



**Increased Costs Associated With
Proposed State Legislation
Impacting PBM Tools**

Prepared for



April 2020

Table of Contents

| | |
|--|-----------|
| I. Executive Summary | 2 |
| II. Costs Associated With Proposed State Legislation Impacting PBM Tools | 4 |
| A. PBM Disclosure Mandates | 4 |
| • Cost Impact of Disclosure Mandates | |
| • CBO Says Disclosure Mandates Could “Compress” Rebates and Discounts | |
| • FTC Says Disclosure Mandates Could Lead to Tacit Collusion | |
| • Compare PBM Negotiations to Sealed-Bid Auctions | |
| • Confidential Plan Sponsor RFP Process Drives Competition Among PBMs | |
| • Plan Sponsors Can Negotiate Full Pass-Through of Manufacturer Rebates | |
| B. PBM Fiduciary Mandates | 6 |
| • Cost Impact of Fiduciary Mandates | |
| • PBMs Are Not Fiduciaries According to DOL and Federal Courts | |
| • Fiduciary Status Would Create Conflicting Obligations for PBMs | |
| • Legal Liabilities and Costs Would Increase Under Fiduciary Mandates | |
| • Fiduciary Mandates Would Decrease the Use of PBM Tools | |
| • Performance-Based Contracting Would Be Undermined by Fiduciary Mandates | |
| • Fiduciary Mandates Would Increase Administrative Costs | |
| C. Limitations on Prior Authorization and Step Therapy | 8 |
| • Cost Impact of Limitations on Prior Authorization and Step Therapy | |
| • PA and ST Used to Help Ensure Prescriptions Are Safe and Appropriate | |
| • FTC Finds Plans Use PA and ST to Lower Costs | |
| • NASEM Suggests Formulary Controls Keep Premiums Low | |
| • NASEM Recommends More, Not Less, Formulary Flexibility | |
| • Every Plan Has an Appeals Process | |
| D. Any Willing Specialty Pharmacy Requirements..... | 10 |
| • Cost Impact of Any Willing Specialty Pharmacy Requirements | |
| • FTC Says Any Willing Pharmacy Provisions Would Reduce Discounts | |
| • Academic Analysis Finds Any Willing Pharmacy Laws Associated With Higher Costs | |
| • Low Volume of Specialty Prescriptions Amplifies Impact of Any Willing Pharmacy Legislation | |
| • Only Select Pharmacies Typically Meet Specialty Pharmacy Network Requirements | |
| • Payer-Aligned Specialty Pharmacies Provide Unique Clinical and Operational Services | |
| • Physicians Say Not All Pharmacies Capable of Dispensing Specialty Drugs | |
| • Accreditation and Credentialing a Key Aspect of Network Requirements | |
| • Impact of Any Willing Pharmacy Legislation on Savings From Specialty Benefit Management | |
| III. Supporting Evidence and Methods..... | 13 |
| Appendix: Ten-Year Cost of Proposals Impacting PBM Tools by State, 2021-2030 | 25 |

I. Executive Summary

Visante was commissioned by the Pharmaceutical Care Management Association (PCMA) to estimate the potential cost impact of four types of state legislation impacting pharmacy benefit management (PBM) tools: PBM disclosure mandates, PBM fiduciary mandates, limits on prior authorization (PA) and step therapy (ST), and any willing specialty pharmacy requirements. As a general rule, such state legislation would affect only plan sponsors for commercial, fully insured plans. These plans provide prescription drug benefits to an estimated 90 million Americans. To make our estimates, we conducted a comprehensive review of the published evidence on how much PBM tools save as they are currently used in the marketplace and created an economic model of the impact of legislative proposals on the use of these tools and the resulting impact on projected drug expenditures for the fully insured commercial market for the next 10 years.

Proposals to restrict the use of PBM tools limit options that plan sponsors can use to manage their drug benefit costs. Some legislation may prohibit the use of a PBM tool entirely, driving savings to zero. Other legislation may negatively affect the full use of PBM tools and compress the range of savings achieved in the marketplace. We modeled how the savings from those tools would be reduced and how projected drug expenditures might increase over the next 10 years as a result.

Major Findings:

- **PBM Disclosure Mandates:** Proposed disclosure mandates include legislative and regulatory measures that would require PBMs to divulge the contractual price concessions they have negotiated with drug manufacturers and pharmacies. According to the Federal Trade Commission (FTC), disclosure mandates could result in tacit collusion and standardization of contract terms. We predict that disclosure mandates **would increase projected drug expenditures by an estimated 5.6% over the next 10 years.**
- **PBM Fiduciary Mandates:** Fiduciary mandates are state proposals to designate PBMs as fiduciaries for their health plan/employer clients. Such mandates would reduce savings from many PBM tools, including PA, ST, and other PBM tools that improve formulary performance and manage drug utilization. Fiduciary mandates would also likely increase PBM costs for liability insurance. We predict that fiduciary mandates **would increase projected drug expenditures by an estimated 6.75% over the next 10 years.**
- **Limitations on Prior Authorization and Step Therapy:** Some states are considering proposals to limit or prohibit the ability of health plans and their PBMs to implement PA and ST protocols. We predict that prohibiting the use of PA and ST **would increase projected drug expenditures by an estimated 6.75% over the next 10 years.**
- **Any Willing Specialty Pharmacy Requirements:** Some states are considering proposals to restrict the ability of health plans and PBMs to selectively contract for the provision of specialty pharmacy services by imposing any willing pharmacy requirements on such contracts. Such proposals would likely reduce specialty pharmacy network discounts and negatively impact the use of PBM tools that improve formulary performance and manage drug utilization. We predict that any willing specialty pharmacy requirements **would increase projected drug expenditures by an estimated 3.4% over the next 10 years.**

In this report, we review the evidence and methods underlying these estimates.

II. Costs Associated With Proposed State Legislation Impacting PBM Tools

A. PBM Disclosure Mandates

Issue: Proposed disclosure mandates include legislative and regulatory measures that would require PBMs to divulge the contractual price concessions they have negotiated with drug manufacturers and pharmacies.

Cost Impact of Disclosure Mandates: Mandatory disclosure would reduce savings from manufacturer rebates and pharmacy network discounts. Savings delivered by these PBM tools are significant. Some brand drugs have rebates of more than 50%. Preferred pharmacy networks deliver incremental discounts of up to 8 percentage points greater than traditional retail networks. We predict the following cost impacts:

- Disclosure mandates would likely result in tacit collusion among manufacturers, creating less variability and standardization around the lower end of the current range of rebates in the market. We predict that this compression in rebates would reduce average rebates by about 3% across all brand drugs.
- Disclosure mandates would also negatively impact pharmacy network discounts, with standardization and a compression of the range of network discounts toward the low end of the current marketplace range. Pharmacy network discounts would be compressed for different pharmacy channels and types of networks. Average retail network discounts (baseline discounts) would be cut by a half of a percentage point relative to cash prices charged to uninsured patients, while the incremental discounts over baseline associated with other pharmacy options such as preferred pharmacies, specialty, and mail-service would be cut in half.
- Combined, these negative effects on rebates and network discounts would increase projected drug expenditures by an estimated 5.6% over the next 10 years.
- PBM clients that currently maximize the use of the affected PBM tools would experience a much greater negative impact than others. These clients would see their projected drug expenditures increase by 8.6%, double the market average.

Discussion: Transparency remains a watchword in the healthcare cost debate. State policymakers have considered various proposals to mandate the disclosure of intermediate prices and discounts within the drug supply chain, including the price concessions that PBMs negotiate with drug manufacturers and pharmacies. However, a recent analysis from the USC School of Public Policy found that most states with transparency laws targeted PBMs and “no state passed laws that together revealed true transaction prices or profits across all supply chain segments.¹ This suggests these laws will fail in their intent because they are focusing on PBMs and not examining the entire supply chain. Moreover, government agencies—including the Congressional Budget Office (CBO) and the Federal Trade Commission (FTC)—have cautioned that such proposals can raise costs.

