



## Trends in Prescription Drug Spending, 2016-2021

### KEY FINDINGS

- In 2021, the U.S. health care system spent \$603 billion on prescription drugs, before accounting for rebates, of which \$421 billion was on retail drugs.
- Spending growth on drugs was largely due to growth in spending per prescription, and to a lesser extent by increased utilization (i.e., more prescriptions).
- Expenditure growth was larger for non-retail drug expenditures (25%) than for retail expenditures (13%).
- Between 2016 and 2021, the location where people received their drugs changed. Americans increasingly received their drugs from mail order pharmacies (35% increase), clinics (45% increase), and home health care (95% increase). During the same time period, there were decreases in drugs received through independent pharmacies (5% decrease), long term care facilities (17% decrease), and federal facilities (9% decrease).
- Drug spending is heavily driven by a relatively small number of high-cost products. The cost of specialty drugs has continued to grow, totaling \$301 billion in 2021, an increase of 43% since 2016. Specialty drugs represented 50% of total drug spending in 2021. While the majority (80%) of prescriptions that Americans fill are for generic drugs, brand name drugs accounted for 80% of prescription drug spending in both retail and non-retail settings, with little change over time. The top 10% of drugs by price make up fewer than 1% of all prescriptions, but account for 15% of retail spending and 20%-25% of non-retail spending.
- Prescription drug spending trends have been less affected by the COVID-19 pandemic than health care services.
- Several provisions in the Inflation Reduction Act address drug pricing, including allowing the Secretary of HHS to negotiate prices in Medicare Parts B and D for selected medications and introducing Medicare rebates for drug prices that rise faster than inflation. These provisions may impact future drug spending trends.

### Introduction

High prescription drug costs are a leading concern among Americans.<sup>1</sup> Americans pay higher prices for prescription drugs than any other country in the world, with prescription drug prices in the U.S. more than 2.5 times as high as those in other similar high-income nations.<sup>2</sup> To support the Administration's efforts to make drug prices and spending more transparent, the goal of this brief is to present the drivers of total spending on prescription drugs between 2016 and 2021. The analyses are disaggregated for retail drugs and non-retail drugs. We also examine spending specifically on brand name drugs, specialty drugs, and the top 10% of drugs by price. By examining trends over time, we capture changes in prescription drug spending during the COVID-19 pandemic.

<sup>1</sup> Bush, L and Sommers, B.D. (2022). Improving Prescription Drug Affordability Through Regulatory Action. JAMA Health Forum 3(8).

<sup>2</sup> Mulcahy, A.W., Whaley, C., Tebeka, M.G., Schwam, D., Edenfield, N., and Becerra-Ornelas, A.U. "International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies," RAND Research Report RR-2956-ASPEC, 2021. Available at: <https://aspe.hhs.gov/sites/default/files/documents/ca08ebf0d93dbc0faf270f35bbecf28b/international-prescription-drug-price-comparisons.pdf>.

## Methods

### Data

The primary data for this analysis were IQVIA National Sales Perspective (NSP) data from 2016 through 2021.<sup>3</sup> IQVIA data are derived from a panel of wholesalers, distributors, and pharmaceutical manufacturers that represent 90% of the pharmaceutical market and are projected to be nationally representative.<sup>3</sup>

We examined two primary outcomes of interest: prescription drug spending and number of prescriptions. Prescription drug spending was measured in inflation adjusted dollars.<sup>4</sup> The IQVIA dataset reports gross drug spending, meaning it does not include rebates.<sup>5</sup> The number of prescriptions was calculated as a measure of the number of units of a drug a manufacturer sold to a wholesaler or pharmacy. The data are at the drug claim level and include where an individual received drugs (i.e., retail or non-retail dispensers). Retail drugs were defined as those that are filled in an outpatient setting, including standalone pharmacies and mail order prescriptions. Non-retail drugs were defined as those administered in an inpatient setting, including hospitals, clinics, physician offices, long term care facilities, and home health. Non-retail spending on prescription drugs was one of the fastest drivers of prescription drug spending; thus, capturing these prescriptions was critical to understanding current prescription drug spending trends.

The drug attributes of interest included brand name and generic drugs, specialty drugs, and the top 10% of drugs based on price. The top 10% of drugs by price were defined on an annual basis, meaning the drugs change for each year of the sample.<sup>6</sup>

## Results

### Total Spending Trends

Table 1 shows the number of prescriptions and drug expenditures from 2016 to 2021. Total inflation-adjusted expenditures on prescription drugs grew from \$520 billion in 2016 to \$603 billion in 2021, a 16 percent increase. This rate of growth was similar to overall national health care spending growth, with prescription drugs maintaining approximately an 18 percent share of total health care expenditures throughout this time period. Overall, retail drug expenditures represented roughly 70% of prescription drug spending and non-retail 30%.

We then examined trends broken out by retail and non-retail drugs. There was a 13 percent increase in retail prescription drug spending over this five-year period, but only a 5.7 percent increase in the *number* of retail prescriptions. On average, there was a 7 percent increase in spending per prescription, which suggests that changes in utilization (i.e., a greater number of prescriptions being filled) were not the primary driver of increased retail drug spending. For non-retail drugs, we observed a 25 percent increase in expenditures and a 19 percent increase in the number of prescriptions. On average, there was a 5 percent increase in the spending per prescription, meaning that the primary driver of increased non-retail prescription drug spending was greater utilization, rather than higher drug prices. The growth in non-retail prescriptions, 19 percent, was 3.4 times higher than the increase in prescriptions for retail drugs.

