2013, according to the Congressional Budget Office. Congressional Budget Office, *Competition and the Cost of Medicare's Prescription Drug Program* (Washington, D.C.: July 2014).

[27]This generic dispensing rate is consistent with other reported data. For example, see Medicare Payment Advisory Commission.

[28]For example, in 2014, the Medicare Part D ingredient costs for drugs that experienced an extraordinary price increase was approximately $4.5 billion, and the ingredient cost paid for all drugs was approximately $119 billion.

including generic drugs on every formulary tier, including those tiers that would require the beneficiary to pay the highest copayments or highest coinsurance rates. Plan sponsors indicated that they may be more limited in their formulary designs for their Medicare Part D offerings, and many of the sponsors we interviewed noted that they have adopted a formulary structure with a "nonpreferred generic" drug tier. The nonpreferred generic tier usually has higher cost sharing than the preferred generic tier, but still less than other formulary tiers.[29] All of the plan sponsors we interviewed indicated that, subject to applicable requirements, some generic drugs whose prices have increased may be excluded from the formulary altogether, particularly if there is another less expensive, therapeutically equivalent generic drug available.

Five of the six plan sponsors we interviewed reported that generic drug prices may have a small effect on changes in beneficiary premiums, and two economists we interviewed noted that some cost increases may eventually be borne by the beneficiary in the form of higher premiums or by the government. However, in general, stakeholders we spoke with said that premium changes are influenced by overall health care costs. Three of the six plan sponsors we interviewed indicated that brand and specialty drug costs—which are typically more expensive than generics—have impacted premiums more than any increases in generic drugs.

Pharmacy associations we interviewed noted that when changes are made to benefit design, pharmacists may have some ability to help beneficiaries manage costs if they facilitate a switch from the high-cost generic to a lower cost, therapeutically equivalent drug when available. However, in some cases, this change must be approved by the prescriber. Pharmacy associations we interviewed reported that, when the price increases are significant and rapid, their members—individual and chain pharmacies—may fill prescriptions at a loss or have difficulty managing buying strategies, which could affect beneficiaries. For example, if generic drug reimbursements do not match the cost pharmacies must pay to acquire the drugs, pharmacy association officials told us that their member pharmacies may choose not to stock the drug,

[29]Medicare Payment Advisory Commission's 2016 report on Medicare Part D reported that in 2015, about 80 percent of enrollees were in plans with five cost-sharing tiers: preferred generic and other generic tiers, preferred and nonpreferred brand-name drug tiers, and a specialty tier.

which would force beneficiaries to find another pharmacy that could fill the prescription.

Manufacturers and Other Stakeholders Reported That Market Competition, Influenced By Production Difficulties, Consolidation, and Other Factors, Drives Generic Drug Prices

The 5 manufacturers we interviewed reported that competition is the primary driver of generic drug prices, and 12 of the 13 remaining stakeholders we interviewed—including pharmacy associations, plan sponsors, and their PBMs—all indicated that competition influenced by various factors impacts the price of generic drugs. The manufacturers told us they set the price of their version of a multi-source generic drug—drugs with the same active ingredient, strength, dosage form, and route of administration for which there are multiple manufacturers—based on the price at which the generic drug is currently being sold in the market. The generic drug market operates like a commodities market, and manufacturers told us they are asked to submit a proposal offering their best possible price to their customers—for example, companies that operate pharmacies or wholesalers. If another manufacturer offers a lower price to a customer, manufacturers we interviewed indicated that they are usually asked to match it or risk losing market share to the other manufacturer. Additionally, manufacturers said that if a company is bringing a generic drug into an established drug market, it typically offers a price that is lower than the current market price in order to build its customer base. Manufacturers also said that as each new manufacturer enters an established generic drug market the price of that generic will fall, with one manufacturer noting that it is typically a 20 percent price decline per entrant. As long as manufacturers continue to enter the market, generic drug prices continue the general downward trend. According to manufacturers, prices remain low until firms begin to exit the market, which can happen if the drug becomes unprofitable, either due to production costs or low market share. As a result of these factors, manufacturers of generic drugs face a competitive threat that serves as an incentive to keep prices low.

Manufacturers and other stakeholders we interviewed provided various reasons for why generic drug prices change, all of which influence the level of competition in the market. These reasons include the following:

- **Access to active pharmaceutical ingredients (API):** Stakeholders indicated that reliable and affordable access to APIs—which are used to manufacture a drug—is critical to ensuring ongoing production of a drug. Any issues obtaining necessary APIs, which could affect multiple manufacturers, could impact the ability of these

manufacturers to produce the drug. If the manufacturers cannot produce the drug, demand is not being met, and prices can increase.

- **Volume of drug production:** According to stakeholders we interviewed, certain drugs, including narcotics and sterile products, are more difficult to manufacture. Because of the special requirements for these drugs, there may be fewer manufacturers for the product. As a result, should there be production difficulties, such as a plant closure or temporary shutdown to correct a manufacturing deficiency, there are fewer manufacturers to help offset the production difficulty, and prices may increase because less of the drug is being produced overall or one manufacturer is not producing at normal volume.
- **Supplier consolidation:** Stakeholders we interviewed indicated that manufacturer consolidation through acquisitions could affect the competitiveness of the generic drug market, as there may be fewer manufacturers producing any specific drug. Stakeholders also stated that manufacturers may exit the market because manufacturing the drug is no longer profitable. This could be due to a small demand for the drug or production costs that exceed the price at which the drug is being sold in the market.
- **Buyer consolidation:** Four of the five manufacturers noted that as buyers consolidate—for example, through mergers between wholesalers and retail pharmacies or through merging of retail pharmacies—there may be two effects on generic drug prices. In one case, the consolidated buying power of these organizations may force prices down further. On the other hand, having fewer buyers may make it harder for smaller manufacturers to gain market share and stay in business. If fewer firms manufacturer the drug, prices may increase.
- **Incentive to enter the market:** If a generic drug serves a small population, some stakeholders indicated there may be little financial incentive for a new manufacturer to enter the market. With fewer manufacturers, the drug may not have the same downward pressure on price, making it more susceptible to price increases. [30]

[30]An issue brief from the Office of the Assistant Secretary of Planning and Evaluation at HHS noted that, in some cases, smaller markets may attract no or very little market entry, which can increase the risk for large price increases. See Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Understanding Recent Trends in Generic Drug Prices* (Washington, D.C.: Jan.27, 2016).

