

# Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers

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## I. Executive Summary

Pharmacy Benefit Managers (PBMs) now implement prescription drug benefits for some 266 million Americans who have health insurance from a variety of sponsors: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program, state government employee plans, managed Medicaid plans, and others. Working under contract to these plan sponsors, PBMs use advanced tools to manage drug benefit programs that give consumers more efficient and affordable access to medications. Visante was commissioned by the Pharmaceutical Care Management Association (PCMA) to estimate the savings that these PBM tools generate for plan sponsors and consumers.

#### **Major Findings:**

- How PBM Tools Produce Savings: PBM tools focus on seven primary areas to produce savings:
  - Negotiating rebates from drug manufacturers;
  - Negotiating discounts from drugstores;
  - o Offering more affordable pharmacy channels;
  - o Encouraging use of generics and affordable brands;
  - o Reducing waste and improving adherence; and
  - Managing high-cost specialty medications.
- Range of Savings from PBM Tools: Based on many factors, plan sponsors decide how extensively PBM tools will be used to manage drug benefits for their enrollees. Increasingly, government regulation could get in the way of using those tools. However, if plan sponsors can elect to have PBMs use best practices with the full range of tools, they can save more than 30% on drug benefit costs compared to sponsors that opt or are required to limit their use of PBM tools. Across marketplaces, the typical use of PBM tools (i.e., the midpoint) produces savings of almost 20% relative to plans with limited management.
- **PBM Savings:** From 2020 to 2029, the current use of PBM tools in the marketplace will save plan sponsors and consumers more than \$1 trillion.
  - o Commercial plan sponsors and their members will save more than \$512 billion;
  - o Medicare Part D and its beneficiaries, more than \$445 billion; and
  - o Managed Medicaid plans, more than \$46 billion.
- **Growth in PBM Savings:** Our estimates for 10-year PBM savings have grown since our previous study in 2016 for three primary reasons:
  - o PBM savings for traditional drugs (i.e., non-specialty) are greater with greater opportunities to substitute lower cost generics for higher cost brand-name drugs. The generic dispensing rate (GDR) grew from 82% in 2014 to 86% in 2018.
  - Specialty drug expenditures are growing rapidly. Our estimates for the 10-year specialty drug expenditures under PBM management have grown from \$1.7 trillion in 2016 to almost \$2.6 trillion in 2020.
  - Rebates have increased dramatically in the past five years. In 2016 we estimated rebates of approximately 15% for brand-name drugs, while in 2020 we estimate rebates of 30%, double the 2016 estimates.

#### II. Discussion

## **PBM Tools Focus on Seven Key Savings Categories**

Since 1980, the share of the health care dollar spent on pharmaceuticals has nearly doubled, from roughly 5% to 10%. New medications and broader insurance coverage have increased outpatient prescription drug expenditures—now totaling more than \$360 billion annually in 2019<sup>2</sup>—and have increased the need for pharmacy benefits management. PBMs have a difficult mission: to maintain prescription drug access while also reducing cost growth.

PBM tools focus on seven primary categories that reduce costs:

- 1. **Negotiating Rebates from Drug Manufacturers:** PBMs negotiate rebates from manufacturers of brand-name drugs that compete with therapeutically similar brands and generics. Manufacturers typically provide a rebate if their product is "preferred," which means it is assigned a copay lower than that of competing products. While this tool has been the subject of some concern among policymakers, a recent report from Altarum concluded that "manufacturer rebates benefit both health plans and consumers" and the "notion that PBMs have diverted a large share of rebates to excess profits is not supported."
- 2. **Negotiating Discounts from Drugstores:** Retail pharmacies provide discounts to be included in a plan's pharmacy network. The more selective the network, the greater the discount, because each pharmacy will gain more business.
- 3. **Offering More Affordable Pharmacy Channels:** Mail-service and specialty pharmacy channels typically give plan sponsors deeper discounts than do retail pharmacies. These channels also help encourage the use of preferred products for additional savings.
- 4. Encouraging Use of Generics and Affordable Brands: PBMs use several tools to encourage the use of generic drugs and preferred brands. These include formularies and tiered cost sharing, prior authorization and step-therapy protocols, generic incentives, consumer education, and physician outreach. As PBMs and plan sponsors strive for greater savings, drug mix becomes even more important.
- 5. **Reducing Waste and Polypharmacy:** PBMs use Drug Utilization Review and other utilization management programs to reduce over-utilization and waste, as well as reducing adverse drug events associated with polypharmacy.
- 6. **Improving Adherence:** PBMs implement medication adherence programs and care management programs to help patients with chronic disease stick to their prescription regimens. These programs improve clinical outcomes and often increase prescription volume and expenditures.
- 7. **Managing High-Cost Specialty Medications:** PBMs combine savings from all the above categories with the unique capabilities of specialty pharmacies in safely storing, handling, and delivering complex, often injectable, medications that cost thousands per dose and in providing effective patient education, monitoring, and support for patients with complex conditions, such as hepatitis C, multiple sclerosis, and cancer.

## Plan-Sponsor Decisions Determine PBM Savings But Within Regulatory Constraints

More than 266 million Americans now have prescription benefits within three primary health insurance markets served by PBMs: private/commercial insurance, Medicare Part D, and Managed Medicaid. Another 21 million covered lives are under state FFS Medicaid programs, where use of PBM tools is limited. More than 28 million

<sup>1</sup> Centers for Medicare & Medicaid Services, National Health Expenditure Data.

<sup>2</sup> Ibid

<sup>3</sup> Charles Roehrig, "The Impact of Prescription Drug Rebates on Health Plans and Consumers," April 2018

Americans are without insurance.<sup>4</sup> The Agency for Healthcare Research and Quality (AHRQ) has found that the uninsured, who have no PBM protection, pay the highest retail out-of-pocket costs across markets.<sup>5</sup>

PBMs and their clients guide how actively pharmacy benefits are managed within the context of applicable regulations. They determine formulary coverage, copay tiers, utilization management, and pharmacy channel options. In making these choices, many factors, including clinical quality, cost, and sponsor/member satisfaction are taken into consideration. This leads to many variations in the PBM tools utilized. For example, research from the Pharmacy Benefit Management Institute shows that while the vast majority of plans use tiered formularies and utilization management tools (e.g., prior authorization and step therapy), some commercial plans have chosen not to use certain PBMs tools yet, including mandatory generic programs (38% not using), and preferred pharmacy (47% not using) or limited pharmacy networks (77% not using).

Plan sponsors typically wish to balance controlling costs against minimizing change for their members, all while ensuring access to needed care. As sophisticated purchasers, most plan sponsors use a competitive bidding process to specify their requirements and contract with the PBM that can best meet their needs. Independent panels of experts known as Pharmacy and Therapeutics Committees ensure that the use of PBM tools is clinically appropriate. If plans can achieve best practice level use of PBM tools, they can potentially realize as much as 30% more savings compared to plans with limited use of PBM tools. However, over 200 bills have been introduced by Congress and the states in the past year that would regulate PBMs and potentially limit the use of these tools. 8

Figure 1: How Plan Decisions Determine PBM Savings



#### **Limited Use of PBM Tools:**

- Open formulary
- Few copay tiers
- ► Little utilization management
- Minimal use of mail-service pharmacy
- "Any willing pharmacy" network
- Little use of specialty pharmacies

Best Practice Use of PBM Tools:

- More selective formulary
- Four or more tiers
- Prior authorization and step therapy utilization management
- Strong incentives to use mail service
- ► High performance pharmacy networks
- Use of specialty pharmacies

Note: Savings relative to unmanaged expenditures. Source: Visante, 2020.

<sup>4</sup> Census Bureau, "Most Uninsured Were Working-Age Adults," September 12, 2018

<sup>5</sup> G. Edward Miller, PhD, Steven C. Hill, PhD, and Yao Ding, PhD, Retail Drug Prices, Out-of-Pocket Costs, and Discounts and Markups Relative to List Prices: Trends and Differences by Drug Type and Insurance Status, 2011 to 2016, Agency for Healthcare Research and Quality, October 2019; The estimate of those covered with PBMs is conservative. In addition to the uninsured there are several government programs where PBMs are generally not utilized, including Medicaid FFS, VA Health, and the Indian Health Service.

<sup>6</sup> Pharmacy Benefit Management Institute (PBMI), "2018 Trends in Drug Benefit Design,"

<sup>7</sup> Note, regulations can often place certain limitations of the use of PBM tools, especially in government programs. For example, Medicare Part D has an "any willing pharmacy" rule for pharmacy networks.

<sup>8 &</sup>quot;PBM" search of Congress.gov and the Statewide Prescription Drug Database of the National Conference of State Legislatures for legislation introduced in 2019

#### **PBM Savings from Current Use of PBM Tools**

From 2020 to 2029, the current use of PBM tools in the marketplace will save plan sponsors and consumers more than \$1 trillion.

- o Commercial plan sponsors and their members will save more than \$512 billion;
- o Medicare Part D and its beneficiaries, more than \$445 billion; and
- o Managed Medicaid plans, more than \$46 billion.

A state-by-state breakdown of PBM savings from current use of PBM tools is provided in Figure 2.

## **Potential Additional Savings with Greater Use of PBM Tools**

If all plan sponsors adopted best practice use of PBM tools, then savings could double, saving an additional \$1 trillion over the next decade.

**Despite strong PBM results in Medicare Part D, there are many restrictions on PBM tools in government programs**. In Medicare Part D, plans extensively use PBMs, but with various regulatory restrictions placed by Centers for Medicare & Medicaid Services (CMS). For example, almost all plans use preferred pharmacy networks, but CMS requires plans to accept "any willing pharmacy" in the basic overall network. Moreover, Part D PBMs can leverage closed formularies for most drug classes, but there are six protected classes that HHS and CMS have acknowledged have limited PBM effectiveness. Specifically, HHS Secretary Alex Azar and CMS Administrator Seema Verma stated, "the lack of any ability for Part D plans to manage drugs in the

#### PBMs Drive Lowest Net Cost in Medicare Part D

PBM tools have generated significant savings for the Medicare prescription drug program. Even greater savings are expected in the future:

- Continued use of PBM tools at their current levels is expected to save Part D \$445 billion, compared to limited management over the next 10 years. Therefore, if the use of PBM tools is restricted in Part D, then costs for the program and its beneficiaries could increase by \$445 billion.
- If all Part D plans were able to adopt high use of PBM tools, then the program and beneficiaries could double the savings, saving an additional \$445 billion over 10 years.
- Both the GAO and the HHS, OIG have recently found that PBM negotiated rebates substantially reduced the growth in spending in Medicare Part D.

protected classes has allowed the pharmaceutical industry to command high prices on protected class drugs in Part D, without patients getting a good deal...Typical private market discounts for these drugs are in the 20 to 30 percent range, but the average discount across all protected classes in Part D is just 6 percent."<sup>10</sup>

Even with these restrictions, the use of PBM tools in Medicare Part D has yielded impressive results. For example, one study found that PBM negotiations resulted in significant cost reductions, such that most therapy classes were between 13 and 62% below list prices after accounting for negotiated discounts and rebates. Moreover, the Government Accountability Office (GAO) recently found that PBMs negotiated rebates and other price concessions grew faster than total Part D expenditures from 2014 through 2016. "During this period, rebates and other price concessions increased 66 percent, to \$29 billion—20 percent of 2016 gross expenditures. Consequently, net expenditures (gross expenditures less rebates and other price concessions) increased only 13 percent, to

<sup>9</sup> Drug Channels Institute, "Preferred Pharmacy Networks Rebound in 2020 Medicare Part D Plans: Details on WellCare, CVS Health, Humana, Cigna, and More," October 22, 2019

<sup>10</sup> HHS Secretary Alex Azar and CMS Administrator Seema Verma, "Proposed Changes to Lower Drug Prices in Medicare Advantage and Part D," Nov 26, 2018

<sup>11</sup> QuintilesIMS Institute (now IQVIA), "Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates," October 2016

\$116.1 billion." Similarly, a recent report from the Department of Health and Human Services, Office of the Inspector General (HHS,OIG) found that "increases in rebates substantially reduced the percentage increase in reimbursement for brand-name drugs in Part D from 2011 to 2015. The GAO study also found that PBMs primarily earned revenue through fees paid by plan sponsors, not through rebate retention and that the research literature reviewed shows that PBM utilization management programs drive further savings for Medicare. Health and Human Services, Office of the Inspector General (HHS,OIG) found that "increases in rebates substantially reduced the percentage increase in reimbursement for brand-name drugs in Part D from 2011 to 2015. The GAO study also found that PBMs primarily earned revenue through fees paid by plan sponsors, not through rebate retention and that the research literature reviewed shows that PBM utilization management programs drive further savings for Medicare.