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<sup>3</sup> Source of the data: IQVIA. U.S. National Data. <<https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data>>.

<sup>4</sup> The spending data includes an adjustment for inflation, thereby representing a “real” dollar. The data represent the value of a real dollar as of quarter 1 of 2022. Source: U.S. Bureau of Economic Analysis, Gross Domestic Product: Implicit Price Deflator [GDPDEF], retrieved from FRED, Federal Reserve Bank of St. Louis; <https://fred.stlouisfed.org/series/GDPDEF>, August 19, 2022.

<sup>5</sup> Retail drugs can be subject to rebates while non-retail drugs do not have rebates. As a result, retail drug spending may be overestimated relative to non-retail spending and personal health expenditures (the NHEA estimates are net of rebates for retail drug spending).

<sup>6</sup> More details about the variable specifications can be found in the appendix.

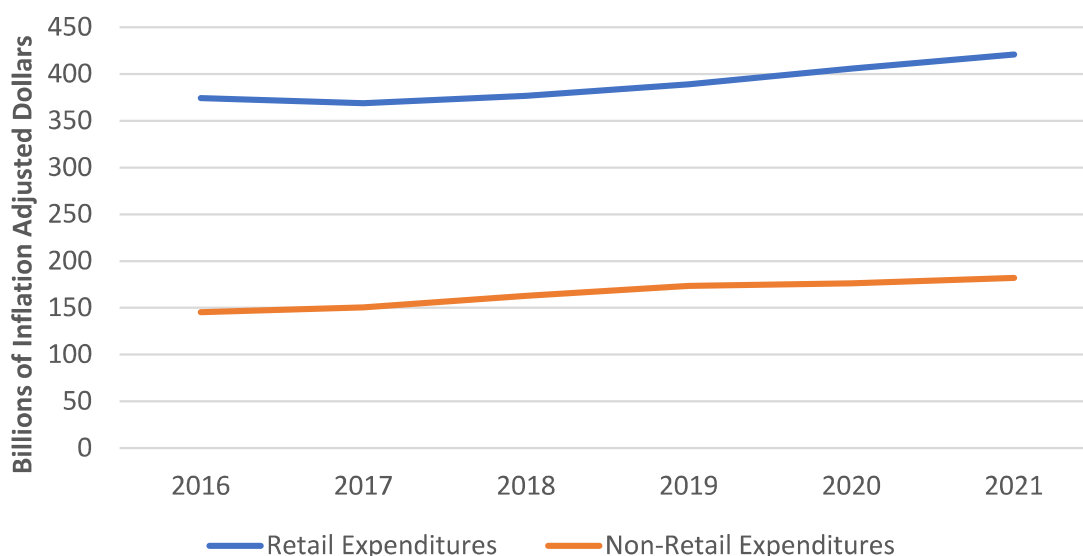
**Table 1. Prescription Drug Expenditures (in Inflation Adjusted Dollars) and Prescriptions, 2016-2021**

|                    | Retail Expenditures Billions, \$ | Retail Prescriptions Millions | Non-Retail Expenditures Billions, \$ | Non-Retail Prescriptions Millions | Total Expenditures Billions, \$ | Total Prescriptions Millions |
|--------------------|----------------------------------|-------------------------------|--------------------------------------|-----------------------------------|---------------------------------|------------------------------|
| 2016               | 374                              | 4,816                         | 146                                  | 3,066                             | 520                             | 7,882                        |
| 2017               | 369                              | 4,923                         | 151                                  | 3,097                             | 519                             | 8,020                        |
| 2018               | 377                              | 5,118                         | 163                                  | 3,214                             | 540                             | 8,332                        |
| 2019               | 389                              | 5,243                         | 173                                  | 3,486                             | 562                             | 8,729                        |
| 2020               | 406                              | 4,970                         | 176                                  | 3,509                             | 582                             | 8,479                        |
| 2021               | 421                              | 5,089                         | 182                                  | 3,654                             | 603                             | 8,743                        |
| % Change 2016-2021 | 12.5%                            | 5.7%                          | 25.1%                                | 19.2%                             | 16.0%                           | 10.9%                        |

**Source:** ASPE analysis of IQVIA National Sales Perspective (NSP) Data. All dollar amounts include an adjustment for inflation so they represent a “real dollar” as of quarter 1 of 2022.

Figure 1 shows the change in retail and non-retail expenditures between 2016 and 2021. Similar to Table 1, we observe growth in both retail and non-retail drug expenditures, with a slightly faster rate of growth for non-retail drug spending.

**Figure 1. Spending (in Inflation Adjusted Dollars) on Retail and Non-Retail Drugs, 2016-2021**



**Source:** ASPE analysis of IQVIA National Sales Perspective Data. All dollar amounts include an adjustment for inflation so they represent a “real dollar” as of quarter 1 of 2022.

**Location of Sale**

Table 2 shows the breakdown of spending over time by location of sale. There were four locations of sale for retail drug expenditures – chain store pharmacy, mail order pharmacy, independent pharmacy, and food store pharmacy. Three of the four locations experienced an increase in sales between 2016 and 2021. Expenditures increased by 4 percent in chain store pharmacies, 35 percent for mail order pharmacies, and 1 percent for food store pharmacies, but decreased 5 percent for independent pharmacies.