Economists we interviewed made comments consistent with those made by other stakeholders, and recent literature highlights the role of competition in exerting downward pressure on generic drug prices. According to economists we interviewed, there is no clear measure of competitiveness in the generic drug market but noted that prices are affected when suppliers produce less of a particular drug than anticipated. Additionally, according to reports from the Food and Drug Administration (FDA), economists from the Federal Trade Commission (FTC), and IMS Institute for Healthcare Informatics—an international company that supplies the pharmaceutical and health care industries with market information—the price of generic drugs falls as new manufacturers enter the market. Based on an analysis of data from 1999-2004, FDA found that the appearance of a second generic manufacturer reduced the average generic price to nearly half the brand name price and that the prices continue to fall as additional manufacturers enter.[31] For products that attract a large number of generic manufacturers, the average generic price falls to 20 percent of the branded price and lower, according to FDA. Additional work from economists at FTC and IMS Institute for Healthcare Informatics published recently supports the FDA's findings. In 2013 and 2014, FTC economists showed that generic drug prices decline based on competition in the market, and a 2016 report from IMS Institute for Healthcare Informatics indicated that the immediate price reduction in the cost of medications following generic entry is substantial and is followed by continued savings in subsequent years.[32] For example, generics that entered the market between 2002 and 2014 reduced the price of those medicines by 51 percent in the first year and 57 percent in the second year. IMS Institute for Healthcare Informatics noted that the price reductions are driven, in part, by the number of competitors in the market.

[31]FDA, "Generic Competition and Drug Prices," accessed May 20, 2015, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

[32]See Steven Tenn and Brett W. Wendling, "Entry Threats and Pricing in the Generic Drug Industry," *The Review of Economics and Statistics*, May 2014, 96(2): 214–228. Tenn and Wendling were with FTC at the time of publication. See also Luke M. Olson and Brett W. Wendling, Bureau of Economics, Federal Trade Commission, *Working Paper No. 317: The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period* (Washington, D.C.: April 2013) and IMS Institute for Healthcare Informatics, *Price Declines after Branded Medicines Lose Exclusivity in the U.S.* (Parsippany, N.J.: January 2016).

Stakeholders indicated competition could be increased if FDA would approve more abbreviated new drug applications (ANDA), which would allow generic drug manufacturers to market a drug, but there is a backlog at FDA. The Generic Drug User Fee Amendments of 2012 (GDUFA) authorized FDA to collect user fees from manufacturers of generic drugs, to be dedicated to reviewing ANDAs consistent with goals identified by the agency.[33] The agency set a goal for FDA to take "first action" on ANDA's submitted beginning in fiscal year 2015 within 15 months.[34] According to FDA, approvals for ANDAs submitted prior to this goal taking effect in fiscal year 2015 can take 40 months or more.[35] Manufacturers stated that FDA's review backlog may represent a barrier to market entry for new generic drug manufacturers. For example, one manufacturer told us that, while ANDAs are pending at FDA, manufacturers must keep facilities operational, which may be costly for smaller drug manufacturers with fewer plants and products.[36]

Agency Comments

We provided a draft of this report to HHS for review and comment. The department provided technical comments, which we incorporated as appropriate.

[33]See Pub. L. No. 112-144, tit. III, 126 Stat. 993, 1008 (codified in pertinent part at 21 U.S.C. §§ 379j-41 et seq.). The goals are set forth in letters from the Secretary of HHS to the Congress.

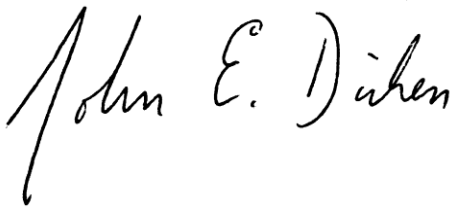
[34]First action could include granting an approval, granting a tentative approval, identifying deficiencies through a response letter, or a refusal to receive the application. When deficiencies are identified, industry usually responds by correcting them and resubmitting the application.

[35]FDA officials acknowledged that the current ANDA workload is larger than it would like as generic manufacturers have submitted more original ANDAs than anticipated at the time that GDUFA was enacted. According to FDA officials, many of the additional applications were submitted by new entrants to the generic drug arena, which requires more review time and review cycles prior to approval. Officials said that new facilities also require formal inspections, and, if these facilities are overseas, there are additional steps in the assessment process.

[36]Evaluating the effect of GDUFA user fee authority on the generic drug approval process was out of the scope of this review.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees and the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in app. IV.



John E. Dicken
Director, Health Care

List of Requesters

The Honorable Susan Collins
Chairman
The Honorable Claire McCaskill
Ranking Member
Special Committee on Aging
United States Senate

The Honorable Bill Nelson
Ranking Member
Committee on Commerce, Science and Transportation
United States Senate

The Honorable Mark Warner
United States Senate

Appendix I: Scope and Methodology for Price Index

To examine how generic drug prices have changed over time under Medicare Part D, we tracked generic drug prices using prescription drug event (PDE) data from the Centers for Medicare & Medicaid Services that contain pharmacy claims for all prescription drugs dispensed under Medicare Part D. Specifically, we analyzed PDE data from the first quarter of 2010 through the second quarter of 2015, which was the most recent data available at the time we conducted our analysis.[1] To identify claims associated with generic drugs, we merged national drug codes (NDC) billed in the PDE data with Red Book data, which contain drug characteristics such as whether a drug is a generic or brand drug.[2] After limiting our analysis to only generic drugs, we grouped claims with the same active ingredient, strength, dosage form, and route of administration to represent a generic drug. We excluded the following data from our analysis: all claims associated with over-the-counter drugs; claims with no active ingredient; certain types of claims, such as those associated with compounded drugs; and other claims for data reliability purposes, such as those with an ingredient cost of less than or equal to zero.[3] These exclusions resulted in a small percentage of generic drug claims being dropped in any given quarter, ranging from 1.2 percent to 4.4 percent over the course of our study.