CBO Says Disclosure Mandates Could “Compress” Rebates and Discounts

CBO has noted that disclosure requirements could allow firms to “observe the prices charged by their rivals, which could lead to reduced competition.”² According to CBO, the “disclosure of rebate data would probably cause the variation in rebates among purchasers to decline,” leading to a “compression in rebates.”³ This compression would likely most adversely impact large program sponsors that would otherwise be able to extract the largest discounts.⁴ At the inception of the Part D program, CBO estimated that PBM disclosure mandates would have increased costs in that program by \$40 billion over 10 years.⁵

¹ Ryan, Martha S., and Neeraj Sood. “Analysis of State-Level Drug Pricing Transparency Laws in the United States.” JAMA network open 2.9 (2019): e1912104-e1912104.

² “Increasing transparency in the pricing of health care services and pharmaceuticals,” Congressional Budget Office, Jun. 5, 2008.

³ Letter to Rep. Joe Barton and Rep. Jim McCrery, U.S. House of Representatives, Congressional Budget Office, Mar. 12, 2007.

⁴ “Assessing the budgetary implications of increasing transparency of prices in the pharmaceutical sector,” The Moran Company, Apr. 2017.

⁵ “H.R. 1 Medicare Prescription Drug and Modernization Act of 2003 as passed by the House of Representatives on June 27, 2003 and S. 1 Prescription Drug and Medicare Improvement Act of 2003 as passed by the Senate on June 27, 2003, with a modification requested by Senate conferees,” Congressional Budget Office Cost Estimate, Jul. 22, 2003.

FTC Says Disclosure Mandates Could Lead to Tacit Collusion

FTC has warned that “whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely.”⁶ FTC concluded that PBM disclosure mandates could “undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford.”⁷

Compare PBM Negotiations to Sealed-Bid Auctions

In the current marketplace, contract negotiations between PBMs, manufacturers, and pharmacies are like sealed-bid auctions: manufacturers and pharmacies are encouraged to offer aggressive price concessions since they don’t know what’s being offered by their competitors. Without confidentiality, economists argue, “disclosure of commercially sensitive contract terms will tend to short-circuit this competitive dynamic” because manufacturers and pharmacies would “know that the granting of any concession will likely lead to pressure for its widespread adoption.”⁸

Confidential Plan Sponsor RFP Process Drives Competition Among PBMs

Confidentiality of contract terms is also vital to encourage competition among PBMs as they bid to win contracts with their clients (plan sponsors). Most plan sponsors use sophisticated consultants to prepare requests for proposals (RFPs) that specify their needs and requirements in both price and non-price terms, auditing rights, and guarantees. The RFPs are typically sent out to four to 12 PBMs,⁹ with each competing PBM blind to how its competitors will respond.

Plan Sponsors Can Negotiate Full Pass-Through of Manufacturer Rebates

Through the RFP process, plan sponsors can negotiate how manufacturer rebates will be handled and what levels of disclosure and reporting they desire from their PBM. Today, about 58% of PBM-client contracts in the commercial sector are negotiated to include full pass-through of manufacturer rebates to the plan sponsor.¹⁰ Other clients elect to have PBMs retain a portion of the rebates to lower administrative fees.

“With no indication that clients of PBMs lack accurate information on the price and quality of the service that they intend to purchase, it is unclear how requiring PBMs to reveal information related to rebates received from pharmaceutical companies would improve market outcomes,” according to FTC.¹¹ More broadly, FTC has concluded that “allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms regulated by government regulation.”¹²

⁶ “Improving health care: a dose of competition,” U.S. Federal Trade Commission and the U.S. Department of Justice, Jul. 2004.

⁷ Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, Jul. 15, 2005; Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, Sept. 3, 2004.

⁸ “Declaration of Adam B. Jaffee, Ph.D. in support of plaintiff’s motion for preliminary injunction,” Pharmaceutical Care Management Association v. G. Steven Rowe, Attorney General of the State of Maine.

⁹ [Statement of the Federal Trade Commission concerning the proposed acquisition of Medco Health Solutions by Express Scripts, Inc.](#), FTC File No. 111-0210, Apr. 2, 2012.

¹⁰ “[PBM research report: 2018 trends in drug benefit design](#),” Pharmacy Benefit Management Institute, January 2019.

¹¹ Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, Jul. 15, 2005.

¹² Letter from FTC to Assemblywoman Nellie Pou, New Jersey General Assembly, Apr. 17, 2007.

B. PBM Fiduciary Mandates

Issue: Fiduciary mandates for PBMs are state proposals to designate PBMs as fiduciaries for their health plan/employer clients.

Cost Impact of Fiduciary Mandates: Fiduciary mandates would reduce savings from many PBM tools, including PA, ST, and a number of other PBM tools. Fiduciary mandates would also increase PBM costs for liability insurance. More specifically, we predict the following impacts:

- Fiduciary mandates would reduce savings from PA, ST, and a number of other PBM tools that improve formulary performance and manage drug utilization. Savings delivered by these PBM tools are significant. Studies have demonstrated that PA can generate savings of up to 50% on drug expenditures for targeted drugs or drug categories, and ST has demonstrated savings of more than 10% for targeted categories. Optimal formulary management tools have demonstrated savings of up to 20% for targeted categories. Other PBM utilization management (UM) tools have demonstrated a reduction of almost 30% in unsafe opioid use.
- Fiduciary mandates would increase liability risks for PBMs and result in more conservative use of PBM tools, which would compress the range of savings achieved in the market. In other words, the PBM clients that are highly conservative in their use of these tools may see little impact, but the majority of clients that make greater use of PBM tools would see compression and reduction of savings. Average savings (across all drug expenditures) would be reduced by an estimated 1 to 2 percentage points for each affected category of PBM tools: PA (2%), ST (1%), and other PBM tools that work to improve formulary performance (2%) and manage drug utilization (2%).
- Fiduciary mandates would also increase PBM costs for additional liability insurance, which would be passed through to PBM clients and would add another 1% to projected drug expenditures.
- Combined, the negative effects of fiduciary mandates would increase projected drug expenditures by an estimated 6.75% over the next 10 years.
- Some PBM clients that currently maximize the use of the affected PBM tools would experience a much greater negative impact than the marketplace average. These clients that are maximizing their savings could see their drug expenditures increase by double the average or 13.5%.

Discussion: In today's marketplace, PBMs serve in administrative and advisory roles for health plans and employer plan sponsors, performing claims processing and other administrative tasks based on negotiated contracts. Proposed state legislation would override these contracts by designating PBMs as fiduciaries for their clients. A fiduciary mandate imposed upon PBMs would entail having discretionary authority over plan assets or making decisions about the scope and design of the benefits being offered by the plan. Today, those responsibilities lie with health insurance plan sponsors, not PBMs. Imposing fiduciary duties on PBMs would raise drug benefit costs by increasing their legal liability and undermining their ability to effectively implement cost management tools for their clients.

PBMs Are Not Fiduciaries According to DOL and Federal Courts

According to the Department of Labor (DOL), Third Party Administrators (TPAs), such as PBMs “who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan...are not fiduciaries of the plan.”¹³ Likewise, PBMs have no “discretionary authority” over plan assets as defined by DOL, which is an essential threshold requirement for fiduciary status under federal law. Moreover, federal courts have struck down state PBM fiduciary mandates as being preempted by the Employee Retirement Income Security Act (ERISA).¹⁴

Fiduciary Status Would Create Conflicting Obligations for PBMs

¹³ 29 CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.

¹⁴ Pharm. Care Mgt Ass'n v. District of Columbia, 613 F.3d 179 (D.C. Cir. 2010).

Imposition of a fiduciary mandate would create a conflict between PBMs' contractual obligations to their clients and the fiduciary duty to act "solely in the interest of plan participants." For example, a PBM's contract may call for the use of PBM tools such as PA and ST that are designed to reduce costs for ALL participants, but which may result in higher costs or less access to a given drug for a particular group of participants. In this case, implementing the contract would conflict with a fiduciary duty. Indeed, such conflicting obligations would likely be common, resulting in second-guessing of every element of the contracts PBMs have negotiated with their clients and requiring substantial and burdensome analysis by both parties to determine if a legally prohibited conflict exists.