The use of PBM tools is much more limited in non-managed care government programs like Medicaid fee-for-service (FFS). This is particularly the case in three areas: (1) little to no use of competitive pharmacy networks to negotiate market-based dispensing fees and discounts; (2) limited use of differential copays to encourage the use of generics and more affordable brands plus copays are statutorily capped at \$4 for preferred drugs; and (3) almost no use of a closed formulary, under which only specific drugs in each therapeutic class are covered. However, states have come to rely on PBMs for technical and clinical expertise in the development of Medicaid preferred drug lists (PDLs), that are in turn leveraged to negotiate supplemental rebates beyond the rebates required by law. 16

Across all sectors, most plan sponsors typically do not place significant limits on PBM tools allowed under applicable regulations. Looking forward, then, the main factor that could limit the use of PBM tools is restrictive government regulations. If enacted, state and federal proposals that mandate coverage of brand-name drugs, increase pharmacy reimbursement levels, limit the use of mail-service pharmacies, and force the disclosure of proprietary contract information could all serve to increase costs.

#### Potential Costs if the Use of PBM Tools Is Restricted

Restricting the use of PBM tools could increase projected prescription drug costs by more than \$1 trillion over the next decade. Drug costs could rise by:

- o \$512 billion in the commercial sector;
- o \$445 billion in Medicare Part D;
- o \$46 billion in Managed Medicaid; and
- o Because the use of PBM tools is generally low and often restricted in Medicaid FFS, no PBM cost savings for Medicaid FFS programs have been estimated.

<sup>12</sup> GAO, "Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization," July 2019.

<sup>13</sup> HHS OIG, "Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015," September 2019, OEI-03-19 00010

<sup>14</sup> IBID

<sup>15</sup> Kaiser Family Foundation, "Management and Delivery of the Medicaid Pharmacy Benefit," December 2019

<sup>16</sup> Kaiser Family Foundation and Avalere, The Role of Clinical and Cost Information in Medicaid Pharmacy Benefit Decisions, September 2011

Figure 2: 10-Year PBM Savings by State, 2020-2029 (millions \$))  $^{17-18*}$ 

	Commercial/ Private Insurance	Medicare Part D	Managed Medicaid	Total
US Total	\$512,068	\$445,046	\$46,246	\$1,003,360
Alabama	\$7,819	\$7,286	*	\$15,106
Alaska	\$929	\$606	*	\$1,535
Arizona	\$10,342	\$9,369	\$1,756	\$21,467
Arkansas	\$4,268	\$4,365	*	\$8,633
California	\$57,659	\$47,170	\$5,728	\$110,557
Colorado	\$8,768	\$6,832	\$50	\$15,649
Connecticut	\$5,738	\$5,339	*	\$11,077
Delaware	\$1,397	\$1,528	\$256	\$3,181
District of Columbia	\$1,109	\$539	\$72	\$1,719
Florida	\$31,364	\$33,586	\$3,200	\$68,150
Georgia	\$17,149	\$12,137	\$684	\$29,970
Hawaii	\$2,162	\$1,839	\$348	\$4,349
Idaho	\$2,984	\$2,294	*	\$5,278
Illinois	\$21,126	\$16,042	\$2,153	\$39,321
Indiana	\$10,550	\$9,622	\$1,152	\$21,324
Iowa	\$5,109	\$4,838	\$689	\$10,636
Kansas	\$5,162	\$3,715	\$371	\$9,249
Kentucky	\$6,520	\$7,165	\$1,156	\$14,842
Louisiana	\$6,249	\$6,304	\$1,405	\$13,957
Maine	\$2,253	\$2,395	*	\$4,647
Maryland	\$10,447	\$6,173	\$706	\$17,326
Massachusetts	\$12,022	\$9,832	\$920	\$22,774
Michigan	\$15,276	\$18,393	\$1,038	\$34,707
Minnesota	\$9,968	\$8,040	\$829	\$18,837
Mississippi	\$4,645	\$4,140	\$417	\$9,203
Missouri	\$10,759	\$9,204	*	\$19,963
Montana	\$1,424	\$1,496	*	\$2,920
Nebraska	\$3,446	\$2,425	\$172	\$6,043
Nevada	\$4,349	\$3,527	\$352	\$8,229
New Hampshire	\$2,484	\$2,031	\$130	\$4,645
New Jersey	\$14,967	\$12,937	\$1,757	\$29,661
New Mexico	\$2,393	\$2,903	\$766	\$6,061
New York	\$27,141	\$27,719	\$6,049	\$60,909
North Carolina	\$16,858	\$14,351	\$0,04 <i>9</i> *	\$31,209
North Dakota	\$1,382	\$1,034	\$36	\$2,452
Ohio	\$18,090	\$19,110	\$2,456	\$39,656
Oklahoma	\$5,864	\$4,820	\$2,430 *	
	\$6,424	\$6,222		\$10,684 \$13,483
Oregon			\$836	\$13,483 \$44,658
Pennsylvania Rhode Island	\$20,447	\$21,323	\$2,887	\$44,658
	\$1,562	\$1,627	\$318	\$3,506
South Carolina	\$7,793	\$7,525	\$703 *	\$16,020
South Dakota	\$1,531	\$1,346		\$2,877
Tennessee	\$10,467	\$9,829	\$76	\$20,373
Texas	\$45,401	\$31,142	\$3,815	\$80,358
Utah	\$6,315	\$2,707	\$138	\$9,159
Vermont	\$971	\$1,044	*	\$2,015
Virginia	\$14,775	\$9,513	\$1,057	\$25,346
Washington	\$12,607	\$8,809	\$1,440	\$22,855
West Virginia	\$2,422	\$3,162	\$329	\$5,913
Wisconsin	\$10,127	\$9,012	*	\$19,139
Wyoming	\$1,054	\$677	*	\$1,732

<sup>17</sup> For Commercial and Medicare Part D, compares current use of PBM tools relative to plans and programs with limited/restricted use.

18 For Managed Medicaid, compares current use of PBM tools in Managed Medicaid vs limited use in FFS Medicaid. Savings not estimated for states with no reported Medicaid managed care (MACPAC 2018).

#### **How PBMs Generate Savings on Specialty Medications**

Specialty medications account for less than 1% of prescriptions but almost 50% of gross costs<sup>19</sup> and almost 40% of net drug expenditures.<sup>20</sup> To manage the cost of specialty medications, PBMs use a wide range of tools, including negotiating price concessions from manufacturers and implementing clinically based formularies, tiered copays, prior authorization, and step-therapy protocols. Most importantly, PBMs encourage the use of specialty pharmacies.

Specialty pharmacies have unique capabilities that allow them to safely store, handle, and deliver complex, often injectable, medications that can cost thousands of dollars per dose. Likewise, specialty pharmacies also have expertise in providing education, monitoring, and support for patients with complex conditions, such as hepatitis C, multiple sclerosis, and cancer.

Over the next 10 years, PBMs and specialty pharmacies will save Medicare, Medicaid, commercial payers, and consumers an estimated total of \$545 billion on the cost of specialty medications and related non-drug medical costs, when compared to what expenditures would be with limited use of PBMs and specialty pharmacies. Of the \$545 billion in specialty savings, commercial plan sponsors and their members will save \$255 billion; Medicare Part D and its beneficiaries, \$251 billion; and Managed Medicaid, \$39 billion. See Appendix for more information on specialty pharmacy.

## **Growth in PBM Savings**

Estimates for 10-year PBM savings have grown since our previous study in 2016 for three primary reasons:

- PBM savings for traditional drugs (i.e., non-specialty) are greater with greater opportunities to substitute lower cost generics for higher cost brand-name drugs. The generic dispensing rate (GDR) grew from 82% in 2014 to 86% in 2018.<sup>21</sup>
- Specialty drug expenditures are growing rapidly. Our estimates for the 10-year specialty drug expenditures under PBM management have grown from \$1.7 trillion in 2016 to almost \$2.6 trillion in 2020.
- Rebates have increased dramatically in the past five years. In 2016 we estimated rebates of approximately 15% for brand-name drugs, while in 2020 we estimate rebates of 30%, double the 2016 estimates.

#### III. Conclusion

PBM tools provide substantial savings to plan sponsors and consumers. Plan sponsors balance controlling costs against minimizing change for their members, all while ensuring access to needed care. Savings can range from 20% to 30%, from limited use to high/incentivized use of PBM tools consistent with best practices. At current/average use, PBM tools will save \$1 trillion compared to low or limited use over the next decade. In addition to these expected savings, an additional \$1 trillion could be saved if all plan sponsors adopted high use of PBM tools best practices. Likewise, \$1 trillion could be lost if PBM tools are limited by government policies or other factors.

<sup>19</sup> IQVIA Institute, "Medicines use and spending in the U.S. a review of 2018 and outlook to 2023." May 2019.

<sup>20</sup> Pembroke Consulting, "2019 economic report on pharmacies and pharmacy benefit managers." March 2019.

<sup>21</sup> A recent report from the HHS Office of the Assistant Secretary for Planning and Evaluation found that despite high generic dispensing in Medicare Part D there are still at least close to \$3b in annual generic substitution opportunities available. ASPE, "Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D," July 23, 2018.

## IV. Methodology

Visante's model for projected PBM savings draws on data from CMS, Government Accountability Office (GAO), Federal Trade Commission (FTC), Congressional Budget Office (CBO), PBM financial filings with the Securities and Exchange Commission, PBM drug trend reports, structured interviews with PBM industry experts, peer-reviewed studies, and commercial third-party drug claims data.

#### **Deriving Baseline Drug Expenditures Managed by PBMs**

To derive baseline drug expenditures managed using PBM tools, Visante began with CMS National Health Expenditure (NHE) projections for outpatient prescription drug expenditures from 2018 to 2027. These expenditures do not include drugs administered in hospitals or physician offices. Visante extrapolated these projections to 2028 and 2029. By these estimates, spending on outpatient prescription drugs will grow from \$379 billion in 2020 to \$642 billion in 2029, for a total of \$5 trillion over the 10-year period. The projections reflect CMS assumptions concerning the impact of health reform, manufacturer price inflation, patent expirations, new drug introductions, follow-on biologics, and other factors. Our model incorporates these assumptions to the extent that they are incorporated into the NHE projections.

