

# Access, Affordability, and Outcomes

THE VALUE OF MANAGED  
CARE PHARMACY







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## LETTER FROM THE CEO

2024 is an election year, so it should come as no surprise that the subject of health care affordability — particularly for prescription drugs — is front and center for many voters. For example, as a part of the Inflation Reduction Act (IRA), Medicare was authorized to negotiate the prices of certain drugs. This was a first for the program, and when the negotiated prices for the first 10 eligible drugs were released in August, it sparked real debate within the health care community. Moreover, it cemented drug prices as a focus for presidential campaigns as well as down-ballot races.

That is one of the many reasons why I'm pleased to share the 2024 edition of AMCP's annual *Access, Affordability, & Outcomes* report. We are publishing this report in October, a few weeks before the election. Now more than ever, it is essential that key policymakers and stakeholders have a reliable source of data to inform the critical decisions they make about health care and prescription drug coverage in the United States.

But this report isn't useful only to those in Washington, DC, and state capitals across the country. AMCP launched this report last year for everyone who is involved in health care — to help them make sense of the complex prescription drug landscape. Patients, providers, health payers, health care advocates, pharmaceutical manufacturers, and countless others can all find something in this report to better understand the role managed care pharmacy plays in facilitating patients' access to their treatments. In fact, new analysis in this year's report looks at cost savings and adherence achieved using 90-day prescriptions instead of the traditional 30-day supply, showing how managed care strategies can improve patient care.

Striking the right balance between access and affordability is crucial to reaching the right outcomes. This has never been truer than now, with innovative but high-cost therapies regularly being launched, many for previously untreatable conditions. And as these new treatments emerge, the market must also develop new coverage strategies that get the right drug to the right patient.

There is more work to be done than ever, but I am optimistic that together we will find solutions to help patients get the medicine they need at a cost they can afford. This report plays an important educational role in that mission.

Sincerely,



**Susan Cantrell, MHL, RPh, CAE**  
Chief Executive Officer



## **ABOUT THE ACADEMY OF MANAGED CARE PHARMACY (AMCP)**

AMCP is the professional association leading the way to help patients get the medications they need at a cost they can afford. AMCP's diverse membership of pharmacists, physicians, nurses, biopharmaceutical professionals, and other stakeholders leverage their specialized expertise in clinical evidence and economics to optimize medication benefit design and population health management and help patients access cost-effective and safe medications and other drug therapies. AMCP members improve the lives of nearly 300 million Americans served by private and public health plans, pharmacy benefit management firms, and emerging care models.

# I. Introduction and Goals of This Report



The health care sector touches the daily lives of millions of Americans. However, there is often confusion or a lack of understanding about why it operates the way it does. Managed care pharmacy — often working behind the scenes but having a profound impact on access to and affordability of prescription medications — is not immune to this challenge. To address this, the Academy of Managed Care Pharmacy (AMCP) publishes this annual report to raise awareness of the existence, prevalence, and importance of managed care pharmacy in the lives of millions of Americans.

If you're looking to better understand the fundamental concepts of managed care pharmacy, this report provides clarity. This report explores how professionals in this field work diligently to facilitate appropriate access to prescription treatments while remaining mindful of rising costs. It discusses key areas of focus such as:

- Pharmacy benefit design and implementation.
- Formulary and medication utilization management.
- Clinical programs.
- Quality and safety program management.
- Promoting affordability.

The report also highlights the most widely used managed care pharmacy tools: prior authorization, drug utilization, medication therapy management, and formulary design and management.

This report goes beyond the basics, offering a deep dive into the challenges facing managed care pharmacy and the opportunities it creates.

Throughout the following pages, you'll find extensive data-driven insights and studies — just as our professionals do daily.

The result is a comprehensive resource that makes a persuasive and detailed case about the value of managed care pharmacy. In a world with a pressing need for affordable access to necessary prescription medications, millions of Americans are looking for balanced solutions. Managed care pharmacy plays a crucial role — and this report demonstrates how.

**AMCP publishes this annual report to raise awareness of the existence, prevalence, and importance of managed care pharmacy in the lives of millions of Americans.**

## II. Overview of Managed Care and the Current State of Prescription Spending in the United States



### What is Managed Care?

Broadly speaking, managed care is “a health care delivery system organized to manage cost, utilization, and quality.”<sup>1</sup> Managed care plans seek to reduce costs while keeping quality high through the use of provider networks, prescription drug tiers, and other forms of utilization management.<sup>2</sup> Managed care is a structured approach to financing and delivering covered health care benefits designed to provide affordable access and cost-effectively improve the quality of care. A managed care organization, or MCO, is a generic term applied to a managed care plan. MCOs manage the cost and utilization of covered services and products to optimize patient care by efficiently using limited resources. Some of the largest MCOs in the United States include UnitedHealth Group, Anthem, Centene, Kaiser Permanente, and Humana.<sup>3</sup>

The roots of managed care can be traced back to two models of health care financing: prepaid medical groups and the early Blue Cross and Blue Shield plans.<sup>4</sup> The Western Clinic in Tacoma, Wash., founded in 1910, is often cited as the first “prepaid medical group,” which offered its members a broad range of medical services through its own providers in exchange for a fixed monthly payment.<sup>5</sup> Later, in 1937, the Kaiser Construction Company began to finance medical care for its workers as it built an aqueduct in California.<sup>6</sup> This organization later evolved into the Kaiser Permanente Health Plan, one of the largest health insurance providers in the United States. The early Blue Cross and Blue Shield plans paid for services provided by contracted physicians and hospitals that serviced Blues patients and other, unaffiliated patients.<sup>7</sup>

1 “Managed Care,” Medicaid.gov (<https://www.medicaid.gov/medicaid/managed-care/index.html>, accessed June 5, 2023).

2 “What is Managed Care?,” Cigna (<https://www.cigna.com/knowledge-center/what-is-managed-care>, accessed June 5, 2023).

3 “2022 Market Share Reports For the Top 125 Accident and Health Insurance Groups and Companies by State and Countrywide,” National Association of Insurance Commissioners (NAIC), 2022, p. 9 (<https://content.naic.org/sites/default/files/publication-msr-hb-accident-health.pdf>, accessed June 5, 2023).

4 Kongstvedt, Peter R., *Health Insurance and Managed Care: What They Are and How They Work*, Fifth Edition (Burlington, MA: Jones & Bartlett Learning, 2020), p. 2.

5 Kongstvedt, *Health Insurance and Managed Care*, p. 2.

6 Kongstvedt, *Health Insurance and Managed Care*, p. 3.

7 Kongstvedt, *Health Insurance and Managed Care*, p. 2.



Blue Cross plans paid for hospital services based on cost-based charge lists (the predecessor to today's hospital "chargemaster"), and Blue Shield plans paid for physician services based on payment rates for defined procedures (the predecessor to today's "usual and customary" pricing).<sup>8</sup>

Managed care has evolved significantly since the first "prepaid health plan" and now encompasses four primary plan types in the commercial and employer market: health maintenance organizations (HMOs), preferred provider organizations (PPOs), point of service (POS) organizations, and exclusive provider organizations (EPOs). Each plan is defined in **Table 1** below:

Managed care plans implement a variety of tools to ensure quality health care delivery at a more affordable cost. Some of the most common characteristics of managed care plans include the following:

- The use of limited provider networks, meaning plans contract with various physicians, medical professionals, labs, facilities, and pharmacies that together create a "provider network."<sup>13</sup> Payment to these providers is negotiated by the plan and is typically less than their full charges.<sup>14</sup>

**Table 1. Managed Care Plans**

TYPE	ACRONYM	DEFINITION
Health maintenance organizations	HMOs	Covers in-network providers only. May require the patient to choose a primary care provider (PCP) who is responsible for referrals to specialists. Generally, the cheapest option for patients but with the least degree of flexibility. <sup>9</sup>
Preferred provider organizations	PPOs	Covers in-network and out of network providers. In-network specialty providers normally do not require a referral. Patients going out of network will incur a higher cost. <sup>10</sup>
Point of service organizations	POS	POS organizations are a cross between HMOs and PPOs. They may still require a PCP, but patients can see out-of-network providers (at a higher cost) if they choose. <sup>11</sup>
Exclusive provider organizations	EPOs	EPOs "allow patients to choose their in-network providers without the need for establishing a PCP and receiving referrals. However, all out-of-network expenses are not covered." <sup>12</sup>

8 Kongstvedt, Health Insurance and Managed Care, p. 4.

9 Joseph Heaton, Prasanna Tadi, "Managed Care Organization," StatPearls, March 6, 2023 (<https://www.ncbi.nlm.nih.gov/books/NBK557797/>, accessed June 6, 2023).

10 Heaton and Tadi, "Managed Care Organization."

11 "What is Managed Care," Cigna.

12 Heaton and Tadi, "Managed Care Organization."

13 Angelo P. Giardino, Orlando De Jesus, "Managed Care," StatPearls, Oct. 24, 2022 (<https://www.ncbi.nlm.nih.gov/books/NBK564410/>, accessed June 5, 2023). See also "What is Managed Care," Cigna.

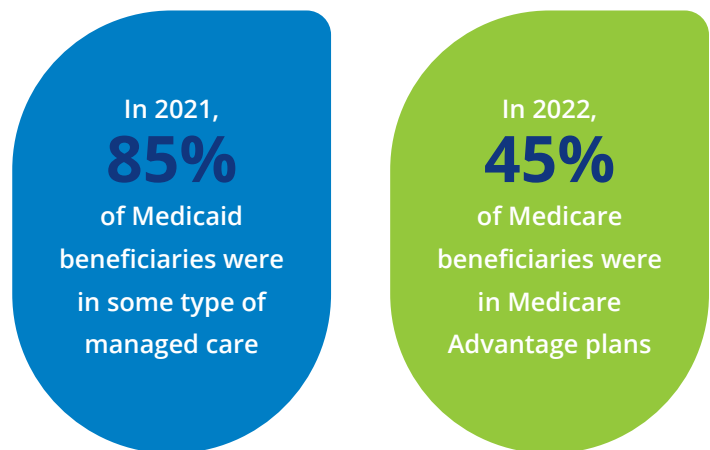
14 Kongstvedt, Health Insurance and Managed Care, p. 280.

- Prior authorization, meaning the requirement that a provider obtain pre-approval by the health plan to ensure coverage of a certain procedure or prescription drug.<sup>15</sup>
- Financial incentives for patients to use in-network providers, meaning patients may have out-of-network coverage depending upon their plan type but will incur higher costs.<sup>16</sup>
- Use of prescription drug tiers, meaning plans will typically place generic medications and preferred brand medications in the lowest tiers, which have the lowest patient cost share.<sup>17</sup>

Not only are the vast majority of privately insured Americans enrolled in some form of managed care — it has also become the dominant form of Medicaid coverage and an increasingly prevalent option for Medicare beneficiaries.<sup>18</sup> By contrast, Medicaid and Medicare beneficiaries who are not enrolled in a managed care plan obtain their coverage directly from the state or federal government under a fee-for-service (FFS) program. Under the FFS model, providers bill the government for services rendered and are paid based on the state or the Centers for Medicare and Medicaid Services (CMS) fee schedule. In contrast, under Medicaid Managed Care or Medicare Advantage (Part C), private health plans engage in capitated models where they take on some financial risk for the beneficiaries they cover on behalf of the state or federal government, meaning they are paid a set amount each month by the government for each covered member in exchange for providing health care benefits. The private plans, in turn, contract with a network of providers that are typically reimbursed at a rate negotiated with the plan.

Under Medicaid, one of the main forms of managed care delivery is through comprehensive risk-based managed care whereby states pay MCOs a flat, capitated rate per member per month in exchange for providing coverage to enrollees.<sup>19</sup> The plans are then financially “at risk” for those members’ care. As of 2021, 85% of Medicaid beneficiaries are enrolled in some form of managed care, and 75% are enrolled in comprehensive managed care through MCOs.<sup>20</sup>

Under Medicare, beneficiaries may obtain inpatient and outpatient medical benefits through Medicare Advantage plans rather than through the traditional FFS program (i.e., Parts A and B). Medicare Advantage plans offered by private insurers also typically include Part D (prescription drug) benefits.<sup>21</sup> In 2022, 45% of Medicare beneficiaries were in Medicare Advantage plans, a figure that is expected to rise.<sup>22</sup> Further, the Medicare Part D prescription drug benefit, broadly introduced in 2006, is offered only through private health plans as Medicare Advantage prescription drug plans (MA-PD plans) or as standalone prescription drug plans (PDPs).



15 Kongstvedt, *Health Insurance and Managed Care*, p. 280. See also “What is Managed Care,” Cigna.

16 Giardino and De Jesus, “Managed Care.”

17 “What is Managed Care,” Cigna.

18 “Managed Care,” Healthinsurance.org (<https://www.healthinsurance.org/glossary/managed-care/>, accessed June 6, 2023).

19 “Managed Care Overview,” Medicaid and CHIP Payment and Access Commission (MACPAC) (<https://www.macpac.gov/subtopic/managed-care-overview/>, accessed June 6, 2023).

20 “Share of Medicaid Enrollees in Managed Care,” Medicaid.gov, July 21, 2023 (<https://data.medicare.gov/dataset/79692ea5-21e1-56bf-8149-97d437120c4b>, accessed Aug. 30, 2023).

21 “Understanding Medicare Advantage Plans,” CMS, July 2022, p. 4 (<https://www.medicare.gov/Pubs/pdf/12026-Understanding-Medicare-Advantage-Plans.pdf>, accessed June 6, 2023).

22 Faith Leonard, Gretchen Jacobson, Lauren A. Haynes, Sara R. Collins, “Traditional Medicare or Medicare Advantage: How Older Americans Choose and Why,” The Commonwealth Fund, Oct. 17, 2022 (<https://www.commonwealthfund.org/publications/issue-briefs/2022/oct/traditional-medicare-or-advantage-how-older-americans-choose>, accessed June 6, 2023).

## What is Managed Care Pharmacy?

A critical component of health insurance coverage is the prescription drug benefit. In fact, the Centers for Disease Control and Prevention (CDC) estimates that 71.9% of physician office visits in 2019 involved drug therapy.<sup>23</sup> Managed care plans have developed specific tools geared at maintaining appropriate access to prescription drugs while containing rising costs. This practice is referred to as “managed care pharmacy.” AMCP defines managed care pharmacy as the application of “clinical and scientific evidence to support the appropriate use of medications to enhance patient and population health outcomes while optimizing use of limited health care resources.”<sup>24</sup> According to AMCP, managed care pharmacy professionals work across the following five key areas to achieve this goal:<sup>25</sup>

### 1. Pharmacy Benefit Design and Implementation

- Ensuring access by defining where care is available.
- Determining which treatments are covered based on individual and population needs.

### 2. Formulary and Medication Utilization Management

- Identifying which medications to include on the formulary.
- Applying drug management strategies and tools.
- Tracking new and developing medications.

### 3. Clinical Programs

- Managing coordinated care programs.
- Conducting drug utilization reviews.
- Implementing initiatives to address health disparities.
- Completing medication therapy management.

### 4. Quality and Safety Program Management

- Assessing and reporting on quality measures.
- Reporting Medicare Advantage and Medicare Part D Star Rating measures.
- Managing drug shortage and safety programs.

## 5. Promotion of Affordability

- Reducing risk for individuals, employers, and other public payers by managing overall cost.
- Protecting against misuse, overuse, and fraud.
- Promoting value-based care.

This report examines the prevalence and impact of some of the most widely used managed care pharmacy tools: prior authorization, step therapy, drug utilization review (DUR), medication therapy management (MTM), and formulary design and management. Next, we will define each of these concepts.

### Prior Authorization

This is an administrative tool health plans or pharmacy benefit managers (PBMs) use that requires prescribers to receive pre-approval for certain drugs to qualify those drugs for coverage under the terms of the pharmacy benefit. Guidelines and administrative policies for prior authorization are developed by pharmacists and/or other qualified health professionals who are employed by or are under contract with a health plan or PBM.<sup>26</sup>

### Step Therapy

Step therapy requires the use of a clinically recognized first-line drug before approval of a more complex and often more expensive medication where the safety, effectiveness, and value has not been well established before a second-line drug is authorized. Step therapy requirements ensure that an established and cost-effective therapy is utilized prior to progressing to other therapies. If the required therapeutic benefit is not achieved by the use of the first-line drug, the prescriber may request use of a second-line medication.<sup>27</sup> Step therapy programs apply coverage rules at the POS when a claim is adjudicated. If a claim is submitted for a second-line drug and the step therapy rule was not met, the claim is rejected, and a message is transmitted to the pharmacy indicating the patient should be treated

23 “National Ambulatory Medical Care Survey: 2019 National Summary Tables,” CDC, p. 33, Table 20 ([https://www.cdc.gov/nchs/data/ahcd/namcs\\_summary/2019-namcs-web-tables-508.pdf](https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2019-namcs-web-tables-508.pdf), accessed June 6, 2023).

24 “What is Managed Care Pharmacy?,” AMCP (<https://www.amcp.org/about/managed-care-pharmacy>, accessed June 7, 2023).

25 “What is Managed Care Pharmacy,” AMCP.

26 “Managed Care Glossary,” AMCP (<https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary>, accessed June 7, 2023).

27 “Prior Authorization: What is Prior Authorization and Why is it an Essential Managed Care Tool?” AMCP (<https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/prior-authorization>, accessed Aug. 10, 2023).

with the first-line drug before coverage of the second-line drug can be authorized.<sup>28</sup>

### Drug Utilization Review (DUR)

This is an authorized, structured, ongoing review of health care provider prescribing, pharmacist dispensing, and patient medication use. Reviews are completed by clinical pharmacists at the PBM of a health plan. There are three forms of DUR: prospective (before dispensing), concurrent (at the time of prescription dispensing), and retrospective (after the therapy dispensing).<sup>29</sup>

Though a DUR is used across payer types, the focus of this report will be on the DUR in Medicaid, where it is statutorily required for FFS and Managed Medicaid.