Legal Liabilities and Costs Would Increase Under Fiduciary Mandates

Fiduciary mandates would subject PBMs to broader legal liabilities than under current law because they would transform an arm's length contractual relationship into one where one party is responsible for assets that belong to another, such as a trustee relationship. This could result in increased risk for litigation between PBMs and their clients. In addition, consumers could argue they have a private right of action to sue PBMs because they are plan participants protected by ERISA. Increased legal risk could result in PBMs needing to purchase additional liability insurance. The added cost of this insurance would then drive prescription drug benefit costs higher for both PBM clients and the individuals enrolled in their plans.

Fiduciary Mandates Would Decrease the Use of PBM Tools

Increased legal liability and conflicting obligations between fiduciary duties and client contracts could result in PBMs adopting defensive business strategies to mitigate the risk of lawsuits. This could lead to PBMs decreasing their use of formulary compliance and drug UM tools such as PA, ST, and quantity limits. This would raise drug benefit costs for both plan sponsors and their enrollees.

Performance-Based Contracting Would Be Undermined by Fiduciary Mandates

DOL has indicated that certain performance fee arrangements may result in fiduciary self-dealing. This could preclude PBM contracts from containing provisions where some of their fees are contingent on performance. Likewise, creating fiduciary responsibilities for PBMs could limit how they structure manufacturer rebate and pharmacy network contract agreements and negatively impact their bargaining leverage. In addition, the increased reporting requirements that would go hand-in-hand with a fiduciary duty would increase the risk of public disclosure of negotiated price concessions, although we have not explicitly factored that into our modeling.

Fiduciary Mandates Would Increase Administrative Costs

State fiduciary mandates would increase costs as PBMs are forced to develop unique administrative processes and revise contracts with other supply chain entities to comply with a state's new requirements, which would be completely different than other states' and at odds with ERISA's goals of a "uniform administrative scheme" for processing claims and distributing benefits.

C. Limitations on Prior Authorization and Step Therapy

Issue: Some states are considering proposals to limit or prohibit the ability of health plans and their PBMs to implement clinical PA and ST protocols.

Cost Impact of Limitations on PA and ST: Prohibiting the use of PA and ST would eliminate the savings delivered by these PBM tools. Our analysis reveals:

- Studies have demonstrated that PA can generate savings of up to 50% for targeted drugs or drug categories. ST has demonstrated savings of more than 10% in targeted categories.
- PA and ST are widely used by PBM clients to help ensure appropriate and cost-effective use of high-cost and/or high-risk drugs. These tools are becoming increasingly important in managing the rapidly growing use of high-cost specialty pharmaceuticals, so the lost savings associated with restrictions on PA and ST would become greater as specialty drug expenditures grow.
- The loss of savings from PA and ST would increase projected drug expenditures by an estimated 6.75% over the next 10 years.

PBM clients that currently maximize the use of the affected PBM tools would experience a much greater cost impact. These clients could see their drug expenditures increase by double the average increase or 13.5%.

Discussion: Health plans and pharmacy benefit managers utilize independent Pharmacy & Therapeutics Committees, comprised of experts that include physicians, pharmacists, and other medical professionals to develop evidence-based guidelines used in drug management programs—including PA and ST—and to ensure that these management controls do not impair the quality of clinical care.

PA is a requirement that a plan pre-approves a drug before a pharmacy can dispense it to the enrollee as a covered benefit. The major goals of PA are to ensure appropriateness and suitability of the prescribed medication for the specific patient as well as to control costs.

ST requires an enrollee to try a medically appropriate first-line drug, typically a generic alternative to a branded product, when a new therapy is initiated. The prescriber is asked to consider ordering a therapeutic alternative. If that medically appropriate alternative was tried earlier and the patient did not achieve optimal outcome, the brand product is approved and dispensed.

As with other drug benefit management techniques, it is up to each PBM client to decide if and how PA and ST will be applied to its health benefit plan.

PA and ST Used to Help Ensure Prescriptions Are Safe and Appropriate

Many drugs can have harmful side effects or adverse interactions with other medications. Some drugs, such as pain medications or antipsychotics, have a high risk of abuse or overuse so PA is required to help ensure appropriate use. Likewise, specialty medications often have significant side effects and require patient education to be taken effectively, so they also often require PA. Many drugs that commonly appear on PA lists are those that are heavily advertised directly to consumers or have off-label uses not approved by the Food and Drug Administration (FDA).

ST ensures that prescribers consider the medically appropriate available therapeutic alternatives before settling on a course of therapy for a specific patient, which can improve quality of care when that patient is on multiple medications. PA is often used to encourage or require physicians to use ST where they try an appropriate but less expensive medication first before moving the patient to a more expensive option.

FTC Finds Plans Use PA and ST to Lower Costs

According to FTC, “large PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance.”¹⁵ FTC also found that “prior authorization often involves a clinical justification for the use of drugs that are prone to misuse or are especially costly.”¹⁶ Any limits or prohibitions on PA and ST could thus raise costs.

NASEM Suggests Formulary Controls Keep Premiums Low

According to the National Academy of Sciences, Engineering, and Medicine (NASEM), “Formularies are used to steer patients and prescribing clinicians toward generic substitutes, biosimilars, drugs with similar therapeutic efficacy for the same disease, or other therapeutic options.”¹⁷ Without formulary controls, “insurance premiums would rise,” notes NASEM.¹⁸ PA and ST are among the most effective formulary controls, thus any state legislation to limit or prohibit their use would likely raise premiums.

NASEM Recommends More, Not Less, Formulary Flexibility

“Some other countries operate formulary systems that provide much greater ability to restrict or exclude drugs from coverage than is the case in the United States,” according to NASEM.¹⁹ One of NASEM’s recent consensus recommendations to make medicines more affordable was to “Expand flexibility in formulary design to allow the selective exclusion of drugs, such as when less costly drugs provide similar clinical benefit.”²⁰ Since PA and ST are less aggressive formulary controls than outright formulary exclusions, it is reasonable to extrapolate that state proposals limiting or prohibiting their use would be an approach at odds with NASEM’s recommendation.

Every Plan Has an Appeals Process

As noted by NASEM, “Every plan, whether Part D or an employer-sponsored pharmacy benefit, has an exception process that permits coverage of a drug not on formulary or reduces out-of-pocket cost if a physician provides information about side effects the patient has experienced from a lower-tiered drug or offers another medical reason for switching.”²¹ In the case of an appeal, health insurers and PBMs work with the patient and the physician to provide access to non-formulary drugs where medically necessary and/or likely to achieve the best outcome. This process safeguards against the use of PA and ST being too restrictive.

¹⁵ “Pharmacy benefit managers: ownership of mail-order pharmacies,” FTC, Aug. 2005.

¹⁶ Ibid.

¹⁷ “Making medicines affordable: a national imperative,” NASEM, Nov. 2017.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Ibid.

²¹ Ibid.

D. Any Willing Specialty Pharmacy Requirements

Issue: Some states are considering proposals to restrict the ability of health plans and PBMs to selectively contract for the provision of specialty pharmacy services, by imposing any willing pharmacy (AWP) requirements on such contracts.

Cost Impact of Any Willing Specialty Pharmacy Requirements: Any willing specialty pharmacy requirements would reduce savings on specialty drugs achieved through the use of tools such as PA, ST, and other PBM tools that improve formulary performance and manage drug utilization. Our analysis reveals:

- Specialty pharmacy network discounts typically deliver incremental discounts of up to 2 percentage points more than traditional retail networks. In addition, specialty formulary management has demonstrated savings of 20% in a drug category, while drug UM has demonstrated savings of 5% to 10% in targeted categories.
- Any willing specialty pharmacy legislation would effectively eliminate specialty pharmacy network discounts, which are typically 1–2 percentage points greater than baseline retail network discounts.
- Average savings associated with other PBM tools would be compressed and reduced because the effectiveness of the tools is often dependent upon specialized, advanced services delivered by specialty pharmacies in close coordination between the PBM and the specialty pharmacy. Most pharmacies are not prepared to deliver such sophisticated and coordinated services, so the optimal savings would not be as feasible under an AWP scenario. Average savings across all drug expenditures would be reduced by an estimated 1–2 percentage points for each affected category of PBM tools: PA (1%), ST (1%), and other PBM tools that work to improve formulary performance (2%) and manage drug utilization (2%).
- This legislation would affect specialty drug expenditures, which are the fastest growing component of prescription drug expenditures and projected to comprise approximately 50% of total drug expenditures over the next 10 years.
- The overall impact of an any willing specialty pharmacy requirement would be to increase projected drug expenditures (combined specialty and non-specialty) by an estimated 3.4% over the next 10 years.
- PBM clients that currently maximize the use of the affected PBM tools would experience an even greater cost impact and see their projected drug expenditures increase by 6.8%.