CMS segments outpatient prescription drug expenditures by payer, including private insurance, Medicare, Medicaid, and other government programs. Visante assumes that nearly all private-insurer expenditures and nearly all Medicare Part D expenditures are associated with the use of PBM tools. Medicaid is slightly more complicated. Prescription drugs for Medicare/Medicaid dual eligibles are paid under Medicare, but other Medicaid drug expenditures are split between Managed Medicaid and FFS Medicaid. 23,24,25 Prescription expenditures in the Veterans Administration, Indian Health Service, and Department of Defense (DOD)/TriCare direct services also were excluded. Children's Health Insurance Program (CHIP) expenditures were included with Medicaid, and DoD/TriCare "purchased services" expenditures on prescriptions outside military treatment facilities were included under private/commercial. 27

Visante next estimated the share of consumer out-of-pocket expenditures arising from copays for prescriptions associated with PBMs and PBM tools. We projected the average cost sharing per prescription based on survey data for plan sponsors. <sup>28,29</sup> We then multiplied average cost sharing by the estimated number of prescriptions each year under both private/commercial insurance and Medicare Part D.

Visante estimated the prescriptions associated with PBM tools based on data published by a variety of sources. In 2018, 3.8 billion prescriptions<sup>30</sup> were filled at chain pharmacies, independent pharmacies, food stores, pharmacies servicing nursing homes, mail-service pharmacies, and specialty pharmacies.<sup>31</sup>

After these calculations, we estimate that 2020 outpatient prescription drug expenditures associated with some use of PBM tools, including plan sponsor and consumer payments, will be approximately \$184 billion for the commercial market, \$142 billion for Medicare Part D, \$25 billion for Managed Medicaid, and \$14 billion for FFS Medicaid. Over the 2020-2029 period, these figures are \$2.3 trillion for the commercial sector, \$2 trillion for Medicare Part D, \$322 billion for Managed Medicaid, and \$186 billion for FFS Medicaid. Note that more PBMs are playing a management role in physician-administered drugs covered by medical benefits (including Medicare Part B) and that our baseline expenditures or savings estimates do not reflect such activity.

<sup>&</sup>lt;sup>22</sup> CMS. National Health Expenditure Data (2020 to 2027 projections extrapolated to 2028-29),

<sup>&</sup>lt;sup>23</sup> Kaiser Family Foundation, "Dual Eligibles as a Percent of Total Medicare Beneficiaries".

<sup>&</sup>lt;sup>24</sup> CMS, State Medicaid Enrollment, March 2019.

<sup>&</sup>lt;sup>25</sup> CMS, MACStats: Medicaid and CHIP Data Book, December 2018.

<sup>&</sup>lt;sup>26</sup> Centers for Medicare & Medicaid Services, "Net Reported Medicaid and CHIP Expenditures."

<sup>27</sup> TriCare drug spend under "purchased services" is estimated at \$3.1 billion for 2014, according to "The Evaluation of the TRICARE Program: Access, Cost, and Quality, Fiscal Year 2015 Report to Congress," Defense Health Agency, Department of Defense, February 2015.

<sup>&</sup>lt;sup>28</sup> Kaiser Family Foundation and Health Research & Educational Trust, "Employer Health Benefits Survey, 2018 Annual Survey."

<sup>&</sup>lt;sup>29</sup> Pharmacy Benefit Management Institute, "2018 Trends in Drug Benefit Design."

<sup>&</sup>lt;sup>30</sup> In other words, prescriptions for a 90-day supply have been adjusted to estimate three 30-day prescriptions.

<sup>&</sup>lt;sup>31</sup> IQVIA Institute. Medicines use and spending in the U.S. a review of 2018 and outlook to 2023. May 2019.

As discussed, CMS's 10-year projections reflect many assumptions regarding marketplace trends. We believe that CMS estimates reasonably capture these trends and reflect the current savings that PBMs achieve in the marketplace. For example, CMS estimates that drug manufacturer rebates to PBMs have increased sharply in the past few years and were expected to have dampened prescription drug spending growth in 2018.<sup>32</sup> However, CMS does not publish the detailed factors underlying its model, so we estimated the factor inputs necessary to model PBM savings and then applied them to baseline expenditures derived from CMS data.

We assume that over the 10-year projection period:

- Expenditures for traditional prescription drugs will show low growth or no growth during the next 10 years, while specialty drug spending will continue to grow more rapidly.<sup>33</sup> The generic dispensing rate was 85.6% (i.e., % unbranded generic prescriptions) in 2018<sup>34</sup> and will grow slowly.<sup>35</sup> We assume that these trends are captured in the CMS projections.
- Specialty medications will be the dominant force driving growth in prescription drug expenditures over the next 10 years. One report estimates that specialty accounts for almost 50% of gross drug spend, total specialty drug revenues increasing from 35% of total in 2018 to 44% in 2023. Most observers project that the specialty pharmacy market will grow much more rapidly than will the market for traditional prescription drugs. We estimate the total specialty share of drug expenditures under the pharmacy benefit growing from 41% in 2020 to 61% in 2029. These estimates do not include specialty drug expenditures covered under the medical benefit and administered in hospitals, clinics, and physician offices, which are not included in CMS projected outpatient drug expenditures and not included in our analysis.
- While more PBMs are playing a management role in physician-administered specialty injectable drugs covered by medical benefits, our projected drug expenditures and PBM savings estimates do not reflect such activity.

We created a state-by-state breakdown for the national projected drug expenditures for various forms of prescription drug coverage (e.g., Commercial, Medicare, Medicaid). Projected national outpatient drug expenditures were then calculated for each state based on Visante's state-by-state enrollment estimates, including state-by-state enrollment estimates for commercial fully insured, commercial self-insured, Medicare, Medicaid managed care and FFS Medicaid based on a number of published references. 38,39,40,41,42,43,44,45

Our methodology results in state-by-state estimates that capture many—but not all—of the factors that may characterize the prescription drug market in individual states. Any unusual circumstances that would not be captured by enrollment patterns would not be reflected in our estimates. Finally, some states may have already enacted laws related to the legislative areas included in our economic model. To the extent that such laws have already raised costs, those costs would be included in the estimates presented in the report.

<sup>32</sup> Cuckler, et al., "National health expenditure projections, 2017–26: despite uncertainty, fundamentals primarily drive spending growth," Health Aff (Millwood). 2018;37(3).

<sup>&</sup>lt;sup>33</sup> Drug Trend Reports from CVS Health, Express Scripts, and Prime Therapeutics.

<sup>&</sup>lt;sup>34</sup> IQVIA Institute. Medicines use and spending in the U.S. a review of 2018 and outlook to 2023. May 2019.

<sup>35</sup> IQVIA and PBM Drug Trend Reports.

<sup>&</sup>lt;sup>36</sup> Pembroke Consulting, "2019 economic report on pharmacies and pharmacy benefit managers," Mar. 2019.

<sup>&</sup>lt;sup>37</sup> Drug Trend Reports from CVS Health, Express Scripts, and Prime Therapeutics.

<sup>&</sup>lt;sup>38</sup> US Census, 2018.

<sup>&</sup>lt;sup>39</sup> US Census - Health Insurance in the United States: 2018- Number and Percentage of People Without Health Insurance Coverage by State: 2017 to 2018

<sup>40</sup> Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and state, AHRQ Medical Expenditure Panel Survey, 2018.

<sup>&</sup>lt;sup>41</sup> More than 99% of covered workers in employer-sponsored plans have a prescription drug benefit. "2019 employer health benefits survey," Kaiser Family Foundation, Sept. 2019.

<sup>&</sup>lt;sup>42</sup> Marketplace Enrollment, 2019, Kaiser Family Foundation.

<sup>&</sup>lt;sup>43</sup> Medicare Enrollment: CMS Medicare Advantage (MA) / Part D Contract and Enrollment Data, Monthly Enrollment by Contract/Plan/State/County November 2019.

<sup>&</sup>lt;sup>44</sup> Medicaid Enrollment Nov 2019: Monthly Medicaid and CHIP Application, Eligibility Determination, and Enrollment Reports, from Medicaid.gov.

<sup>&</sup>lt;sup>45</sup> MACStats: Medicaid and CHIP Data Book, Medicaid and CHIP Payment and Access Commission, December 2018.

#### **Developing a Model of PBM Savings**

Using the 10-year projections described above, we developed an economic model to estimate PBM savings relative to drug expenditures that might be seen in a completely unmanaged environment, such as an uninsured population. We did this by adjusting key variables to reflect potential changes in the level of PBM management. These models let us estimate the <u>average use</u> savings that PBMs generate—as well as estimate both <u>limited use</u> and <u>best practice</u> savings estimates, depending on the approach of different plan sponsors. For our savings model, we assume that the NHE projections reflect the "average" level of PBM savings for commercial plans and Medicare Part D. For Managed Medicaid markets we compare to a "limited" level of PBM savings for FFS Medicaid (based on two studies estimating savings of 23-27%). 46,47

Our economic model is based on a review of the evidence associated with broad savings categories. These include manufacturer rebates and pharmacy discounts, formulary management to promote the use of generics and preferred brands, prior authorization and step therapy, utilization management, care management and adherence programs.

#### Evidence and Estimates of Savings Associated with PBM Tools in Commercial and Medicare

To assess the cost impact of legislation restricting the use of PBM tools in Commercial/Private Insurance and Medicare Part D, Visante conducted a comprehensive review of the published evidence on how much PBM tools save as they are currently used in the marketplace. Our evidence comes from a wide range of sources that often use different benchmarks against which to measure savings. While we report on each of these sources using their original benchmarks, it was necessary to then translate and restate this evidence in terms of a common benchmark that we refer to as "projected drug expenditures." As outlined above, our "projected drug expenditures" for the next 10 years are based on CMS's projected national health expenditures and are assumed to reflect the average use of PBM tools.

We use our model to produce estimates that reasonably isolate the impact of individual PBM tools and predict realistic costs and savings under different legislative scenarios that would restrict the use of specific tools. We do this by comparing the savings achieved by the following plans:

- 1. Plans with "limited use" of PBM tools.
- 2. Plans with typical or "average use" of PBM tools.
- 3. Plans that with optimal or "best practice" use of PBM tools.

In the PBM marketplace, plan sponsors determine the extent to which they use PBM tools based on their resources, objectives, and any regulatory constraints. Decisions made by plan sponsors not only guide how actively benefits are managed, but also determine formulary coverage, copay tiers, utilization management (UM), and pharmacy channel options. In making choices about the drug benefits being offered to their enrollees, plans' sponsors weigh many factors, including clinical quality, cost, and member satisfaction. The need to control costs is typically weighed against minimizing change for their enrollees, all while ensuring access to needed care.

Government mandates to restrict the use of PBM tools limit the options that plan sponsors can use to manage their drug benefit costs. In these cases, we model how the savings from those tools would be reduced and how projected drug expenditures would change over the next 10 years as a result. We have examined savings associated with PBM tools falling into the following categories:

- Pharmacy network contract discounts (e.g., retail, preferred, mail-order, specialty);
- Manufacturer rebates;
- PBM tools that improve formulary performance;
- Prior authorization and step therapy;
- Other PBM tools that manage drug utilization; and
- Care management and medication adherence programs.

<sup>&</sup>lt;sup>46</sup> Medicaid Pharmacy Savings Opportunities: National and State-Specific Estimates. The Menges Group, October 2016.

<sup>&</sup>lt;sup>47</sup> Pharmacy Benefit Management Can Save Medicaid Drug Programs Over \$100 Billion. UnitedHealth Group, March 2018.

#### Pharmacy Network Contract Discounts (Retail, Specialty, Mail)

**Retail Pharmacy Network Discounts:** Plan sponsor survey data indicate that pharmacy network discounts amount to 20-22% of the average wholesale price for brands and 56-61% of the average wholesale price for generics. <sup>48</sup> These reported pharmacy network discounts have increased as a percent of average wholesale price in recent years. However, the historically large gap between cash prices and pharmacy network prices has actually narrowed for generic drugs due to the widespread adoption of generic drug discount programs (such as \$4 prescription programs) now offered by most major retailers.