### Medication Therapy Management (MTM)

According to the American Pharmacists Association (APhA), MTM is defined as a distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision of a medication product.<sup>30</sup>

The core elements of MTM are:

- **Medication Therapy Review (MTR):** A systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them. The MTR can be comprehensive or targeted.<sup>31</sup>

As it relates to the Medicare Part D program, where MTM is a statutory requirement, the CMS defines comprehensive medication review (CMR) and targeted medication review (TMR) as follows:

- **CMR** is a real-time, interactive, person-to-person or telehealth review of a patient's medications (including prescriptions, over-the-counter medications, herbal medicine, and dietary supplements). It is performed by a pharmacist or other qualified provider and must be offered at least once a year.<sup>32</sup>
- **TMR** is used for ongoing monitoring and may be performed to address a specific or potential medication-related problem. TMRs are performed quarterly "to assess medication use, to monitor whether any unresolved issues need attention, to determine if new drug therapy problems have arisen, or to assess if the beneficiary has experienced a transition in care."<sup>33</sup>
- **Personal Medication Record:** A comprehensive record of the patient's medications (prescription and nonprescription medications, herbal products, and other dietary supplements).<sup>34</sup>
- **Medication-Related Action Plan:** A patient-centric document containing a list of actions for the patient to use in tracking progress for self-management.<sup>35</sup>
- **Intervention and/or Referral:** The pharmacist provides consultative services and intervenes

28 "Managed Care Glossary," AMCP.

29 "Managed Care Glossary," AMCP.

30 "Medication Therapy Management (MTM)," APhA Foundation (<https://www.aphafoundation.org/medication-therapy-management>, accessed June 7, 2023).

31 "Managed Care Glossary," AMCP.

32 "CY 2016 Medication Therapy Management Program Guidance and Submission Instructions," CMS, April 7, 2015, pp. 708 (<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2016-Medication-Therapy-Management-MTM-Program-Submission-v-040715.pdf>, accessed June 6, 2023).

33 "Contract Year 2016 Medication Therapy Management Program Guidance and Submission Instructions," CMS, pp. 11012.

34 "Managed Care Glossary," AMCP.

35 "Managed Care Glossary," AMCP.

to address medication-related problems; when necessary, the pharmacist refers the patient to a physician or other health care professional.<sup>36</sup>

- **Documentation and Follow-up:** MTM services are documented in a consistent manner, and a follow-up MTM visit is scheduled based on the patient's medication-related needs or after-care transition.<sup>37</sup>

The focus of this report will be on MTM in the Medicare Part D program, where it is statutorily required.

### Formulary Design and Management

AMCP defines formulary management as an integrated patient care process that enables physicians, pharmacists, and other health care professionals to work together to promote clinically sound, cost-effective care and positive therapeutic outcomes. The formulary management process provides the managed health care system with the ability to objectively discriminate between superior and marginally effective drug products.<sup>38</sup>

Many of the managed care pharmacy tools explained above are used by private health plans and in the government FFS program to promote cost-effective care. However, there are differences in how and to what extent these tools are used in the FFS program versus by MCOs.

### Why is Managed Care Pharmacy So Important?

Prescription drug spending in the United States has risen drastically over the past few decades. According

to data from the National Health Expenditure Accounts, prescription drug spending (net of rebates) increased from \$40 billion in 1990 to \$406 billion in 2022, a tenfold increase.<sup>39</sup> The period from 1980 until the mid-2000s saw an increase in prescription drug spending in per capita terms and as a share of total health expenditures.<sup>40</sup> This rise in spending was driven by the availability and utilization of new therapies as well as higher price tags on branded drugs.<sup>41</sup> Thanks to the increasing availability of cheaper generic drugs, that spending growth moderated from the mid-2000s through 2018 except for 2013–2015 when there were sharp increases in spending driven by expensive Hepatitis C (Hep C) therapies.<sup>42</sup>

While spending on prescription drugs as a percentage of total health care spending has fallen slightly in recent years, it still accounted for 8.9% of total health care spending in 2021 (down from 10.2% in 2009).<sup>43</sup> In recent years, expensive specialty drugs have accounted for a higher share of net drug spending. Such drugs made up 55% of net spending in 2021 compared with 28% a decade earlier.<sup>44</sup> Further, drug spending in the United States is expected to grow in the coming years. IQVIA forecasts growth of 1-4% (after discounts and rebates) from 2022 to 2026, driven by newly launched innovative products, including those in oncology, complex specialty drugs, or those with orphan status.<sup>45</sup> Though innovative therapies can deliver life-changing benefits to patients, they often come at a high price. For patients to have continued access to these critical but expensive therapies, managed care plans must have tools in place to ensure appropriate prescription drug use.

36 "Managed Care Glossary," AMCP.

37 "Managed Care Glossary," AMCP.

38 "Managed Care Glossary," AMCP.

39 "Table 02 National Health Expenditures; Aggregate, Annual Percent Change, Percent Distribution and Per Capita Amounts, by Type of Expenditure," CMS National Health Expenditure Accounts (<https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpend-data/nationalhealthaccountshistorical>, "NHE Tables ZIP," accessed September 23, 2024); "National Health Expenditure Accounts: Methodology Paper, 2022," CMS National Health Expenditure Accounts (<https://www.cms.gov/files/document/definitions-sources-and-methods.pdf>, accessed June 7, 2023). Per p. 13 of the methodology document, prescription drug expenditure estimates are net of rebates.

40 "Prescription Drugs: Spending, Use, and Prices," Congressional Budget Office (CBO), January 2022 (<https://www.cbo.gov/publication/57772>, accessed June 7, 2023).

41 "Prescription Drugs: Spending, Use, and Prices," CBO.

42 "Prescription Drugs: Spending, Use, and Prices," CBO.

43 "Table 02 National Health Expenditures," CMS. Calculated as "Prescription Drugs" divided by total "National Health Expenditures".

44 "The Use of Medicines in the U.S. 2022," IQVIA Institute, April 21, 2022, p. 26 (<https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022>, accessed June 8, 2023).

45 "The Use of Medicines in the U.S. 2022," IQVIA Institute, p. 47.

### III. Key Statistics on Health Insurance and Prescription Drug Coverage in the United States



In 2021, roughly 92% of the U.S. population was covered by some type of health insurance, whether public or private. See **Table 2** below for a breakdown of the population by type of coverage.

**Table 2. U.S. Prescription Drug Coverage, by Insurance Type, 2021**

Nearly all insured Americans have prescription drug coverage. Of all the insurance types, Medicare has the lowest rate of prescription drug coverage, at 89%.

	MEDICAL COVERAGE		PREScription COVERAGE
	NUMBER (IN THOUSANDS)	% OF TOTAL	% OF CATEGORY
<b>Total [1]</b>	328,074		
<b>Uninsured [1]</b>	27,187	8.3%	<b>0%</b>
<b>Any Health Plan [1]</b>	300,887	91.7%	
<b>Any Public [1]</b>	117,095	35.7%	
<b>Medicare [1]</b>	60,226	18.4%	<b>89% [4]</b>
Traditional (FFS) [2]	34,270	10.4%	
Medicare Advantage (Part C) [2]	25,956	7.9%	
<b>Medicaid [1]</b>	61,940	18.9%	<b>100% [5]</b>
Traditional (FFS) [3]	9,106	2.8%	
<b>Any type of Managed Care [3]</b>	52,834	16.1%	
<b>CHAMPVA and VA [1]</b>	3,151	1.0%	<b>100% [6]</b>
<b>Any Private [1]</b>	216,366	66.0%	
<b>Employer [1]</b>	178,285	54.3%	<b>98% [7]</b>
<b>Direct Purchase/Marketplace [1]</b>	33,555	10.2%	<b>100% [8]</b>
<b>Tricare [1]</b>	8,299	2.5%	<b>100% [9]</b>

Sources on next page

**Notes/Sources:**

- 1 Katherine Keisler-Starkey, Lisa N. Bunch, "Health Insurance Coverage in the United States: 2021," Census, September 2022, p. 4, Table 1 (<https://www.census.gov/content/dam/Census/library/publications/2022/demo/p60-278.pdf>, accessed June 6, 2023). The estimates by type of coverage are not mutually exclusive; people can be covered by more than one type of health insurance during the year.
- 2 "Medicare Monthly Enrollment," CMS, February 2023 (<https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment/>, accessed June 15, 2023). Limited to national data from 2021. FFS share is calculated as ORGNL\_MDCR\_BENES/TOT\_BENES. Medicare Advantage share is calculated as MA\_AND\_OTH\_BENES/TOT\_BENES. The calculated shares are then applied to the total Medicare beneficiaries, per census.
- 3 "Share of Medicaid Enrollees in Managed Care," Medicaid.gov, July 21, 2023 (<https://data.medicaid.gov/dataset/79692ea5-21e1-56bf-8149-97d437120c4b>, accessed Aug. 30, 2023). Includes individuals enrolled in comprehensive managed care programs as well as any type of managed care. Limited to national data from 2021. FFS share is calculated as Total Medicaid Enrollees minus the number of enrollees enrolled in any type of managed care, divided by total enrollees. The calculated shares are then applied to the total Medicaid beneficiaries, per Census.
- 4 "Report to the Congress: Medicare Payment Policy," MEDPAC, March 2022, p. 466 ([https://www.medpac.gov/wp-content/uploads/2022/03/Mar22\\_MedPAC\\_ReportToCongress\\_Ch13\\_SEC.pdf](https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch13_SEC.pdf), accessed June 7th, 2023). Reflects the total portion of Medicare beneficiaries in 2021 estimated to have prescription drug coverage, whether directly through Medicare Part D plans (76%), through employer-sponsored plans that received Medicare's retiree drug subsidy (2%) or through some other source (11%). MedPAC estimates that the remaining 11% either have no coverage or coverage less generous than Part D. For purposes of this table, all 11% is treated as no coverage.
- 5 "Prescription Drugs," Medicaid.gov (<https://www.medicaid.gov/medicaid/prescription-drugs/index.html>, accessed June 7, 2023). Per Medicaid.gov, all states provide coverage for outpatient prescription drugs within their state Medicaid programs.
- 6 "Pharmacy Service," Benefits.gov (<https://www.benefits.gov/benefit/305>, accessed June 7, 2023). Per Benefits.gov, "VA's prescription benefit program is part of its comprehensive medical benefits package." For purposes of this table, this statement is interpreted to mean 100% coverage for prescriptions.
- 7 Gary Claxton, Matthew Rae, Emma Wager, Gregory Young, Heidi Whitmore, Jason Kerns, Greg Shmavonian, Anthony Damico, "Employer Health Benefits Annual Survey," Kaiser Family Foundation, October 2022, p. 144 (<https://files.kff.org/attachment/Report-Employer-Health-Benefits-2022-Annual-Survey.pdf>, accessed June 7, 2023). Per the Kaiser Family Foundation Employer Health Benefits Survey, in 2022, "Nearly all (98%) covered workers are at a firm that provides prescription drug coverage in its largest health plan." Note that for purposes of this table, we assume that 98% of individuals with employer-sponsored health insurance have prescription drug coverage. However, the actual portion may be lower if not all covered workers have selected the largest health plan and their selected plan does not include drug coverage.
- 8 "Marketplace Coverage and Prescriptions: What You Need to Know," Healthcare.gov, May 7 2020 (<https://www.healthcare.gov/blog/marketplace-coverage-prescription-drugs/>, accessed June 7, 2023). Per Healthcare.gov, "All marketplace plans cover prescription drugs." No data located for Direct Purchase, but it is assumed that all direct purchase plans cover prescriptions.
- 9 "Covered Services," Tricare.mil, May 2, 2023 (<https://www.tricare.mil/CoveredServices/Pharmacy/Drugs>, accessed June 7, 2023). Per Tricare.mil, "Tricare provides prescription drug coverage with most Tricare health plans." For purposes of this table, "most" is interpreted as 100%.

## IV. Comparison of Prescription Utilization and Average Out-of-Pocket (OOP) Spending on Prescription Drugs by the Insured Versus Uninsured/Cash-Paying Populations



Though the focus of this report is on the tools utilized by managed care pharmacy professionals for patients with health insurance, health insurance plays a critical role more generally in terms of access to prescription drugs. Those with health insurance typically have a higher utilization of prescription drugs and lower out-of-pocket (OOP) spending than those who lack coverage.

According to IQVIA, patients paying cash for their prescriptions were dispensed an average of 8.2 prescriptions per year in 2021, the fewest of any patient group. By contrast, those with third-party insurance were dispensed 22.4 prescriptions, Medicare Part D beneficiaries were dispensed 31.7 prescriptions, and Medicaid beneficiaries were dispensed nine prescriptions, as shown in **Figure 1**.<sup>46</sup>

Further, numerous studies have examined the impact of gaining insurance coverage on prescription utilization and consistently suggest that patients with insurance are dispensed more prescriptions than those without insurance. For example, researchers found increases in prescription drug use for those who gained private or Medicaid coverage through the Affordable Care Act (ACA). From 2013 to 2014, individuals who went from uninsured to Medicaid had an average of 13.3 more prescriptions filled and those going from uninsured to private had an average of four more prescriptions filled.<sup>47</sup> Another study found that Medicaid expansion through the ACA led to a 19% increase in Medicaid prescriptions or roughly nine additional prescriptions annually per newly eligible beneficiary.<sup>48</sup> Importantly, the largest increase in prescriptions were for those drugs treating chronic disease, such as diabetes and heart disease.<sup>49</sup>

46 "The Use of Medicines in the U.S. 2022," IQVIA Institute, p. 17. Reflects adjusted prescriptions (i.e., for days' supply length). Cash-paying patients may include those with insurance who choose to pay cash for a particular prescription rather than utilize their insurance.

47 Andrew W. Mulcahy, Christine Eibner, and Kenneth Finegold, "Gaining Coverage Through Medicaid Or Private Insurance Increased Prescription Use and Lowered Out-Of-Pocket Spending," *Health Affairs*, Volume 35, no. 9, September 2016, p. 1729 (<https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0091>, accessed June 7, 2023).

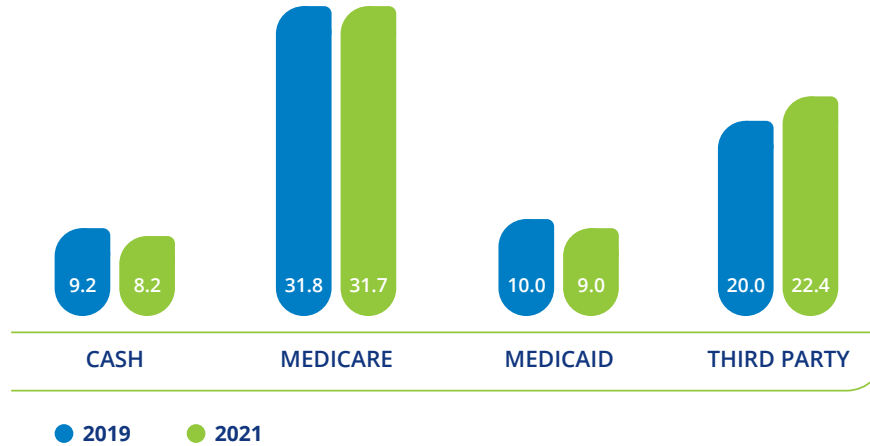
48 Ausmita Ghosh, Kosali Simon, Benjamin D. Sommers, "The Effect of Health Insurance on Prescription Drug Use Among Low-Income Adults: Evidence from Recent Medicaid Expansions," *Journal of Health Economics*, Volume 63, January 2019, p. 66 (<https://doi.org/10.1016/j.jhealeco.2018.11.002>, accessed June 6, 2023).

49 Ghosh, Simon, and Sommers, "The Effect of Health Insurance on Prescription Drug Use Among Low-Income Adults," p. 66.



## Figure 1. Volume of Dispensed Prescriptions Per Enrollee by Method of Payment, 2019 and 2021

Medicare and commercial (third-party) insured members access higher numbers of prescriptions than Medicaid or cash.



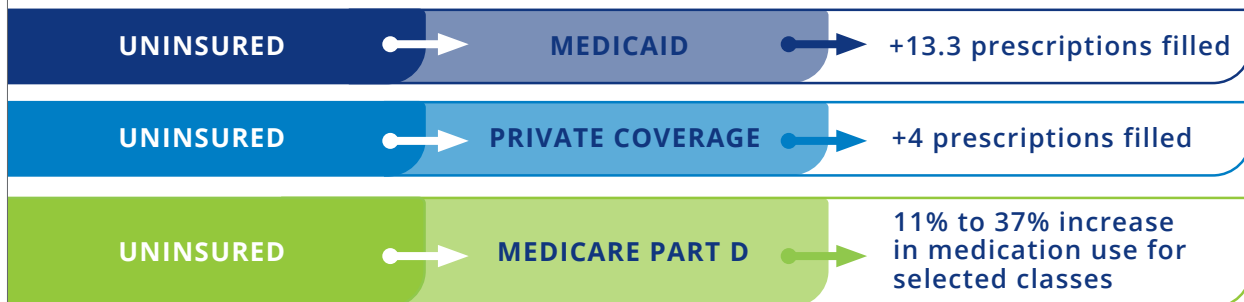
Source: IQVIA, "The Use of Medicines in the U.S. 2022," Exhibit 12, p. 17.

Lastly, researchers examined the change in prescription utilization for selected medication classes among seniors without prior drug benefits following their enrollment in Medicare Part D. The authors found that Medicare Part D was associated with increases in utilization of 22% for statins, 11% for clopidogrel, and 37% for proton pump inhibitors.<sup>50</sup>

The uninsured also pay more out of pocket for their prescriptions, as demonstrated in **Figure 3**. According to IQVIA, cash-paying patients paid an average of \$43.62 per prescription in 2021, over five times more than any other patient group. The commercial, Medicare, and Medicaid averages paid per prescription were \$7.43, \$6.17, and \$0.26, respectively.<sup>51</sup>

## Figure 2: Impact of Gaining Insurance

Uninsured patients who gained insurance coverage filled a greater number of prescriptions after coverage began.