Discussion: Over the next 10 years, specialty drugs—high cost, often injectable or infusible medications—will likely account for just 1% of prescriptions but roughly 50% of projected drug expenditures.²² Today, entities known as specialty pharmacies fulfill the complex product handling, clinical support, patient education, and UM requirements associated with specialty drugs. Health plans and PBMs typically contract to include only selected specialty pharmacies in their pharmacy networks to ensure high-quality services for consumers, avoid waste, and ensure appropriate use of high-cost specialty medications. Thus, an AWP requirement could be particularly harmful when applied to specialty pharmacies, resulting in additional costs beyond the already anti-competitive impact associated with AWP requirements more generally.

FTC Says Any Willing Pharmacy Provisions Would Reduce Discounts

According to the FTC, AWP requirements significantly reduce providers' incentive to engage in price competition. If pharmacies know they will automatically be included in a network, they have a reduced incentive to offer plans and PBMs their most competitive terms. FTC has noted that “requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies.”²³

²² Visante estimates.

²³ “Contract year 2015 policy and technical changes to the Medicare advantage and the Medicare prescription drug benefit programs,” FTC letter to CMS, Mar. 7, 2014.

Academic Analysis Finds Any Willing Pharmacy Laws Associated With Higher Costs

An academic analysis of AWP laws concluded that such legislation leads to less competition and higher prices for consumers while providing no compensating benefits with “cost increases of ~5%.”²⁴ Likewise, another academic analysis specific to state AWP laws found that such legislation “is associated with increased pharmaceutical expenditures.”²⁵

Low Volume of Specialty Prescriptions Amplifies Impact of Any Willing Pharmacy Legislation

When applied to specialty pharmacies, the consequences of AWP legislation would likely be greater than when simply applied to brick-and-mortar pharmacies. Because specialty drugs are dispensed in such low volumes and target rare conditions, it is infeasible for most retail drugstores to stock these medications and provide the specialized services patients require. Specialty pharmacies can serve an entire region or country using sophisticated information technology and logistics to dispense medications directly to the patient’s home or physician’s office. This approach allows specialty pharmacies to achieve economies of scale and offer deeper discounts due to a predictable volume of prescriptions flowing through the pharmacy. These economies of scale would not be possible if AWP legislation were to result in drugstores across the country dispensing these medications.

Only Select Pharmacies Typically Meet Specialty Pharmacy Network Requirements

States do not legally differentiate specialty pharmacies from traditional pharmacies, so essentially any licensed pharmacy can market itself as a specialty pharmacy. Some pharmacies that market themselves as specialty pharmacies are actually affiliated with drug manufacturers, which has led to the use of questionable practices to circumvent the benefit design choices of plan sponsors in some cases.²⁶ PBMs actively work with payers to identify specialty pharmacies that can best serve patient and healthcare provider needs. These payer-aligned specialty pharmacies must meet payers’ terms and conditions to be included in preferred pharmacy networks. Terms and conditions focus on quality clinical care, performance, and cost-saving criteria. Qualified specialty pharmacies must also meet payer reimbursement rates to be included in networks.

Payer-Aligned Specialty Pharmacies Provide Unique Clinical and Operational Services

Unlike traditional brick-and-mortar drugstores, payer-aligned specialty pharmacies included in plan networks employ highly trained teams of pharmacists, nurses, and clinicians to work with doctors and patients to ensure that complex specialty medications are administered on time, conveniently, safely, and effectively. The unique clinical services that specialty pharmacies provide include:

- Providing around-the-clock access to specially trained clinicians who offer patients guidance and insight on disease states, as well as the use of specialty drugs;
- Consulting directly with physicians to address patient side effects, adverse drug reactions, non-adherence, and other patient concerns;
- Performing disease- and drug-specific patient care management services;
- Collecting data and tracking outcomes for specific patients;
- Managing patient adherence and persistency of drug regimens; and
- Managing care for manufacturer Risk Evaluation and Mitigation Strategies, including reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling.

²⁴ Klick, Jonathan and Wright, Joshua D., “[The Effect of Any Willing Provider and Freedom of Choice Laws on Prescription Drug Expenditures](#),” Am. L. & Econ. Rev. 192 (2015)

²⁵ Durrance, C., “The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures,” *Atlantic Economic Journal*, 2009.

²⁶ Chen, C., and Elgin, B., “Philidor said to modify prescriptions to boost Valeant sales,” *Bloomberg Business*, Oct. 29, 2015.

Unique operational services provided by payer-aligned specialty pharmacies in plan networks include:

- *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.
- *Care coordination:* Offers coordinating services with other healthcare 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, UM, and PA 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 these benefit structures.

Physicians Say Not All Pharmacies Capable of Dispensing Specialty Drugs

A 2015 survey of 400 physicians in the cardiology, neurology, gastroenterology, endocrinology, rheumatology, nephrology, infectious disease, oncology, pulmonology, and hematology specialties who prescribe specialty medications showed that two-thirds of those who work with specialty pharmacies think that only some or none of traditional drugstores have the expertise to provide the range of specialty medications to patients.²⁷

Accreditation and Credentialing a Key Aspect of Network Requirements

Specialty pharmacy accreditation and credentialing are among the baseline requirements a pharmacy must meet for inclusion in a plan's network. Of the roughly 64,000 pharmacies in the U.S., only about 400—less than 1%—are accredited as specialty pharmacies by the Utilization Review Accreditation Commission. In addition, PBMs utilize credentialing to evaluate a pharmacy's ability to implement plan design, encourage formulary compliance, and meet other contractual obligations.

Impact of Any Willing Pharmacy Legislation on Savings From Specialty Benefit Management

Legislation that prevents PBMs from creating limited networks of specialty pharmacies would likely significantly impact the performance of formulary management, UM, and care management programs for patients using specialty medications. The effective use of these tools has a significant impact on costs. For example, the Pennsylvania Medicaid program's use of specialty pharmacies helped save 21% on overall health expenditures for beneficiaries using specialty drugs, including 12% on specialty drug costs and 56% on inpatient hospital costs.²⁸ Numerous other studies have demonstrated that specialty pharmacies save 10% to 50% on drug costs and non-drug medical costs.^{29,30,31,32,33,34,35,36,37,38,39,40,41,42}

²⁷ "Key findings from the survey of New York physicians regarding specialty medications," North Star Opinion Research, Apr. 2015.

²⁸ "Managing Medicaid pharmacy benefits: current issues and options," Kaiser Commission on Medicaid and the Uninsured, Sept. 2011.

²⁹ 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 Managed Care Pharm.* 2011;17(1):51-59.

³⁰ "Express Scripts' Miller says hepatitis C price war to save billions," Reuters, Jan. 22, 2015.

³¹ "Specialty pharmacy: rare disease management," Russek, S., and Szymanski, J., Medco, presented at the PCMA Specialty Pharmacy Symposium, Jun. 2005.

³² Barlow, J. et al., "Impact of specialty pharmacy on treatment costs for rheumatoid arthritis," *Am J Pharm Benefits.* 2012;4(Special Issue):SP49-SP56.

³³ Dorholt, M., "Advancing drug trend management in the medical benefit," *Managed Care*, Jun. 2014.

³⁴ "Personalizing the specialty business," Miller, S., presentation at the PCMA Specialty Pharmacy Business Forum, Apr. 4, 2012.

³⁵ Visaria, J., and Frazee, S., "Role of pharmacy channel in adherence to hepatitis C regimens," *Am J Pharm Benefits.* 2013;5(1):17-24.

³⁶ "Exploring the impact of dispensing channel on medication adherence among multiple sclerosis patients," Tang, J., and Faris, R., presented at the 14th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), May 2009.

³⁷ Mitra, et al., "Treatment patterns and adherence among patients with chronic hepatitis C virus in a US managed care population," *Value Health.* 2010;Jun-Jul;13(4):479-486.