Visante analysis of CMS data on prices paid to pharmacies for prescriptions filled by individuals with commercial third-party insurance versus cash-paying customers in 2013 indicated average savings for third-party insurers of 9% to 10% on brands and 20% to 25% on generics. Due to changing market conditions during the past 5 years, we estimate those savings on brands have changed from 11% to 13% on brands and 15% to 20% on generics. Assuming that brand drugs will be 88% and generics will be 12% of projected drug expenditures over the next 10 years, we estimate retail network discounts of 12.5% relative to full retail prices charged by pharmacies to cash-paying consumers. We assume 12.5% is a midpoint of a 10% to 15% marketplace range. We consider this range as a baseline network discount achieved through all PBM-managed pharmacy channels, with additional discounts then available from preferred pharmacies, mail-service, and specialty pharmacies, as outlined below.

**Preferred Retail Pharmacy Networks:** In the commercial market, half of employer-sponsored plans now offer a preferred network, and about 20% of employer-sponsored plans offer a limited network.<sup>51</sup> Because data on preferred pharmacy network savings are more readily available for Part D plans, we are using Part D data as a proxy for savings in the commercial sector. According to CMS, preferred pharmacies had average weighted unit costs that were about 6% less expensive than other network pharmacies. CMS also reports that the four largest plans, accounting for 93% of claims, had average unit cost savings of 8% at preferred pharmacies.<sup>52,53</sup> Therefore, we estimate savings for prescriptions filled through preferred/limited network pharmacies can be up to 8% relative to baseline retail pharmacy network discounts.

CMS analysis also indicates that preferred retail pharmacies dispense up to 63% of retail, non-specialty prescriptions in plans that are using preferred networks in Part D.<sup>54</sup> But since preferred retail networks mainly fill non-specialty prescriptions, their impact is limited to the approximately 50% of overall drug expenditures that we estimate will be on non-specialty drugs over the 2020 to 2029 period.<sup>55</sup> Therefore, preferred or limited retail networks may deliver up to 2.5% in additional savings (e.g.,  $8\% \times 63\% \times 50\% = 2.5\%$ ), in addition to baseline retail pharmacy network discounts. But since a portion of plans do not use preferred/limited retail networks, the savings impact on a plan-by-plan basis ranges from 0% to 2.5% relative to expenditures without preferred pharmacies. Assuming a normal distribution, we estimate average savings of 1.25% across all plans.

**Mail-Service Pharmacy Discounts:** Based on a national survey of employer plan sponsors, the median mail-service pharmacy discount on brand drugs is 25% of the average wholesale price, which is 3-5 percentage points better than the discount achieved by retail drugstores.<sup>56</sup> In addition, the survey found that 55% of plan

<sup>&</sup>lt;sup>48</sup> 2018 Pharmacy Benefit Management Institute, op. cit.

<sup>&</sup>lt;sup>49</sup> Visante analysis of CMS National Average Retail Price (NARP) survey data from 2Q2013. NARP data provided average prescription revenues for more than 4,000 of the most commonly dispensed brand and generic outpatient drugs. The NARP data included: (1) the amounts paid for drug ingredient costs, (2) customer copays or coinsurance, and (3) dispensing fees. These monthly data were based on 50 million nationwide retail pharmacy claims gathered from independent data suppliers. NARP data reflected prices paid for drugs to retail community pharmacies for individuals with (1) commercial third-party insurance (including Medicaid managed care and Medicare Part D) and with (2) Medicaid fee-for-service, and (3) cash-paying customers. The NARP survey was suspended by CMS in July 2013.

<sup>&</sup>lt;sup>50</sup> Unbranded generic spend 11.7% of total. "Medicines use and spending in the U.S. a review of 2018 and outlook to 2023," IQVIA Institute, May 2019.

<sup>&</sup>lt;sup>51</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>&</sup>lt;sup>52</sup> "CMS Part D claims analysis: negotiated pricing between preferred and non-preferred pharmacy networks," CMS, Apr. 30, 2013.

<sup>53 &</sup>quot;New CMS study: preferred pharmacy networks are cheaper," Drug Channels, Jul. 11, 2013.

<sup>54 &</sup>quot;CMS Part D claims analysis," op. cit.

<sup>&</sup>lt;sup>55</sup> During the next 10 years, Visante assumes that approximately 50% of drug spending is "traditional drugs" and approximately 50% of drug spending is "specialty drugs." This is based on Visante estimates of historical and projected trends in the growth of specialty expenditures.

<sup>&</sup>lt;sup>56</sup> Pharmacy Benefit Management Institute, op. cit.

sponsors pay no dispensing fees to mail-service pharmacies,<sup>57</sup> which we estimate adds close to 1 additional percentage point of savings for brands and 4% of savings for generics.

Visante estimates that 10% to 15% of 30-day equivalent prescriptions are currently filled via mail ("30-day equivalent prescriptions" were adjusted so that one 90-day prescription is normalized to three 30-day prescriptions). Reports on drug trends published by PBMs indicate that plan sponsors can achieve mail-service penetration of 30% or more. Approximately 28% of employers report that they require the use of mail-service pharmacies for prescriptions needed on an ongoing basis. Based on this evidence, we estimate savings from mail-service pharmacies range from zero savings for plans with no mail-service pharmacies to up to 1.2% of total expenditures for plans with full use of mail-service. The upper bound 1% estimate is based on a discount of 5-6 percentage points relative to retail, 30% mail-service penetration for non-specialty prescriptions, and 50% of total prescription expenditures being non-specialty. Assuming a savings range with a normal distribution of 0% to 1%, we estimate average mail-service savings of 0.5% on overall drug costs relative to expenditures without mail-service pharmacies. These savings are in addition to "baseline" retail network discounts.

**Specialty Pharmacy Discounts:** Plan-sponsor survey data indicate that discounts off average wholesale price for specialty pharmacy networks are approximately 2 points better than average network discounts through retail drugstores.<sup>63</sup> To estimate the marketplace impact of specialty pharmacy network discounts, we apply this 2-point discount to expenditures on specialty pharmaceuticals (50% of total drug expenditures), which results in specialty pharmacy network discounts generating savings of approximately 1% relative to drug expenditures without specialty network discounts. Because a portion of the market does not take advantage of specialty pharmacy network discounts, the savings range is estimated to be a normal distribution of 0% to 1%, with an average of 0.5%. These savings are in addition to "baseline" retail network discounts.

Figure 3: PBM Savings on Unit Costs Through Pharmacy Discounts

	Limited	Average	Best Practice	
Estimated Savings vs Unma	anaged/ Uninsur	ed		
Retail Pharmacy Network Discounts	10%	12.5%	15%	
Preferred and Limited Retail Pharmacy Networks (in addition to retail)	0%	1.25%	2.5%	
Mail-Service Pharmacy Discounts (in addition to retail)	0%	0.5%	1%	
Specialty Pharmacy Discounts (in addition to retail)	0%	0.5%	1%	
All Pharmacy Discounts	10%	14.75%	19.5%	
Increased % Savings vs Lin	Increased % Savings vs Limited Use of PBM Tools			
All Pharmacy Discounts		4.75%	9.5%	

Source: Visante, 2020.

<sup>&</sup>lt;sup>57</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>&</sup>lt;sup>58</sup> According to Quintiles IMS Institute ("Medicines use and spending in the U.S. a review of 2018 and outlook to 2023"), prescription counts are adjusted for length of prescriptions and re-aggregated, with prescriptions for an 84-day supply or more factored by three and those under 84 days unchanged.

<sup>&</sup>lt;sup>59</sup> "Changing rules, changing roles," CVS Caremark Insights, 2011.

<sup>60 &</sup>quot;Driving mail service usage reduces pharmacy costs," OptumRx, 2013.

<sup>61</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>&</sup>lt;sup>62</sup> During the next 10 years (2020-2029), Visante assumes that approximately 50% of drug spending is "traditional drugs" and approximately 50% of drug spending is "specialty drugs." This is based on Visante estimates of historical and projected trends in the growth of specialty expenditures.

<sup>&</sup>lt;sup>63</sup> Baldini, C., and Culley, E., "Estimated cost savings associated with the transfer of office-administered specialty pharmaceuticals to a specialty pharmacy provider in a medical injectable drug program," *J Manag Care Pharm.* 2011;17(1):51-59.

#### Manufacturer Rebates

Based on Visante estimates and analysis of data from SSR Health and other sources, manufacturer rebates negotiated by PBMs across all branded drugs in the commercial sector average 30% of Wholesale Acquisition Cost (WAC) in 2018. This is a sales-weighted average across brand drugs. Rebates have increased significantly during the past 5 years. Some brands may have rebates of more than 50%, while other brand drugs may have no rebates at all. Visante's estimates, which exclude Medicaid rebates, are roughly consistent with other published estimates. 64,65,66,67,68,69 Our modeling assumes no significant changes to rebates in the future.

Average rebates for commercial sector payers depend on how fully plan sponsors elect to have their drug benefit managed. It is reasonable to assume that plan sponsors that opt to use the full range of PBM formulary management tools may achieve average brand rebates of up to 5 percentage points greater than the average for the marketplace as a whole, while plans that make limited use of formulary management may achieve rebates averaging 5 percentage points below the marketplace average. Under these assumptions, the average rebate across all brand-name drugs ranges from a high of 35% of WAC to a low of 25% of WAC.

We note that many high-cost specialty medications often have less competition and lower (or no) rebates compared with non-specialty medications. However, manufacturer competition is also becoming more important in the specialty area. For example, in late 2014, AbbVie obtained FDA approval to compete against Gilead's market-leading drugs for hepatitis C. PBMs immediately took advantage of the opportunity to obtain discounts of approximately 46%, 70 creating savings estimated at \$4 billion in the U.S. for 2015. 71 However, the weighted average rebate for the 47 top specialty drug products in 2016 was less than 20% of WAC, and more than half of these specialty products had rebates of less than 10% of WAC, based on our estimates and analysis of data from SSR Health. 72 Another estimate pegs rebates for traditional drugs at 40%, but rebates for specialty drugs at only 20%. 73

Limitations on Rebates: The FTC and CBO each have concluded that government policies resulting in the disclosure of rebates could lead to tacit collusion among manufacturers and result in higher costs as rebate contracts standardize toward terms more favorable to the drug makers. We believe that such policies could cause average rebates to cluster toward the lower bound of the current marketplace range of 25% to 35% of WAC. To model this effect, we have assumed that the current 25% to 35% range of average rebates compresses to a new range bounded by the current low of 25% and a new upper bound equal to the current marketplace average of 30%. Assuming a normal distribution, this would result in a new marketplace average rebate of approximately 27% of WAC, a compression of about 3 percentage points from the current marketplace average. This estimated impact is reasonably consistent with a 2017 analysis of disclosure mandates by budget analysts, which suggests that "CBO could reasonably conclude that the effect on branded drug pricing could be greater than 2% over time."

We understand that there are a variety of PBM business models and pricing schemes in the marketplace today, some of which factor "rebate retention" into the overall administrative fee structure for the PBM client. We see this as independent from our analysis. In other words, we are examining the potential impact on the manufacturer rebate contracts themselves. Whether some clients choose to use a portion of their rebate dollars to help reduce their administrative fees is independent from our analysis.

To assess the impact on overall drug expenditures by a reduction in average rebates on brand drug expenditures, we estimate that brand drugs will account for 88% of total drug expenditures over the next 10 years, based on

<sup>&</sup>lt;sup>64</sup> "Medicines use and spending in the U.S. a review of 2018 and outlook to 2023," IQVIA Institute, May 2019.

<sup>65 &</sup>quot;Report to the Congress: Medicare Payment Policy," MedPAC, March 2019.