50 Sebastian Schneeweiss, Amanda R. Patrick, Alex Pedan, Laleh Varasteh, Raisa Levin, Nan Liu, and William H. Shrank, "The Effect Of Medicare Part D Coverage On Drug Use And Cost Sharing Among Seniors Without Prior Drug Benefits," *Health Affairs*, Volume 28, No. Supplement 1, 2009, p. 311 (<https://doi.org/10.1377/hlthaff.28.2.w305>, accessed Aug. 30, 2023).

51 "The Use of Medicines in the U.S. 2022," IQVIA Institute, p. 38. Prescription costs normalized to 30 days.

This higher average OOP spending by the cash-paying/uninsured population also resulted in their disproportionate contribution to overall OOP spending. In 2020, patients paying cash accounted for 20% of total OOP drug spending despite contributing just 4% to prescription volume.<sup>52</sup> In another study, researchers found that gaining Medicaid coverage led to \$205 less in annual OOP spending in 2014, and gaining private coverage led to an \$85 reduction compared with the prior year.<sup>53</sup> The same study that examined the impact of gaining Medicare Part D coverage on utilization also found a decrease of over 50% in patient OOP spending for the classes examined.<sup>54</sup>

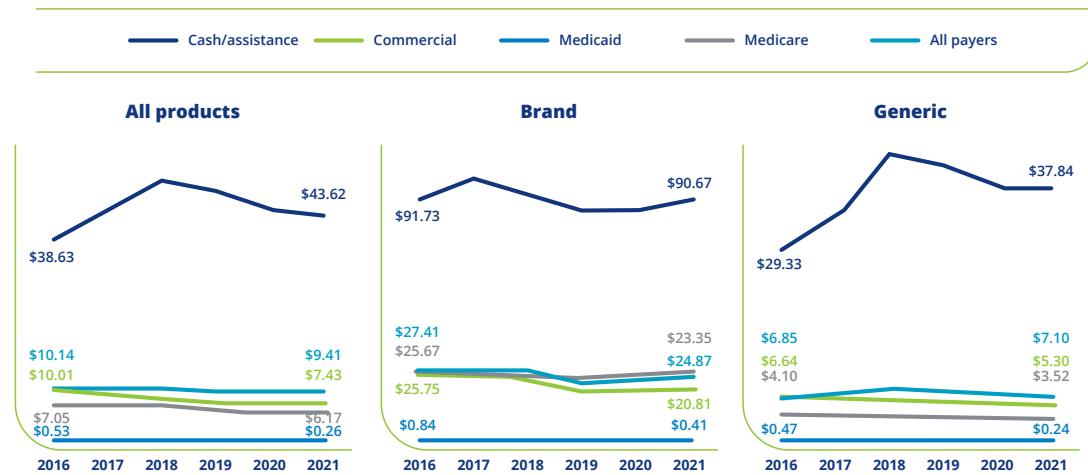
Higher OOP spending by the uninsured can lead to a lack of medication adherence. In fact, the CDC — through the National Health Interview Survey in 2017 — found that 33.6% of uninsured individuals did not

take their medication as prescribed to reduce their prescription drug costs. This is compared to 8.4% with private health insurance and 12.5% of those with Medicaid.<sup>55</sup> IQVIA Institute notes that cash-paying patients “have significantly higher costs for brand prescriptions with 12% having OOP costs greater than \$125,” which likely contributes to “higher abandonment of brands among these patients.”<sup>56</sup> Cash-paying patients have also been filling fewer prescriptions in recent years (9.2 adjusted prescriptions per cash patient in 2019 versus 8.2 in 2021).<sup>57</sup>

The uninsured population’s disproportionate — contribution to OOP spending on vital prescription medications and their lower utilization of prescription medication underscores the important role of health insurance in managing prescription drug affordability and patient access.

### Figure 3. Average final out-of-pocket cost per retail prescription by product type and method of payment

Cash-paying patients had higher out-of-pocket costs for retail prescriptions across product types than insured patients.



Source: IQVIA Institute, “The Use of Medicines in the U.S. 2022,” Exhibit 31.

52 “The Use of Medicines in the U.S. 2022,” IQVIA Institute, p. 36.  
 53 Mulcahy, Eibner, and Finegold, “Gaining Coverage Through Medicaid or Private Insurance Increased Prescription Use and Lowered Out-Of-Pocket Spending,” p. 1730.  
 54 Schneeweiss et al., “The Effect Of Medicare Part D Coverage On Drug Use And Cost Sharing Among Seniors Without Prior Drug Benefits,” p. 311.  
 55 Robin A. Cohen, Peter Boersma, Anjel Vahratian, “Strategies Used by Adults Aged 18-64 to Reduce Their Prescription Drug Costs, 2017,” CDC, March 2019 (<https://www.cdc.gov/nchs/products/databriefs/db333.htm>, accessed June 7, 2023).  
 56 “The Use of Medicines in the U.S. 2022,” IQVIA Institute, p. 41.  
 57 “The Use of Medicines in the U.S. 2022,” IQVIA Institute, p. 17.

## V. Examination of the Prevalence of Managed Care Pharmacy Tools and Their Impact on Health Care Costs and Patient Outcomes



We will now explore the prevalence and impact of the managed care pharmacy tools defined above.

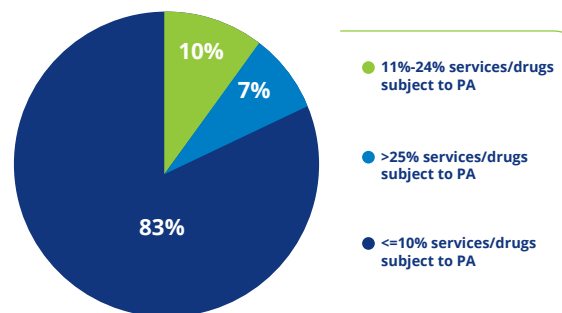
### Prior Authorization

Prior authorization for prescription drugs is a widely used tool in commercial insurance, Medicare, and Medicaid. A study by Avalere of commercial plan formularies in 2020 found that the prevalence of prior authorization for single-source brand drugs in the commercial market was above 40% for five therapeutic areas examined: multiple sclerosis (51%), rheumatoid arthritis (42.9%), chronic myeloid leukemia (52.0%), multiple myeloma (49.7%), and psoriasis (44.6%). The other therapeutic areas evaluated (depression, diabetes SGLT2, diabetes GLP1, cardiovascular, atypical antipsychotics, asthma/allergy corticosteroids, and HIV) had a prevalence of 11% or less.<sup>58</sup> Though certain therapeutic areas are commonly subject to prior authorization, most enrollees are in plans where a limited number of drugs are subject to prior authorization. America's Health Insurance Plans (AHIP) found that 83% of commercial enrollees are in

plans where fewer than 10% of drugs are subject to prior authorization as seen in **Figure 4**.<sup>59</sup>

### Figure 4. Portion of Commercial Enrollees by Percentage of Drugs Subject to Prior Authorization

More than 8 in 10 commercial enrollees had 10 percent or less of their covered drugs subject to prior authorization.



Source: AHIP, "Key Results of Industry Survey on Prior Authorization," p. 10.

Among Medicare PDPs and MA-PD plans, 28% and 26% of drugs, respectively, were subject to prior

58 Tiernan Meyer, Rebecca Yip, Yonatan Mengesha, Daymelis Santiesteban, Richard Hamilton, "Utilization Management Trends in the Commercial Market, 2014-2020," Avalere, Nov. 24, 2021, p. 7, Table 1 (<https://avalere.com/wp-content/uploads/2021/11/UM-Trends-in-the-Commercial-Market.pdf>, accessed June 7, 2023).

59 "Key Results of Industry Survey on Prior Authorization," AHIP, p. 10 (<https://www.ahip.org/documents/Prior-Authorization-Survey-Results.pdf>, accessed June 7, 2023).

authorization in 2021.<sup>60</sup> Evidence shows that prior authorization requirements have increased in Medicare Part D, from 8% in 2007 to 24% of covered drugs in 2019.<sup>61</sup> Further, certain drug classes and more expensive medications are more likely to face prior authorization requirements. For example, in 2021, researchers found that 90.5% to 100% of Part D plans required prior authorization for covered psoriasis and psoriatic arthritis specialty medications.<sup>62</sup> Those same researchers note that the median POS price for these drugs before rebates/discounts ranged from \$3,620 to \$23,493 for each fill.<sup>63</sup>

According to the Kaiser Family Foundation (KFF), as of 2018, every state uses prior authorization in its Medicaid FFS drug programs, and at least 30 states apply the same medical necessity criteria to FFS and managed care for at least one drug.<sup>64</sup> No findings on the portion of drugs subject to prior authorization by Medicaid FFS or Medicaid Managed Care plans were identified as of the writing of this report. However, according to the KFF, though states may require prior authorization for any drug covered by Medicaid, they normally require it for expensive specialty drugs or for drugs not on the Preferred Drug List (PDL).<sup>65</sup>

One of the main critiques of the prior authorization process is the time and effort required of providers and their staff to obtain authorizations. However, as

noted above, only a subset of drugs is subject to prior authorization. In fact, in June of 2019, AMCP conducted a multistakeholder forum regarding step therapy and prior authorization. Participants of the forum aligned on the following characteristics of medications that warrant the use of these utilization management tools:<sup>66</sup>

- Specific safety concerns, including certain drug interactions.
- Availability of more affordable alternatives.
- Potential for off-label use.
- Potential for misuse or abuse.
- Limited distribution or special handling requirements.
- Multiple indications across benefits (e.g., medical and cosmetic).

Further, there is a significant opportunity to reduce the administrative strain of the prior authorization process by moving more prior authorization requests to electronic form.

### Step Therapy

Like prior authorization, step therapy is another form of utilization management. Its goal is to identify the most appropriate nexus of affordability, efficacy, and safety as the first line of medication therapy before moving to more costly treatments. If there is a reason a patient should not use the lowest tier of treatment, exception processes are in place to ensure the patient receives the appropriate care. The same Avalere study that examined prior authorization in the commercial market also

60 "A Data Book: Health Care Spending and the Medicare Program," MedPAC, July 2021, p. 161, Chart 10-13 ([https://www.medpac.gov/wp-content/uploads/2021/10/July2021\\_MedPAC\\_DataBook\\_Sec10\\_SEC.pdf](https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec10_SEC.pdf), accessed June 7, 2023).

61 "Cornerstones of 'Fair' Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals," Institute for Clinical and Economic Review (ICER), Sept. 28, 2020, p. 11 (<https://icer.org/wp-content/uploads/2020/11/Cornerstones-of-Fair-Drug-Coverage--September-28-2020.pdf>, accessed June 7, 2023).

62 Sarah P. Pourali, Leonce Nshuti, and Stacie B. Dusetzina "Out-Of-Pocket Costs of Specialty Medications for Psoriasis and Psoriatic Arthritis Treatment in the Medicare Population," JAMA Network Dermatology, Volume 157, no. 10, September 15, 2021, p. 1239 (10.1001/jamadermatol.2021.3616, accessed June 7, 2023).

63 Pourali, Nshuti, and Dusetzina "Out-Of-Pocket Costs of Specialty Medications for Psoriasis and Psoriatic Arthritis Treatment in the Medicare Population," p. 1240.

64 Rachel Dolan, Marina Tian, "Management and Delivery of the Medicaid Pharmacy Benefit," Kaiser Family Foundation, December 2019, p. 2 (<https://www.kff.org/wp-content/uploads/2019/12/Management-and-Delivery-of-Pharmacy-Benefits-in-Medicaid.pdf>, accessed June 7, 2023); Kathleen Gifford, Eileen Ellis, Barbara Coulter Edwards, Aimee Lashbrook, Elizabeth Hinton, Larisa Antonisse, Robin Rudowitz, "States Focus on Quality and Outcomes Amid Waiver Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2018 and 2019," Kaiser Family Foundation, October 2018, p.75 (<https://files.kff.org/attachment/Report-States-Focus-on-Quality-and-Outcomes-Amid-Waiver-Changes-Results-from-a-50-State-Medicaid-Budget-Survey-for-State-Fiscal-Years-2018-and-2019>, accessed June 7, 2023).

65 Dolan and Tian, "Management and Delivery of the Medicaid Pharmacy Benefit," p. 2.

66 "AMCP Partnership Forum: Optimizing Prior Authorization for Appropriate Medication Selection," JMCP, Volume 26, Issue 1, January 2020, p. 56, Table 1 (<https://doi.org/10.18553/jmcp.2020.26.1.55>, accessed June 7, 2023).

evaluated the prevalence of step therapy. Step therapy prevalence exceeded 50% for only one therapeutic area (rheumatoid arthritis at 53.5%) but was near or above 20% for six others: multiple sclerosis (24.6%), chronic myeloid leukemia (19.2%), psoriasis (48.7%), depression (35.5%), diabetes SGLT2 (33.3%), diabetes GLP-1 (22.8%).<sup>67</sup>

Separately, researchers examined the use of step therapy for high-cost, specialty medications by 17 of the largest commercial health plans in the United States and found that 38.9% of drug coverage policies applied step therapy.<sup>68</sup> The proportion of each plan's coverage policies that included step therapy, however, varied by plan, ranging from 20.6% to 57.5%.<sup>69</sup> The average number of steps was 1.5, with 66.6% of policies requiring a single step, 22.7% requiring two steps, 7.6% requiring three steps, and 3.1% requiring four or more steps.<sup>70</sup> The same study also evaluated whether the step therapy protocols applied by plans were consistent with treatment guidelines (such as those issued by national clinical organizations). Protocols were consistent with clinical guidelines 34% of the time, more stringent 55.6% of the time, and less stringent 6.1% of the time.<sup>71</sup>

Other research, however, suggests that step therapy protocols are consistent with fair access criteria nearly all the time. The Institute for Clinical and Economic Review (ICER) used data from Managed Market Insights & Technology, LLC (MMIT), for 19 drugs across 18 formularies, including 15 of the largest commercial

formularies, the formulary of the Veterans Administration (VA) and the formularies of the two largest state ACA exchange plans. These data were analyzed to determine concordance of step therapy protocols with ICER's fair access criteria. Concordance was found to be 98%.<sup>72</sup>

The Institute for Clinical and Economic Review found that step therapy protocols were concordant with fair access criteria

**98%**  
of the time

The prevalence of step therapy in Medicare Part D is substantially lower than in the commercial market. According to the Medicare Payment Advisory Commission (MedPAC), just 1% of drugs in the standalone PDP and MA-PD plans were subject to step therapy.<sup>73</sup>

In 2019, 45 out of 50 states reported using step therapy in their Medicaid programs.<sup>74</sup> No data quantifying the percentage of drugs or protocols subject to step therapy, however, were identified for Medicaid as of the time of writing of this report.

67 Meyer et al., "Utilization Management Trends in the Commercial Market, 2014–2020," p. 7, Table 1.

68 Kelly L. Lenahan, Donald E. Nichols, Rebecca M. Gertler, James D. Chambers, "Variation In Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans," *Health Affairs*, Volume 40, no. 11, November 2021, p. 1749 (<https://doi.org/10.1377/hlthaff.2021.00822>, accessed June 7, 2023).

69 Lenahan et al., "Variation in Use and Content of Prescription Drug Step Therapy Protocols," p. 1749.

70 Lenahan et al., "Variation in Use and Content of Prescription Drug Step Therapy Protocols," pp. 1751–1752.

71 Lenahan et al., "Variation in Use and Content of Prescription Drug Step Therapy Protocols," p. 1749.

72 "Assessment of Barriers to Fair Access," ICER, Jan. 17, 2023, p. 15, Table 10 (<https://icer.org/wp-content/uploads/2023/01/2022-Barriers-to-Fair-Access-Assessment-Final-Report-011723.pdf>, accessed June 7, 2023). The fair access criteria evaluated were as follows: 1) The first-step therapy is clinically appropriate for all or nearly all patients and does not pose a greater risk of any significant side effect or harm. 2) Patients will have a reasonable chance to meet their clinical goals with first-step therapy. 3) Failure of the first-step drug and the resulting delay in beginning the second-step agent will not lead to long-term harm for patients. 4) Patients are not required to retry a first-line drug with which they have previously had adverse side effects or an inadequate response at a reasonable dose and duration. See p. 12.

73 "A Data Book: Health Care Spending and the Medicare Program," MedPAC, p. 161.

74 Kathleen Gifford, Anne Winter, Linda Wiant, Rachel Dolan, Marina Tian, Rachel Garfield, "How State Medicaid Programs are Managing Prescription Drug Costs," Kaiser Family Foundation, April 2020, p. 12, Table 3 (<https://files.kff.org/attachment/How-State-Medicaid-Programs-are-Managing-Prescription-Drug-Costs.pdf>, accessed June 7, 2023).