To calculate the price for each generic drug, we determined the claims-weighted median per-unit ingredient cost among all claims for that drug in each quarter from the first quarter of 2010 through the second quarter of 2015. To do so, we first calculated the per-unit cost for each claim by dividing the ingredient cost reported on the claim by the quantity

[1]Due to data availability at the time we conducted our study, the second quarter of our 2015 Medicare Part D claims data is limited to data from April and May.

[2]NDCs are the universal product identifiers for drugs for human use. The Food and Drug Administration (FDA) assigns the first segment of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug; the second segment identifies a specific strength, dosage form, and formulation for a particular drug; and the third segment identifies package size. Three-segment NDCs are denoted by 11 digits while two-segment NDCs are denoted by 9 digits, and do not account for package size. We used data as of June 2015 from Red Book, which is a compendium published by Truven Health Analytics.

[3]Some PDE claims contain only supplies, such as needles, and therefore contain no active ingredient. A drug is compounded through the process of mixing, combining, or altering ingredients, to create a customized drug tailored to the medical needs of an individual patient upon receipt of a prescription.

dispensed to the beneficiary.[4] The ingredient cost is the negotiated amount plan sponsors pay to pharmacies for the drug itself.[5] The quantity dispensed is the number of units, such as capsules or tablets, dispensed to the beneficiary. For example, a claim with 100 tablets and an ingredient cost of $50 would have a per-unit cost of $0.50.[6] Once we determined the per-unit cost for all claims, we ranked the claims by their per-unit cost and took the per-unit cost from the median claim.[7]

To track the change in prices over time, we created chained Fisher price indexes using the claims-weighted median per-unit ingredient cost as our measure of price and the total quantity dispensed in each quarter as our measure of volume. A Fisher price index minimizes the problem of understating or overstating price changes by using the utilization from the first and last period of our analysis as weights. A chained index also allows for new products to be incorporated and allows for substitution between drugs over time. The first chained Fisher price index we created tracks the prices of a changing basket of drugs, which includes established drugs—that is, drugs that were billed under Medicare Part D for each quarter of our study—and drugs that were only billed for part of our time period but not others, such as new generic drugs that became available or drugs that exited the market in the middle of our study period.

[4]We did not adjust the per-unit cost for inflation during our study period. General inflation, as measured by the chained Consumer Price Index for All Urban Consumers (C-CPI-U), was very low over the course of our study and would not significantly affect our results. Specifically, the C-CPI-U increased by a total of approximately 9 percent over the course of our study.

[5]The ingredient cost does not include other costs often associated with purchasing a drug, such as sales tax and a dispensing fee. Also, the ingredient cost does not reflect rebates that may occur outside the point of sale.

[6]We also implemented edits to identify and fix potential errors in the quantity dispensed field. For example, for claims with per-unit costs that deviated substantially from the median per-unit cost for that drug, we examined and corrected the quantity dispensed field when obvious errors were present, such as implausibly high or low values.

[7]Alternatives to a claims-weighted median price include a unit-weighted median or a mean price that is weighted by claims or units. A unit-weighted measure assigns a greater weight to claims with a large number of units. For example, under a unit-weighted median, a claim with 100 units would receive more weight than a claim with 30 units; those two claims receive equal weight under a claims-weighted median price. We chose a claims-weighted median as our primary measure of price, for both our price index analyses and our analyses of individual drugs that experienced extraordinary price increases, because such a measure is less sensitive to extreme outliers.