For non-retail drug spending, there were more potential locations of sale, but the majority of these locations dispensed small volumes of drugs. Over the full five-year period, the most common location of sale for non-retail drug expenditures were clinics. Spending in clinics increased from \$76 billion in 2016 to \$110 billion in 2021, a 45 percent increase. The other location with substantial sales of non-retail drugs were non-federal hospitals. Non-federal hospitals spent \$39 billion on non-retail drugs in 2016 which increased by 4 percent to \$41 billion in 2021. The location with the largest increase in use was home health care, where there was a 95 percent increase from 2016 through 2021. Five locations of sale experienced declines in non-retail drug expenditures over the time span. These was a 31 percent drop in non-retail drug spending in universities, a 17 percent drop in non-retail expenditures in long term care facilities, a 15 percent drop in “other” non-retail settings, a 10 percent drop in prison non-retail drug expenditures, and a 9 percent drop in federal facilities.

*Table 2. Expenditures (in Inflation Adjusted Dollars) on Drugs Based on Location of Sale, 2016-2021*

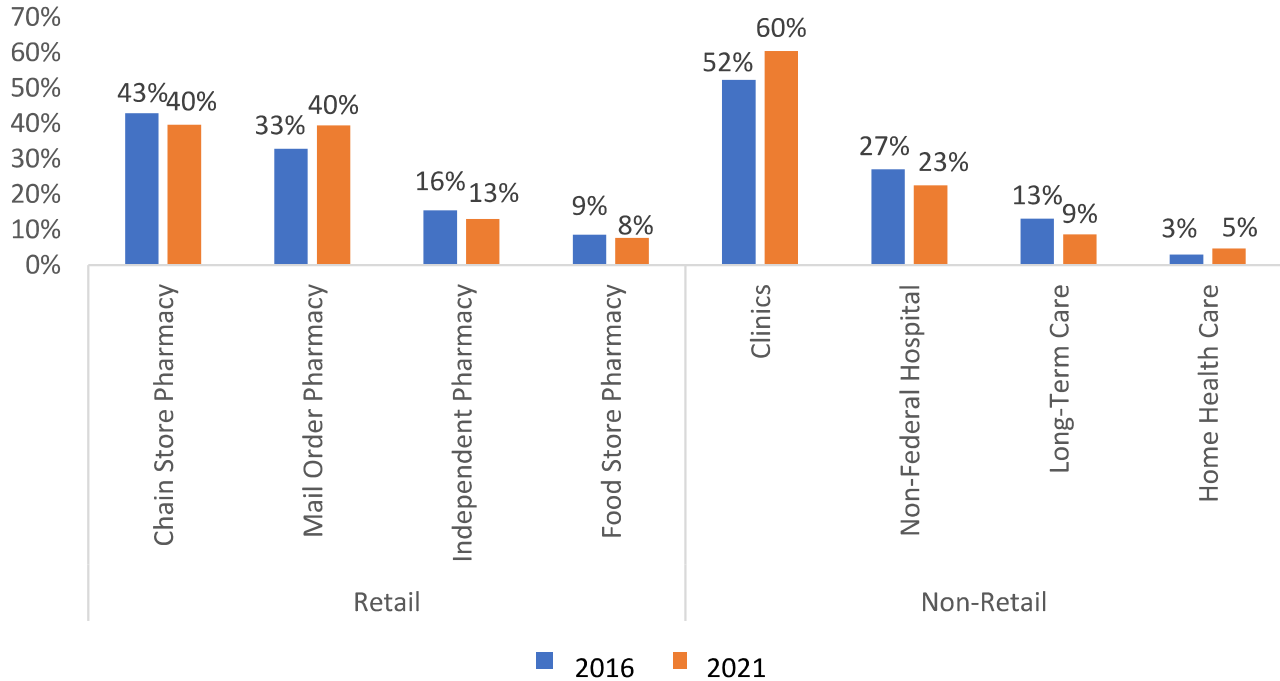
| Location of Sale  |                      | 2016         | 2017 | 2018 | 2019 | 2020 | 2021 | % Change<br>2016-2021 |
|-------------------|----------------------|--------------|------|------|------|------|------|-----------------------|
|                   |                      | Billions, \$ |      |      |      |      |      |                       |
| <b>Retail</b>     | Chain Store Pharmacy | 161          | 154  | 156  | 158  | 164  | 167  | 4                     |
|                   | Mail Order Pharmacy  | 123          | 128  | 136  | 146  | 158  | 166  | 35                    |
|                   | Independent Pharmacy | 58           | 57   | 56   | 55   | 54   | 55   | -5                    |
|                   | Food Store Pharmacy  | 32           | 30   | 29   | 30   | 31   | 33   | 1                     |
| <b>Non-Retail</b> | Clinics              | 76           | 82   | 91   | 101  | 106  | 110  | 45                    |
|                   | Non-Federal Hospital | 39           | 39   | 40   | 41   | 39   | 41   | 4                     |
|                   | Long-Term Care       | 19           | 19   | 19   | 17   | 16   | 16   | -17                   |
|                   | Home Health Care     | 4.4          | 4.8  | 6.3  | 7.5  | 8.2  | 8.6  | 95                    |
|                   | Federal Facilities   | 3.0          | 3.1  | 3.1  | 3.2  | 2.9  | 2.8  | -9                    |
|                   | HMO                  | 1.8          | 2.0  | 2.1  | 2.4  | 2.5  | 2.1  | 21                    |
|                   | Other                | 0.6          | 0.7  | 0.5  | 0.6  | 0.6  | 0.5  | -15                   |
|                   | Prisons              | 0.6          | 0.6  | 0.6  | 0.6  | 0.5  | 0.5  | -10                   |
|                   | Universities         | 0.32         | 0.33 | 0.33 | 0.32 | 0.23 | 0.22 | -31                   |

**Source:** ASPE analysis of IQVIA National Sales Perspective (NSP) Data. All dollar amounts include an adjustment for inflation so they represent a “real dollar” as of quarter 1 of 2022.