## Medication Therapy Management

Pursuant to 42 CFR § 423.153(d), all Part D plan sponsors (whether standalone PDP or MA-PD) must establish MTM programs that meet certain minimum standards, which are offered on an “opt-out” basis to beneficiaries meeting specific criteria, such as the presence of multiple chronic conditions, the use of multiple Part D-covered drugs, and the likelihood of incurring high drug expenditures.<sup>75</sup> TMRs are to be performed quarterly and CMRs annually.<sup>76</sup> No similar requirement exists for Medicaid<sup>77</sup> or the commercial market and, therefore, this report will focus on MTM in Medicare Part D. However, evidence exists of the clinical and financial benefits of MTM for commercial and Medicaid patients as well.<sup>78</sup>

According to BRG’s analysis, approximately four million beneficiaries were enrolled in MTM programs as of 2019, or 8% of total Part D enrollees that year.<sup>79</sup> Not everyone enrolled, however, receives MTM services. CMS’ 2023 Star Ratings indicate that 54% of standalone PDP MTM enrollees and 83% of MA-PD MTM enrollees received a CMR.<sup>80</sup>

Various studies support the benefits of MTM services, which can include reductions in cost of care and hospital utilization, a decrease in adverse drug events, and an improvement in medication adherence. For example, a 2010 retrospective analysis of standalone PDP and MA-PD plan beneficiaries participating in MTM programs found meaningfully higher medication adherence rates for beneficiaries with congestive heart

failure (11-40% higher), chronic obstructive pulmonary disease (11-26% higher), and diabetes (15-35% higher) as compared to non-participating beneficiaries.<sup>81</sup>

In an MTM intervention that targeted Part D beneficiaries with diabetes or coronary artery disease who were not taking statins but could benefit from doing so, participants had roughly 65% greater uptake of statins compared with the control group. The study’s authors estimated this increased uptake could result in avoidance of one major cardiovascular event and \$12,323 in event-associated costs for every 220 beneficiaries.<sup>82</sup>

Further, researchers at Humana found that receipt of MTM services targeted at resolution of medication-related problems through TMR or through a combination of TMR and CMR were associated with reductions in overall health care utilization (i.e., inpatient admissions and/or emergency department (ED) visits) and increases in medication adherence. In 2014 and 2015, there were 55.2 and 30.8 fewer inpatient admissions per 1,000 individuals, respectively, for patients receiving TMR interventions. In 2015, there were significant reductions in ED visits for participants receiving TMR-only interventions (26.1 fewer ED visits per 1,000 individuals) or TMR/CMR interventions (12.0 fewer ED visits per 1,000 individuals). In both years, researchers found that a larger percentage of MTM participants (0.4% for oral diabetes medications; 7.7% for antihypertensives; 3.0% for statins) had greater improvements in medication adherence.<sup>83</sup>

- 75 42 CFR § 423.153(d) (<https://www.govinfo.gov/content/pkg/CFR-2012-title42-vol3/pdf/CFR-2012-title42-vol3-sec423-153.pdf>, accessed Aug. 30, 2023); Ryan Beringer, Bingyan Fan, Daekun Heo, Josh Oh, Lois Olinger, Kristy Piccinini, Dimitra Politi, Yuchen Qian, Kamila Saldanha, Edward Sung, Anqi Wang, David Wright, Lucy Yao, Willow Burns, Susan Hassell, Angelina Lee, Lauren Mercincavage, Kevin Neipp, Jennifer Nooney, Shannon Reefer, Natalie Teixeira Bailey, “Evaluation of the Part D Enhanced Medication Therapy Management (MTM) Model: Fifth Evaluation Report,” CMS, February 2023, p. 2 (<https://innovation.cms.gov/data-and-reports/2023/mtm-fifth-evalrept>, accessed June 7, 2023).
- 76 “Contract Year 2016 Medication Therapy Management Program Guidance and Submission Instructions,” CMS, pp. 3, 7.
- 77 In fact, as of 2019, only nine of 49 responding states reported paying pharmacists to provide MTM services in the FFS Medicaid program. See Gifford et al., “How State Medicaid Programs are Managing Prescription Drug Costs,” p. 23.
- 78 See, for example, “Pharmacist-Provided Medication Therapy Management in Medicaid,” CDC, May 2021, p. 2 ([https://www.cdc.gov/dhbsp/docs/MTM\\_in\\_Medicaid-508.pdf](https://www.cdc.gov/dhbsp/docs/MTM_in_Medicaid-508.pdf), accessed June 8, 2023).
- 79 Reflects the count of beneficiaries in the 2019 “Part D Medication Therapy Management Data File” (~4M). Total beneficiaries reflects the number of beneficiaries with more than zero months of Part D coverage, based on the 2019 “Master Beneficiary Summary File Base”.
- 80 “2023 Medicare Advantage and Part D Star Ratings,” CMS (<https://www.cms.gov/newsroom/fact-sheets/2023-medicare-advantage-and-part-d-star-ratings>, accessed June 8, 2023). No equivalent data reported for TMRs.
- 81 “Evidence Supporting Enhanced Medication Therapy Management,” CMS, p. 1 (<https://innovation.cms.gov/files/x/mtm-evidencebase.pdf>, accessed June 8, 2023).
- 82 “Evidence Supporting Enhanced Medication Therapy Management,” CMS, p. 3.
- 83 Erin Ferries, Joseph T. Dye, Benjamin Hall, Lilian Ndehi, Phil Schwab, Jamieson Vaccaro, “Comparison of Medication Therapy Management Services and Their Effects on Health Care Utilization and Medication Adherence,” *JMCP*, Volume 25, Issue 6, June 2019, p. 688 (<https://www.jmcp.org/doi/full/10.18553/jmcp.2019.25.6.688>, accessed June 8, 2023).

From 2017 to 2021, CMS ran an “enhanced” Part D MTM pilot program, which included increased flexibility and payment incentives for participating PDP sponsors. The enhanced program did not result in total medical expenditure cost savings or improvements in medication use for enrolled participants.<sup>84</sup> The pilot was not offered to MA-PD plan sponsors. However, the result suggests there is still room to improve the design and delivery of MTM services in the Part D program to achieve even greater patient impact.

## Drug Utilization Review

Since 1993, section 1927(g) of the Social Security Act has required each state to develop a Medicaid DUR program. DUR is not statutorily required in the Medicare or commercial markets, so this paper focuses on DUR in Medicaid where it is defined as “structured, ongoing review of health care provider prescribing, pharmacist dispensing, and patient use of medication. DUR involves a comprehensive review of patients’ prescription and medication data and dispensing to help ensure appropriate medication decision-making and positive patient outcomes. Potentially inappropriate prescriptions, unexpected and potentially troublesome patterns, data outliers, and other issues can be identified when reviewing prescriptions through prospective DUR or retrospective DUR activities.”<sup>85</sup>

According to CMS, state FFS programs saved an average of \$57 million in 2017 through prospective DUR, and \$1.46 million through retrospective review<sup>86</sup> although there is no uniform standard for how states measure this savings. The same data are not available for Managed Medicaid programs.

As of the time of writing of this report, no data have been identified for Medicaid that measure the impact of DUR on patient outcomes.

## Formulary Design and Management

A formulary is a list of drugs covered by a particular prescription drug benefit plan. The formulary development process is complex and evidence-based and involves input from three key groups.<sup>87</sup> The first is the internal clinical review team, which comprises physicians, pharmacists, and other health care professionals employed by the health plan. The clinical review team collects and synthesizes information about the products under review and shares that information with the second group, the Pharmacy and Therapeutics (P&T) committee. The P&T committee — also comprising physicians, pharmacists, and other health care professionals — reviews the information provided by the clinical review team and votes to approve or deny recommendations for inclusion or exclusion of a product from the plan’s formulary. The final group is the value committee, tasked with evaluating the cost-effectiveness of a therapy and with negotiating its cost. The value committee is an internal team of health care professionals, data analysts, and other stakeholders whose role is to ensure a balance between medication access and cost. Health plans will routinely implement a firewall between these three teams to limit business influences on clinical decision-making.<sup>88</sup>

There are two types of formularies: open and closed. In an open formulary, nearly all legally prescribed drugs are covered, but cost sharing may be substantially higher for drugs not listed on the formulary.<sup>89</sup> In a closed

84 Beringer et al., “Evaluation of the Part D Enhanced Medication Therapy Management (MTM) Model: Fifth Evaluation Report,” p. xi.

85 “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements,” CMS, Dec. 18, 2020, p. 255 (<https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf>, accessed June 8, 2023).

86 “Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2017 Annual Report,” CMS, October 2018, p. 25 (<https://www.medicaid.gov/medicaid/prescription-drugs/downloads/drug-utilization-review/2017-dur-summary-report.pdf>, accessed June 8th, 2023). CMS continues to report DUR savings by state in its “Drug Utilization Review Annual Reports.” However, the most recent data (from 2021) are no longer summarized in the national report and are only available in each state’s individual report. See “Drug Utilization Review Annual Report,” Medicaid.gov, Jan. 17, 2023 (<https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html>, accessed June 8, 2023).

87 Sara Linnerooth, Ben Penley, Griffin Sauvageau, Jane Ha, Amy Beal, Jennifer Craven, Ellen Feeney, Patty Taddei-Allen, Norrie Thomas, John Watkins, Tasmina Hyderi, “Methodology for conducting a comprehensive product review in managed care,” JMCP, Volume 29, Issue 3, March 2023, p. 238 (<https://doi.org/10.18553/jmcp.2023.29.3.237>, accessed June 8, 2023).

88 Linnerooth et al., “Methodology for Conducting a Comprehensive Product Review in Managed Care,” p. 238.

89 Kongstvedt, Health Insurance and Managed Care, p. 145.

formulary, there is no coverage at all for non-formulary drugs unless the physician requests an exception.<sup>90</sup> A formulary is typically organized by therapeutic class, and drugs within the same therapeutic class are placed on tiers, with the lowest tier having the lowest patient cost share (usually low-cost generics) and the highest tier having the highest patient cost share (usually high-cost specialty brand drugs).<sup>91</sup>

The number of tiers will vary by plan. According to Kaiser's Employer Health Benefits Survey, 90% of covered workers were in a plan with tiered cost sharing for prescription drugs, and 84% were in a plan with three or more formulary tiers in 2022.<sup>92</sup> For those in a plan with three or more tiers, the average copayment (copay) for drugs in tier 1 was \$11, for tier 2 was \$37, for tier 3 was \$67 and for tier 4 was \$116.<sup>93</sup>

In the Part D program, larger plans typically use five tiers: preferred generic, other generic, preferred brand, non-preferred brand, and a specialty tier.<sup>94</sup> In 2021, for PDPs that were available nationwide, median generic copays were zero for preferred generics and \$5 for other generics.<sup>95</sup> Of the top 10 PDPs with the largest enrollment, preferred brand drugs were generally subject to a \$40 copay and a median coinsurance rate of 40% for non-preferred drugs although cost sharing varied widely across plans.<sup>96</sup> Drugs on the specialty tier were normally subject to a 25% coinsurance.<sup>97</sup> In 2022, the CMS began allowing plan sponsors to use two

specialty tiers (a preferred and non-preferred tier) with higher cost sharing on the non-preferred specialty tier.<sup>98</sup>

Formularies do not apply in the traditional sense to Medicaid. Because of the structure of the Medicaid Drug Rebate Program (MDRP), Medicaid operates on an essentially open formulary, meaning nearly all FDA-approved drugs of manufacturers participating in the MDRP are covered by Medicaid.<sup>99</sup> Further, because cost sharing for Medicaid beneficiaries with income at or below 150% of the federal poverty level is limited to nominal amounts,<sup>100</sup> Medicaid's ability to use copays to steer patients to the most cost-effective therapies is more limited as compared to commercial and Medicare plans. Instead, states use a PDL, which is a list of outpatient prescription drugs states encourage providers to prescribe over other available alternatives. Though a PDL is not a closed formulary, states use incentives to encourage prescribing from the PDL, such as requiring prior authorization or higher copays for drugs not on the PDL.<sup>101</sup> According to the KFF, as of 2019, 46 states used a PDL in their FFS programs and some states required Managed Medicaid plans to use the FFS PDL (i.e., they utilize a "uniform" PDL). Nine states used a uniform PDL for all drug classes and seven used it for some drug classes.<sup>102</sup>

Increasing generic utilization is one of the most effective tools for reducing drug costs, and formulary design is key to achieving high generic utilization. The Association

90 Kongstvedt, *Health Insurance and Managed Care*, p. 145.

91 "What is a Tiered Formulary and What Does it Mean for Me," United Healthcare (<https://www.uhc.com/news-articles/medicare-articles/what-is-a-tiered-formulary-and-what-does-it-mean-for-me>, accessed June 8th, 2023).

92 Gary Claxton, Mathew Rae, Emma Wager, Gregory Young, Heidi Whitmore, Jason Kerns, Greg Shmavonian, Anthony Damico, "Employer Health Benefits 2022 Annual Survey," Kaiser Family Foundation, October 2022, p. 144 (<https://files.kff.org/attachment/Report-Employer-Health-Benefits-2022-Annual-Survey.pdf>, accessed June 8th, 2023).

93 Claxton et al., "Employer Health Benefits 2022 Annual Survey," p. 146.

94 "Report to Congress: Medicare Payment Policy," MEDPAC, March 2022, p. 480 ([https://www.medpac.gov/wp-content/uploads/2022/03/Mar22\\_MedPAC\\_ReportToCongress\\_v3\\_SEC.pdf](https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_v3_SEC.pdf), accessed June 8th, 2023).

95 "Report to Congress: Medicare Payment Policy," MEDPAC, p. 481.

96 "Report to Congress: Medicare Payment Policy," MEDPAC, p. 481.

97 "Report to Congress: Medicare Payment Policy," MEDPAC, p. 481.

98 "Report to Congress: Medicare Payment Policy," MEDPAC, p. 477.

99 Rachel Dolan, "Understanding the Medicaid Prescription Drug Rebate Program," Kaiser Family Foundation, Nov. 12, 2019 (<https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/>, accessed June 8, 2023).

100 "Cost Sharing," Medicaid.gov (<https://www.medicaid.gov/medicaid/cost-sharing/index.html>, accessed June 8, 2023).

101 Dolan and Tian, "Management and Delivery of the Medicaid Pharmacy Benefit," p. 2.

102 "State Medicaid Preferred Drug Lists," Kaiser Family Foundation, July 1, 2019 (<https://www.kff.org/other/state-indicator/medicaid-preferred-drug-lists/>, accessed June 8, 2023). Another 18 states did not have a uniform PDL, two did not respond, and for 15 states, this question was not applicable because the states do not have comprehensive capitated managed care or have carved out the pharmacy benefit.



for Accessible Medicines (AAM) estimates that generic and biosimilar drugs generated \$445 billion in savings in 2023 across the commercial, Medicare Part D, Medicaid, and cash payer classes.<sup>103</sup> Generic and biosimilar prescriptions account for an estimated 90 percent of prescriptions filled but only 13.1 percent of prescription drug spending.<sup>104</sup> Plans encourage patients to fill generic by assigning these drugs the lowest cost share on their formularies. Plans, typically through a PBM, also encourage pharmacies to fill generic whenever possible using maximum allowable cost (MAC) lists. A MAC list contains multiple source drug products subject to a specified reimbursement limit.<sup>105</sup> PBMs use MAC lists to ensure all drugs of the same product form and strength (i.e., interchangeable products) are reimbursed at the same rate regardless of the manufacturer's list price, thus encouraging pharmacies to purchase the lowest-cost generic available to them and to dispense generic whenever possible. This, in turn, ensures consumers and health plans do not overpay for generic drugs or for brand drugs with a generic available.

Generic utilization, however, varies widely by payer type. Cash patients have the highest share of generic utilization, at 97% in 2020,<sup>106</sup> likely reflecting the cost sensitivity of this population and the mix of drugs they can reasonably afford without insurance. In 2020, commercial plans experienced 90.5% generic utilization with Medicare Part D at 89.5%. In Medicaid, managed care plans achieved higher generic utilization than FFS plans (92.5% versus 89.5%).<sup>107</sup>

Generics are not the only component of a well-designed formulary. For drug classes with no generics available, plans may place drugs with the lowest net cost on a more preferred tier. The lowest net cost could be driven by a combination of lower list price and/or higher manufacturer rebates. In the commercial and Medicare Part D space, PBMs typically negotiate with drug manufacturers for rebates on behalf of their health plan clients. In exchange for offering more favorable rebates, a manufacturer's drug is typically placed on a more preferred tier with lower patient cost share, thus encouraging higher utilization of that drug over alternatives.<sup>108</sup>

A well-designed formulary — one that encourages generic utilization and utilization of the most cost-effective brands where no generic is available — can achieve significant cost savings. In a 2021 study, researchers examined the cost savings achieved by two large, self-insured employers that modified their formularies to reduce wasteful prescription drug spending. Two hundred and ninety-three potentially wasteful drugs were identified, 95% of which (279) were excluded from the original formulary and replaced with less expensive alternatives and 5% of which (~15) became subject to prior authorization or step therapy.<sup>109</sup> After these formulary changes were made, annual spending per member per month after rebates across all drugs on each employer's formulary decreased by 9% for one employer and 15% for the other.<sup>110</sup> The 279 drugs ultimately removed from formulary fell into three categories: (1) multisource drugs [76] (i.e., the wasteful

103 "The U.S. Generic & Biosimilar Medicines Savings Report," Association for Accessible Medicines, September 2024, p. 7 (<https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf>, accessed September 23, 2024).

104 "The U.S. Generic & Biosimilar Medicines Savings Report," Association for Accessible Medicines, September 2024, p. 7.

105 "Managed Care Glossary," AMCP.

106 "The Use of Medicines in the U.S.," IQVIA Institute, May 27, 2021, p. 25 (<https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>, accessed June 8, 2023).

107 "The Use of Medicines in the U.S.," IQVIA Institute, p. 25.

108 Medicaid rebates operate differently. The MDRP sets out a statutory formula for calculating brand and generic rebates through which Medicaid ensured the lowest net price available. Further, 47 states and the District of Columbia participate in supplemental rebate agreements (SRAs) whereby they receive additional rebates from manufacturers over and above what is federally required. Statutory and supplemental rebates are paid on FFS and managed care utilization. See "Medicaid Pharmacy Supplemental Rebate Agreements (SRA)," Medicaid.gov, June 2022 (<https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxxsupplemental-rebates-chart-current-qr.pdf>, accessed June 8, 2023).

109 Mariana P. Socal, Ge Bai, Thomas Cordeiro, et al, "Association Between Waste-Free Formularies and Prescription Drug Spending Among Self-Insured Employers," *JAMA Network Open*, Volume 4, no. 10, Oct. 28, 2021, p. 2. (<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785573>, accessed June 8, 2023). Note that the numbers in brackets exclude 14 potentially wasteful drugs that were placed under prior authorization or step therapy rather than being excluded from formulary altogether.

110 Socal et al., "Association Between Waste-Free Formularies and Prescription Drug Spending Among Self-Insured Employers," p. 2.

product is a brand with a generic available), (2) me-too products [118] (i.e., the wasteful drug has minimal differences compared with a cheaper alternative but no major difference in clinical effectiveness) and (3) same-class drugs [85] (i.e., the wasteful product has a cheaper alternative within the same therapeutic class).<sup>111</sup>

A 2018 report from the Department of Health and Human Services (HHS) examined dispensing of brand-name drugs in Part D where generics were available. HHS found that more than 600 brand-name drugs were paid for by Part D plans in 2016 despite the availability of a generic. Had full substitution of multiple source brands (i.e., those with an available generic) occurred, HHS estimates that the Part D program would have saved \$2.8 billion in 2016, although the analysis does not account for rebates.<sup>112</sup> HHS' findings suggest further opportunities to maximize generic utilization in Part D through more effective formulary design and incentive alignment.