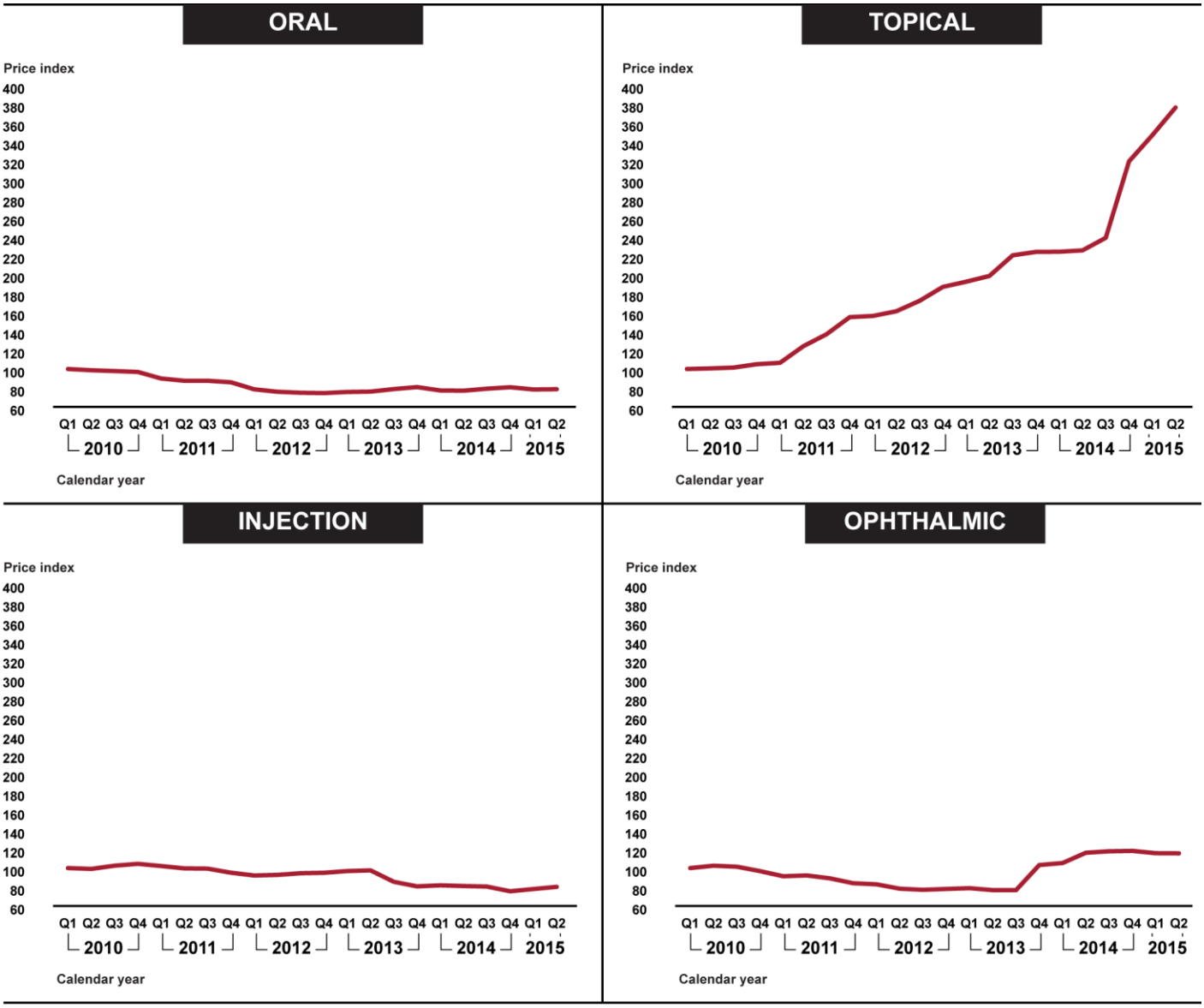
To be included in our indexes, drugs had to meet certain volume and data quality standards—for example, we required a drug to have at least 100 claims in each quarter.[8] To calculate the chained Fisher price index, we 1) created a Laspeyres index, which calculates weights using the base period utilization, for each of our 21 time periods (for example, the first quarter of 2010 to the second quarter is one time period); 2) created a Paasche index, which calculates weights using last period utilization, for each of our 21 time periods; 3) took the geometric mean of the Laspeyres and Paasche indexes for each time period to create values for a Fisher price index; and 4) multiplied these values together for each of the 21 time periods to create a chained Fisher price index. To create our index of established drugs, we limited the population of drugs to only established drugs and then implemented the same steps as we did for our changing basket of drugs. We also created separate chained Fisher price indexes limited to other subgroups of drugs—new drugs, drugs with certain routes of administration, and established drugs that did not experience an extraordinary price increase of 100 percent or more from the first quarter of a year to the first quarter of the next.

[8]To ensure drugs were not newly introduced immediately prior to when we begin tracking prices—in the first quarter of 2010, we required a drug to be billed in all four quarters of 2009 to be included in our basket of established drugs. A total of 1,441 drugs met these criteria. Creating a volume threshold ensures we had sufficient data to determine the price of a drug and reduces the volatility of prices from quarter to quarter.

Appendix II: Price Trends by Route of Administration

The price trend for our basket of 1,441 established generic drugs is driven by oral medications, such as capsules and tablets, as they represent approximately three quarters of the established drugs in our analysis. The price for oral drugs in our established basket declined by 21 percent from 2010 through second quarter of 2015. However, other routes of administration for established drugs, all of which account for a relatively small number of drugs, experienced different patterns. For example, among the 117 topical generic drugs—drugs such as creams and ointments—in our established basket, the average price was 276 percent higher in the second quarter of 2015 compared to the first quarter of 2010 (see fig. 7).

Figure 7: Price Trends for Established Generic Drugs under Medicare Part D by Route of Administration, First Quarter 2010 through the Second Quarter of 2015



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

Note: To be considered an established drug, a drug had to be in the Medicare Part D claims data for each quarter from the first quarter of 2009 through the second quarter of 2015 and meet certain other data reliability standards. The oral, topical, injection, and ophthalmic drug indexes contain 1,127; 117; 51; and 45 drugs, respectively. Routes of administration with less than 30 drugs are not pictured. Due to data availability at the time we conducted our study, the second quarter of our 2015 Medicare Part D claims data is limited to data from April and May.

Appendix III: Established Generic Drugs under Medicare Part D That Experienced Extraordinary Price Increases and Years of Increase

Table 2: Established Generic Drugs under Medicare Part D That Experienced Extraordinary Price Increases and Years of Increase

				Experienced an extraordinary price increase				
Active ingredient	**Strength**	**Dosage form**	**Route of administration**	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
Acetaminophen Butalbital Caffeine	325mg-50mg-40mg	Tablet	Oral					X
Acetaminophen Butalbital Caffeine Codeine Phosphate	325mg-50mg-40mg-30mg	Capsule	Oral					X
Acetazolamide	125mg	Tablet	Oral					X
Acetazolamide	250mg	Tablet	Oral					X
Acyclovir	200mg/5ml	Suspension	Oral					X
Albuterol Sulfate	2mg	Tablet	Oral				X	
Albuterol Sulfate	4mg	Tablet	Oral				X	
Alclometasone Dipropionate	0.05%	Cream	Topical application				X	
Allopurinol	300mg	Tablet	Oral					X
Amantadine Hydrochloride	100mg	Capsule	Oral			X		
Amantadine Hydrochloride	100mg	Capsule, liquid filled	Oral			X		
Amcinonide	0.1%	Cream	Topical application			X		
Amiloride Hydrochloride Hydrochlorothiazide	5mg-50mg	Tablet	Oral		X			
Aminocaproic Acid	500mg	Tablet	Oral				X	
Amitriptyline Hydrochloride	100mg	Tablet	Oral					X
Amitriptyline Hydrochloride	10mg	Tablet	Oral					X
Amitriptyline Hydrochloride	150mg	Tablet	Oral					X
Amitriptyline Hydrochloride	25mg	Tablet	Oral					X
Amitriptyline Hydrochloride	50mg	Tablet	Oral					X
Amitriptyline Hydrochloride	75mg	Tablet	Oral					X
Amitriptyline Hydrochloride Perphenazine	25mg-2mg	Tablet	Oral		X			
Amphetamine Salt Combination	1.25mg-1.25mg-1.25mg-1.25mg	Tablet	Oral		X			
Amphetamine Salt Combination	12.5mg	Tablet	Oral		X			
Amphetamine Salt Combination	2.5mg-2.5mg-2.5mg-2.5mg	Tablet	Oral		X			