³⁸ Tan, et al., "Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis," *Adv Ther.* 2011;28(1):51-61.

³⁹ Specialty Pharmacy News, Jun. 2013;10(6).

⁴⁰ Tschida, et al., "Outcomes of a specialty pharmacy program for oral oncology medications," *Am J Pharm Benefits.* 2012;4(4):165-174.

⁴¹ Tschida, et al., "Managing specialty medication services through a specialty pharmacy program: the case of oral renal transplant immunosuppressant medications," *J Managed Care Pharm.* 2013;19(1):26-41.

⁴² Visaria, et al., "Specialty pharmacy improves adherence to imatinib," *Am J Pharm Benefits.* 2013;5(Special Issue):SP33-SP39.

III. Supporting Evidence and Methods

A. Methodology: Impact of Restricting PBM Tools

To assess the cost impact of legislation restricting the use of PBM tools, 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.” These projections are discussed in more detail in Section B below, but it is important to note that our “projected drug expenditures” for the next 10 years are based on the Centers for Medicare & Medicaid Services (CMS) 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 that use PBM tools to a limited extent or “limited use of PBM tools.”
2. Plans that use PBM tools to an average extent or “average use of PBM tools.”
3. Plans that optimize the use of PBM tools to their full extent 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 and objectives. Decisions made by plan sponsors not only guide how actively benefits are managed, but also determine formulary coverage, copayment tiers, 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 plans’ sponsors can use to manage their drug benefit costs. Some legislation may prohibit the use of a PBM tool entirely, driving savings to zero. Other legislation may negatively affect the “best practice” use of PBM tools, thereby compressing the range of savings in the marketplace toward the low end. 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:

- Manufacturer rebates
- Pharmacy network contract discounts (e.g., retail, preferred, mail-order, specialty)
- PA and ST
- Other PBM tools that improve formulary performance
- Other PBM tools that manage drug utilization

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 now average more than 30% of Wholesale Acquisition Cost (WAC). This is a sales-weighted average across brand drugs. Moreover, the Government Accountability Office (GAO) recently found that in Medicare Part D, 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 \$116.1 billion.”⁴³ Similarly, a

⁴³ GAO, “Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization,” July 2019.

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."⁴⁴

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.^{45,46,47,48,49,50} Our modeling assumes no significant changes to rebates in the future, although there are currently proposals that could result in significant changes, such as elimination of the rebate safe harbor in Medicare Part D.

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%,⁵¹ creating savings estimated at \$4 billion in the U.S. for 2015.⁵² 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.⁵³ Another estimate pegs rebates for traditional drugs at 40%, but rebates for specialty drugs at only 20%.⁵⁴

Potential Impact of State Legislation on Rebates: As discussed earlier in this report, 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 drugmakers. 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."⁵⁵

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.

⁴⁴ 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

⁴⁵ "Medicines use and spending in the U.S. a review of 2018 and outlook to 2023," IQVIA Institute, May 2019.

⁴⁶ "Report to the Congress: Medicare Payment Policy," MedPAC, March 2019.

⁴⁷ "Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates - A Study of Original Branded Products in the US," IQVIA Institute, October 2016.

⁴⁸ "The pharmaceutical supply chain: gross drug expenditures realized by stakeholders," Berkeley Research Group, Jan. 2017.

⁴⁹ "How do PBM's make money?" Barclay's Equity Research, Mar. 2017.

⁵⁰ "Exploring future US pricing pressure," Credit Suisse Equity Research, Apr. 2017.

⁵¹ "What Gilead's big hepatitis C discounts mean for biosimilar pricing," Drug Channels, Feb. 5, 2015.

⁵² "Express Scripts' Miller says hepatitis C price war to save billions," Reuters, Jan. 22, 2015.

⁵³ 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."

⁵⁴ "2019 economic report on pharmacies and pharmacy benefit managers," Pembroke Consulting, March 2019.

⁵⁵ "Assessing the budgetary implications of increasing transparency of prices in the pharmaceutical sector," The Moran Company, Apr. 2017.

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 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). Mandatory disclosure would compress the range to the lower end, resulting in a new range of 22% to 27%. The market average would be reduced from 27% to 24.5%. With this decrease in average rebates due to mandatory disclosure requirements, projected drug expenditures would increase an estimated 3.1%. This estimated impact does not include the impact such mandates would have on pharmacy network discounts, as discussed below.

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.⁵⁶ 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.⁵⁷ Due to changing market conditions during the past 5 years, we estimate those savings on brands have changed to 11% to 13% on brands and 15% to 20% on generics. Assuming that brand drugs will be 88% and generics will 12% of projected drug expenditures over the next 10 years,⁵⁸ 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 and Limited 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.⁵⁹ 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.^{60,61} 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.⁶² 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 2021 to 2030 period.⁶³ Therefore, preferred or limited retail networks may deliver up

⁵⁶ 2018 Pharmacy Benefit Management Institute, [op. cit.](#)

⁵⁷ 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 copayments 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.

⁵⁸ 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.

⁵⁹ Pharmacy Benefit Management Institute, [op. cit.](#)

⁶⁰ "[CMS Part D claims analysis: negotiated pricing between preferred and non-preferred pharmacy networks.](#)" CMS, Apr. 30, 2013.

⁶¹ "[New CMS study: preferred pharmacy networks are cheaper.](#)" Drug Channels, Jul. 11, 2013.

⁶² "[CMS Part D claims analysis.](#)" [op. cit.](#)

⁶³ 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.

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 doesn't 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 an 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.⁶⁴ In addition, the survey found that 55% of plan sponsors pay no dispensing fees to mail-service pharmacies,⁶⁵ 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).⁶⁶ Reports on drug trends published by PBMs indicate that plan sponsors can achieve mail-service penetration of 30% or more.^{67,68} Approximately 28% of employers report that they require the use of mail-service pharmacies for prescriptions needed on an ongoing basis.⁶⁹ 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.⁷⁰ 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.⁷¹ 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.

Potential Impact of State Legislation on Network Discounts

Impact of Disclosure Mandates: Anti-competitive government policies, such as disclosure mandates, would restrict the ability to negotiate pharmacy network discounts, eliminate the largest network discounts, compress the range of discounts toward the low end of the range, and (assuming a normal distribution) thereby reduce the market average discounts to the midpoint of the new range. We predict that retail network discounts would be reduced from a range of 10% to 15% to a new range of 10% to 12.5%, so the average would decrease from 12.5% to 11.25%. Preferred pharmacy savings would be cut from 0% to 2.5% to a new range of 0% to 1.25%, with the average savings dropping from 1.25% to 0.63%. Mail-service savings would change from 0% to 1% down to 0% to 0.5%, with the average cut from 0.5% to 0.25%. Savings from specialty network discounts would change from 0% to 1% down to 0% to 0.5%, and average savings would drop from 0.5% to 0.25%. Again, these savings are all relative to expenditures in the absence of these negotiated discounts. Based on these reductions in average network discounts,

⁶⁴ Pharmacy Benefit Management Institute, [op. cit.](#)

⁶⁵ Pharmacy Benefit Management Institute, [op. cit.](#)

⁶⁶ 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.

⁶⁷ "[Changing rules, changing roles](#)," CVS Caremark Insights, 2011.

⁶⁸ "[Driving mail service usage reduces pharmacy costs](#)," OptumRx, 2013.

⁶⁹ Pharmacy Benefit Management Institute, [op. cit.](#)

⁷⁰ During the next 10 years (2021-2030), 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.

⁷¹ 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.

projected drug expenditures would increase 2.5%. This estimated impact is only for lost savings related to pharmacy network discounts and does not include other cost impacts on savings from manufacturer rebates discussed above.

We understand that there are a variety of PBM business models and pricing schemes in the marketplace today, some of which factor pharmacy network discounts and direct and indirect remuneration fees 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 pharmacy contracts themselves. Whether some clients choose to use a portion of their pharmacy savings to help reduce their administrative fees is independent from our analysis.