HMO = Health Maintenance Organization

Figure 2 shows the change in the total share of prescriptions filled by location of sale between 2016 and 2021. In 2016, the plurality of retail prescriptions, 43 percent, were purchased at a chain store pharmacy, but by 2021, there were equal shares of retail drug expenditures at chain store pharmacies and mail order pharmacies (40 percent each). In the non-retail setting, clinics were the most common location of sale in 2016 and they increased their share of non-retail drug expenditures by 8 percent in 2021. The increase was the result of a 4 percent decrease each in the share of non-retail drug expenditures in non-federal hospitals and long-term care facilities.

**Figure 2. Percent of Spending on each Location of Sale, 2016-2021**



**Note:** Four categories (Health Maintenance Organizations, Other, Prisons, and Universities) were not included because they represented fewer than 2% of prescriptions in 2016 and 2021)

**Source:** ASPE analysis of IQVIA National Sales Perspective Data

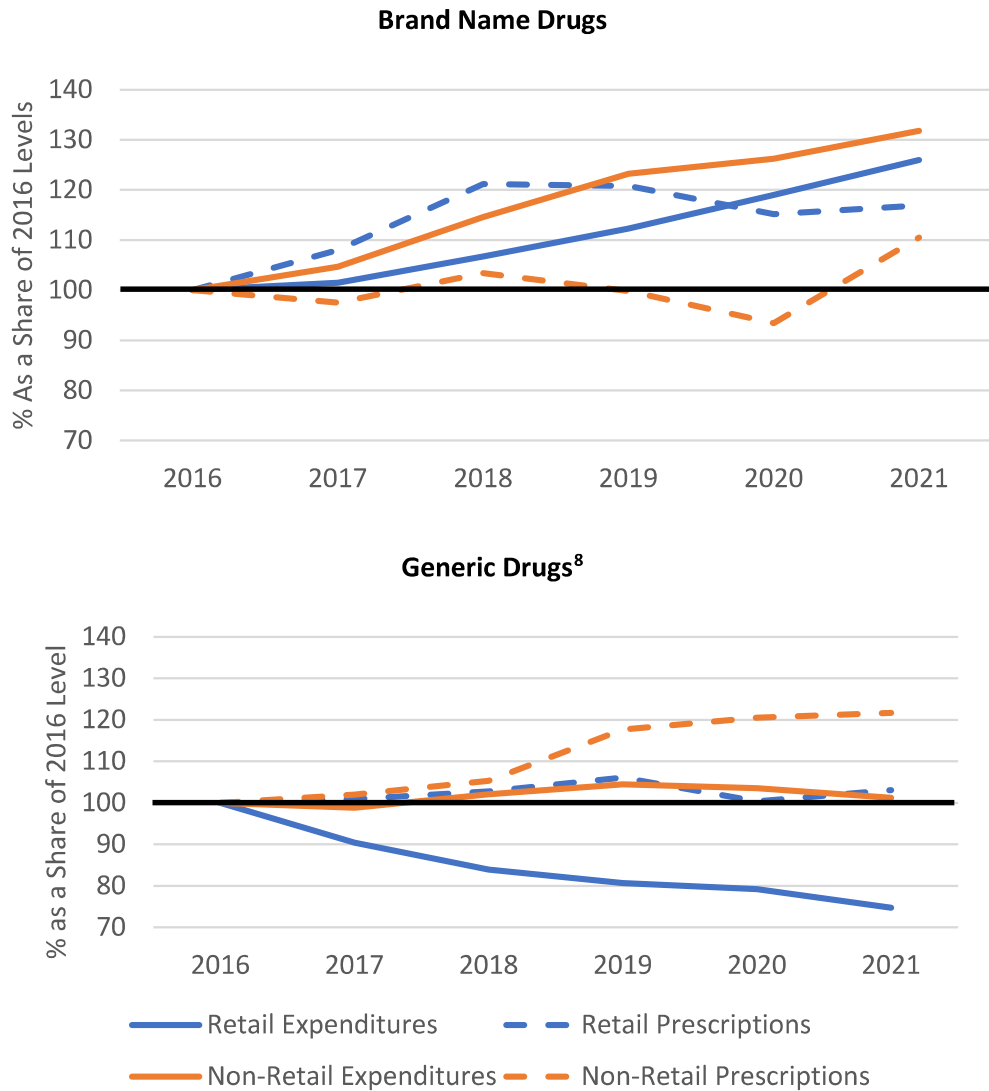
### Brand vs. Generic Drug Changes

Figure 3 breaks down changes in prescription drug spending and number of prescriptions by brand name versus generic drugs. Among brand name drugs, there was growth in both retail and non-retail drug expenditures across the five-year time span, including during 2020. The trend for brand name drug expenditures was consistent with the trend seen for overall prescription drug spending in Figure 1.<sup>7</sup> The trends in expenditures and prescriptions for generic drugs were different than for brand name drugs. For generic drugs, from 2016 to 2021, there was a steady decline in retail generic drug expenditures and a steady increase in non-retail generic drug expenditures.