Active ingredient	Strength	Dosage form	Route of administration	Experienced an extraordinary price increase				
				2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Amphetamine Salt Combination	5mg-5mg-5mg-5mg	Tablet	Oral		X			
Amphetamine Salt Combination	7.5mg-7.5mg-7.5mg-7.5mg	Tablet	Oral		X			
Anagrelide Hydrochloride	1mg	Capsule	Oral					X
Atenolol Chlorthalidone	100mg-25mg	Tablet	Oral					X
Atenolol Chlorthalidone	50mg-25mg	Tablet	Oral					X
Atropine Sulfate	1%	Solution	Ophthalmic	X				
Atropine Sulfate Diphenoxylate Hydrochloride	0.025mg-2.5mg	Tablet	Oral					X
Baclofen	10mg	Tablet	Oral					X
Baclofen	20mg	Tablet	Oral					X
Benazepril Hydrochloride Hydrochlorothiazide	10mg-12.5mg	Tablet	Oral				X	
Benazepril Hydrochloride Hydrochlorothiazide	20mg-12.5mg	Tablet	Oral				X	
Benazepril Hydrochloride Hydrochlorothiazide	20mg-25mg	Tablet	Oral				X	
Benazepril Hydrochloride Hydrochlorothiazide	5mg-6.25mg	Tablet	Oral				X	
Benzonatate	100mg	Capsule, liquid filled	Oral					X
Betamethasone Dipropionate	0.05%	Cream	Topical application		X			
Betamethasone Dipropionate	0.05%	Lotion	Topical application		X			
Betamethasone Dipropionate	0.05%	Ointment	Topical application	X	X			
Betamethasone Dipropionate Augmented	0.05%	Ointment	Topical application	X				
Betamethasone Dipropionate Clotrimazole	1%-0.05%	Cream	Topical application		X			
Betamethasone Dipropionate Clotrimazole	1%-0.5%	Lotion	Topical application		X			
Betamethasone Valerate	0.1%	Cream	Topical application		X			
Betamethasone Valerate	0.1%	Lotion	Topical application		X	X		
Betamethasone Valerate	0.1%	Ointment	Topical application		X			
Bumetanide	0.5mg	Tablet	Oral					X

Active ingredient	Strength	Dosage form	Route of administration	Experienced an extraordinary price increase				
				2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Bumetanide	1mg	Tablet	Oral					X
Bumetanide	2mg	Tablet	Oral					X
Butorphanol Tartrate	10mg/1ml	Spray	Nasal					X
Cal Chl KCl Na Chl Na Lactate	20mg/100ml-30mg/100ml-600mg/100ml-310mg/100ml	Solution	Intravenous	X				
Captopril	100mg	Tablet	Oral				X	
Captopril	12.5mg	Tablet	Oral				X	X
Captopril	25mg	Tablet	Oral				X	
Captopril	50mg	Tablet	Oral				X	
Captopril Hydrochlorothiazide	25mg-15mg	Tablet	Oral					X
Captopril Hydrochlorothiazide	25mg-25mg	Tablet	Oral					X
Captopril Hydrochlorothiazide	50mg-15mg	Tablet	Oral					X
Captopril Hydrochlorothiazide	50mg-25mg	Tablet	Oral					X
Carbamazepine	100mg	Tablet, chewable	Oral					X
Carbamazepine	200mg	Tablet	Oral					X
Carisoprodol	350mg	Tablet	Oral				X	
Ceftazidime	6gm	Powder for solution	Intravenous				X	
Cefuroxime Axetil	250mg	Tablet	Oral					X
Cefuroxime Axetil	500mg	Tablet	Oral					X
Cephalexin	125mg/5ml	Powder for suspension	Oral					X
Cephalexin	250mg/5ml	Powder for suspension	Oral					X
Chlorothiazide	250mg	Tablet	Oral					X
Chlorothiazide	500mg	Tablet	Oral					X
Chlorpromazine Hydrochloride	100mg	Tablet	Oral		X			X
Chlorpromazine Hydrochloride	10mg	Tablet	Oral		X			
Chlorpromazine Hydrochloride	200mg	Tablet	Oral		X			X

				Experienced an extraordinary price increase				
Active ingredient	Strength	Dosage form	Route of administration	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Chlorpromazine Hydrochloride	25mg	Tablet	Oral		X			
Chlorpromazine Hydrochloride	25mg/1ml	Solution	Injection			X		
Chlorpromazine Hydrochloride	50mg	Tablet	Oral		X			
Chlorzoxazone	500mg	Tablet	Oral				X	
Ciclopirox	8%	Solution	Topical application				X	
Cimetidine	400mg	Tablet	Oral				X	
Ciprofloxacin Hydrochloride	100mg	Tablet	Oral					X
Clarithromycin	250mg	Tablet	Oral		X			
Clarithromycin	500mg	Tablet	Oral		X			
Clindamycin Phosphate	1%	Gel/jelly	Topical application			X		
Clindamycin Phosphate	1%	Lotion	Topical application				X	
Clindamycin Phosphate	1%	Solution	Topical application			X		
Clobetasol Propionate	0.05%	Cream	Topical application					X
Clobetasol Propionate	0.05%	Emollient cream	Topical application					X
Clobetasol Propionate	0.05%	Gel/jelly	Topical application					X
Clobetasol Propionate	0.05%	Ointment	Topical application					X
Clobetasol Propionate	0.05%	Solution	Topical application					X
Clomipramine Hydrochloride	25mg	Capsule	Oral				X	
Clomipramine Hydrochloride	50mg	Capsule	Oral				X	
Clomipramine Hydrochloride	75mg	Capsule	Oral				X	
Clotrimazole	1%	Solution	Topical application					X
Cortisone Acetate	25mg	Tablet	Oral			X		X
Cyclopentolate Hydrochloride	1%	Solution	Ophthalmic		X			
Cyclophosphamide	500mg	Powder for solution	Intravenous	X				
Desonide	0.05%	Cream	Topical application		X		X	
Desonide	0.05%	Lotion	Topical application		X			
Desonide	0.05%	Ointment	Topical application		X		X	
Dexamethasone Neomycin Sulfate Polymyxin B Sulfate	1mg-3.5mg-10000units/Gm	Ointment	Ophthalmic	X				