<sup>66 &</sup>quot;Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates - A Study of Original Branded Products in the US." IQVIA Institute, October 2016.

<sup>67 &</sup>quot;The pharmaceutical supply chain: gross drug expenditures realized by stakeholders," Berkeley Research Group, Jan. 2017.

<sup>&</sup>lt;sup>68</sup> "How do PBM's make money?" Barclay's Equity Research, Mar. 2017.

<sup>&</sup>lt;sup>69</sup> "Exploring future US pricing pressure," Credit Suisse Equity Research, Apr. 2017.

<sup>&</sup>lt;sup>70</sup> "What Gilead's big hepatitis C discounts mean for biosimilar pricing," Drug Channels, Feb. 5, 2015.

<sup>71 &</sup>quot;Express Scripts' Miller says hepatitis C price war to save billions," Reuters, Jan. 22, 2015.

<sup>&</sup>lt;sup>72</sup> Visante estimates and analysis of non-Medicaid markets based on 2016 data from SSR Health. Further discussion of Visante's methodology for estimating average rebates is available in our June 2017 analysis for PCMA, "Increasing prices set by drugmakers not correlated with rebates."

<sup>73 &</sup>quot;2019 economic report on pharmacies and pharmacy benefit managers," Pembroke Consulting, March 2019.

<sup>&</sup>lt;sup>74</sup> "Assessing the budgetary implications of increasing transparency of prices in the pharmaceutical sector," The Moran Company, Apr. 2017.

current marketplace dynamics. Therefore, rebates of 25% to 35% of WAC for brand-only drugs would be equivalent to 22% to 31% of total drug expenditures (i.e., brands and generics).

Figure 4: PBM Savings on Unit Costs Through Manufacturer Rebates

	Limited	Average	Best Practice
Estimated Rebate Savings vs. Unmanaged/Uninsured	22%	26.5%	31%
Increased % Savings vs. Limited Use of Rebates		4.5%	9%

Source: Visante, 2020.

#### Formulary Management Tools To Promote the Use of Generics and Preferred Brands

PBMs use a variety of other tools to improve formulary management and promote the use of more cost-effective formulary drugs. These tools all work together to improve formulary performance and deliver drug cost savings:

- Formularies and therapeutic substitution;
- Copay tiers; and
- Consumer education.

**Formularies and Therapeutic Substitution:** PBMs implement a variety of tools to improve formulary management/compliance and reduce costs. For example, 73% of plan sponsors opt to have PBMs implement formulary exclusions and 58% opt for mandatory generic programs among many other tools and techniques used alone or in combination.<sup>75</sup> More recently, the HHS, Office of the Assistant Secretary for Planning and Evaluation found that in Medicare Part D alone, there are at least \$2.8 billion in additional annual generic substitution savings opportunities. An additional \$2 billion per year could be saved if state laws were reformed to always allow generic substitution at pharmacy.<sup>76</sup> Similarly, CBO examined potential substitution for seven therapeutic classes and concluded that if generics were used in lieu of single-source brand-name prescriptions, prescription drug costs would have fallen by 7%.<sup>77</sup> Several other studies have demonstrated significant cost savings associated with best practices approaches to formulary management.<sup>78,79,80,81,82,83,84,85</sup> Some research on PBM therapeutic substitution suggests savings up to 5% relative to drug expenditures without such

<sup>&</sup>lt;sup>75</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>&</sup>lt;sup>76</sup> ASPE, "Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D," July 23,2018

<sup>77 &</sup>quot;Effects of using generic drugs on Medicare's prescription drug spending," Congressional Budget Office, Sept. 2010.

<sup>&</sup>lt;sup>78</sup> Shirneshan, et al., "Impact of a transition to more restrictive drug formulary on therapy discontinuation and medication adherence," *J Clin Pharm Ther*. 2016;41(1):64-69.

<sup>&</sup>lt;sup>79</sup> Parra, et al., "Retrospective evaluation of the conversion of amlodipine to alternative calcium channel blockers," *Pharmacotherapy*. 2000;20(9):1072-

<sup>&</sup>lt;sup>80</sup> Usher-Smith, et al., "Evaluation of the cost savings and clinical outcomes of switching patients from atorvastatin to simvastatin and losartan to candesartan in a primary care setting," *Int J Clin Pract*. 2007;61(1):15-23.

<sup>81</sup> Good, et al., "Therapeutic substitution of cimetidine for nizatidine was not associated with an increase in healthcare utilization," Am J Manag Care. 2000;6(10):1141-1146.

<sup>82</sup> Benedetto, et al., "Impact of interventions designed to increase market share and prescribing of fexofenadine at HMOs," Am J Health Syst Pharm. 2000;57(19):1778-1785.

<sup>&</sup>lt;sup>83</sup> Meissner, et al., "Drug and medical cost effects of a drug formulary change with therapeutic interchange for statin drugs in a multistate managed Medicaid organization," *J Manag Care Pharm.* 2006;12(4):331-340.

<sup>84</sup> McKinley, et al., "Intraocular pressure control among patients transitioned from latanoprost to travoprost at a Veterans Affairs Medical Center Eye Clinic," J Ocul Pharmacol Ther. 2009;25(2):153-157.

<sup>85</sup> Schneeweiss, et al., "A therapeutic substitution policy for proton pump inhibitors: clinical and economic consequences," Clin Pharmacol Ther. 2006;79(4):379-388.

substitutions. 86 One PBM reported commercial clients that adopted a more highly managed formulary approach saved 8 percentage points more than clients that did not use this approach.<sup>87</sup>

Formulary management savings are available for both traditional and specialty drugs. Specialty drug categories with formulary-preferred brands have most often included growth hormone, multiple sclerosis, rheumatoid arthritis, blood modifiers, and hepatitis C. One plan increased the market share of the formulary-preferred human growth hormone from 27% to 82% within 12 months, generating savings of 20% in this expensive category.<sup>88</sup> As more biosimilars are approved during the next several years—with discounts of up to 50% relative to their brand competitors—these savings will extend to more specialty categories and become increasingly significant for specialty drug expenditures. A Rand study predicted that biosimilars will lead to a \$54 billion reduction in direct spending on biologic drugs from 2018 to 2027, or about 3% of total biologic spending over the same period.<sup>89</sup>

We estimate that formulary management and therapeutic substitution programs save 2% to 6% on drug expenditures across all therapeutic categories. However, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depend on them being implemented together in an integrated fashion. Therefore, to be conservative and avoid doublecounting of savings, we adjust these estimated savings down to a range of 1% to 3%, relative to expenditures without the use of these PBM tools.

Copay Tiers: During the past 20 years, plan sponsors have dramatically increased the use of tiered copay structures to encourage greater use of generics and preferred brands. Benefit designs with three or more tiers have replaced two-tier benefit designs; the difference between the copay tiers has increased from about \$10 up to approximately \$30.90 The implementation of tiered copays has created stronger aligned incentives for consumers and helped create more effective formulary management. One study examined the addition of a three-tier copay, with relatively modest copays of \$8/\$15/\$25. Payer costs dropped 17%, with 10% attributed to the absolute increase in copays and 7% to the utilization of lower-cost drugs. 91 Another study found that changing from a single-tier or two-tier formulary to a three-tier formulary was associated with a decrease in total drug spending of 5% to 15%, depending on the copay structures. 92 Other studies demonstrated that the introduction of a third tier for non-preferred brands induced a shift to lower-tiered drugs and strengthened plans' ability to negotiate price discounts. 93,94 Another study examined the effect of the size of the copay differential and found that each \$5 increase in copays was associated with decreased rates of switching to a relatively more expensive drug and an increased rate of switching to drugs of equal or lesser cost. 95

Our savings model examines combined drug expenditures for both payers and consumers, so reallocating costs from payers to consumers is not counted as savings. That said, there is uncertainty about what the "optimal amount of consumer cost sharing" should be. According to one literature review, 85% of studies that examined changes in patient cost sharing revealed that increasing cost sharing had a negative effect on adherence. 96 Costrelated non-adherence has prompted some employers to reevaluate their cost-sharing policies. Some plan sponsors have reduced or eliminated copays for selected medications in accordance with value-based insurance designs and demonstrated improvements in adherence as a result. 97,98

<sup>86</sup> Kaiser Family Foundation, op. cit.

<sup>87 &</sup>quot;Mid-year drug trend: prime held spending increases to 0.8% for commercial clients, generated negative trend for government program clients," Prime Therapeutics, Oct. 2017.

<sup>88 &</sup>quot;Specialty pharmacy: historical evolution and current market needs," presented at PCMA Specialty Pharmacy Symposium, May 5, 2008.

<sup>&</sup>lt;sup>89</sup> Mulcahy, et al., "Biosimilar cost savings in the United States," The Rand Corporation, Oct. 2017. <sup>90</sup> "2017 Employer Health Benefits Survey," Kaiser HRET, Sept. 2017.

<sup>&</sup>lt;sup>91</sup> Motheral, et al., "Effect of three-tier prescription copay on pharmaceutical and other medical utilization," Med Care. Dec. 2001;39(12):1293-1304.

<sup>&</sup>lt;sup>92</sup> Landon, et al., "Incentive formularies and changes in prescription drug spending," Am J Manag Care. Jun. 2007;13(part 2):360-369.

<sup>93</sup> Joyce, et al, op. cit.

<sup>&</sup>lt;sup>94</sup> Huskamp, et al., "The impact of a three-tier formulary on demand response for prescription drugs," *J Econ Manag Strategy*. Jul. 2005;14(3):729-753.

<sup>95</sup> Saito, et al., "Copayment level and drug switching: findings for type 2 diabetes," Am J Pharm Benefits. 2010;2(6):412-420.

<sup>96</sup> Eaddy, et al., "How patient cost-sharing trends affect adherence and outcomes—a literature review," Pharm Ther. Jan. 2012;37(1):45-55.

<sup>&</sup>lt;sup>97</sup> Chernew, et al., "Impact of decreasing copayments on medication adherence within a disease management environment," *Health Aff (Millwood)*.

<sup>98</sup> Maciejewski, et al., "Copayment reductions generate greater medication adherence in targeted patients. Health Aff (Millwood). 2010;29(11):2002-2008.

Based on the published evidence, we estimate a range of savings of 2% to 10% associated with more advanced approaches to copay tiers. Again, we count only savings associated with the use of lower-cost drugs. Any shift in the distribution of costs from plan sponsors to consumers is not counted as savings. However, as stated above, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depends on these tools being used in an integrated fashion. Therefore, in order to be conservative and avoid double-counting of savings, we adjust these estimated savings down to the range of 1% to 5%. In other words, moving from a one- or two-tiered copay to more advanced copay tiers may promote use of lower-cost drugs, creating savings of 1% to 5%. Assuming a normal distribution, we estimate average savings of 3%, relative to expenditures with rudimentary copay structures.

**Consumer Education:** PBMs use a variety of educational programs to increase consumer understanding of their pharmacy benefit. For example, a recent survey revealed that 71% of employer clients provide online tools and mobile apps, 57% provide clinical support and counseling, and 42% provide personalized health information. <sup>99</sup> In addition to stand-alone consumer education programs, PBMs may include incentives in their pharmacy network contracts to achieve improved formulary compliance and use of generic alternatives. For example, one PBM study estimated that consumer education can save up to 4% by combining generic incentives with consumer education. <sup>100</sup>

While some plans and PBMs may save up to 4%, other plans invest little time or money in consumer education. Therefore, we estimate a range of savings of approximately 0% to 4% associated with consumer education. However, as stated above, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depend on working together in an integrated fashion. To be conservative and avoid double-counting of savings, we adjust these estimated savings down to a savings range of 0% to 2%. Assuming a normal distribution, we estimate average savings of 1%, achieved relative to drug expenditures by plans with no consumer education programs.