CVS Caremark, one of the nation's largest PBMs, estimates that clients who are aligned to its template formularies as opposed to a formulary without exclusions will save \$4.3 billion in 2023.<sup>113</sup> According to the company, CVS Caremark reviews its formularies quarterly to identify "hyperinflated" drugs (i.e., expensive drugs that have readily available, clinically appropriate, and more cost-effective alternatives). CVS Caremark estimates that its hyperinflation strategies, which include removing certain drugs from formulary, saved clients \$629.9M in 2020.<sup>114</sup> Express Scripts, another major PBM, projected a savings of \$3.2 billion in 2019 for plans aligned to its National Preferred Formulary, which also excludes certain medications that have lower-cost alternatives.<sup>115</sup>

111 Socal et al., "Association Between Waste-Free Formularies and Prescription Drug Spending Among Self-Insured Employers," p. 2.

112 "Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D," HHS, July 23, 2018, p. 3 (<https://aspe.hhs.gov/sites/default/files/private/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf>, accessed June 8, 2023).

113 "Formulary Management: Helping Lower Client Cost While Ensuring Members Have Access to Clinically Appropriate Medications," CVS Health (<https://payorsolutions.cvshealth.com/programs-and-services/cost-management/formulary-management>, accessed June 8, 2023).

114 "Eliminating Wasteful Spend on Hyperinflated Drugs: Mitigating the cost impact of overpriced medications," CVS Health, June 17, 2021 (<https://payorsolutions.cvshealth.com/insights/eliminating-wasteful-spend-on-hyperinflated-drugs>, accessed June 8, 2023).

115 "Adding Value: National Preferred Formulary Generates Savings for Plans and Patients," Express Scripts, October 2019, pp. 2-3 (<https://corporate-site-labs-dev.s3.amazonaws.com/2019-10/The%20NPF%20-%20Adding%20Value.pdf>, accessed Aug. 16, 2023).

## VI. Overview of Pharmacy Types and Pharmacy Networks

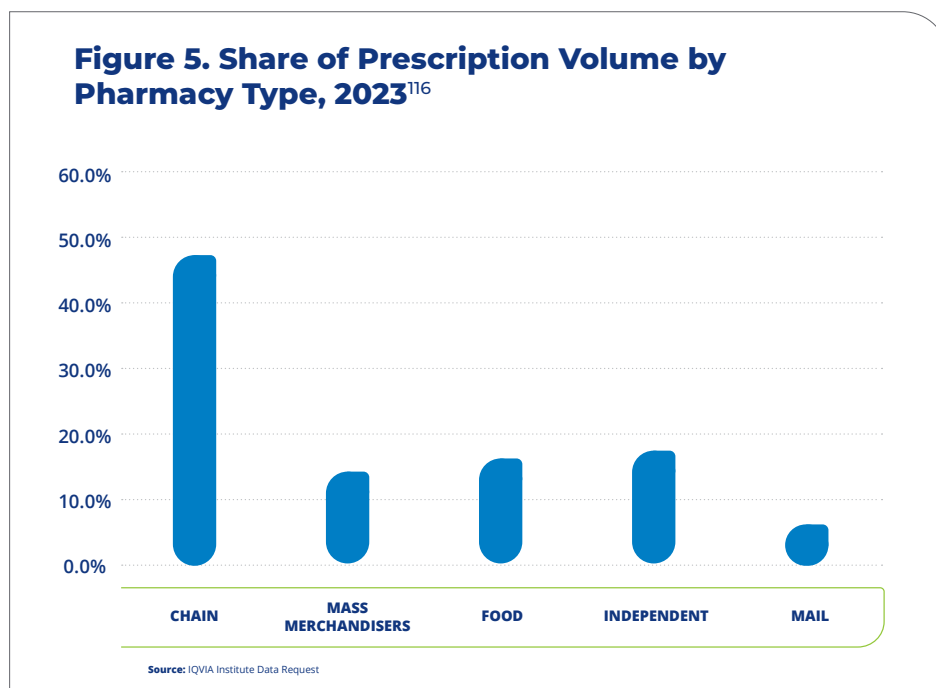


### Pharmacy Types

There are five main types of retail pharmacies in the United States:

1. Chain pharmacies (e.g., Walgreens, CVS)
2. Mass merchandisers (e.g., Walmart)
3. Food stores (e.g., Kroger, Safeway)
4. Independent pharmacies
5. Mail order pharmacies

Figure 5 below shows the share of prescriptions that flowed through each pharmacy type in 2023:



116 IQVIA Institute Special Data Request.

Note that while mail order pharmacies make up a relatively small portion of retail prescriptions dispensed, they contribute much more to spending, as specialty medications tend to be dispensed through the mail. A report by McKinsey found that mail order pharmacies made up 10% of prescriptions dispensed in 2021 but 39% of spending.<sup>117</sup> This is further supported by IQVIA's analysis that as of June 2022, claims for specialty medications accounted for 83.4% of all mail order pharmacy spending.<sup>118</sup>

There is also some overlap in the characteristics of each pharmacy type and the typical medications dispensed by each. For example, some specialty pharmacies can have physical locations while others operate exclusively through mail order. CVS Caremark notes that its specialty pharmacies can be mail order or brick-and-mortar: “[M]ail order pharmacies are used primarily for maintenance medications, while the specialty mail order pharmacies and retail specialty pharmacy stores are used for the delivery of advanced medications to individuals with chronic or genetic diseases and disorders.”<sup>119</sup> Specialty pharmacies are accredited by one of two main institutions: Utilization Review Accreditation Commission (URAC) and Accreditation Commission for Health Care (ACHC).<sup>120</sup>

## Pharmacy Networks

Managed care plans, typically through their contracted PBM, contract with various different pharmacies nationwide that together make up the plan's pharmacy network. When a plan member visits one of these in-network pharmacies to fill a prescription, their out-of-pocket cost share is typically lower than it would be if

the member filled the same prescription at an out-of-network pharmacy. A plan may not cover the drug at all if the pharmacy is not in-network. In creating a pharmacy network, the PBM seeks a mix of local community pharmacies (i.e., chain, independent and food stores), specialty pharmacies, and mail order options. When a pharmacy agrees to be a part of a plan's network, it agrees to contracted reimbursement rates negotiated by the PBM.

In order for a pharmacy to participate in a PBM/plan's network, it must meet certain standards set by the PBM related to patient safety as well as requirements set by government agencies.<sup>121</sup> Pharmacies go through an initial credentialing process when they first join a network and renew their credentials typically every three years.<sup>122</sup>

One of the key roles of a PBM is to monitor patients' prescriptions for potential safety issues, including drug interactions. The PBM does this across all network pharmacies even if a patient fills prescriptions at multiple pharmacies.<sup>123, 124</sup>

Another key function of a PBM is to perform pharmacy compliance audits on behalf of their plan sponsor clients. These audits may be performed off-site or at the pharmacy, and they help to ensure that the pharmacy is in compliance with the terms of its network agreement. Pharmacy compliance audits may verify that patients received the correct medication and the appropriate dose by comparing the original prescription to the medication dispensed. They are also used to detect potential fraud, waste, and abuse, such as inconsistencies

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- 117 Alok Ladsariya, Alec McLeod, BJ Tevelow, Garam Noh and Nikhil Sahni, “Meeting changing consumer needs: The US retail pharmacy of the future,” McKinsey, March 2023, p. 3 (<https://www.mckinsey.com/industries/healthcare/our-insights/meeting-changing-consumer-needs-the-us-retail-pharmacy-of-the-future>, accessed September 12th, 2024).
- 118 Gina Shaw, “Specialty Drugs Represent Half of Nondiscounted Drug Spending: IQVIA Report,” Specialty Pharmacy Continuum, September 23, 2022 (<https://www.specialtypharmacycontinuum.com/Online-First/Article/09-22/Specialty-Drugs-Represent-Half-of-Nondiscounted-Drug-Spending-IQVIA-Report/68130?ses=ogst>, accessed September 12th, 2024).
- 119 CVS Health Corporation, Form 10-K for the fiscal year ended December 31, 2023, p. 10 (<https://d18rn0p25nwr6d.cloudfront.net/CIK-0000064803/28e54055-44dd-4a6d-a517-6ffc18161213.pdf>, accessed September 12, 2024).
- 120 Adam Fein, “The Top 15 Specialty Pharmacies of 2023: Market Shares and Revenues at the Biggest PBMs, Health Plans, and Independents,” Drug Channels, April 16th, 2024 (<https://www.drugchannels.net/2024/04/the-top-15-specialty-pharmacies-of-2023.html>, accessed September 12th, 2024).
- 121 Jen Awsumb, “Three Ways to Optimize a Pharmacy Network,” Evernorth, May 25th, 2022 (<https://www.evernorth.com/articles/learn-about-pharmacy-networks>, accessed September 12th, 2024).
- 122 Awsumb, “Three Ways to Optimize a Pharmacy Network.”
- 123 “Pharmacy Benefit Manager (PBM) Basics: Innovative Tools and Techniques,” PCMA, 2017 (<https://www.pcmnet.org/wp-content/uploads/2021/09/Explaining-Innovative-PBM-Tools-and-Techniques-2017.pdf>, accessed September 12th, 2024).
- 124 Note that the PBM only has visibility to prescriptions that patients fill using health insurance.

between the quantity of a drug billed to payers and the pharmacy's purchases of that drug from wholesalers. Pharmacy compliance audits thus play an important role in ensuring patient safety and discouraging fraud, waste, and abuse.

There are three main types of pharmacy networks:<sup>125</sup>

### (1) Open

An open network design offers plan members access to a broad network of pharmacies. A plan member can go to virtually any pharmacy to fill their prescription and will have the same cost share regardless of which pharmacy they select. Open network designs are increasingly rare in today's market, as plans seek to control increasing pharmaceutical spending.

### (2) Preferred

A preferred network design places certain pharmacies within the network on a preferred tier and others on a standard tier. Preferred pharmacies offer plans better prescription drug pricing in exchange for increased volume, which, in turn, allows plans to

offer their members lower cost share when visiting a preferred pharmacy. Plan members can still go to a non-preferred pharmacy in the network but will face a higher cost share.

In some cases, plans or their PBMs will enter into risk-sharing arrangements with preferred pharmacies that encourage increased generic utilization rates.<sup>126</sup> Such risk-sharing structures may also incentivize the pharmacy to engage in patient care management. In fact, preferred pharmacy networks may incorporate a pharmacist's patient care services into accountable care arrangements that may help produce better health outcomes at a lower cost.<sup>127</sup>

Within Medicare Part D, 94% of standalone prescription drug plans (PDPs) in 2024 had a preferred network compared with 51% of Medicare Advantage prescription drug plans (MA-PDs). Among standalone PDP plans, the use of preferred networks has grown significantly over time, as shown in **Figure 6**.<sup>128</sup> According to AMCP, about 50% of employer-sponsored health plans utilize a narrow or preferred network.<sup>129</sup>

125 "Finding the Formula for Drug Savings: the Role of Pharmacy Benefit Managers in the Health Care System," PCMA, 2017, p. 29 ([https://www.pcmagnet.org/wp-content/uploads/2017/09/PBM-Basics-Slide-Deck\\_012717.pdf](https://www.pcmagnet.org/wp-content/uploads/2017/09/PBM-Basics-Slide-Deck_012717.pdf), accessed September 12th, 2024).

126 "Preferred Pharmacy Networks," AMCP (<https://www.amcp.org/resource/preferred-pharmacy-networks>, accessed September 12th, 2024).

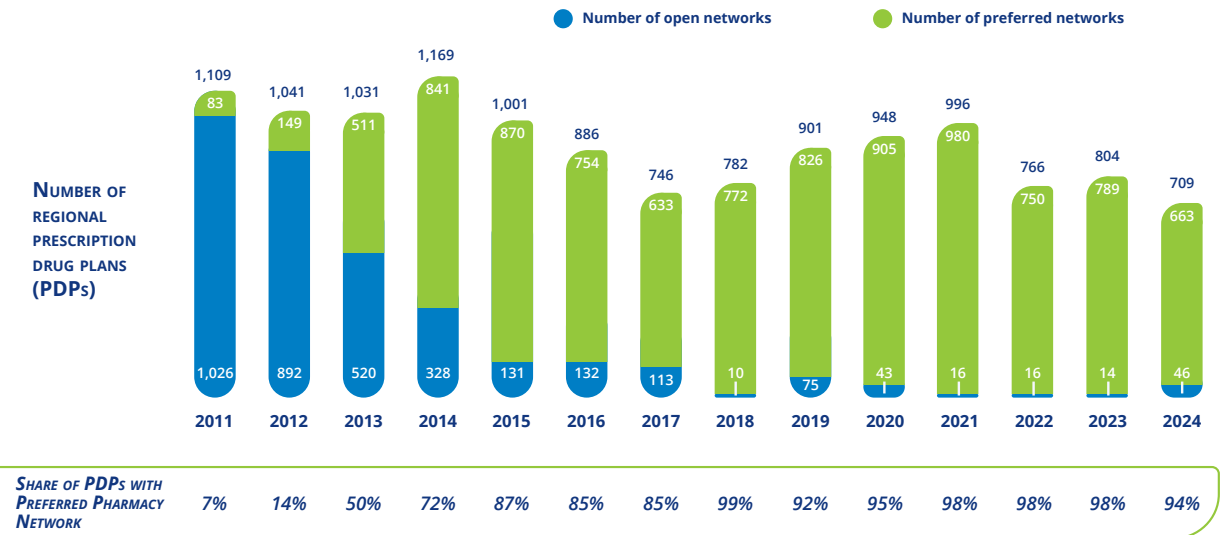
127 "Preferred Pharmacy Networks," AMCP.

128 Adam Fein, "Medicare Part D in 2024: The Seven Largest Companies' Preferred Pharmacy Networks and the Coming Collapse of the PDP Market," Drug Channels, October 24th, 2023 (<https://www.drugchannels.net/2023/10/medicare-part-d-in-2024-seven-largest.html>, accessed September 12th, 2024).

129 "Preferred Pharmacy Networks," AMCP.

## Figure 6. Medicare Part D PDPs with Preferred Pharmacy Networks, 2011 to 2024

From 2011 – 2024, the share of PDPs with open pharmacy networks declined significantly in favor of preferred networks.



PDP: Prescription Drug Plan

Sources: Drug Channels Institute analysis of Centers for Medicare & Medicaid Services data; Kaiser Family Foundation. Figures exclude: employer-sponsored plans; plans from U.S. territories and possessions; employer/union-only group plans; and Medicare Advantage plans.

Published on Drug Channels ([www.drugchannels.net](http://www.drugchannels.net)) on October 24, 2023.

### (1) Limited

A limited network design, sometimes also referred to as a “narrow” network, is made up of select pharmacies that offer the plan deeper discounts. Members can visit any pharmacy in the limited network and will have the same cost share. This network design includes fewer pharmacies than a preferred or open network.

PBMs work with their clients to provide a variety of network management options, taking into account such variables as membership size, geographic area, and financial and clinical goals.<sup>130</sup> When deciding on the type of network to offer to members, a plan

must balance the cost savings that may be derived from the use of narrower networks with the need to provide members with robust access to convenient pharmacies.

### Cost Savings Achieved Through Carefully Designed Pharmacy Networks and Other Plan Design Strategies

Numerous studies support the cost savings derived from preferred and limited networks. In 2019, the PBM Navitus found that its plan sponsors saved an average of 3-5% on annual retail drug spend when they participated in its narrow network.<sup>131</sup> The PBM Elixir found that one of its health plan clients saved 9.6% on

130 “Understanding the Role of Pharmacy Benefit Managers in Healthcare,” Elevance Health Public Policy Institute, October 2022, p. 7 ([https://www.elevancehealth.com/content/dam/elevance-health/articles/ppi\\_assets/55/EHPPI\\_PBM\\_r5\\_Final.pdf](https://www.elevancehealth.com/content/dam/elevance-health/articles/ppi_assets/55/EHPPI_PBM_r5_Final.pdf), accessed September 12th, 2024).

131 “Want to Save More on Your Pharmacy Benefits?” Navitus Health Solutions, August 6th, 2020, (<https://blog.navitus.com/narrow-network-strategy>, accessed September 12th, 2024).

drug spend when it switched from a broad to a narrow network.<sup>132</sup> A 2013 study by Milliman estimated that preferred pharmacy networks would reduce Medicare spending by \$870 million in 2014.<sup>133</sup> In 2014, in response to CMS proposed rules that would have limited Part D plans' ability to construct preferred pharmacy networks, the Federal Trade Commission issued a letter to CMS stating, "Evidence suggests that prescription drug prices are likely to rise if Prescription Drug Plans (PDPs) are less able to assemble selective pharmacy networks."<sup>134</sup>

Further, managed care plans seek to derive savings on prescription drugs through (1) use of mail order pharmacies and (2) use of 90-days' supply prescriptions (rather than 30-days' supply) filled at community pharmacies. BRG analyzed the cost savings from these strategies for both commercial and Medicare plans for 15 of the most commonly dispensed brand and generic drugs (measured by days' supply).<sup>135, 136, 137</sup>

To assess cost savings derived through the use of mail order pharmacies, we compared the cost per unit by drug (product, form, and strength) of prescriptions dispensed at a mail order pharmacy for a days' supply between 84 and 100 to the cost per unit of prescriptions

dispensed for those same drugs at a community pharmacy for the same days' supply range.<sup>138</sup> We examined both the total cost per unit<sup>139</sup> and the patient pay per unit<sup>140</sup> and calculated the weighted average percent difference between the mail cost per unit and the community pharmacy cost per unit. For brand medications reimbursed by commercial payers, we found average total savings at mail order of 1% (with 14 out of 15 drugs exhibiting savings) and average patient savings of 13% (with 13 out of 15 drugs exhibiting savings for the patient). For generic medications reimbursed by commercial payers, we found average total savings at mail order of 38% (with 13 out of 15 drugs exhibiting savings) and average patient savings of 22% (with 14 out of 15 drugs exhibiting savings for the patient). For brand medications reimbursed by Medicare, we found average total savings at mail order of 2% (with 14 out of 15 drugs exhibiting savings) and average patient savings of 12% (with 14 out of 15 drugs exhibiting savings for the patient).<sup>141</sup> See **Figure 7** below.