However, the number of brand name prescriptions varied by year for both brand name and generic drugs. Among retail brand name prescriptions, there was a growing number of prescriptions from 2016 to 2018 and then a plateau between 2018 and 2021, with a slight dip in 2020. Despite this variation in the number of prescriptions, there was a continual increase in total expenditures on brand name drugs throughout this five-year period, which is likely the result of growth in spending per prescription. For non-retail brand name prescriptions and retail generic drugs, there was year to year variation, as seen in Figure 3. For non-retail generic prescriptions, there was some year-to-year fluctuation between 2018 and 2021, but, across the full time period, there was no change. Examining these trends collectively, utilization increases played a role in increased expenditures among retail brand name drugs but played no role in expenditure growth for non-retail drugs.

<sup>7</sup> For brand name prescription expenditures, the data presented does not include rebates. Rebates for generic drugs and non-retail drugs are minimal.

**Figure 3. Change in Expenditures (in Inflation Adjusted Dollars) and Prescriptions for Brand Name and Generic Drugs, 2016-2021**

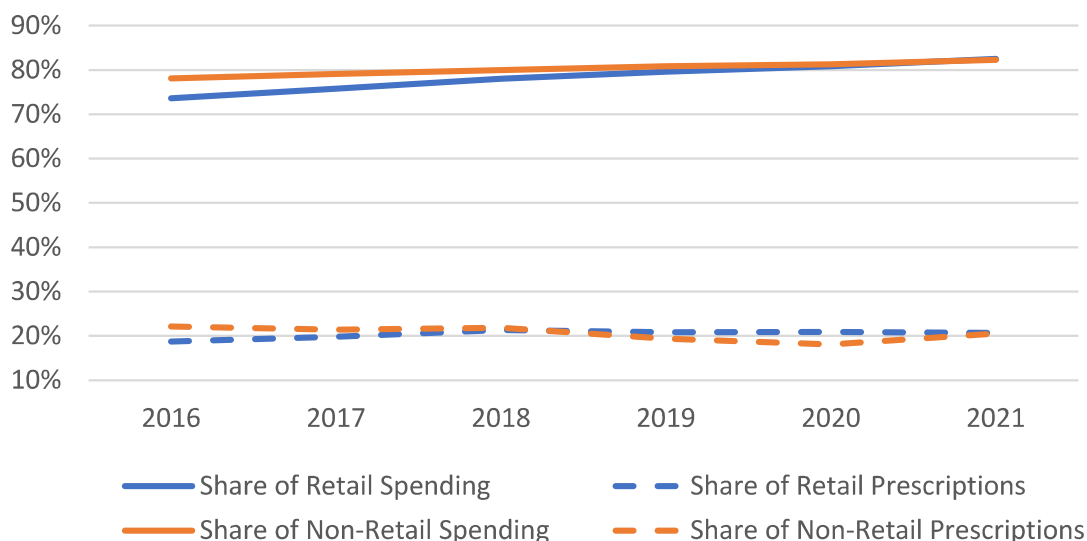


**Source:** ASPE analysis of IQVIA National Sales Perspective Data. All dollar amounts include an adjustment for inflation so they represent a “real dollar” as of quarter 1 of 2022.

Figure 4 shows the share of all prescriptions and expenditures for brand name drugs from 2016 to 2021. There was almost no change over this period for either measure. Brand name drugs accounted for 80 percent of prescription drug expenditures in both retail and non-retail settings, despite accounting for only 20 percent of retail and non-retail prescriptions, with little change over time. However, there was a noticeable dip in non-retail prescriptions in 2020 that was likely related to a drop in office visits during the early stages of the COVID-19 pandemic. However, there was no corresponding dip in spending on non-retail drugs.

<sup>8</sup> “Generic drugs” includes both true generics and branded generics

**Figure 4. Brand Name Drugs as a Share of All Prescription Drug Spending and Prescriptions<sup>9</sup>**



**Source:** ASPE analysis of IQVIA National Sales Perspective Data

### Specialty Drugs

Table 3 shows trends in specialty drug spending between 2016 and 2021 (see Appendix for definition of specialty drugs). The overall changes resemble what was evident for all drugs, spending growth was largely due to higher prices per prescription, not increases in utilization. By 2021, specialty drugs were more than 40 percent of retail drug spending and nearly 70 percent of non-retail drug spending.<sup>10</sup>

Specialty drug spending between 2016 and 2021 increased by 43 percent for a total of \$301 billion in 2021, despite there being only a 0.5 percent increase in the number of specialty prescriptions. Disaggregating the data for the retail and non-retail settings, the percent of retail drug spending on specialty drugs increased 22 percent between 2016 and 2021. The number of retail prescriptions for specialty drugs increased from 2016 through 2019, but there was a drop in 2020 and 2021. When examining the five-year trend, there was a net 18 percent drop in the specialty share of retail prescriptions. In contrast, when examining non-retail specialty drugs, the percent of spending on specialty drugs increased 20 percent over the five-year time horizon and the number of prescriptions for specialty drugs increased by 40 percent, despite decreases in prescriptions in 2019, 2020, and 2021.