Figure 5: Formulary Management To Promote the Use of Generics and Preferred Brands

	Limited	Average	<b>Best Practice</b>	
Estimated Savings vs Unma	nnaged/Uninsure	d		
Formularies and Therapeutic Substitution	1%	2%	3%	
Copay Tiers	1%	3%	5%	
Consumer Education	0%	1%	2%	
All Formulary Management	2%	6%	10%	
Increased % Savings vs Limited Use of PBM Tools				
All Formulary Management		4%	8%	

Source: Visante, 2020.

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<sup>99</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>&</sup>lt;sup>100</sup> Visante analysis of PBM Drug Trend Reports.

#### Prior Authorization and Step Therapy

**Prior Authorization (PA):** Today, PA is used by 92% of employer plan sponsors to improve clinical safety and decrease inappropriate utilization and waste. A range of studies demonstrate that PA substantially reduces expenditures in targeted drug categories. For example, one study found that PA for a high-cost antibiotic resulted in 37% lower pharmacy costs and 38% lower total cost of care for patients prescribed the antibiotic. One specialty pharmacy program that used PA to identify inappropriate utilization across six drug categories based on nationally recognized clinical guidelines achieved a 24% cost reduction in targeted categories. A study of 22 state Medicaid programs found that PA lowered total drug expenditures by 0.6% based on its use in just one drug category alone. Other studies have demonstrated that PA for specialty drugs can generate savings of up to 50% for targeted drugs or categories. While most plan sponsors use PA, the number of drugs to which it is applied varies widely across plans. We also believe the use of PA is increasing in tandem with the growth of specialty pharmaceuticals. Based on these sources and assumptions, we estimate PA savings to range from 2% to 8%. Assuming a normal distribution, we estimate a market average of 5%, relative to drug expenditures without PA.

**Step Therapy (ST):** About 82% of employer plan sponsors used ST to some degree in 2017.<sup>107</sup> A number of studies have found that ST generates savings. For example, one study examined ST applied to three drug classes and found it generated savings of approximately 2.3% relative to *total* drug expenditures without ST (i.e., total expenditures for the plan, not limited to only the three targeted drug classes).<sup>108</sup> Another study evaluated ST for antihypertensive drugs and found that antihypertensive drug costs were 13% lower for the patients in the ST intervention group.<sup>109</sup> Another study examined ST for antidepressants and reported average antidepressant drug cost per day decreased by 9% for patients following the protocol.<sup>110</sup> Taken together, the evidence suggests savings from ST of up to 2% to 3% relative to drug expenditures in the absence of ST. Trends indicate that ST is being used by an increasing number of plan sponsors and being applied to an increasing number of therapeutic categories. Thus, we assume the higher savings of up to 3% relative to expenditures without ST. Since nearly 20% of employer plan sponsors are not yet using ST, we assume a range of ST savings in the market of 0% to 3%. Assuming a normal distribution, we estimate a market average savings of 1.5% relative to drug expenditures without ST.

<sup>&</sup>lt;sup>101</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>102</sup> Starner, et al., "A linezolid prior authorization program: clinical and economic outcomes," Am J Pharm Benefits. 2014;6(2):81-88.

<sup>103 &</sup>quot;Specialty pharmacy: historical evolution and current market needs," op. cit.

<sup>104</sup> Fischer, et al., "Medicaid prior-authorization programs and the use of cyclooxygenase-2 inhibitors," N Engl J Med. 2004;351:2187-2194.

<sup>105 &</sup>quot;Specialty utilization management proves effective: ampyra prior authorization improves safety and saves money," Prime Therapeutics, 2011.

<sup>106 &</sup>quot;Specialty prior authorizations reduce costs and enhance medication safety," Walgreens Specialty Pharmacy, 2009.

<sup>&</sup>lt;sup>107</sup> Pharmacy Benefit Management Institute, op. cit.

Motheral, et al., "Plan-sponsor savings and member experience with point-of-service prescription step therapy," Am J Manag Care. 2004;10:457-464.

Yokoyama, et al., "Effects of a step therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy," *J Manag Care Pharm.* 2007;13(3):235-244.

<sup>110</sup> Dunn, J., et al., "<u>Utilization and drug costs outcomes of a step-therapy edit for generic antidepressant in an HMO in an integrated health system</u>," J Manag Care Pharm. 2006;12(4):294-302.

Figure 6: PBM Savings Through Prior Authorization and Step Therapy

	Limited	Average	Best Practice	
Estimated Savings vs Unma	anaged/ Uninsure	ed		
PA	2%	5%	8%	
ST	0%	1.5%	3%	
PA & ST	2%	6.5%	11%	
Increased % Savings vs Limited Use of PBM Tools				
PA & ST		4.5%	9%	

Source: Visante, 2020.

## Utilization Management (UM) Tools

PA and ST are often used as UM tools, but PBMs offer their clients other UM tools as well, including drug utilization review (DUR), refill-too-soon checks, and quantity limits. PBMs use DUR and other utilization management programs to reduce over-utilization and waste, as well as reducing adverse drug events associated with polypharmacy.

**DUR:** DUR programs improve quality and safety by preventing drug duplication, drug interactions, and polypharmacy. Such programs also reduce dangerous over-utilization of prescription drugs. Some DUR programs occur while the prescription is being filled in the pharmacy and the prescription claim is processing through the PBM. These checks include drug-drug interactions, drug duplications, and potential overuse. In addition to these concurrent checks during the claims processing, many employers also use retrospective DUR programs that occur after the prescription has been filled. Approximately 50% of employer plan sponsors now use retrospective DUR services, and 30% use prescriber profiling. More than 75% of employers use DUR programs focused on opioids and other controlled substances, while more than 80% of employers use specialty care management programs that include DUR activities.<sup>111</sup> Numerous studies have documented drug cost savings associated with DUR programs. One study examined DUR programs and found average savings of 6.9% relative to total drug expenditures without DUR programs (i.e., total expenditures under the plan, not limited to only drug categories targeted by the DUR programs). 112 An opioid DUR program demonstrated a 28% reduction in potentially unsafe opioid use. 113 DUR savings apply to both traditional (i.e., non-specialty) and specialty drug expenditures. Specialty pharmacies also use DUR to reduce product waste. One specialty pharmacy demonstrated that hemophilia assay management and waste reduction using DUR reduced targeted expenditures by 7.7%, that dose optimization using DUR saved 6.6% on a targeted medication, and that a waste reduction program using DUR reduced drug expenditures on targeted therapy by 1%.<sup>114</sup> Based on this evidence. we estimate a range of DUR savings in the marketplace of 3% to 7%. Assuming a normal distribution, we estimate a market average savings of 5% relative to drug expenditures without DUR.

**Refill-Too-Soon Checks:** About 92% of employer health plan sponsors use refill-too-soon checks in the claims processing system. A refill-too-soon alert is sent to the pharmacy if, say, a pharmacy dispenses a 30-day

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<sup>&</sup>lt;sup>111</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>112</sup> Moore, et al., "Systemwide effects of Medicaid retrospective drug utilization review programs," J Health Polit Policy Law. Aug. 2000;25(4):653-688.

<sup>113</sup> Qureshi, et al., "Effectiveness of a retrospective drug utilization review on potentially unsafe opioid and central nervous system combination therapy," J Manag Care Spec Pharm. Oct. 2015;21(10):938-944.

<sup>&</sup>quot;Specialty Pharmacy: Historical Evolution and Current Market Needs," op. cit.

<sup>&</sup>lt;sup>115</sup> Pharmacy Benefit Management Institute, op. cit.

supply of medication and the patient tries to refill it 10 days later. We estimate that virtually all plan sponsors obtain savings of 1% based on refill-too-soon checks (savings relative to expenditures without refill-too-soon checks).

Quantity Limits: More than 90% of employers report using quantity limits for top drug categories. 116 Research suggests that specific drug limits and general limitations can save up to 1% of drug expenditures. 117 PBMs publish their standard lists of drugs and quantity limits, which are all very similar. 118 We estimate that virtually all plan sponsors obtain savings of 1% (savings relative to drug expenditures without the use of quantity limits).

Figure 7: PBM Savings Through Utilization Management Programs

	Limited	Average	Best Practice	
Estimated Savings vs Unma	anaged/ Uninsur	ed		
DUR	3%	5%	7%	
Refill Too Soon	1%	1%	1%	
Quantity Limits	1%	1%	1%	
All Utilization Mgmt	5%	7%	9%	
Increased % Savings vs Limited Use of PBM Tools				
All Utilization Mgmt		2%	4%	

Source: Visante, 2020.

#### Medication Adherence and Care Management Programs

Some PBM tools actually increase drug utilization, but are targeted attempts to reduce overall healthcare spending. For example, evidence suggests that improving patient adherence to an appropriately prescribed drug therapy lowers overall health care costs.

Medication Adherence: PBM tools for increasing clinical quality and patient health may boost the numbers of prescriptions. This can occur in the PBM programs focused on ensuring that patients adhere to prescribed drug therapies for such chronic diseases as diabetes, hypertension, and heart failure. Numerous studies have demonstrated that improved patient adherence delivers improved clinical outcomes and reduces non-drug medical costs. 119,120 Research has shown that 90-day supplies filled via mail service, with lower copayscombined with refill reminders, auto-refills, patient education, and other adherence strategies—can improve adherence by 5-10 percentage points. 121,122,123,124 Adherence programs have historically focused on mail-service

<sup>&</sup>lt;sup>116</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>117</sup> Visante analysis of PBM Drug Trend Reports.

<sup>118</sup> Visante analysis of PBM published quantity limits.

<sup>&</sup>quot;Module diagysis of Part patients of Pharmacy Care, Volume 3," CVS Caremark, 2013. 
120 "Insights. Advancing the Science of Pharmacy Care," CVS Health, Fall 2014.

<sup>&</sup>lt;sup>121</sup> Express Scripts, "Is Compliance Really Better in Home Delivery? Evidence across Three Chronic Therapy Classes," 2008.

<sup>122</sup> Duru, O., et al., "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," Am J Managed Care 16(1):33-40, 2010.

<sup>123</sup> Iyengar, et al., "Dispensing Channel and Medication Adherence: Evidence across 3 Therapy Classes," Am J Manag Care 19(10):798-804, 2013.

<sup>124</sup> Iyengar, R., et al., "Association between Dispensing Channel and Medication Adherence among Medicare Beneficiaries Taking Medications to Treat Diabetes, High Blood Pressure, or High Blood Cholesterol," J Manag Care Pharm 20(8):851-861, 2014.

pharmacy; however, evidence suggests that adherence is also improved by using similar strategies at retail pharmacies, <sup>125</sup> particularly with 90-day at-retail prescriptions increasingly being incorporated into pharmacy benefit designs. In 2018, the fulfillment of a 90-day supply of drugs from network retail pharmacies was offered by most employer-plan sponsors. <sup>126</sup>

Our savings model looks at total drug spend (i.e., both "payor spend" and "consumer spend"), so shifting costs from payers to consumers would not be counted as "cost savings." That said, there is uncertainty about what the "optimal amount of consumer cost sharing" should be. According to one literature review, 85% of studies that examined changes in patient cost sharing revealed that increasing cost sharing had a negative effect on adherence. Cost-related nonadherence has prompted some employers to reevaluate their cost-sharing policies. Some plan sponsors have reduced or eliminated copays for selected medications in accordance with value-based insurance designs, and demonstrated improvements in adherence as a result. 128,129

The CBO estimated that for every 5 percentage point improvement increase in adherence (measured by number of prescriptions), total medical costs are reduced by 1%. Based on Visante's analysis, in 2018, a 1% decrease in hospital and physician costs equaled \$20 billion. Coincidentally, in 2018, a 5% increase in prescription drug expenditures equaled approximately the same amount. We can therefore adopt a more simplified version of CBO's methodology to infer that a 5% increase in prescription drug expenditures (related only to improved adherence, NOT price increases) will result in a 1% decrease in medical costs. For the purposes of Visante's model, we have assumed that each dollar of increased drug expenditure from increased adherence results in an equal dollar decrease in non-drug medical costs. While this methodology may apply generally to a broad spectrum of drug categories, it may not apply to each specific, individual drug.