132 "Bigger Isn't Always Better: Determining the Best Pharmacy Network for You and Your Members," Elixir, ([https://page.elixirsolutions.com/hubfs/Documents/elixir\\_solutionoverview\\_narrow%20network\\_20-5214\\_vpf5.pdf](https://page.elixirsolutions.com/hubfs/Documents/elixir_solutionoverview_narrow%20network_20-5214_vpf5.pdf), accessed September 12th, 2024).

133 Stephen J. Kaczmarek, Andrea Sheldon, David M. Liner, "The Impact of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014 – 2023," Milliman, October 2013, p. 1 (<https://www.pcmnet.org/wp-content/uploads/2017/05/Milliman-Medicare-preferred-pharmacy-networks-study.pdf>, accessed September 12th, 2024).

134 "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," FTC, March 7th, 2014, p. 1 ([https://www.ftc.gov/system/files/documents/advocacy\\_documents/federal-trade-commission-staff-comment-centers-medicare-medic-aid-services-regarding-proposed-rule/140310cmscomment.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medic-aid-services-regarding-proposed-rule/140310cmscomment.pdf), accessed September 12th, 2024).

135 Drugs selected based on contribution to days' supply. For purposes of this analysis, we define a 30-days' supply as any days' supply between 28 and 30, and we define a 90-days' supply as any days' supply between 84 and 100. For the comparison of community pharmacy 90-days' supply to community pharmacy 30-days' supply, we examine 15 of the most commonly dispensed brands and 15 of the most commonly dispensed generics at community pharmacies where the days supplied is between 84 and 100. For the comparison of mail order 90-days' supply to community pharmacy 90-days' supply, we examine 15 of the most commonly dispensed brands and 15 of the most commonly dispensed generics at mail order pharmacies where the days supplied is between 84 and 100. Because a single drug can be dispensed in multiple strengths and forms, we selected the most commonly dispensed version of each drug within a product family so as to avoid analyzing multiple versions of the same product within our top 15 list.

136 In the Merative MarketScan commercial claims data, the RXMR flag distinguishes mail order from community/retail prescriptions. In the Medicare data, the PHRMCY\_SRVCTYPE\_CD indicates the type of pharmacy.

137 For Medicare, analysis is limited to patients that did not receive the low-income subsidy. Further, patient savings is evaluated for claims occurring entirely within the initial coverage phase; total savings is evaluated across all phases.

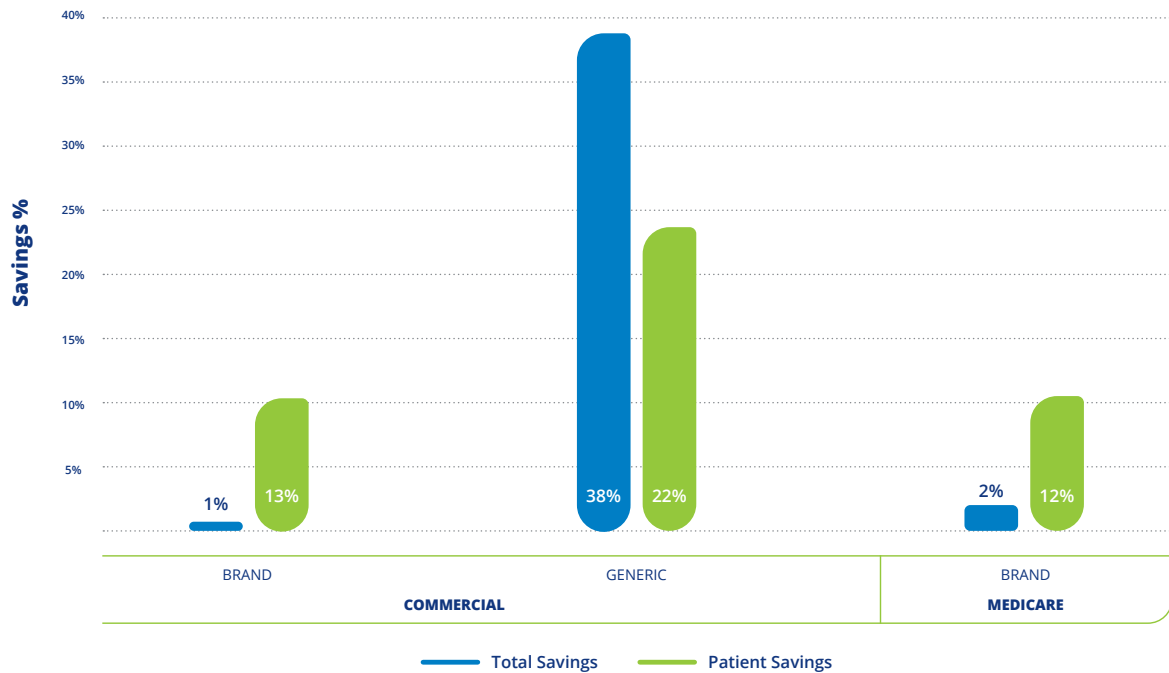
138 Our analysis is at the gross drug cost level and does not take into account rebates, which are proprietary to each manufacturer. Rebates should not impact our results for generic drugs. For brand drugs, we expect our results to remain directionally correct at the net cost level (i.e., post rebates), assuming similar rebates are achieved for the plans represented in each comparison group.

139 Field TOT\_RX\_CST\_AMT in the Medicare data; field PAY in the Merative MarketScan data.

140 Sum of fields PTNT\_PAY\_AMT, OTHR\_TROOP\_AMT, PLRO\_AMT in the Medicare data; sum of fields COPAY, COINS, DEDUCT in the Merative MarketScan data.

141 Mail order savings for generic drugs reimbursed by Medicare is not shown due to an anomaly we observed in the Medicare claims data. We hope to analyze this issue further and will update our reporting in the future.

**Figure 7. Mail Order 90-Days' Supply Savings Relative to Community Pharmacy 90-Days' Supply<sup>142</sup>**



Source: 1) Proprietary BRG analysis of MarketScan commercial claims data. Merative MarketScan Research Databases, TM. All rights reserved. 2) Chronic Conditions Data Warehouse. Centers for Medicare & Medicaid Services.

To assess cost savings derived through the use of 90-days' supply prescriptions at community pharmacies, we compared the cost per unit by drug (product, form, and strength) of prescriptions dispensed at a community pharmacy for a supply between 84 and 100 days to the cost per unit of prescriptions dispensed for those same drugs at a community pharmacy for a supply between 28 and 30 days. For brand medications reimbursed by commercial payers, we found average total savings from a 90-days' supply of 9% (with 15 out of 15 drugs exhibiting savings) and average patient savings of 32% (with 15 out of 15 drugs exhibiting savings for the patient). For generic medications reimbursed by commercial payers, we found average total savings from a 90-days' supply

of 18% (with 15 out of 15 drugs exhibiting savings) and average patient savings of 23% (with 15 out of 15 drugs exhibiting savings for the patient). For brand medications reimbursed by Medicare, we found average total savings from a 90-days' supply of 2% (with 15 out of 15 drugs exhibiting savings) and average patient savings of 7% (with 12 out of 15 drugs exhibiting savings for the patient). For generic medications reimbursed by Medicare, we found average total savings from a 90-days' supply of 19% (with 15 out of 15 drugs exhibiting savings) and average patient savings of 30% (with 15 out of 15 drugs exhibiting savings for the patient). See **Figure 8** below.

142 Savings % is calculated as (Mail 90 Cost – Community 90 Cost)/Community 90 Cost, weighted by the quantity of each product dispensed at a mail order pharmacy for a days' supply of 84-100.



**Figure 8. Community Pharmacy 90-Days' Supply Savings Relative to 30-Days' Supply<sup>143</sup>**



Source: 1) Proprietary BRG analysis of MarketScan commercial claims data. Merative MarketScan Research Databases, TM. All rights reserved. 2) Chronic Conditions Data Warehouse. Centers for Medicare & Medicaid Services.

## Medication Adherence — Benefits of 90-days' Supply Prescriptions Dispensed at Mail or Community Pharmacies

Numerous studies have shown increased medication adherence when patients receive their medications for chronic conditions, such as cholesterol or diabetes, in 90-days' supply. For this report, BRG analyzed medication adherence to statin therapies over a 365-day period among commercial patients in the following three categories: (1) patients who filled all their statin prescriptions as a 30-days' supply at a community pharmacy (~170,000 patients), (2) patients who filled all their statin prescriptions as a 90-days' supply at a community pharmacy (~350,000 patients), and (3) patients who filled all their statin prescriptions as a 90-days' supply at a mail order pharmacy (~140,000

patients).<sup>144</sup> Thus, our analysis allowed us to differentiate between patients receiving a 30-days' supply and a 90-days' supply through community pharmacies versus mail order pharmacies.

We examined commercial patients who filled a statin or statin combination prescription in the first quarter of 2021 and were continuously enrolled 395 days after their initial statin prescription. We followed such patients for 365 days following their initial prescription in Q1-2021. We limited our analysis to patients that had at least 90 days covered in the 365-day measurement period to increase the comparability of the community pharmacy 30-days' supply group and the other two groups.

143 Savings % is calculated as (Community 90 Cost – Community 30 Cost)/Community 30 Cost, weighted by the quantity of each product dispensed at a community pharmacy for a days' supply of 84-100.

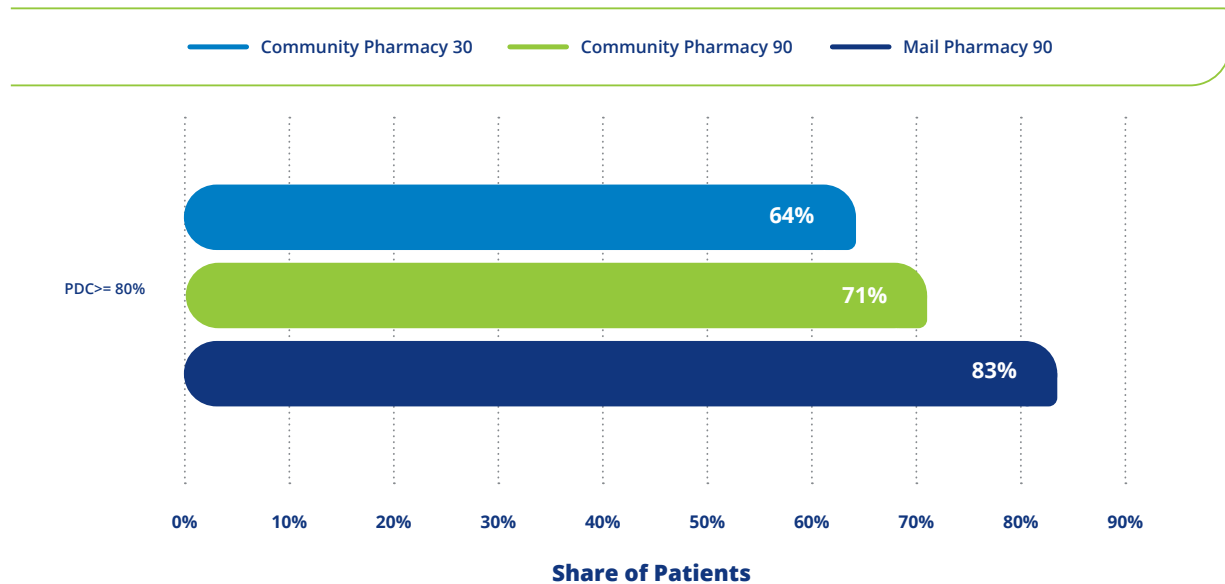
144 For purposes of this analysis, we defined a 30-days' supply as any days' supply less than 84 and a 90-days' supply as any days' supply of 84 or more.

We found that the mail order patient group had the highest therapy adherence, as measured by a proportion of days covered<sup>145</sup> of 80% or more, followed by the community pharmacy 90-days' supply group, followed by the community pharmacy 30-days' supply group. See **Figure 9** below.

Managed care pharmacy strategies that emphasize 90-day prescriptions for maintenance therapies result in more patients reaching the generally accepted 80% threshold for adherence. Our analysis suggests that patients receiving a 90-days' supply through the mail achieve even better adherence than those receiving a 90-days' supply through a community pharmacy.<sup>146</sup>

### Figure 9: Comparison of Medication Adherence to Statin Therapies Amongst Community 30, Community 90, and Mail Patients

Mail-order patients were most likely to meet accepted threshold for proportion of days covered



145 Proportion of days covered (PDC) measures the number of days that a patient had their medication on hand during a particular time period. Unlike the medication possession ratio (MPR), PDC is a more conservative measure because it counts each day covered only once whereas the MPR adds up the total days' supply without adjusting for overlapping prescriptions. The maximum PDC is 1.0 whereas the MPR can exceed 1.0.

146 As with any medication adherence study, we cannot control for whether the patient was compliant with taking the medication that they had on hand, nor can we control for automatic refills at mail order pharmacies.

## VII. Overview of the Medical vs. the Pharmacy Benefit



### Explanation of Each Benefit

In many cases, a patient's medical benefit (e.g., physician office visits, hospital stays, laboratory testing, surgery, etc.) and pharmacy benefit (e.g., prescription drugs) are administered by entirely different companies. As we see more consolidation in the health care supply chain — particularly as large health plans become aligned with pharmacy benefit managers — the two benefits may be administered by increasingly integrated health care companies.

### Prescription Drugs: Medical or Pharmacy Benefit?

While plan members may associate prescription drugs with the pharmacy benefit, many drugs are covered under a plan's medical benefit. Historically, drugs administered in a physician's office or other outpatient clinical setting (e.g., infusion therapies administered intravenously) were covered under medical benefits, whereas self-administered drugs (e.g., self-injectables and oral medications) were covered under pharmacy benefits. Drugs covered under the medical benefit are typically acquired by the provider and billed to the

insurance company (so called "buy and bill") along with a separate bill to cover the administration of the drug.<sup>147</sup> By contrast, drugs covered under the pharmacy benefit are typically dispensed to patients through a pharmacy. The pharmacy submits a claim to the patient's PBM or health insurer for the drug cost plus a dispensing fee to cover the pharmacy's services. Depending on a beneficiary's plan design, there may be a single deductible toward which both medical and pharmacy spending accrues, or the two benefits may have standalone deductibles that must be separately satisfied. There are also typically distinct member cost sharing arrangements under medical versus pharmacy benefits.

For purposes of this report, we focus on outpatient drug spending (i.e., spending on prescription drugs dispensed at pharmacies or administered in outpatient settings, as opposed to drugs furnished during an inpatient hospital or nursing facility stay).

### Contribution to Spending

Certain drugs — usually those administered by a health care professional in a clinical setting — may be

147 Caroline Pearson, Lindsey Schapiro, Steven Pearson, "White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market," ICER, April 19th 2023, p. 7 ([https://icer.org/wp-content/uploads/2023/04/ICER-White-Paper\\_-\\_White-Bagging-Brown-Bagging-and-Site-of-Service-Policies.pdf](https://icer.org/wp-content/uploads/2023/04/ICER-White-Paper_-_White-Bagging-Brown-Bagging-and-Site-of-Service-Policies.pdf), accessed September 12th, 2024).

covered under a plan's medical benefit rather than its pharmacy benefit, depending on the plan's design and the setting of administration.<sup>148</sup> In fact, some plans may cover the same drug under both the medical and pharmacy benefit.<sup>149</sup> Typically drugs covered under both benefits are specialty medications used to treat complex conditions (e.g., rheumatoid arthritis, multiple sclerosis), are higher in cost, may require specific storage and handling, and often necessitate more intense patient monitoring and training.<sup>150</sup> Spending on specialty pharmaceuticals is estimated to account for over 50% of medication spending annually, despite such therapies treating only ~3% of patients.<sup>151</sup>

A 2022 report by Evernorth found that 65% of specialty medications are paid for under the pharmacy benefit and that plan spending per beneficiary per year on specialty medications is \$38,000 on average, compared with \$492 for non-specialty medications.<sup>152</sup>

### Novel Strategies to Control Costs<sup>153</sup>

Under the "buy and bill" structure used for drug claims processed under the medical benefit, when a drug is administered in the hospital setting (as opposed to a physician-office), the markups charged to payers can be as high as 200-300% of the base price of the drug.<sup>154</sup> In another study, researchers focused on cancer therapies found that median price markups above hospital

acquisition costs ranged from 118% to 634% depending on the therapy analyzed.<sup>155</sup> AHIP found that, on average, hospitals were reimbursed over twice as much for the same drugs as compared to specialty pharmacies, and that physician offices were reimbursed 23% more on average as compared to specialty pharmacies.<sup>156</sup> Given that specialty therapies can cost hundreds of thousands of dollars per patient annually, such markups — particularly those in the hospital setting — contribute substantially to health care spending and put upward pressure on insurance premiums.<sup>157</sup>

The significant differences in cost for specialty drugs driven by site of care (specialty pharmacy versus physician office versus hospital outpatient department (HOPD)) can be attributed, at least in part, to the method of reimbursement utilized in each setting. In 2018, Drug Channels analyzed commercial reimbursement methods for provider administered drugs by site of care (physician office and HOPD) and found that a much higher proportion of plans reimbursed HOPDs based on a percentage of charges.<sup>158</sup>

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- 148 "The Growth in Specialty Drug Spending From 2013 to 2014," Blue Cross Blue Shield Blue Health Intelligence, May 2016, p. 1 (<https://www.bcbs.com/sites/default/files/file-attachments/health-of-america-report/HoA-SpecialtyRxCost.pdf>, accessed September 12th, 2024).
- 149 A. Alex Levine, Ari D Panzer, Teresa L Kauf, Amy K O'Sullivan, Lauren Strand, James D Chambers, "Specialty drug coverage varies between health plans' medical and pharmacy benefit policies," *J Manag Care Spec Pharm*, Volume 29, Issue 6, June 2023, p. 607 (<https://doi.org/10.18553/jmcp.2023.29.6.607>, accessed September 12th, 2024).
- 150 ThienLy Neal, "What Are Specialty Pharmacies," GoodRx, October 26, 2021 (<https://www.goodrx.com/drugs/medication-basics/specialty-pharmacies>, accessed September 12th, 2024).
- 151 "The Use of Medicines in the U.S. 2023," IQVIA Institute, April 2023, p. 30 (<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023>, accessed September 12th, 2024).
- 152 Jennie Iverson, "What is Drug Trend and How to Manage it," Evernorth, April 20th, 2022 (<https://www.evernorth.com/articles/specialty-drug-trends-and-utilization>, accessed September 12th, 2024).
- 153 Pearson et al., "White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market," p. 3.
- 154 Pearson et al., "White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market," p. 3.
- 155 Roy Xiao, Joseph S. Ross, Cary P. Gross, Stacie B. Dusetzina, J. Michael McWilliams, Rosh K. V. Sethi, Vinay K. Rathi, "Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance," *JAMA Internal Medicine*, Volume 182, Issue 6, April 18th, 2022, p. 603 (<https://doi.org/10.1001/jamainternmed.2022.1022>, accessed September 12th, 2024).
- 156 "Hospital Price Hikes: Markups for Drugs Cost Patients Thousands of Dollars," AHIP, April 2023 ([https://ahiporg-production.s3.amazonaws.com/documents/202304-AHIP\\_1P\\_Specialty\\_Pharmacy\\_report\\_update-v02.pdf](https://ahiporg-production.s3.amazonaws.com/documents/202304-AHIP_1P_Specialty_Pharmacy_report_update-v02.pdf), accessed September 12th, 2024).
- 157 Pearson et al., "White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market," p. 3-4.
- 158 Adam Fein, "Still Possible: Hospitals Overcharge Health Plans for Specialty Drugs," Drug Channels, August 8th, 2018 (<https://www.drugchannels.net/2018/08/still-possible-hospitals-overcharge.html>, accessed September 12th, 2024).