Impact of Any Willing Specialty Pharmacy Legislation: “Any willing specialty pharmacy” legislation would effectively eliminate specialty pharmacy network discounts. Because specialty drugs account for just 1% of prescription volume, we believe that an any willing pharmacy requirement would spread this small volume across too many pharmacies and effectively eliminate the ability of any one pharmacy to achieve the economies of scale necessary to offer the level of discounting currently offered by in-network specialty pharmacies. Under this scenario, specialty pharmacy contract discounts would revert to the lower baseline discounts associated with standard retail pharmacies. We estimate this would increase projected drug expenditures (including specialty and non-specialty) by 0.5%. This estimated impact is only for lost network discounts and does not include the additional cost impact that any willing pharmacy legislation would have on savings derived from other PBM tools, which we have modeled separately.

Prior Authorization and Step Therapy

PA: Today, PA is used by 92% of employer plan sponsors to improve clinical safety and decrease inappropriate utilization and waste.⁷² 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.⁷³ 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.⁷⁴ 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.⁷⁵ Other studies have demonstrated that PA for specialty drugs can generate savings of up to 50% for targeted drugs or categories.^{76,77} 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.

ST: About 82% of employer plan sponsors used ST to some degree in 2017.⁷⁸ 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).⁷⁹ Another study evaluated ST for antihypertensive drugs and found that antihypertensive drug costs were 13% lower for the patients in the ST intervention group.⁸⁰ Another study examined ST for antidepressants and reported average antidepressant drug cost per day decreased by 9% for patients following the protocol.⁸¹ 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

⁷² Pharmacy Benefit Management Institute, [op. cit.](#)

⁷³ Starner, et al., “[A linezolid prior authorization program: clinical and economic outcomes.](#)” *Am J Pharm Benefits.* 2014;6(2):81-88.

⁷⁴ “Specialty pharmacy: historical evolution and current market needs,” *op. cit.*

⁷⁵ Fischer, et al., “[Medicaid prior-authorization programs and the use of cyclooxygenase-2 inhibitors.](#)” *N Engl J Med.* 2004;351:2187-2194.

⁷⁶ “Specialty utilization management proves effective: ampyra prior authorization improves safety and saves money,” Prime Therapeutics, 2011.

⁷⁷ “Specialty prior authorizations reduce costs and enhance medication safety,” Walgreens Specialty Pharmacy, 2009.

⁷⁸ Pharmacy Benefit Management Institute, [op. cit.](#)

⁷⁹ Motheral, et al., “Plan-sponsor savings and member experience with point-of-service prescription step therapy,” *Am J Manag Care.* 2004;10:457-464.

⁸⁰ 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.

⁸¹ Dunn, J., et al., “[Utilization and drug costs outcomes of a step-therapy edit for generic antidepressant in an HMO in an integrated health system.](#)” *J Manag Care Pharm.* 2006;12(4):294-302.

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.

Potential Impact of State Legislation on Prior Authorization and Step Therapy

Impact of Limits on Use of PA and ST: Various limitations on PA and ST have been proposed in different states, including prohibiting the use of these important PBM tools. Such a prohibition would eliminate the savings generated from these tools altogether, eliminating the average PA savings of 5% and ST savings of 1.5% relative to expenditures without these tools, respectively. With the loss of these savings, projected drug expenditures would increase 6.75%.

Impact of Fiduciary Mandate on PA and ST: Government policies, such as fiduciary mandates, would increase liability risks for PBMs and result in more conservative use of PBM tools, including limited use of PA and ST. With scaled back PA and ST, the range of savings would be compressed toward the low end of the range and, assuming a normal distribution, reduce the market average savings to the midpoint of the new range. Thus, savings from PA would be reduced from a range of 2% to 8% to a range of 2% to 5%, and the market average would decrease from 5% to 3.5%. ST savings would be cut from 0% to 3% to 0% to 1.5%, with average savings dropping from 1.5% to 0.75%. Again, these savings ranges are all stated relative to drug expenditures in the absence of PA and ST. Based on these reductions in savings, projected drug expenditures would increase 2.3% as a result of fiduciary mandates limiting the application of PA and ST. Fiduciary mandates would also have other impact savings from formulary and UM programs, which we have modeled separately.

Other PBM Tools That Improve Formulary Performance

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

- Formularies and therapeutic substitution
- Copay tiers
- Consumer education

Formularies and Therapeutic Substitution: Based on the decisions of plan sponsors, 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.⁸² 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%.⁸³ Several other studies have demonstrated significant cost savings associated with more aggressive approaches to formulary management.^{84,85,86,87,88,89,90,91} Some research on PBM therapeutic substitution suggests savings up to 5% relative to drug expenditures without such substitutions.⁹² One PBM reported commercial

⁸² Pharmacy Benefit Management Institute, [op. cit.](#)

⁸³ “Effects of using generic drugs on Medicare’s prescription drug spending,” Congressional Budget Office, Sept. 2010.

⁸⁴ Shirmeshan, 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.

⁸⁵ Parra, et al., “Retrospective evaluation of the conversion of amlodipine to alternative calcium channel blockers,” *Pharmacotherapy.* 2000;20(9):1072-1078.

⁸⁶ 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.

⁸⁷ 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.

⁸⁸ 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.

⁸⁹ 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.

⁹⁰ 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.

⁹¹ Schneeweiss, et al., “A therapeutic substitution policy for proton pump inhibitors: clinical and economic consequences,” *Clin Pharmacol Ther.* 2006;79(4):379-388.

⁹² Kaiser Family Foundation, [op. cit.](#)

clients that adopted a more highly managed formulary approach saved 8 percentage points more than clients that did not use this approach.⁹³

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.⁹⁴ 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 recent 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.⁹⁵

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 double-counting 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 \$30.⁹⁶ 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 copayments and 7% to the utilization of lower-cost drugs.⁹⁷ 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.⁹⁸ 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.^{99,100} Another study examined the effect of the size of the copay differential and found that each \$5 increase in copayment 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.¹⁰¹

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.¹⁰² Cost-related non-adherence has prompted some employers to reevaluate their cost-sharing policies. Some plan sponsors have reduced or eliminated copayments for selected medications in accordance with value-based insurance designs and demonstrated improvements in adherence as a result.^{103,104}

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

⁹³ “[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.

⁹⁴ “Specialty pharmacy: historical evolution and current market needs,” presented at PCMA Specialty Pharmacy Symposium, May 5, 2008.

⁹⁵ Mulcahy, et al., “[Biosimilar cost savings in the United States.](#)” The Rand Corporation, Oct. 2017.

⁹⁶ “[2017 Employer Health Benefits Survey.](#)” Kaiser HRET, Sept. 2017.

⁹⁷ Motheral, et al., “Effect of three-tier prescription copay on pharmaceutical and other medical utilization,” *Med Care*. Dec. 2001;39(12):1293-1304.

⁹⁸ Landon, et al., “Incentive formularies and changes in prescription drug spending,” *Am J Manag Care*. Jun. 2007;13(part 2):360-369.

⁹⁹ Joyce, et al, [op. cit.](#)

¹⁰⁰ 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.

¹⁰¹ Saito, et al., “[Copayment level and drug switching: findings for type 2 diabetes.](#)” *Am J Pharm Benefits*. 2010;2(6):412-420.

¹⁰² Eaddy, et al., “How patient cost-sharing trends affect adherence and outcomes—a literature review,” *Pharm Ther*. Jan. 2012;37(1):45-55.

¹⁰³ Chermew, et al., “Impact of decreasing copayments on medication adherence within a disease management environment,” *Health Aff (Millwood)*. 2008;27(1):103-112.

¹⁰⁴ Maciejewski, et al., “Copayment reductions generate greater medication adherence in targeted patients. *Health Aff (Millwood)*. 2010;29(11):2002-2008.

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 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.¹⁰⁵ 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.¹⁰⁶ 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.

Other PBM Tools That Manage Drug Utilization

Prior authorization is often used as a UM tool, but PBMs offer their clients other UM tools as well, including drug utilization review (DUR), refill-too-soon checks, and quantity limits.

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.¹⁰⁷ 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).¹⁰⁸ An opioid DUR program demonstrated a 28% reduction in potentially unsafe opioid use.¹⁰⁹ 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

¹⁰⁵ Pharmacy Benefit Management Institute, [op. cit.](#)

¹⁰⁶ Visante analysis of PBM Drug Trend Reports.