**Specialty Pharmacy:** Utilization management and patient adherence programs play an important role in specialty pharmacy. One specialty pharmacy, for instance, identified inappropriate utilization according to nationally recognized clinical guidelines for six therapy categories. Applying these clinical guidelines with 52 clients cut costs by 24% in these categories. Other studies have demonstrated that prior authorization, a commonly used specialty pharmacy tool, generates savings of up to 50%. Specialty pharmacies can also reduce product waste by eliminating excessive quantities of expensive pharmaceuticals. One specialty pharmacy demonstrated that hemophilia assay management and waste reduction reduce expenditures by 7.7%, that Revlimid dose optimization saves 6.6%, and that a Synagis waste reduction program saves 1%. All Patient adherence is often crucial to successful therapy in diseases related to specialty pharmacy (e.g., multiple sclerosis, hepatitis C, HIV, transplant). Specialty pharmacy improved adherence for multiple sclerosis from 84% to 90%; for hepatitis C from 70% to 78%; for HIV from 81% to 90%; and for transplant patients from 76% to 85%. Numerous studies suggest that the improved adherence resulting from specialty pharmacy interventions can reduce non-drug medical costs through care coordination, clinical assessments, and patient

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<sup>125</sup> Cutrona, S., et al., "Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence," Am J Managed Care 16(12):929-994, 2010

<sup>&</sup>lt;sup>126</sup> Pharmacy Benefit Management Institute, op. cit.

<sup>127</sup> Eaddy, M., et al., "How Patient Cost-Sharing Trends Affect Adherence and Outcomes—A Literature Review," P&T Jan;37(1):45-55, 2012.

<sup>&</sup>lt;sup>128</sup> Chernew, M., et al., "Impact of Decreasing Copayments on Medication Adherence within a Disease Management Environment," *Health Aff* 27(1):103-112, 2008

<sup>&</sup>lt;sup>129</sup> Maciejewski, M., et al., "Copayment Reductions Generate Greater Medication Adherence in Targeted Patients," *Health Affairs* 29(11):2002-2008, 2010.

<sup>130 &</sup>quot;Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services," Congressional Budget Office, November 2012.

<sup>131 &</sup>quot;Specialty Pharmacy: Historical Evolution and Current Market Needs," op. cit.

<sup>132 &</sup>quot;Specialty Utilization Management Proves Effective: Ampyra Prior Authorization Improves Safety and Saves Money," Prime Therapeutics, 2011.

<sup>133 &</sup>quot;Specialty Prior Authorizations Reduce Costs and Enhance Medication Safety," Walgreens Specialty Pharmacy, 2009.

<sup>134 &</sup>quot;Specialty Pharmacy: Historical Evolution and Current Market Needs," op. cit.

<sup>135</sup> Tang, J., and Faris, R., "Exploring the Impact of Dispensing Channel on Medication Adherence among Multiple Sclerosis Patients," presented at the 14th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), May 2009.

<sup>136</sup> Visaria, J., and Frazee, S., "Role of Pharmacy Channel in Adherence to Hepatitis C Regimens," Am J Pharm Benefits 5(1):17-24, 2013.

<sup>&</sup>lt;sup>137</sup> Miller, S., "Personalizing the Specialty Business," presentation at the PCMA Specialty Pharmacy Business Forum, April 4, 2012.

<sup>138</sup> Ibid.

education and support. <sup>139,140,141,142,143,144,145</sup> However, an assessment by the Institute for Clinical and Economic Review suggests that the introductory prices of some new specialty drugs would need to be three times lower to create net savings to the health system. <sup>146</sup>

Because pharmacies and pharmaceutical manufacturers have an economic incentive to promote patient adherence in order to increase prescription volume, we also assume that some adherence impact would be present for an unmanaged benefit.

Therefore, due to medical cost offsets to increased drug costs with increased adherence, we estimate no net increase in total costs (drug costs + medical costs) associated with medication adherence and care management programs.

Figure 8: PBM Savings Through Medication Adherence and Care Management Programs

	Limited	Average	Best Practice
Estimated Savings vs Unmanaged/Uninsured	0%	0%	0%
Increased Savings vs Limited Use of PBM Tools	ł	1	

Source: Visante, 2020.

#### **PBMs' Low Administrative Costs**

PBMs have created the most efficient claims processing system in the health care industry. No other health care segment (physicians, hospitals, long-term care, home care, etc.) can yet duplicate the PBM system's speed and low cost. In the 1980s, PBMs were already connected online with pharmacies throughout the nation. This connectivity and online claims processing system allows each prescription claim to be adjudicated in seconds—with great cost efficiency.

PBM-pioneered systems also speed vital information and data to pharmacists. For example, if a patient uses multiple pharmacies, the PBM system can compare the new prescription with the patient's entire claims history across all pharmacies, identify a potentially dangerous drug-drug interaction, and alert the pharmacist before the new prescription is filled. No other U.S. health care segment has been able to replicate this innovation.

PBMs also use advanced computer algorithms and auditing techniques to efficiently detect and combat fraud, waste, and abuse. Most PBMs screen for fraud, waste, and abuse both before and after a claim is paid, and problem claims can often be detected automatically.

PBM fees are low compared with the value of PBM services. One industry report estimates PBM margins of only 0.5-2% for brand-name drugs (which account for almost 90% of total expenditures) and 5-10% for generic

<sup>&</sup>lt;sup>139</sup> Mitra, D., et al., "Treatment Patterns and Adherence among Patients with Chronic Hepatitis C Virus in a U.S. Managed Care Population," Value Health Jun-Jul;13(4):479-486, 2010.

<sup>140</sup> Tan, H., et al., "Impact of Adherence to Disease-Modifying Therapies on Clinical and Economic Outcomes among Patients with Multiple Sclerosis," Adv Ther Jan;28(1):51-61, 2011.

<sup>141</sup> Specialty Pharmacy News, June:10(6), 2013.

<sup>&</sup>lt;sup>142</sup> Tschida, S., et al., "Outcomes of a Specialty Pharmacy Program for Oral Oncology Medications," Am J Pharm Benefits 4(4):165-174, 2012.

<sup>&</sup>lt;sup>143</sup> Tschida, S., et al., "Managing Specialty Medication Services through a Specialty Pharmacy Program: The Case of Oral Renal Transplant Immunosuppressant Medications," *J Managed Care Pharm* 19(1):26-41, 2013.

<sup>&</sup>lt;sup>144</sup> Russek, S., and Szymanski, J., Medco, "Specialty Pharmacy: Rare Disease Management," presented at the PCMA Specialty Pharmacy Symposium, June 2005.

<sup>145</sup> Barlow, J., et al., "Impact of Specialty Pharmacy on Treatment Costs for Rheumatoid Arthritis," Am J Pharm Benefits 4(Special Issue):SP49-SP56, 2012

<sup>&</sup>lt;sup>146</sup> "PCSK9 Inhibitors for Treatment of High Cholesterol: Effectiveness, Value, and Value-Based Price Benchmarks," Institute for Clinical and Economic Review, November 24, 2015.

drugs. 147 We estimate that gross operating margins associated with PBM services (excluding filling prescriptions in owned specialty/mail-order pharmacies) account for approximately 6% of revenue (i.e., drug spend).148

## Summary for Commercial/Private Insurance and Medicare Part D

Based on the sources and methodology above, Visante estimates additional % savings of:

- approximately 20% for average use of PBM tools vs limited; and
- approximately 40% for best practice use of PBM tools vs limited.

Figure 9: Additional PBM Savings vs. Limited/Restricted Management

Sarings Catagory	Level of Pharmacy Benefits Management		
Savings Category	Limited	Average	Best Practice
Pharmacy Discounts (Retail, Mail, Specialty)	ł	4.75%	9.5%
Manufacturer Rebates		4.5%	9%
Formulary Management Encouraging Generics and Preferred Brands		4%	8%
Prior Authorization & Step Therapy		4.5%	9%
Other Utilization Management		2%	4%
Care Management and Adherence Programs			
TOTAL		19.75%	39.5%

Source: Visante, 2020.

According to one PBM report, "Compared to (relatively) unmanaged plans, tightly managed plans spent 27.6% less on traditional drugs." Our analysis is consistent with this report and suggests that a plan using best practices could achieve 30% or greater savings than a plan with limited use of PBM tools.

<sup>149</sup> Express Scripts Drug Trend Report, April 2015.

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 <sup>147 &</sup>quot;2019 economic report on pharmacies and pharmacy benefit managers," Pembroke Consulting, March 2019.
 148 Securities and Exchange Commission, Forms 10-Q, Express Scripts, CVS Health

### Methodology: Estimating Savings for PBM Tools in Medicaid Managed Care

Medicaid is different from Private/Commercial insurance and Medicare Part D for many reasons, including different populations, different age mix, different disease and drug mix, problems with patients accessing care, etc. But most important for this analysis, two important PBM tools are essentially removed from our savings model:

- 1. Tiered copays are not applicable to Medicaid. Prescription copays in most states are between \$0-3 per prescription, typically with no difference between brands and generics. <sup>150</sup>
- 2. Rebate savings are not applicable to Medicaid. Following implementation of the Affordable Care Act, 35 of 39 MCO states reported that the pharmacy benefit was "generally carved-in" for rebate purposes.<sup>151</sup>

However, there are also additional opportunities for savings when compared to the limited use of PBM tools in FFS State Medicaid programs. Two studies have examined these savings opportunities which are unique to state Medicaid programs, and estimated % savings of 23-27%. According to one study, using the full range of PBM tools and strategies in state Medicaid programs nationwide could save 27.3% savings in Medicaid drug expenditures. <sup>152</sup> These savings could be achieved by optimizing the use of PBM tools such as:

- Encouraging the Use of Generics and More Affordable Brands;
- Negotiating Market-Based Pharmacy Reimbursements;
- Utilizing Lower-Cost Pharmacy Options; and
- Reduced Polypharmacy, Fraud, Waste and Abuse.

According to another study, the optimal use of all pharmacy benefit management tools for all Medicaid prescriptions would yield additional savings of 24.9% savings in Medicaid drug expenditures. These savings could be achieved by optimizing the use of PBM tools such as:

- Driving Use of Lowest-Cost Brands;
- Driving Use of Lowest-Cost Generics;
- Shifting Utilization from Brands to Generics;
- Employing Utilization Management Practices;
- Establishing Preferred Pharmacy Networks; and
- Detecting and Preventing Fraud, Waste, and Abuse.

Based on the evidence and analysis cited in these studies, we estimate that total savings of 25% could be achieved in Medicaid by moving from "Limited Use of PBM Tools in FFS" to "High or Optimized Use of PBM tools in Managed Medicaid." Similar to our model for Commercial and Medicaid, we estimate the "average savings" falls in the middle of 0-25% savings, or 12.5% savings.

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<sup>150</sup> Medicaid and CHIP Eligibility, Enrollment, and Cost Sharing Policies as of January 2019. Kaiser Family Foundation. March 2019.

Medicaid Moving Ahead in Uncertain Times: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2017 and 2018. Kaiser Family Foundation, October 2017

<sup>152</sup> Medicaid Pharmacy Savings Opportunities: National and State-Specific Estimates. The Menges Group, October 2016.