<sup>9</sup> The rate of generic drugs as a share of all prescription drug spending and prescriptions is the inverse of the brand name spending and prescriptions.

<sup>10</sup> Rebates for specialty drugs with competition can be substantial, were is not accounted for in this analysis.

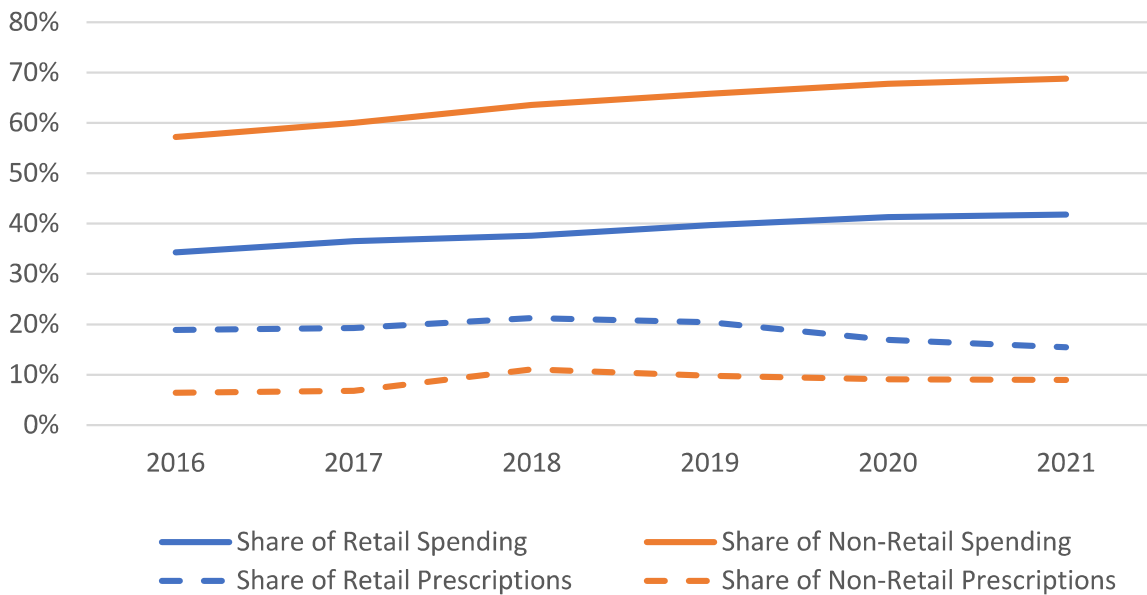
**Table 3. Specialty Drug Expenditures (in Inflation Adjusted Dollars), 2016-2021**

|                    | Total Specialty Spending Billions, \$ | Number of Specialty Prescriptions Millions | Retail Spending                |                                     | Non-Retail Spending                |   |
|--------------------|---------------------------------------|--|--------------------------------|-------------------------------------|------------------------------------|---|
|                    |                                       |  | % Retail Spending on Specialty | % Retail Prescriptions on Specialty | % Non-Retail Spending on Specialty | % Non-Retail Prescriptions on Specialty |
| 2016               | 211                                   | 1,107                                      | 34.3                           | 18.9                                | 57.2                               | 6.4                                     |
| 2017               | 225                                   | 1,160                                      | 36.5                           | 19.3                                | 60.0                               | 6.8                                     |
| 2018               | 245                                   | 1,443                                      | 37.6                           | 21.3                                | 63.6                               | 11.0                                    |
| 2019               | 268                                   | 1,413                                      | 39.7                           | 20.4                                | 65.8                               | 9.8                                     |
| 2020               | 287                                   | 1,161                                      | 41.3                           | 16.9                                | 67.8                               | 9.1                                     |
| 2021               | 301                                   | 1,113                                      | 41.8                           | 15.4                                | 68.8                               | 8.9                                     |
| % Change 2016-2021 | 42.5%                                 | 0.5%                                       | 21.9%                          | -18.3%                              | 20.3%                              | 40.0%                                   |

Source: ASPE analysis of IQVIA data. All dollar amounts include an adjustment for inflation so they represent a “real dollar” as of quarter 1 of 2022.

Figure 5 shows trends over time in the share of retail and non-retail drug spending and prescriptions for specialty drugs. Between 2016 and 2021, there was a slight increase, up to 10 percent, in the share of both retail and non-retail spending for specialty drugs. But there was very little change over time in the number of prescriptions for specialty drugs; the share of retail prescriptions on specialty drugs rarely exceeded 20 percent and the share of non-retail prescriptions on specialty drugs rarely exceeded 10 percent.