See **Figure 10**. Since hospitals set their own charges and charges are often not tied to specific reference prices or acquisition costs, reimbursement set at a percentage of charges can create a significant markup.

BRG's analysis of three physician-administered drugs supports these conclusions. We analyzed Prolia, Entyvio, and Ocrevus using Merative MarketScan commercial claims data for 2022 and found that HOPDs were reimbursed significantly more than pharmacies for the same drugs. We also compared pharmacy reimbursement to physician office reimbursement and found somewhat higher payments to physician offices for certain drugs. See **Figure 11**.

For all three drugs analyzed, we found significantly higher costs to plan sponsors in the HOPD setting relative to the pharmacy setting (72% higher for Ocrevus, 65% higher for Entyvio, and 69% higher for Prolia). The difference in cost to plan sponsors when these drugs were administered in an office setting was

less pronounced and varied by drug. Ocrevus and Prolia were 12% and 2% more expensive in the physician office setting than the pharmacy setting, respectively, whereas Entyvio was slightly less expensive in the physician office setting (0.2% less compared with the pharmacy setting).

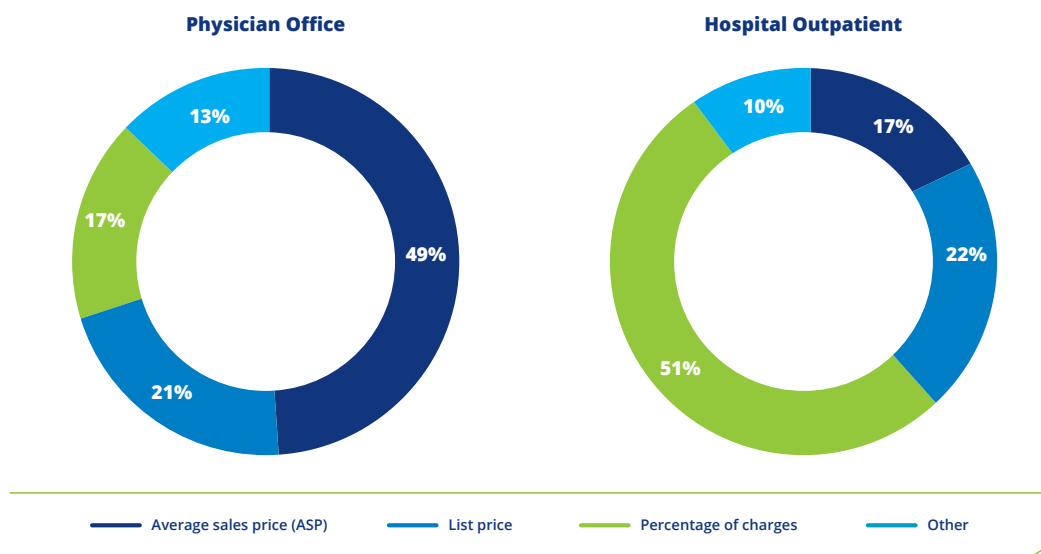
In response to such markups on provider administered drugs — particularly in the HOPD setting — payers have looked for strategies to control the specialty drug spending flowing through the medical benefit. The two primary strategies that have been utilized in recent years are (1) “bagging” policies and (2) “site of service” requirements.

### Bagging policies

There are various forms of bagging policies, including white bagging, brown bagging, and gold bagging (previously referred to as clear bagging). An explanation of each policy is described in **Figure 12**.

## Figure 10: Reimbursement Methods for Provider-Administered Drugs Paid Under the Commercial Medical Benefit, by Site of Care, 2017

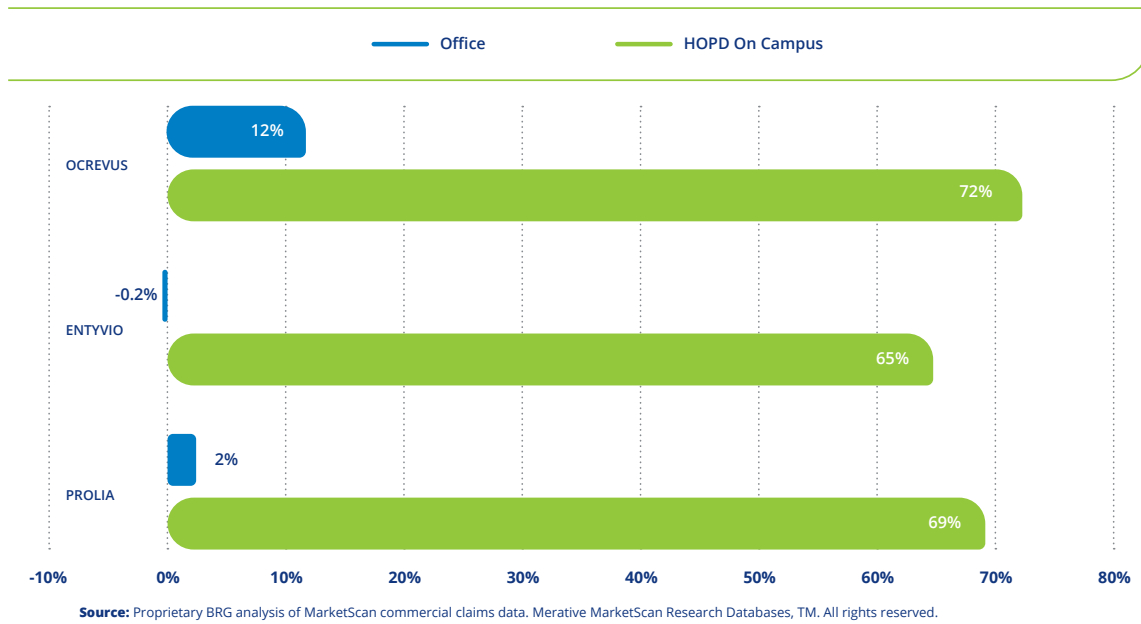
Hospital outpatient depts (HOPD) are more likely to be reimbursed under a higher-cost “percentage of charges” arrangement than other sites of care.



**Source:** Drug Channels Institute analysis of EMD Serono Specialty Digest, 14th edition, 2018. Other reimbursement models include capitated payments and a combination of methods. List price includes reimbursement based on Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC). Physician office figures show reimbursement method for oncologist offices.

Published on Drug Channels ([www.DrugChannels.net](http://www.DrugChannels.net)) on August 8, 2018.

**Figure 11: Average Markup for Drugs Administered in HOPDs and Physician Offices Relative to Pharmacies: Commercial Lives, 2022<sup>159</sup>**



**Figure 12. “Bagging” Policy Definitions<sup>160</sup>**

POLICY	DESCRIPTION
<b>White bagging</b>	Drug is delivered to the provider by a specialty pharmacy.
<b>Brown bagging</b>	Drug is delivered to the patient by a specialty pharmacy; patient then transports the medication to the provider for administration.
<b>Clear/gold bagging</b>	Drug is sourced from the hospital’s internal specialty pharmacy, which dispenses the drug and delivers it to the site of service. Clear bagging thus serves as a provider strategy to offer an alternative to white bagging and brown bagging, thereby retaining the revenue associated with specialty drug delivery

**Source:** National Association of Boards of Pharmacy, ICER

159 We limited the outpatient services data to drugs of interest using the procedure code field and further limited to claims where the units dispensed corresponded to the dosing schedule for each drug. For example, both Prolia and Xgeva are billed under J0897. We identified Prolia administrations as those billed under J0897 where the units dispensed were 60 (thus excluding claims for Xgeva where the units dispensed were 120). In the pharmacy claims data, we identified claims of interest based on the national drug code (NDC). We then normalized the allowed amount in each dataset to a cost per MG. Markup % for HOPD is calculated as (HOPD cost per mg – Pharmacy cost per mg)/pharmacy cost per mg. Markup % for Physician office is calculated as (Physician office cost per mg – Pharmacy cost per mg)/pharmacy cost per mg.

160 Pearson et al., “White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market,” p. 11-12; “White and Brown Bagging: Emerging Practices, Emerging Regulation,” The National Association of Boards of Pharmacy, April 2018 ([https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018\\_Final-1.pdf](https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf), accessed September 12th, 2024).

By sourcing the drug through a specialty pharmacy, “bagging” policies — particularly white and brown bagging — seek to capitalize on the negotiating leverage of PBMs and large specialty pharmacies, which can often obtain drugs at lower costs. Moving coverage of the drug to the pharmacy benefit also enables payers to implement traditional utilization management tools — such as tiered formularies, prior authorization, and step therapy — all of which are less common and more difficult to apply under the medical benefit.<sup>161</sup> Shifting utilization to the pharmacy benefit may also afford greater access to manufacturer rebates, which can further reduce drug costs.<sup>162</sup> In addition, white bagging encourages collaboration between managed care organizations and specialty pharmacies to promote integrated patient care.<sup>163</sup>

These policies have faced criticism by hospital groups and patients who claim that such policies hinder patient safety and create administrative burdens for providers. Critics of the policy cite shipping delays that may lead to treatment delays, potential drug waste, and the need for providers to accept delivery of and then properly store medications on a patient’s behalf until treatment. For example, a study by Avalere specifically examined drug waste that can occur as a result of hospitals having to discard product in cases where a patient’s treatment changes or there are dosing changes related to weight or treatment tolerance.<sup>164</sup> Avalere conducted a survey of non-hospital infusion providers ranging in size from smaller community practices to multi-site systems. Its survey respondents reported average waste associated with white bagging ranging from \$35,000 to \$652,000 per site per year, in what they describe as costs borne primarily by payers.<sup>165</sup>

While BRG’s analysis and numerous other studies demonstrate the cost savings that can be achieved by utilizing a specialty pharmacy for drug acquisition, it is still beneficial for PBMs and plans to monitor their bagging policies to ensure the needs of various stakeholders are met and to measure any unintended increases in costs. AMCP acknowledges these challenges, stating, “To fully capitalize on bagging procedures’ advantages, a harmonious balance between their advantages and difficulties is required.”<sup>166</sup>

The Indiana Department of Health, in a report on specialty drug management, offers certain best practice guidelines that plans and PBMs may consider as they implement their bagging policies.<sup>167</sup> These include:

- Plans can consider site-neutral reimbursement as an alternative to white/brown bagging.
- Plans should have a robust exception policy in place to allow patients to access medications through buy-and-bill when certain unforeseen circumstances arise, such as dose changes or weather-related emergencies.
- Plans should review the specialty drugs that are subject to bagging with their Pharmacy and Therapeutics Committees and obtain pharmacist input on the appropriateness of bagging for their selected therapies.
- Plans should monitor the specialty pharmacies that deliver white or brown bagged drugs to ensure they are performing adequately. Plans may monitor member or provider complaints, turnaround times and the number of expedited exceptions.
- Plans should provide frequent and thorough communication to patients about bagging policies.

161 Pearson et al., “White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market,” p. 3.

162 “White, Brown, Clear, and Gold Bagging,” AMCP, June 27th, 2024 (<https://www.amcp.org/resource/white-brown-clear-and-gold-bagging>, accessed September 12th, 2024).

163 “White, Brown, Clear, and Gold Bagging,” AMCP.

164 “Payer White-Bagging Requirements: Considerations for Access to Infusion Care,” Avalere, June 2024, p. 3 ([https://avalere.com/wp-content/uploads/2024/06/Payer-White-Bagging-Requirements\\_Considerations-for-Access-to-Infusion-Care.pdf](https://avalere.com/wp-content/uploads/2024/06/Payer-White-Bagging-Requirements_Considerations-for-Access-to-Infusion-Care.pdf), accessed September 12th, 2024).

165 “Payer White-Bagging Requirements: Considerations for Access to Infusion Care,” Avalere, June 2024, p. 1.

166 “White, Brown, Clear, and Gold Bagging,” AMCP.

167 “Specialty Drug Channel Management Report,” Indiana Department of Health, July 1, 2021, p. 6-8 ([https://iga.in.gov/publications/agency\\_report/isdh-report.pdf](https://iga.in.gov/publications/agency_report/isdh-report.pdf), accessed September 12th, 2024).

## Site of Service Policies

The second primary strategy payers have adopted involves requirements on the site of service where a patient receives their physician-administered medication. Such policies seek to transition patients from hospital outpatient settings toward lower-cost sites (e.g., provider's office, standalone infusion center, or at home).<sup>168</sup> Since markups for drugs processed under the medical benefit can vary significantly by site of service, these policies are intended to require patients to receive their drug administration in a setting with lower markups. For example, researchers examined 2019 claims data pertaining to numerous Blue Cross Blue Shield plans for 38 of the most commonly infused cancer drugs.<sup>169</sup> They found that the prices paid by Blue Cross Blue Shield plans when these drugs were administered in a hospital outpatient department setting were up to double (99%-104% higher) the cost of the same drugs administered in

physicians' offices. The researchers concluded that had these plans excluded HOPDs from their networks and instead required patients to receive their infusion in a physician office, they would have saved \$1.28 billion per year, or 26% of what they actually paid.<sup>170</sup> **Figure 13** describes each site of service.

BRG's analysis of the cost of Prolia, Entyvio, and Ocrevus demonstrates why these site of service policies can help health plans save significantly on drug spend.

The HOPD setting was 65% more expensive than the physician office setting for Prolia and Entyvio and 54% more expensive for Ocrevus.

As spending on prescription drugs increases, driven in large part by specialty therapies, managed care plans must implement strategies to contain these costs while balancing patient safety and access.

**Figure 13. Site of Service Categories and Definitions<sup>171</sup>**

SITE OF SERVICE	DESCRIPTION
<b>Physician office</b>	An independent clinic that is owned by a physician, equipped with capability to provide routine diagnostic and therapeutic services including administering infusion-based drugs
<b>Hospital-based outpatient department (HOPD)</b>	An HOPD is owned by and usually attached to a hospital. Services such as imaging and laboratory tests are provided at HOPD
<b>Infusion center</b>	An infusion center is an outpatient clinic where infusion therapy is administered. The cost of infusion therapy to a payer is typically less at an infusion center compared to physician office or HOPD
<b>Home infusion</b>	When a clinician provides an infusion at the home of a patient

Source: ICER

168 Pearson et al., "White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market," p. 4.

169 James C. Robinson, Christopher M. Whaley, Timothy T. Brown, "Price Differences To Insurers For Infused Cancer Drugs In Hospital Outpatient Departments And Physician Offices," Health Affairs, Volume 40, Issue 9, September 2021, p. 1396 (<https://doi.org/10.1377/hlthaff.2021.00211>, accessed September 12th, 2024).

170 Robinson et al., "Price Differences To Insurers For Infused Cancer Drugs In Hospital Outpatient Departments And Physician Offices," p. 1395.

171 Pearson et al., "White Bagging, Brown Bagging, and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market," p. 12.



## VIII. Comparative Spending on Prescription Drugs by Fee-for-Service (FFS) Medicaid Versus Managed Medicaid



To demonstrate the savings that can be generated by effective use of managed care pharmacy tools, we compared spending by FFS Medicaid versus Managed Medicaid for the Hep C class of drugs. Hepatitis C antiviral therapies first came to market in 2013 and were a game-changer in terms of their curative ability and their price tag. In 2013, Sovaldi, manufactured by Gilead, cost \$84,000 for a typical 12-week course of treatment.<sup>172</sup> The Hep C class of drugs would evolve in the decade following Sovaldi's launch, with lower-cost branded and then authorized generic options becoming available. The State Drug Utilization Data (SDUD) maintained by CMS provides an opportunity to compare average pre-rebate spending for Hep C therapies by FFS and Managed Medicaid plans from 2013 to 2022.