¹⁰⁷ Pharmacy Benefit Management Institute, [op. cit.](#)

¹⁰⁸ Moore, et al., "Systemwide effects of Medicaid retrospective drug utilization review programs," *J Health Polit Policy Law*. Aug. 2000;25(4):653-688.

¹⁰⁹ 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.

by 1%.¹¹⁰ 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.¹¹¹ A refill-too-soon alert is sent to the pharmacy if, say, a pharmacy dispenses a 30-day 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.¹¹² Research suggests that specific drug limits and general limitations can save up to 1% of drug expenditures.¹¹³ PBMs publish their standard lists of drugs and quantity limits, which are all very similar.¹¹⁴ We estimate that virtually all plan sponsors obtain savings of 1% (savings relative to drug expenditures without the use of quantity limits).

Potential Impact of State Legislation on Other Formulary and Utilization Management Programs

Impact of Fiduciary Mandate: Government policies such as fiduciary mandates would increase liability risks for PBMs and result in more limited use of formulary and UM programs. As these programs are scaled back, the range of savings would be compressed toward the low end of the current marketplace range, and thereby reduce the average. We predict that the range of formulary management savings would compress from 2% to 10% to 2% to 6%, with market average savings dropping from 6% to 4%. Savings from DUR programs would decrease from 3% to 7% to 3% to 5%, with the average savings cut from 5% to 4%. Again, these savings are all relative to drug expenditures in the absence of these PBM tools. Based on these reductions in average savings, projected drug expenditures would increase 3%. This estimated impact is only for lost savings related to formulary and UM, and does not include other cost impacts on savings from PA and ST discussed above.

Impact of Any Willing Specialty Pharmacy Legislation: The effectiveness of PA, ST, formulary management, and UM programs in managing specialty drug expenditures often hinges on active participation by specialty pharmacies. Specialty pharmacies have highly trained teams of pharmacists, nurses, and other experts to deliver advanced patient care services, customized for individual patients and individual drug therapies. Specialty pharmacy operations may be coordinated with a PBM's PA, ST, formulary, and UM programs, including special training, staff, and information systems. Any willing specialty pharmacy legislation would bring in specialty pharmacies that do not have specialized resources and expertise and are not coordinated with PBM programs. Therefore, the effectiveness of these PBM programs would be hampered. Without active participation by specialty pharmacies, the range of savings would be compressed toward the low end of the range and, assuming a normal distribution, thereby reduce the market average savings. The range of formulary management savings would decrease from 2% to 10% to 2% to 6%, with the market average savings dropping from 6% to 4%. Savings from DUR programs would decrease from a range of 3% to 7% to a range of 3% to 5%, with the average savings dropping from 5% to 4%. Again, these savings are all relative to drug expenditures in the absence of these PBM tools. This negative impact on PBM savings would be limited to specialty drug expenditures, which are expected to represent approximately 50% of projected drug expenditures during the next 10 years. Based on these reductions in average savings on specialty drug costs, overall projected drug expenditures (i.e., specialty and non-specialty) would increase 2.9%. This estimated impact is only for lost savings related to formulary and UM and does not include other negative impacts on savings from other PBM tools discussed above (e.g., specialty pharmacy, network discounts, PA, and ST).

Potential Impact of Fiduciary Mandates: Additional Costs of Liability Insurance

Requiring PBMs to owe a fiduciary duty to covered entities would expose PBMs to increased legal risk that may result in the need to adopt defensive business and operating strategies to avoid the threat of litigation. The added cost of increased insurance exposure could drive pharmaceutical costs higher. Operationally, we believe that an important

¹¹⁰ "Specialty Pharmacy: Historical Evolution and Current Market Needs," op. cit.

¹¹¹ Pharmacy Benefit Management Institute, [op. cit.](#)

¹¹² Pharmacy Benefit Management Institute, [op. cit.](#)

¹¹³ Visante analysis of PBM Drug Trend Reports.

¹¹⁴ Visante analysis of PBM published quantity limits.

impact of the legislation is to expose PBMs to legal liability for the drug benefits that they manage. PBMs would have to boost their liability insurance and might limit the use of utilization techniques to avoid potential lawsuits.

The most reliable data on medical liability insurance costs were published in 2010.¹¹⁵ These data suggested that total liability insurance costs for doctors and hospitals were approximately 1% of total U.S. expenditures for doctors and hospitals. We estimate that PBMs would be forced to purchase liability insurance that might be priced in a similar manner. Therefore, we apply the same ratio to PBMs and drug expenditures (i.e., additional PBM liability insurance costs will be approximately 1% of covered drug expenditures). In other words, projected drug expenditures would increase 1%. This estimated impact is only for the additional cost of liability insurance and does not include other cost impacts on savings from other PBM tools discussed above.

We interviewed a number of legal experts who believe that this methodology is reasonable. However, given the limited information available, it probably understates the potential cost of additional insurance, particularly since this would be a new type of insurance coverage and thus carry additional risk and additional price premiums from liability insurers.

In addition, fiduciary mandates would result in additional costs from administering benefits under a patchwork of varying legal requirements across states. Additional costs and risks could result from private actions for damages by a client or a consumer, as a result of a “fiduciary” label. All those costs would be passed back inevitably to the plan sponsors, but we are unable to specifically estimate these potential costs. Therefore, we believe our estimates for both insurance and other costs associated with fiduciary requirements are conservative and understated.

Summary: Potential Impact of State Legislation on PBM Tools and Savings

The table below summarizes which PBM tools would be negatively affected by four types of state legislation.

| PBM Tools/Impact | Disclosure Mandate | Fiduciary Mandate | Prohibit PA and ST | Any Willing Specialty Pharmacy |
|--|---------------------------|--------------------------|---------------------------|---------------------------------------|
| Manufacturer rebates | ✓ | | | |
| Pharmacy network contract discounts | ✓ | | | ✓ |
| PA and ST | | ✓ | ✓ | ✓ |
| Other PBM tools that improve formulary performance | | ✓ | | ✓ |
| Other PBM tools that manage utilization | | ✓ | | ✓ |
| Additional liability insurance | | ✓ | | |
| Increase in projected drug expenditures | 5.6% | 6.75% | 6.75% | 3.4% |

B. Projected Drug Expenditures (2021 to 2030) and State-by-State Breakdowns

To derive baseline drug expenditures managed using PBM tools, Visante began with CMS National Health Expenditure (NHE) projections for outpatient prescription drug expenditures from 2021 to 2028. These expenditures do not include drugs administered in hospitals or physician offices. Visante extrapolated these projections to 2029 and 2030. By these estimates, spending on outpatient prescription drugs will grow from \$376 billion in 2021 to \$621 billion in 2030, for a total of almost \$5 trillion over the 10-year period.¹¹⁶

¹¹⁵ Mello, et al., “National costs of the medical liability system,” *Health Aff (Millwood)*. 2010;29(9):1569-1577.

¹¹⁶ National Health Expenditure Data (2021 to 2028 data extrapolated to 2030), CMS.

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 outpatient drug expenditure projections reflect net costs to payers, including plan sponsors and consumers. Manufacturer and pharmacy discounts are reflected in CMS figures. CMS segments outpatient prescription drug expenditures by payer, including private insurance, Medicare, Medicaid, and other government programs. Visante assumes that nearly all commercial/private insurer expenditures are associated with the use of PBM tools. Visante also estimated the share of consumer out-of-pocket expenditures arising from copayments/cost sharing for prescriptions associated with PBMs and PBM tools, based on survey data for commercial plan sponsors.^{117,118}

After these calculations, we estimate that outpatient prescription drug expenditures for the commercial market (associated with average use of PBM tools, including plan sponsor and consumer payments) will be approximately \$172 billion in 2021 and \$2.1 trillion over the 10-year period 2021 to 2030. Drug expenditures for the fully insured portion of the commercial market will be \$83 billion in 2021 and more than \$1 trillion over the 10-year period from 2021 to 2030.

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 pharmacy benefit managers have increased sharply in the past few years and have dampened prescription drug spending growth.¹¹⁹ 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. Our modeling assumes no significant changes to rebates in the future, although there are currently proposals that could result in significant changes, such as elimination of the rebate safe harbor in Medicare Part D,

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 rapidly.¹²⁰ The generic dispensing rate was 85.6% in 2018¹²¹ and will grow slowly.¹²² 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 total specialty drug revenues increasing from 35% of total in 2018 to 44% in 2023.¹²³ Most observers project that the specialty pharmacy market will grow much more rapidly than will the market for traditional prescription drugs.¹²⁴ We estimate the total specialty share of drug expenditures under the pharmacy benefit growing from 41% in 2021 to 61% in 2030. 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.