**Figure 5. Specialty Drugs as a Share of All Retail Prescription Drug Spending and Prescriptions**

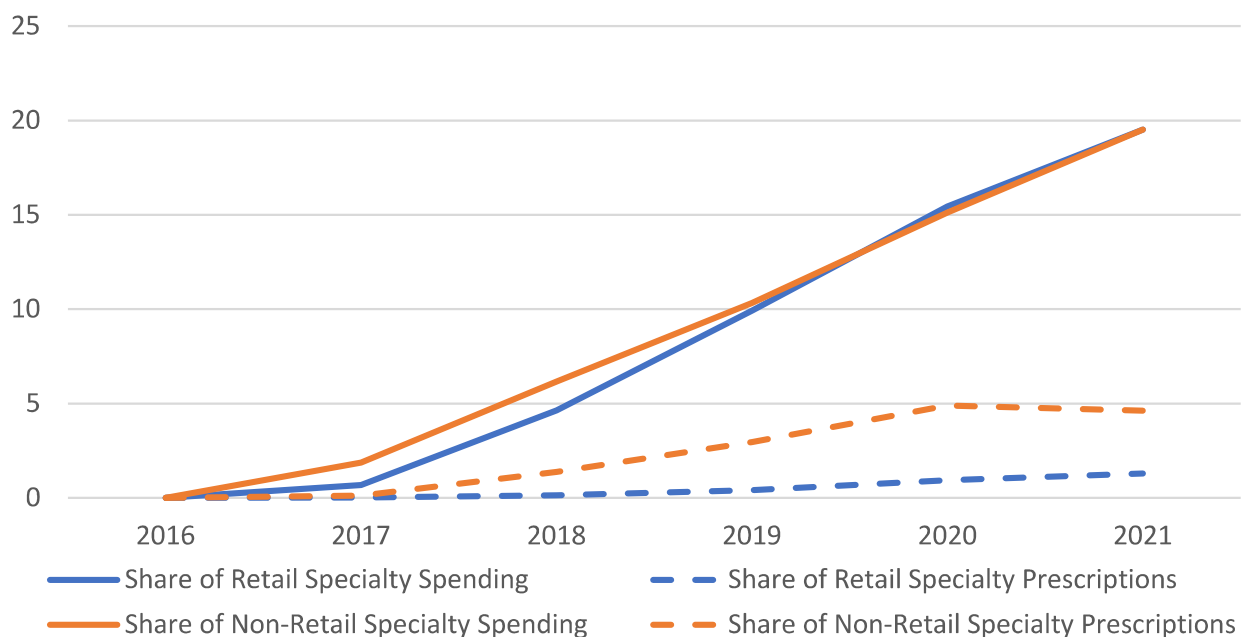


Source: ASPE analysis of IQVIA National Sales Perspective Data



Over the past decade, there has been a trend towards a larger share of new drug approvals for specialty drugs.<sup>11</sup> Figure 6 shows the annual share of specialty drug spending on new drugs, defined as those drugs introduced after 2016. By 2021, the share of specialty drug spending on new drugs, in both the retail and non-retail settings, was 20 percent. Among all specialty drug prescriptions, fewer than 5 percent of prescriptions were for new drugs, in both the retail and non-retail settings. This means that in the retail setting, 1 percent of prescriptions for new specialty drugs accounted for 20 percent of spending (\$25 billion).

**Figure 6. Share of New Drugs (Introduced Since 2016) as a Share of Specialty Drug Spending, 2016-2021**



Source: ASPE analysis of IQVIA National Sales Perspective Data

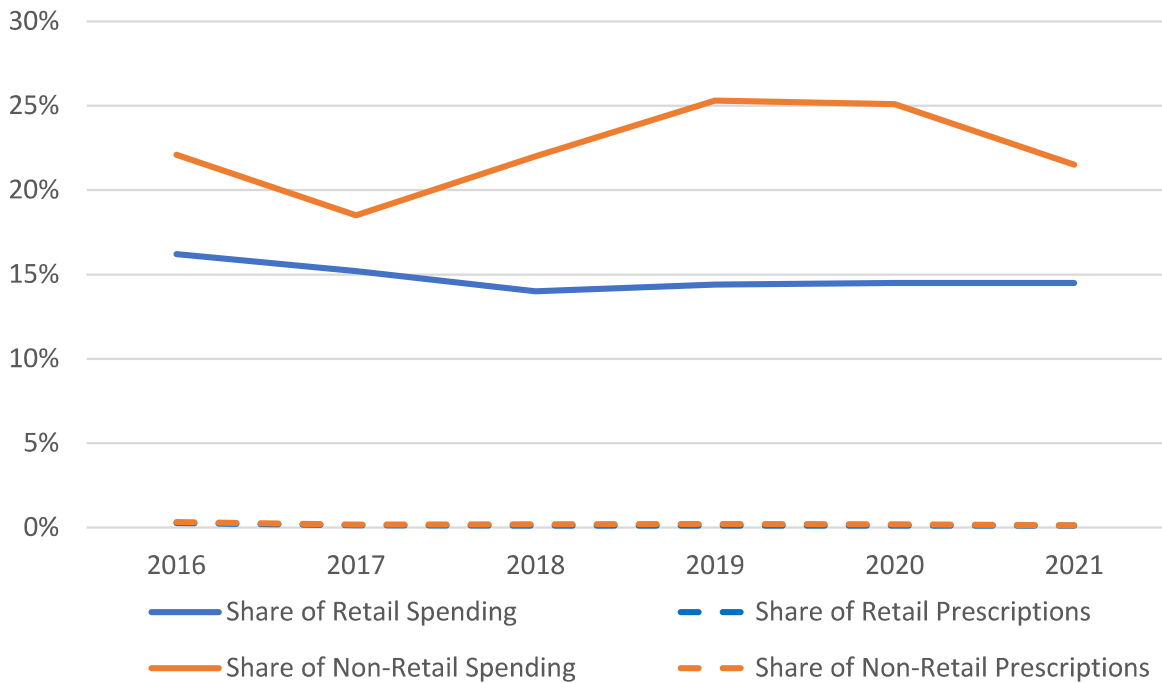
### Most Expensive Drugs

Figure 7 shows the share of spending and prescriptions for the top ten percent of drugs by price<sup>12</sup>. The top 10 percent of drugs by price made up 15 percent of retail spending between 2016 and 2021, with little change over time. The top 10 percent of drugs by price made up 20 to 25 percent of non-retail spending, depending on the year. For both retail and non-retail prescriptions, the top 10 percent of drugs by price made up less than 1 percent of total prescriptions.