<sup>153</sup> Pharmacy Benefit Management Can Save Medicaid Drug Programs Over \$100 Billion. UnitedHealth Group, March 2018.

## **Projected 10-Year Drug Expenditures**

Using the estimated savings % for limited, average, and high/best-practice use of PBM tools, we calculate the 10-year projected drug expenditures for each of the three scenarios as follows:

Figure 10: Projected 10-Year Drug Expenditures Under Three Scenarios (Dollar figures in billions)

\*Assume that projected expenditures for Private, Medicare, and Managed Medicaid reflect "Average" levels of management.

D	Level of Pha	rmacy Benefit Ma	anagement*
Payer Type	Limited Average Best		Best Practice
Private Insurance	\$2,832	\$2,320	\$1,808
Medicare Part D	\$2,461	\$2,016	\$1,571
Managed Medicaid	\$370	\$324	\$277

Source: Visante, 2020.

#### **PBM Savings from Current Use of PBM Tools**

From 2020 to 2029, the current use of PBM tools in the marketplace will save plan sponsors and consumers more than \$1 trillion.

- o Commercial plan sponsors and their members will save \$512 billion;
- o Medicare Part D and its beneficiaries, \$445 billion; and
- Managed Medicaid plans, \$46 billion.

## **Potential Additional Savings with Greater Use of PBM Tools**

If all plan sponsors adopted high/best-practice use of PBM tools, then projected prescription drug expenditures could save an additional \$1 trillion over the next decade.

- o Commercial plan sponsors and their members could save \$512 billion;
- o Medicare Part D and its beneficiaries, \$445 billion;
- Managed Medicaid, \$46 billion.

## V. Appendix: Focus on Specialty Pharmacy

While our analysis of PBM savings and services includes management of both traditional and specialty medications, the management of specialty drugs is receiving increased attention from patients, providers, payers, and policy makers due to the high prices of new specialty drugs and their aggregate impact on health care costs. Due to growing utilization rates, a pipeline of expensive new specialty drugs, and ongoing drug manufacturer price increases, specialty medications have grown to almost 50% of gross costs and almost 40% of net drug expenditures. See a services increases, specialty medications have grown to almost 50% of gross costs.

To manage costs, increase affordability and improve patient outcomes, health plan sponsors and payers contract with PBMs to manage traditional and specialty drug benefits and utilization. PBMs use a number of tools to manage drug benefits effectively and increase the affordability, quality, and continuity of care that patients receive. In the case of specialty drugs, PBMs manage patient access to these medications, while working with specialty pharmacies to provide advanced clinical management programs that ensure the value of therapy is being optimized at the lowest possible cost.

#### **Specialty Pharmacies**

Specialty pharmacies were established in direct response to the industry's need to better procure, store, and dispense specialty drugs, as well as better manage therapy for patients on specialty drugs. Among other things, these pharmacies specialize in the unique storage and shipping requirements that oral, injectable, inhalable, and infusible products require. Pharmacists and personnel working for these specialty pharmacies provide patient education and clinical support beyond the capabilities of a traditional retail pharmacy.

Specialty pharmacies must offer a full range of clinical and operational services to enhance the safety, quality, and affordability of care for patients receiving specialty medications. This includes:

#### Clinical Services

- Health care provider access: Specially trained pharmacists, nurses, and clinicians are accessible to patients
  around the clock to provide guidance and insight on disease states, as well as the use and management of
  specialty drugs.
- *Physician consultations:* Consults directly with physicians to address patient side effects, adverse drug reactions, non-compliance, and other patient concerns.
- Care management: Performs disease and drug-specific patient care management services that meet the
  unique needs of each patient and incorporate multiple safeguards when dispensing and delivering the drug to
  ensure patient safety.
- Clinical outcome measures: Collects data and tracks outcomes for specific patients.
- Patient adherence programs: Manages patient adherence and persistency of drug regimens.
- REMS programs: Manages care for manufacturer Risk Evaluation and Mitigation Strategies (REMS)
  program requirements, including REMS reporting, Phase IV trials, the dispensing of FDA trial drugs under
  strict protocols, and related clinical and cognitive counseling.

#### **Operational Services**

• Supply chain management: Adheres to rigorous storage, shipping, and handling standards to meet product label shipping requirements, such as temperature control and the timely delivery of products in optimal conditions.

<sup>154</sup> Hirsch et al. The impact of specialty pharmaceuticals as drivers of health care costs. Health Affairs, 33 (10):1714-1720.

<sup>155</sup> IQVIA Institute, "Medicines use and spending in the U.S. a review of 2018 and outlook to 2023." May 2019.

<sup>&</sup>lt;sup>156</sup> Pembroke Consulting, "2019 economic report on pharmacies and pharmacy benefit managers." March 2019.

- *Care coordination:* Offers coordinating services with other health care providers, including those providing skilled nursing services, custodial care, infusion administration, and direct-to-physician distribution.
- *Insurance navigation:* Expedites access to therapy by working directly with insurers and navigating their benefits, utilization management, and prior authorization processes.
- *Patient assistance:* Facilitates eligible patients' enrollment in patient assistance programs and access to charitable resources.
- *Plan optimization:* Aligns economic incentives across medical and pharmacy benefits while helping patients navigate the complexity of sometimes-siloed benefit structures.

#### Specialty Pharmacy Accreditation

Specialty pharmacies undergo formal accreditation reviews to demonstrate their ability to meet predetermined criteria and standards established by independent, professional accrediting agencies. Although specialty pharmacy accreditation is a baseline requirement for inclusion in PBM preferred specialty pharmacy networks, it is not necessarily a requirement to dispense specialty drugs to patients.

Multiple organizations accredit specialty pharmacies and provide an external validation of the services offered to patients, providers, and payers. Accreditation organizations collaborate with industry experts to create standards that ensure quality is maintained throughout all aspects of pharmacy operations, patient care management, and quality improvement processes. Of the 64,000 pharmacies in the U.S., approximately 378 have achieved specialty pharmacy accreditation from one of the top two accreditation entities.

Accreditation criteria do not include requirements for how economics are managed, how to carry out payer plan design, or how to encourage the lowest-cost drug option. Because of this, PBMs maintain their own criteria for specialty pharmacies to be included in their preferred networks. These criteria come into play where accreditation organizations leave off in terms of fulfilling payer and plan sponsor specialty benefit plan design.

#### **Specialty Benefit Design and Management**

In addition to routing specialty prescriptions to qualified specialty pharmacies, PBMs employ a number of other strategies and tools to support the needs of patients who are prescribed specialty drugs (as well as their health care providers) while controlling costs for health plans. These strategies include:

#### Formulary Management

Among the most important tools used by PBMs to manage specialty drug costs are drug formularies. The primary consideration in the development of a formulary is clinical appropriateness: what is the most appropriate therapy for a given disease or condition? PBMs use panels of experts called Pharmacy and Therapeutics (P&T) Committees to determine the most clinically appropriate drugs for a given drug class and indication. PBMs design their formularies based on P&T Committee recommendations and factor in a number of cost-saving elements, such as biosimilar availability and negotiated rebates.

Development and maintenance of formularies is an ongoing activity, as they must be constantly updated to keep pace with new therapies, recent evidence from clinical research, changes in medical practice, and FDA guidance. Effective use of formularies can minimize overall medical costs, improve patient access to more affordable care, and provide patients an improved quality of life.

#### **Utilization Management**

Utilization management tools are especially important in specialty drug classes. They can limit a patient's exposure to inappropriate drugs and lower the high cost of treatment by favoring clinically effective, lower price products. PBMs and plan sponsors manage specialty drug costs by employing a number of tools, including:

• Drug Utilization Review (DUR): Point-of-sale DUR immediately detects potentially inappropriate drug utilization for individual prescription drug claims, such as drug interactions or multiple fills of the same drug. Conversely, retrospective DUR is conducted to detect broad patterns of inappropriate prescribing and utilization over time.

- *Prior authorization (PA):* This is the requirement for the pre-approval of a drug before a pharmacy dispenses it to a patient. PA is generally used for drugs that have significant off-label use, are very expensive, have less expensive alternatives available, or require medical justification to assure safety or cost-effectiveness.
- *Step Therapy:* These programs apply clinical guidelines to encourage the use of a preferred, first-line drug before a more expensive, second-line drug.
- *Comparative Effectiveness:* By using literature reviews to compare the effectiveness of two different treatments, information can be gathered that allows payers to encourage clinicians to prescribe (and patients to use) more effective and higher value alternative treatments.<sup>157</sup>

#### Reducing Medication Waste

Specialty pharmacies can reduce product waste by eliminating excessive quantities of expensive pharmaceuticals. Quantity limits or dose limits can be effective in helping to reduce waste and assure clinically appropriate dosing for improved patient safety. One specialty pharmacy demonstrated that hemophilia assay management and waste reduction reduce expenditures by 7.7%, that Revlimid dose optimization saves 6.6%, and that a Synagis waste reduction program saves 1%.<sup>158</sup>

#### Medication Adherence

PBMs and specialty pharmacies offer patients a comprehensive suite of clinical programs that promote safe and effective medication therapy to improve health. Through these programs, specialty pharmacies give patients the information and clinical support they need to make decisions about their health care and derive the most value from their treatment. By utilizing a variety of tools, including interactive voice response calls, emails, texts, letters, mobile app medication reminders, and one-on-one pharmacist outreach and consultation, specialty pharmacies help patients manage side effects and other issues that could otherwise result in their premature discontinuation of treatment and sub-optimal outcomes. These programs are designed to improve patient outcomes and reduce the overall cost of care. Through these specialty pharmacy programs, patients receive tailored care for high-risk and high-cost conditions.

Studies have found that patients using specialty pharmacies with integrated refill reminders and comprehensive care management programs are more likely to achieve optimum adherence compared with patients who do not use specialty pharmacies. <sup>159</sup> Specialty pharmacies have demonstrated increased adherence rates nearly 10 percent higher than those seen in the retail pharmacy sector. <sup>160</sup>

#### Site of Care Optimization

PBMs work in close collaboration with specialty pharmacies to manage the site of care where drugs are delivered, since more specialty products can be administered by the patient at home instead of at costly sites, such as hospital outpatient facilities. Over the last two years, more health plans in conjunction with PBMs have begun implementing these site-of-care strategies. <sup>161</sup> Research finds that implementing site-of-care management can save between 12 and 34%. <sup>162</sup> To realize these savings, PBMs and plan sponsors may:

- Redirect specialty medication and administration from hospital outpatient settings to doctor offices, ambulatory clinics, or patient homes where clinically appropriate;
- Re-contract with outpatient networks to establish drug-pricing benchmarks; and
- Recommend that clients move specialty medications from the medical benefit to the pharmacy benefit when clinically appropriate.

<sup>&</sup>lt;sup>157</sup> Health Affairs. (2013, Nov 25). Health Policy Brief: Specialty Pharmaceuticals.

<sup>&</sup>lt;sup>158</sup> "Specialty Pharmacy: Historical Evolution and Current Market Needs," op. cit.

<sup>159</sup> Visaria et al. (2013, Dec 5). Specialty Pharmacy Improves Adherence to Imatinib. American Journal of Pharmacy Benefits.

<sup>&</sup>lt;sup>160</sup> UnitedHealth Group. (2014). The growth of specialty pharmacy: Current trends and future opportunities.

<sup>&</sup>lt;sup>161</sup> EMD Serono. (2015). EMD Serono Specialty Digest<sup>TM</sup>, 11th Edition.

<sup>&</sup>lt;sup>162</sup> Dorholt M. (2014, Jun). Advancing drug trend management in the medical benefit. Managed Care.