During that time, FFS Medicaid and Managed Medicaid paid pharmacies a total of \$7.3 billion and \$11.7 billion for Hep C drugs, respectively. However, given the significantly higher Managed Medicaid utilization, these

total spending figures are not comparable. Rather, we examine the average yearly per unit spending by the two programs<sup>173</sup> and find that between 2017 and 2021, Managed Medicaid achieved a markedly lower blended per unit reimbursement (i.e., weighted average across all drugs in the class) compared to FFS. This per-unit savings translates into \$1.42 billion in total pre-rebate savings achieved by Managed Medicaid from 2017 to 2021 and, stated in the inverse, \$780 million in unrealized pre-rebate savings by the FFS program. Our analysis relies on the SDUD data, which do not include information on rebates. Therefore, our findings reflect pre-rebate savings only. While rebates will offset a significant portion of gross spending, studies have shown that managed Medicaid plans still achieve lower net costs (i.e., post rebate costs) than FFS plans, as discussed later in this section.<sup>174</sup>

172 Richard Knox, "\$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices," NPR, Dec. 30, 2013 (<https://www.npr.org/sections/health-shots/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices>, accessed June 8, 2023).

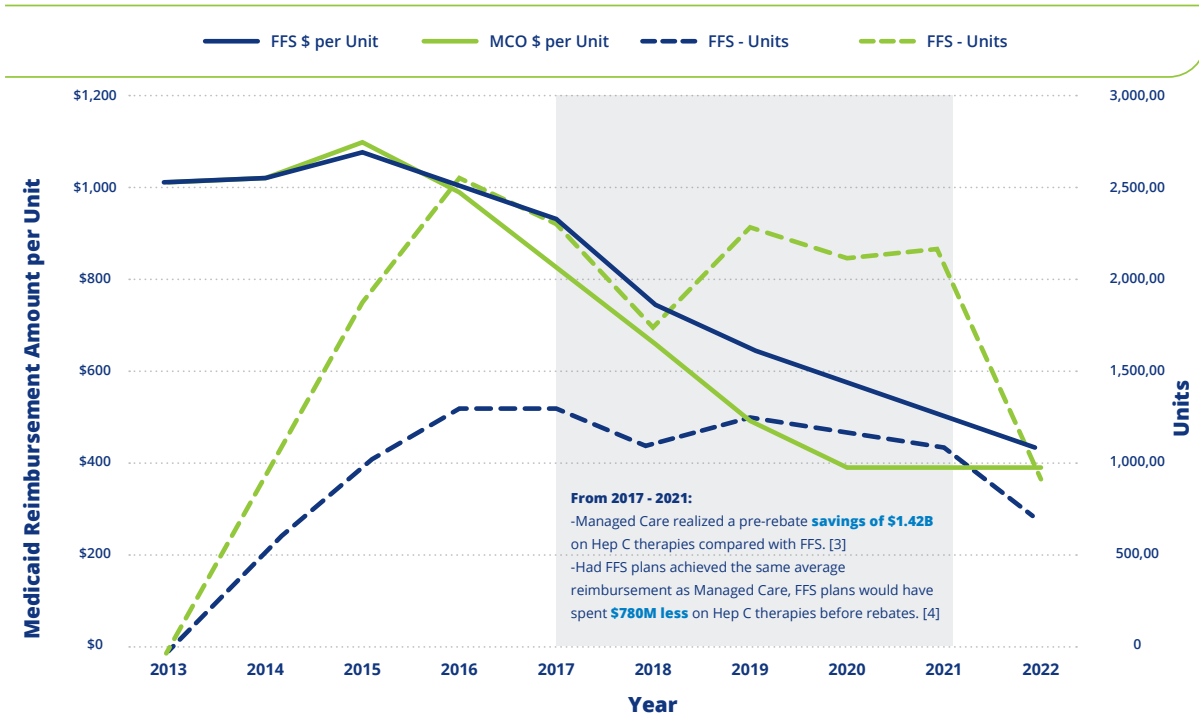
173 Per-unit rather than per-prescription spending is used because the typical dosing for Hep C therapies is one tablet per day. Therefore, per unit is the most directly comparable metric because it avoids the impact of differences in average units per prescription by each program on per-prescription spending. Mavyret's dosing is an exception where three tablets are taken daily and each tablet is represented as a single unit in SDUD. Mavyret is normalized in our analysis to the other Hep C therapies by dividing total units by three (i.e., one "unit" of Mavyret in our analysis is actually three tablets).

174 The SDUD data reflect rates reimbursed to pharmacies, and therefore, our analysis does not include statutory or supplemental rebates or additional rebates that managed care plans may negotiate directly with manufacturers. The potential impact of this limitation is discussed later in this section.

As can be seen in **Figure 14**, Medicaid reimbursement per unit for the Hep C class of drugs decreased substantially from 2015 to 2020 for FFS and Managed Medicaid.

However, the rate of that decline was more significant for Managed Medicaid in most years between 2016 and 2020.

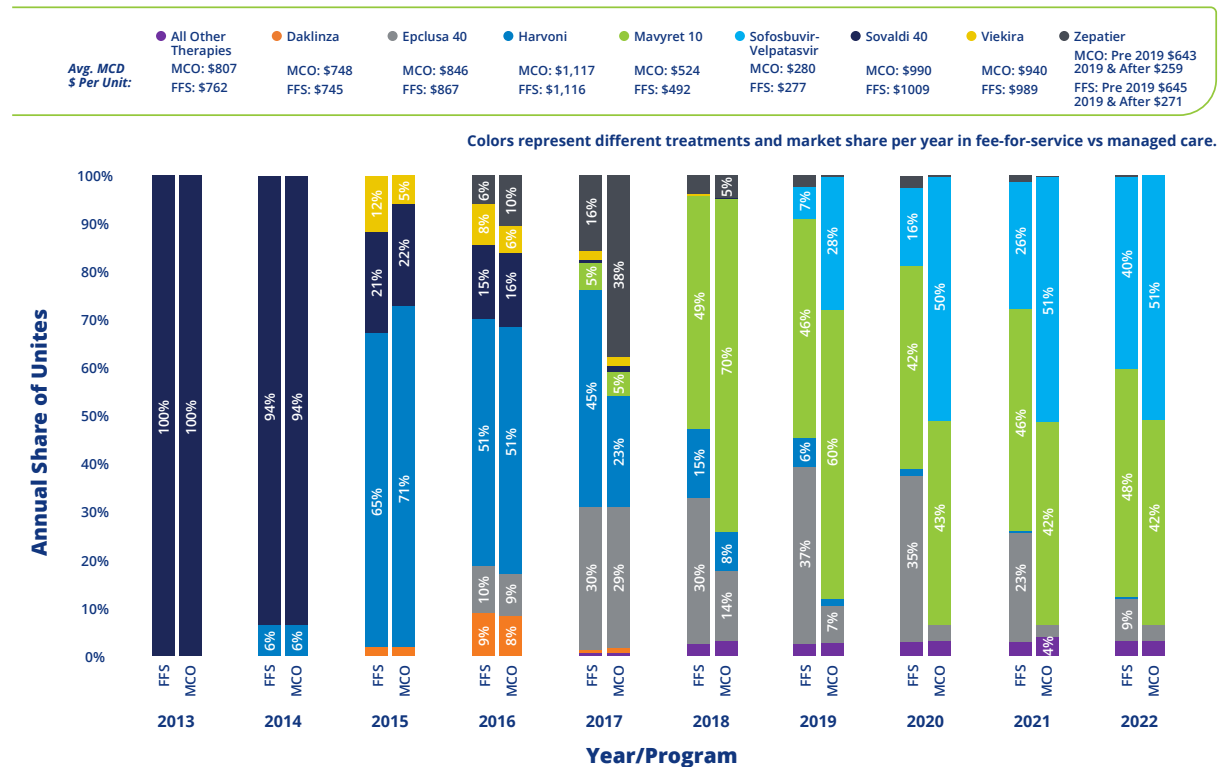
**Figure 14. Average Medicaid Reimbursement Amount per Unit, HCV Antivirals [1] [2]**



**Notes:**  
 [1] Sourced to State Drug Utilization Data available from CMS. 2022 is through Q3. Because Mavyret's dosing is for 3 tablets daily whereas other HCV therapies are one tablet or one package of tablets daily, Mavyret's units are divided by 3 to normalize to other therapies. MCO refers to managed care organization.  
 [2] HCV Antivirals identified as NDCs in the SDUD data that are associated with the Medispan AHFS Level 06 indicator "HCV Antivirals".  
 [3] Reflects the difference in average yearly reimbursement per unit between FFS and MCO, multiplied by the number of MCO units reimbursed.  
 [4] Reflects the difference in average yearly reimbursement per unit between FFS and MCO, multiplied by the number of FFS units reimbursed.

The decline in average reimbursement experienced by both programs was driven by the availability of lower-cost alternatives to Sovaldi and Harvoni, such as Zepatier, Mavyret, and sofosbuvir-velpatasvir (the authorized

generic of Epclusa). Changes in the share of the different Hep C therapies used by FFS versus Managed Medicaid, along with their average per unit reimbursement, can be seen in **Figure 15**.

**Figure 15: Market Share by Product, HCV Antivirals [1] [2] [3]****Notes:**

[1] Sourced to State Drug Utilization Data available from CMS. 2022 is through Q3. Market share calculated based on each product's share of total units reimbursed. Because Mavyret's dosing is for 3 tablets daily whereas other HCV therapies are one tablet or one package of tablets daily, Mavyret's units are divided by 3 to normalize to other therapies. MCO refers to managed care organization.

[2] "All Other Therapies" includes VOSEVI 400; Ledipasvir; HARVONI O; HARVONI, T; EPLUSA 20; MAVYRET OR; and Epclusa, O.

[3] HCV Antivirals identified as NDCs in the SDUD data that are associated with the MediSpan AHFS Level 06 indicator "HCV Antivirals".

As seen in **Figure 14**, Managed Medicaid's average reimbursement per unit for Hep C is similar to FFS from 2013 to 2016 and then becomes significantly lower starting in 2017 and lasting through 2021. The average rates begin to converge again in 2022. Managed Medicaid's lower rate from 2017 to 2021 is driven by a more successful shift in utilization to lower-cost alternatives:

- In 2017, 38% of Managed Medicaid utilization is on Zepatier (with an average Medicaid reimbursement amount of ~\$645 per unit in 2017) compared with only 16% of FFS (with much of the remaining FFS utilization on Harvoni, with an average reimbursement of ~\$1,100 per unit).
- In 2018, 70% of Managed Medicaid utilization is on Mavyret (\$600 per unit) compared with 49% of

FFS. The remaining FFS utilization is across Harvoni (~\$1,100 per unit) and across Epclusa at \$865 per unit).

- In 2019, not only does Managed Medicaid successfully shift more utilization to generic sofosbuvir-velpatasvir (28% of Managed Medicaid at \$277 per unit versus only 7% of FFS), its Mavyret share remains above that of FFS (60% versus 46%, respectively). Epclusa (more expensive), on the other hand, accounts for 37% of FFS versus only 7% of Managed Medicaid volume.
- In 2020, Managed Medicaid's sofosbuvir-velpatasvir share further increases to 50% of units with a corresponding decline in Mavyret. However, we observe a similar shift for FFS: more sofosbuvir-velpatasvir and less Mavyret. Because FFS Medicaid's Epclusa share remains relatively unchanged at 35%

in 2020 (whereas Managed Medicaid has 93% of its utilization on lower-priced sofosbuvir-velpatasvir and Mavyret), Managed Medicaid's average reimbursement per unit for this year remains below FFS.

- In 2021, the average rates converge a bit more, but Managed Medicaid is still below FFS largely due to persistent FFS utilization of Epclusa (at 23%).
- In 2022, the average reimbursement rates converge further. Managed Medicaid's product mix and average reimbursement is steady from 2020 to 2022, and FFS continues to drive more utilization to lower gross cost products. In 2022, there is a notable decline in Epclusa's share of FFS utilization (down to 9%).

Though the SDUD data do not reflect information on PDLs, patient cost share, step therapy, or prior authorization, it is reasonable to conclude the significant pre-rebate savings obtained by Managed Medicaid plans is due, in large part, to these plans' ability to use many of the tools discussed above in this report to more quickly and effectively steer patients to lower-priced, clinically appropriate options.

Though our analysis examines pre-rebate savings only,<sup>175</sup> our conclusion that managed care plans achieve cost savings is consistent with a Menges Group analysis

for AHIP, which does incorporate rebates and which found that Medicaid managed care plans' net costs per prescription were 27% lower than FFS Medicaid, yielding \$6.5 billion in savings in federal fiscal year 2018 alone.<sup>176</sup> Another study by the Menges Group found that "MCOs are achieving much more favorable initial (pre rebate) costs per prescription due to their management of the mix of drugs – particularly a much higher reliance on use of generic medications" and even though "larger rebates in the FFS setting close much of this initial gap," managed care plans are still achieving considerable net savings relative to FFS.<sup>177</sup> Just as BRG's analysis found with the Hep C class of drugs, the Menges Group also found a higher generic dispensing rate by Medicaid managed care across all therapeutic classes: 88% versus 84% for FFS in 2018.<sup>178</sup> IQVIA's analysis also supports Managed Medicaid's higher generic dispensing rate (92.5% versus 89.5% in 2020), which IQVIA also attributes, at least in part, to differences in "plan designs and incentives."<sup>179</sup> We acknowledge the possibility that under certain circumstances FFS plans could achieve lower net costs (i.e., post-rebate costs) than managed care plans for this class of drugs.<sup>180</sup> However, this possibility does not detract from our finding that managed care plans more successfully steered Hep C drug utilization to products with lower gross prices, including brands and generics.

175 Rebates are confidential to each manufacturer.

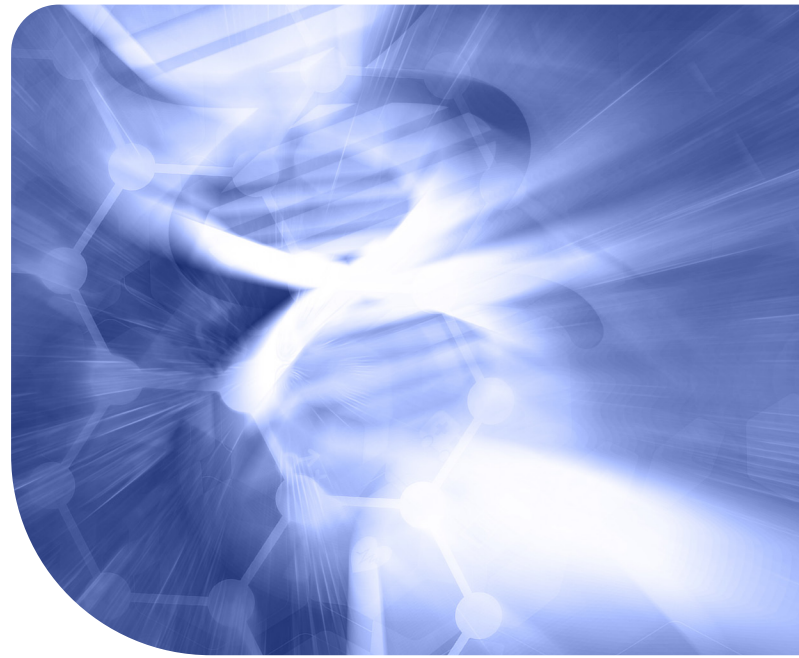
176 "The Value of Medicaid Managed Care: Making Prescription Drugs Affordable for States and Taxpayers," AHIP, February 2020, p. 2 ([https://ahiporg-production.s3.amazonaws.com/documents/AHIP-MMCResearch\\_RxDrugs.pdf](https://ahiporg-production.s3.amazonaws.com/documents/AHIP-MMCResearch_RxDrugs.pdf), accessed June 8, 2023). The federal fiscal year runs from October to September.

177 "Medicaid Prescription Drug Benefit Management: Performance Comparison Across Different State Policy Approaches," The Menges Group, March 2022, p. 2 ([https://themengesgroup.com/wp-content/uploads/2022/06/menges\\_group\\_rx\\_paper\\_march\\_2022.pdf](https://themengesgroup.com/wp-content/uploads/2022/06/menges_group_rx_paper_march_2022.pdf), accessed June 8, 2023).

178 "The Value of Medicaid Managed Care," AHIP, p. 5.

179 "The Use of Medicines in the U.S.," IQVIA Institute, p. 25.

180 This could arise if the Medicaid unit rebate amount (URA) or supplemental rebate amount (SRA) on a product that FFS utilizes more heavily than managed care is sufficiently high, meaning that it results in a lower net cost than a product that managed care more heavily utilizes (and which contributed to managed care's lower gross cost). Such a URA could occur if there is a low best price or a high additional rebate amount (i.e., inflation rebate). SRAs are not statutorily required but states may negotiate with manufacturers for supplemental rebates.



## IX. Conclusion

Managed care pharmacy tools play an important role in improving clinical outcomes, ensuring the appropriate use of medications, and containing rising costs. Through MTM and DUR, pharmacists can discover and help resolve medication-related issues or identify patients who would benefit from adding (or removing) certain medications from their drug regimens. Such interventions can help reduce adverse events or unnecessary hospitalizations, which are an undesired clinical outcome and a contributor to avoidable health care spending.

Prior authorization and step therapy seek to achieve evidence-based use of medications and to avoid unnecessarily costly medication when appropriate alternatives exist. Though opportunities exist to reduce the administrative burden of these protocols on clinical staff, these opportunities remain an important tool in containing rising drug spending. A well-designed formulary also plays a key role in providing patients with access to appropriate medications while encouraging

utilization of cost-effective products. Likewise, development of pharmacy networks that balance access to conveniently located pharmacies while allowing health plans to reduce spending on prescription drugs is an important component of managed care pharmacy's strategies to contain rising drug spending. Lastly, use of white/brown bagging and site of service policies can significantly reduce plan spending on specialty medications.

Prescription drug spending in the United States is forecasted to grow in the coming years. This growth will be driven by the emergence of innovative, potentially life-changing therapies, but many of those will come with a high cost. Managed care pharmacy's role is to ensure those costs are reasonably contained while ensuring patients can access critical therapies. Managed care pharmacy tools play a key role in achieving the balance between access and cost.





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Its diverse membership includes pharmacists, students, physicians, nurses, and industry experts charting the future of managed care.



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