¹¹⁷ “[2019 employer health benefits survey](#),” Kaiser Family Foundation, Sept. 2019.

¹¹⁸ Pharmacy Benefit Management Institute, [op. cit.](#)

¹¹⁹ Cuckler, et al., “[National health expenditure projections, 2017–26: despite uncertainty, fundamentals primarily drive spending growth](#),” *Health Aff (Millwood)*, 2018;37(3).

¹²⁰ Drug Trend Reports from CVS Health, Express Scripts, and Prime Therapeutics.

¹²¹ IQVIA Institute, “unbranded generics,” [op. cit.](#)

¹²² IQVIA and PBM Drug Trend Reports.

¹²³ “[2019 economic report on pharmacies and pharmacy benefit managers](#),” Pembroke Consulting, Mar. 2019.

¹²⁴ Drug Trend Reports from CVS Health, Express Scripts, and Prime Therapeutics.

We created a state-by-state breakdown for the national projected drug expenditures for the fully insured commercial population (which includes fully insured employer-sponsored plans and individually purchased insurance both within and outside health exchanges). 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, and Medicaid based on a number of published references.^{125,126,127,128,129,130,131,132}

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.

¹²⁵ [US Census, 2018.](#)

¹²⁶ [US Census - Health Insurance in the United States: 2018- Number and Percentage of People Without Health Insurance Coverage by State: 2017 to 2018](#)

¹²⁷ [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.

¹²⁸ 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.

¹²⁹ [Marketplace Enrollment, 2019](#), Kaiser Family Foundation.

¹³⁰ [Medicare Enrollment: CMS Medicare Advantage \(MA\) / Part D Contract and Enrollment Data, Monthly Enrollment by Contract/Plan/State/County](#) November 2019.

¹³¹ [Medicaid Enrollment Nov 2019: Monthly Medicaid and CHIP Application, Eligibility Determination, and Enrollment Reports](#), from Medicaid.gov.

¹³² [MACStats: Medicaid and CHIP Data Book](#), Medicaid and CHIP Payment and Access Commission, December 2018.

Appendix: Ten-Year Cost of Proposals Impacting PBM Tools by State, 2021-2030

| <i>Fully Insured Commercial Sector Only</i> | | <i>Potential PBM Savings Lost (millions, 2021-30)</i> | | | |
|---|---|---|----------------------------------|---|---|
| State | Beneficiaries in Fully Insured Plans | Cost of Disclosure Mandate | Cost of Fiduciary Mandate | Cost of Prohibition on PA and ST | Cost of Any Willing Specialty Pharmacy |
| Alabama | 1.1 million | \$724 million | \$867 million | \$867 million | \$433 million |
| Alaska | 134,000 | \$88 million | \$106 million | \$106 million | \$53 million |
| Arizona | 1.2 million | \$807 million | \$1.0 billion | \$966 million | \$483 million |
| Arkansas | 483,000 | \$317 million | \$379 million | \$379 million | \$190 million |
| California | 9.6 million | \$6.3 billion | \$7.6 billion | \$7.6 billion | \$3.8 billion |
| Colorado | 1.1 million | \$705 million | \$0.8 billion | \$0.8 billion | \$422 million |
| Connecticut | 0.7 million | \$463 million | \$554 million | \$554 million | \$277 million |
| Delaware | 154,000 | \$101 million | \$121 million | \$121 million | \$60 million |
| District of Columbia | 172,000 | \$113 million | \$135 million | \$135 million | \$68 million |
| Florida | 3.5 million | \$2.3 billion | \$2.8 billion | \$2.8 billion | \$1.4 billion |
| Georgia | 1.9 million | \$1.2 billion | \$1.5 billion | \$1.5 billion | \$0.7 billion |
| Hawaii | 496,000 | \$325 million | \$390 million | \$390 million | \$195 million |
| Idaho | 342,000 | \$224 million | \$269 million | \$269 million | \$134 million |
| Illinois | 2.8 million | \$1.8 billion | \$2.2 billion | \$2.2 billion | \$1.1 billion |
| Indiana | 1.3 million | \$844 million | \$1.0 billion | \$1011 million | \$505 million |
| Iowa | 535,000 | \$351 million | \$420 million | \$420 million | \$210 million |
| Kansas | 638,000 | \$419 million | \$501 million | \$501 million | \$251 million |
| Kentucky | 0.6 million | \$391 million | \$468 million | \$468 million | \$234 million |
| Louisiana | 0.9 million | \$597 million | \$714 million | \$714 million | \$357 million |
| Maine | 338,000 | \$222 million | \$265 million | \$265 million | \$133 million |
| Maryland | 1.3 million | \$0.9 billion | \$1.0 billion | \$1.0 billion | \$522 million |
| Massachusetts | 1.9 million | \$1.2 billion | \$1.5 billion | \$1.5 billion | \$727 million |
| Michigan | 1.9 million | \$1.3 billion | \$1.5 billion | \$1.5 billion | \$0.8 billion |
| Minnesota | 1.0 million | \$680 million | \$0.8 billion | \$814 million | \$407 million |
| Mississippi | 553,000 | \$363 million | \$435 million | \$435 million | \$217 million |
| Missouri | 1.3 million | \$0.8 billion | \$1.0 billion | \$1.0 billion | \$507 million |
| Montana | 161,000 | \$106 million | \$127 million | \$127 million | \$63 million |
| Nebraska | 340,000 | \$223 million | \$267 million | \$267 million | \$134 million |
| Nevada | 631,000 | \$414 million | \$496 million | \$496 million | \$248 million |
| New Hampshire | 312,000 | \$205 million | \$245 million | \$245 million | \$123 million |
| New Jersey | 2.0 million | \$1.3 billion | \$1.5 billion | \$1.5 billion | \$0.8 billion |
| New Mexico | 317,000 | \$208 million | \$249 million | \$249 million | \$124 million |
| New York | 4.0 million | \$2.6 billion | \$3.1 billion | \$3.1 billion | \$1.6 billion |
| North Carolina | 1.4 million | \$0.9 billion | \$1.1 billion | \$1.1 billion | \$0.6 billion |
| North Dakota | 142,000 | \$93 million | \$112 million | \$112 million | \$56 million |
| Ohio | 1.6 million | \$1.1 billion | \$1.3 billion | \$1.3 billion | \$0.6 billion |
| Oklahoma | 0.7 million | \$442 million | \$529 million | \$529 million | \$264 million |
| Oregon | 1.0 million | \$654 million | \$0.8 billion | \$782 million | \$391 million |
| Pennsylvania | 2.8 million | \$1.9 billion | \$2.2 billion | \$2.2 billion | \$1.1 billion |
| Rhode Island | 233,000 | \$153 million | \$183 million | \$183 million | \$92 million |
| South Carolina | 0.8 million | \$520 million | \$0.6 billion | \$622 million | \$311 million |
| South Dakota | 191,000 | \$125 million | \$150 million | \$150 million | \$75 million |
| Tennessee | 1.2 million | \$0.8 billion | \$1.0 billion | \$1.0 billion | \$489 million |
| Texas | 5.3 million | \$3.4 billion | \$4.1 billion | \$4.1 billion | \$2.1 billion |
| Utah | 0.7 million | \$444 million | \$532 million | \$532 million | \$266 million |
| Vermont | 111,000 | \$73 million | \$87 million | \$87 million | \$44 million |
| Virginia | 1.9 million | \$1.2 billion | \$1.5 billion | \$1.5 billion | \$0.7 billion |
| Washington | 1.6 million | \$1.1 billion | \$1.3 billion | \$1.3 billion | \$646 million |
| West Virginia | 266,000 | \$175 million | \$209 million | \$209 million | \$105 million |
| Wisconsin | 1.2 million | \$786 million | \$0.9 billion | \$0.9 billion | \$471 million |
| Wyoming | 108,000 | \$71 million | \$85 million | \$85 million | \$43 million |