				Experienced an extraordinary price increase				
Active ingredient	Strength	Dosage form	Route of administration	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Dexamethasone Neomycin Sulfate Polymyxin B Sulfate	1mg/1ml-3.5mg/1ml-10000units/1ml	Suspension	Ophthalmic	X				
Dextroamphetamine Sulfate	10mg	Tablet	Oral			X		
Dextroamphetamine Sulfate	5mg	Tablet	Oral			X		
Dicyclomine Hydrochloride	10mg/5ml	Syrup	Oral				X	
Diflorasone Diacetate	0.05%	Cream	Topical application		X			
Diflorasone Diacetate	0.05%	Ointment	Topical application		X			
Digoxin	0.125mg	Tablet	Oral				X	
Digoxin	0.25mg	Tablet	Oral				X	
Diltiazem Hydrochloride	360mg	Capsule, extended release, 24 hr	Oral					X
Divalproex Sodium	250mg	Tablet, extended release	Oral				X	
Divalproex Sodium	500mg	Tablet, extended release	Oral				X	
Doxazosin Mesylate	1mg	Tablet	Oral				X	
Doxazosin Mesylate	2mg	Tablet	Oral				X	
Doxazosin Mesylate	4mg	Tablet	Oral				X	
Doxazosin Mesylate	8mg	Tablet	Oral				X	
Doxepin Hydrochloride	100mg	Capsule	Oral		X			
Doxepin Hydrochloride	75mg	Capsule	Oral		X			X
Doxycycline Hyclate	100mg	Capsule	Oral			X	X	
Doxycycline Hyclate	100mg	Tablet	Oral				X	
Doxycycline Hyclate	50mg	Capsule	Oral			X	X	
Econazole Nitrate	1%	Cream	Topical application					X
Enalapril Maleate	10mg	Tablet	Oral					X
Enalapril Maleate	2.5mg	Tablet	Oral					X
Enalapril Maleate	20mg	Tablet	Oral					X
Enalapril Maleate	5mg	Tablet	Oral					X
Erythromycin	2%	Solution	Topical application			X		
Erythromycin	250mg	Capsule, delayed release	Oral	X	X			
Erythromycin	250mg	Tablet	Oral	X		X		
Erythromycin	500mg	Tablet	Oral	X		X		X

				Experienced an extraordinary price increase				
Active ingredient	Strength	Dosage form	Route of administration	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Erythromycin Ethylsuccinate	400mg	Tablet	Oral	X		X		
Estropipate	3mg	Tablet	Oral					X
Ethosuximide	250mg/5ml	Syrup	Oral			X		
Etodolac	200mg	Capsule	Oral		X			
Etodolac	300mg	Capsule	Oral			X		
Etodolac	400mg	Tablet	Oral				X	
Etodolac	400mg	Tablet, extended release	Oral				X	
Etodolac	500mg	Tablet	Oral				X	
Etodolac	500mg	Tablet, extended release	Oral				X	
Fenoprofen Calcium	600mg	Tablet	Oral		X			
Fentanyl Citrate	0.05mg/1ml	Solution	Injection			X		
Fluconazole	100mg	Tablet	Oral				X	
Fluconazole	150mg	Tablet	Oral				X	
Fluconazole	200mg	Tablet	Oral				X	
Fluconazole	50mg	Tablet	Oral				X	
Fluocinolone Acetonide	0.01%	Solution	Topical application		X	X		
Fluocinolone Acetonide	0.025%	Cream	Topical application			X		
Fluocinolone Acetonide	0.025%	Ointment	Topical application			X		
Fluocinonide	0.05%	Cream	Topical application		X			X
Fluocinonide	0.05%	Emollient cream	Topical application					X
Fluocinonide	0.05%	Gel/jelly	Topical application					X
Fluocinonide	0.05%	Ointment	Topical application		X			X
Fluocinonide	0.05%	Solution	Topical application		X	X		
Fluorometholone	0.1%	Suspension	Ophthalmic					X
Fluoxetine Hydrochloride	20mg	Tablet	Oral					X
Furosemide	10mg/1ml	Solution	Injection			X		
Gentamicin Sulfate	0.1%	Cream	Topical application			X		
Gentamicin Sulfate	0.1%	Ointment	Topical application			X		
Gentamicin Sulfate	3mg/1ml	Solution	Ophthalmic	X				
Glycopyrrolate	0.2mg/1ml	Solution	Injection				X	