<sup>11</sup> Congressional Budget Office. (2021). A Comparison of Brand-Name Drug Prices Among Selected Federal Programs. <https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf>

<sup>12</sup> Price was defined as the reported drug price (i.e., gross drug cost before rebates) in the IQVIA data.

**Figure 7. Top 10% of Drugs by Price as a Fraction of All Drug Expenditures (in Inflation Adjusted Dollars) on Prescription Drugs**



Source: ASPE analysis of IQVIA National Sales Perspective Data

## Conclusion

This brief shows trends in prescription drug spending between 2016 and 2021, disaggregated by retail and non-retail settings, generic vs. brand drugs, and specialty and high-cost drugs. We found a steady increase in prescription drug spending from \$520 billion in 2016 to \$603 billion in 2021. This increase was driven by increases in spending per prescription, and less so by increases in the number of prescriptions. The largest rate of growth occurred among non-retail drugs, which increased by 40 percent. There was also a continued increase in the share of spending on specialty drugs. These trends are a continuation of the findings from an ASPE Issue Brief that examined prescription drug spending between 2009 and 2015, despite rapid change in the prescription drug market during this period, including the increase in specialty drugs use and the use of rebates for high-cost drugs with competition.<sup>13</sup>

Despite our time period coinciding with the COVID-19 pandemic, we saw little impact of the pandemic on prescription drug spending. Among the measures of drug spending we examined, only one measure – brand name prescriptions – experienced a noticeable change in 2020 and 2021 that was different than the trend established between 2016 and 2019. This suggests that spending on prescription drugs was not impacted as significantly by the pandemic as other health care services.

The passage of the Inflation Reduction Act (IRA) of 2022 will introduce several new provisions intended to affect drug spending trends in the future.<sup>14</sup> The HHS Secretary will have the authority to negotiate drug prices for

<sup>13</sup> Observations on Trends in Prescription Drug Spending. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. March 2016.

[https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files//142181/Drugspending.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//142181/Drugspending.pdf)

<sup>14</sup> U.S. Congress. (2022). H.R.5376 - Inflation Reduction Act of 2022. <https://www.congress.gov/bill/117th-congress/house-bill/5376>

selected products in Medicare; the first group of drugs for negotiation will be identified in 2023, with negotiated prices effective starting in 2026.<sup>15</sup> Drugs qualify as negotiation-eligible based on absence of generic or biosimilar competitors; total spending in Medicare Part B and Medicare Part D; and time elapsed since FDA approval. By targeting the highest spending drugs without competition, this provision of the IRA aims to slow the rate of increase in drug spending over time. The IRA also requires manufacturers who raise Medicare Part B and Medicare Part D drug prices faster than inflation to pay rebates to Medicare. The goal of this policy is to lower year-over-year increases in the price of prescription drugs, particularly brand name drugs, which make up 80 percent of all prescription drug spending. Since the primary driver of increased prescription drug spending has been increases in spending per prescription, not greater utilization, discouraging price increases above inflation for drugs already on the market may help reduce future growth in prescription drug spending. Other IRA provisions include eliminating Medicare Part D cost-sharing for recommended vaccines and capping Medicare Part B and Part D insulin cost-sharing at \$35 per insulin product per month beginning in 2023; eliminating cost sharing for beneficiaries in the catastrophic phase of the Part D benefit, expanding the low-income subsidy program, and ensuring premium stabilization beginning in 2024; and capping beneficiary out-of-pocket Medicare Part D costs at \$2,000 and implementing a new manufacturer discount program beginning in 2025. These provisions may also impact future drug spending trends.

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<sup>15</sup> Congressional Research Service. (2022). Selected Health Provisions of the Inflation Reduction Act. <https://crsreports.congress.gov/product/pdf/IF/IF12203>.

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## Appendix

The variable used to measure the number of prescriptions throughout this brief is the “eaches” variable in IQVIA data, which is defined as “the number of single items (such as vials, syringes, bottles, or packet of pills) contained in a unit or shipping package and purchased by pharmacies in a specific time period. An each is not a single pill or dosage of medicine (unless one package consists of a single dose). An each may be the same as a unit if the unit does not subdivide into packages.”

Specialty drugs are defined by IQVIA as products used to treat chronic, rare or complex diseases and that meet 4 or more of the following criteria<sup>3</sup>:

- Initiated and maintained by a specialist
- Generally injectable and/or not self-administered
- Products that require an additional level of care in their chain of custody (i.e., refrigerated, frozen, chemo, biohazard, etc.)
- Expensive (USD \$6K annual cost of therapy)
- Unique distribution (e.g., specialty MO, REMS)
- Requires extensive or in-depth monitoring/patient counseling
- Requires reimbursement assistance
- Products that clearly meet the above criteria are defined as Specialty. Products that are borderline (e.g. meet three, rather than four criteria) will be brought before the Specialty Governance Board for review and final decision.

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### SUGGESTED CITATION

Parasrampur, S. and Murphy, S. Trends in Prescription Drug Spending, 2016-2021. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2022.

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