				Experienced an extraordinary price increase				
Active ingredient	Strength	Dosage form	Route of administration	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Gramicidin Neomycin Sulfate Polymyxin B Sulfate	0.025mg-1.75mg-10000units/Ml	Solution	Ophthalmic				X	
Halobetasol Propionate	0.05%	Cream	Topical application				X	
Halobetasol Propionate	0.05%	Ointment	Topical application				X	
Haloperidol	0.5mg	Tablet	Oral				X	
Haloperidol	1mg	Tablet	Oral				X	
Haloperidol	2mg	Tablet	Oral				X	
Haloperidol	5mg	Tablet	Oral				X	
Haloperidol Decanoate	100mg/1ml	Suspension	Intramuscular	X				
Haloperidol Decanoate	50mg/1ml	Suspension	Intramuscular	X				
Hydrochlorothiazide Propranolol Hydrochloride	25mg-40mg	Tablet	Oral	X				
Hydrochlorothiazide Propranolol Hydrochloride	25mg-80mg	Tablet	Oral	X				
Hydrochlorothiazide Spironolactone	25mg-25mg	Tablet	Oral				X	
Hydrochlorothiazide Triamterene	50mg-75mg	Tablet	Oral			X		
Heparin Sodium	1000units/1ml	Solution	Injection	X				
Hydrocortisone	1%	Ointment	Topical application		X			
Hydrocortisone	20mg	Tablet	Oral			X		
Hydrocortisone Butyrate	0.1%	Solution	Topical application					X
Hydrocortisone Valerate	0.2%	Cream	Topical application				X	
Hydrocortisone Valerate	0.2%	Ointment	Topical application		X			
Hydromorphone Hydrochloride	2mg/1ml	Solution	Injection	X				
Hydroxychloroquine Sulfate	200mg	Tablet	Oral					X
Hyoscyamine Sulfate	0.125mg/5ml	Elixir	Oral			X		X
Indapamide	1.25mg	Tablet	Oral					X
Indapamide	2.5mg	Tablet	Oral					X
Isosorbide Dinitrate	10mg	Tablet	Oral			X		
Isosorbide Dinitrate	20mg	Tablet	Oral			X		
Isosorbide Dinitrate	30mg	Tablet	Oral				X	
Isosorbide Dinitrate	5mg	Tablet	Oral			X		
Ketoconazole	2%	Cream	Topical application					X
Ketoconazole	200mg	Tablet	Oral					X
Labetalol Hydrochloride	100mg	Tablet	Oral			X		

Active ingredient	Strength	Dosage form	Route of administration	Experienced an extraordinary price increase				
				2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Labetalol Hydrochloride	300mg	Tablet	Oral			X		
Levobunolol Hydrochloride	0.5%	Solution	Ophthalmic		X			
Lidocaine	5%	Ointment	Topical application			X		
Lidocaine Hydrochloride	3%	Cream	Topical application		X			
Meclofenamate Sodium	100mg	Capsule	Oral		X			
Mercaptopurine	50mg	Tablet	Oral					X
Methadone Hydrochloride	5mg	Tablet	Oral					X
Methazolamide	25mg	Tablet	Oral	X				X
Methazolamide	50mg	Tablet	Oral	X				X
Methotrexate Sodium	2.5mg	Tablet	Oral				X	
Methylphenidate Hydrochloride	10mg	Tablet	Oral				X	
Methylphenidate Hydrochloride	10mg	Tablet, extended release	Oral				X	
Methylphenidate Hydrochloride	20mg	Tablet	Oral				X	
Methylphenidate Hydrochloride	5mg	Tablet	Oral				X	
Methylprednisolone	4mg	Tablet	Oral		X			
Metronidazole	0.75%	Cream	Topical application		X			
Metronidazole	0.75%	Gel/jelly	Topical application			X		
Metronidazole	0.75%	Lotion	Topical application		X			
Metronidazole	250mg	Tablet	Oral		X			
Metronidazole	500mg	Tablet	Oral		X			
Mexiletine Hydrochloride	250mg	Capsule	Oral					X
Morphine Sulfate	100mg	Tablet, extended release	Oral				X	
Morphine Sulfate	200mg	Tablet, extended release	Oral				X	
Morphine Sulfate	30mg	Tablet, extended release	Oral				X	
Morphine Sulfate	60mg	Tablet, extended release	Oral				X	

Active ingredient	Strength	Dosage form	Route of administration	Experienced an extraordinary price increase				
				2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Multivitamin	100mg-0.15mg-5mg-0.006mg-1mg-20mg-10mg-1.7mg-1.5mg	Capsule, liquid filled	Oral					X
Nadolol	20mg	Tablet	Oral			X	X	
Nadolol	40mg	Tablet	Oral				X	
Nadolol	80mg	Tablet	Oral				X	
Nefazodone Hydrochloride	250mg	Tablet	Oral					X
Nefazodone Hydrochloride	50mg	Tablet	Oral					X
Nicardipine Hydrochloride	20mg	Capsule	Oral					X
Nicardipine Hydrochloride	30mg	Capsule	Oral					X
Nitrofurantoin	100mg	Capsule	Oral	X				
Nitrofurantoin Macrocrystals Nitrofurantoin Monohydrate	100mg	Capsule	Oral	X				
Nystatin	100000units/1gm	Cream	Topical application		X			
Nystatin	100000units/1gm	Ointment	Topical application		X			
Nystatin	100000units/1gm	Powder	Topical application			X		
Nystatin Triamcinolone Acetonide	100000units/1gm-0.1%	Cream	Topical application		X	X		
Nystatin Triamcinolone Acetonide	100000units/1gm-0.1%	Ointment	Topical application		X	X		
Ofloxacin	0.3%	Solution	Ophthalmic					X
Oxaprozin	600mg	Tablet	Oral			X		
Oxybutynin Chloride	5mg	Tablet	Oral				X	
Oxycodone Hydrochloride	20mg/1ml	Solution	Oral	X		X		
Oxycodone Hydrochloride	5mg	Capsule	Oral				X	
Oxycodone Hydrochloride	5mg/5ml	Solution	Oral			X		
Permethrin	5%	Cream	Topical application		X			
Phenazopyridine Hydrochloride	100mg	Tablet	Oral					X
Phenazopyridine Hydrochloride	200mg	Tablet	Oral	X				X
Phenobarbital	100mg	Tablet	Oral			X		
Phenobarbital	15mg	Tablet	Oral		X		X	
Phenobarbital	16.2mg	Tablet	Oral			X		
Phenobarbital	30mg	Tablet	Oral		X			
Phenobarbital	32.4mg	Tablet	Oral		X	X		

				Experienced an extraordinary price increase				
Active ingredient	Strength	Dosage form	Route of administration	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Phenobarbital	60mg	Tablet	Oral		X			
Phenobarbital	64.8mg	Tablet	Oral			X		
Phenobarbital	97.2mg	Tablet	Oral			X		
Phenytoin Sodium Extended	100mg	Capsule, extended release	Oral					X
Pilocarpine Hydrochloride	1%	Solution	Ophthalmic	X				
Pilocarpine Hydrochloride	2%	Solution	Ophthalmic	X				
Pilocarpine Hydrochloride	4%	Solution	Ophthalmic	X				
Pilocarpine Hydrochloride	5mg	Tablet	Oral					X
Pindolol	10mg	Tablet	Oral	X				
Pindolol	5mg	Tablet	Oral	X				
Piroxicam	10mg	Capsule	Oral	X				
Piroxicam	20mg	Capsule	Oral	X				
Potassium Chloride	10meq	Tablet, extended release	Oral	X				
Potassium Chloride	20meq/15ml	Solution	Oral				X	X
Potassium Chloride	40meq/15ml	Solution	Oral			X		X
Potassium Chloride	8meq	Tablet, extended release	Oral	X				
Potassium Citrate	10meq	Tablet, extended release	Oral	X				
Potassium Citrate	5meq	Tablet, extended release	Oral	X				
Pravastatin Sodium	10mg	Tablet	Oral				X	
Pravastatin Sodium	40mg	Tablet	Oral				X	
Prazosin Hydrochloride	1mg	Capsule	Oral					X
Prednisolone Acetate	1%	Suspension	Ophthalmic				X	
Prednisolone Sodium Phosphate	5mg/5ml	Solution	Oral				X	
Prednisone	10mg	Tablet	Oral				X	
Prednisone	2.5mg	Tablet	Oral				X	
Prednisone	20mg	Tablet	Oral				X	
Prednisone	5mg	Tablet	Oral				X	

Active ingredient	Strength	Dosage form	Route of administration	Experienced an extraordinary price increase				
				2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Prochlorperazine	25mg	Suppository	Rectal				X	
Promethazine Hydrochloride	12.5mg	Suppository	Rectal			X	X	
Promethazine Hydrochloride	25mg	Suppository	Rectal				X	
Propylthiouracil	50mg	Tablet	Oral			X		
Pyrazinamide	500mg	Tablet	Oral				X	
Quinidine Gluconate	324mg	Tablet, extended release	Oral				X	
Ranitidine Hydrochloride	300mg	Capsule	Oral			X		
Ranitidine Hydrochloride	300mg	Capsule, liquid filled	Oral			X		
Salsalate	500mg	Tablet	Oral	X				X
Salsalate	750mg	Tablet	Oral	X				X
Selegiline Hydrochloride	5mg	Tablet	Oral	X				
Sodium Chloride	0.9%	Solution	Inhalation		X			
Sulfacetamide Sodium	10%	Solution	Ophthalmic	X			X	
Sulfamethoxazole Trimethoprim	200mg/5ml-40mg/5ml	Suspension	Oral					X
Terbutaline Sulfate	2.5mg	Tablet	Oral					X
Tetracycline Hydrochloride	250mg	Capsule	Oral				X	
Tetracycline Hydrochloride	500mg	Capsule	Oral				X	
Theophylline	100mg	Tablet, extended release, 12 hr	Oral					X
Thiothixene	10mg	Capsule	Oral					X
Thiothixene	1mg	Capsule	Oral					X
Thiothixene	2mg	Capsule	Oral					X
Thiothixene	5mg	Capsule	Oral					X
Timolol Maleate	0.25%	Gel-forming solution	Ophthalmic					X
Timolol Maleate	0.5%	Gel-forming solution	Ophthalmic					X
Tobramycin	0.3%	Solution	Ophthalmic		X			
Tretinoin	0.01%	Gel/jelly	Topical application					X
Tretinoin	0.025%	Cream	Topical application					X
Tretinoin	0.025%	Gel/jelly	Topical application					X

Active ingredient	Strength	Dosage form	Route of administration	Experienced an extraordinary price increase				
				2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Tretinoin	0.05%	Cream	Topical application					X
Tretinoin	0.1%	Cream	Topical application					X
Triamcinolone Acetonide	0.025%	Cream	Topical application	X				
Triamcinolone Acetonide	0.025%	Ointment	Topical application	X				
Triamcinolone Acetonide	0.1%	Cream	Topical application	X				
Triamcinolone Acetonide	0.1%	Ointment	Topical application	X				
Triamcinolone Acetonide	0.5%	Cream	Topical application	X				
Triamcinolone Acetonide	0.5%	Ointment	Topical application	X				
Triazolam	0.125mg	Tablet	Oral				X	
Triazolam	0.25mg	Tablet	Oral				X	
Trifluoperazine Hydrochloride	10mg	Tablet	Oral				X	
Trifluoperazine Hydrochloride	1mg	Tablet	Oral				X	
Trifluoperazine Hydrochloride	5mg	Tablet	Oral				X	
Tropicamide	1%	Solution	Ophthalmic		X			
Ursodiol	300mg	Capsule	Oral					X

Legend: %=percent; mg=milligrams; ml=milliliters; meq=milliequivalents

Source: GAO analysis of Medicare Part D prescription drug event data and Red Book. | GAO-16-706

Note: A price increase of at least 100 percent from the first quarter of one year to the first quarter of the next is considered an extraordinary price increase. To be considered an established drug, a drug had to be in the Medicare Part D claims data for each quarter from the first quarter of 2009 through the second quarter of 2015 and meet certain other data reliability standards. A total of 1,441 drugs met these criteria. The information presented in this appendix was obtained from Medicare Part D prescription drug event data and Red Book. In general, we reprinted the abbreviations and acronyms as provided in the data.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

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Related GAO Products

Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices. GAO-14-578. Washington: D.C: June 30, 2014.

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