



**Proposed New York Legislation
Could Increase Prescription Drug Costs
\$6 Billion Over 10 Years**

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Executive Summary

In New York, the State Senate and the State Assembly are considering legislation that if enacted into law would raise prescription drug costs in the state by billions of dollars over the next decade and reduce the quality of care for patients taking specialty medications for conditions such as multiple sclerosis, hepatitis C, and rheumatoid arthritis. These bills effectively exempt retail pharmacies from meeting the same safety and performance standards—contractual *terms and conditions*—that health plans require of mail-service and specialty pharmacies.

Visante analyzed the potential cost impact of S.2530 and A.6194 based on the legislation's likely impact of reducing the ability of plans to negotiate effective pharmacy network contracts in New York. Visante projects significant costs associated with this legislation.

Major Findings:

- If enacted, the legislation could increase prescription drug costs and related medical costs in New York by close to \$400 million in 2016. Over 10 years, the estimated cost could be more than \$6 billion.
- The legislation would raise costs and undermine care in New York by exempting retail pharmacies from meeting standards related to credentialing, drug utilization evaluation activities, clinical prior authorization, quality-of-care reviews, and formulary compliance.
- By reducing the effectiveness of pharmacy network contracts, the legislation is not likely to result in a rush of drugstores offering new price concessions, but rather the undermining of the current price concessions offered by mail-service and specialty pharmacies, which are based on superior economies of scale and performance in areas such as formulary compliance.

The major findings above are based on a 2013 analysis by the Centers for Medicare and Medicaid Services (CMS) found that mail-service prescriptions are an average of 16% lower than to the same prescriptions filled at retail pharmacies. The proposed legislation would take away the ability of mail-service pharmacies to continue to provide such savings. Likewise, specialty pharmacies have demonstrated average savings of 10% on drug costs and substantial savings on non-drug medical costs compared to retail pharmacies. The legislation would put these savings at risk.

Discussion

Mail-service pharmacies and specialty pharmacies are widely utilized by pharmacy benefit managers, health insurance companies, and plan sponsors to help manage prescription drug costs and improve quality of care. Much of these savings are derived from competitive pricing (i.e., lower prices for greater volume) and economies of scale (i.e., greater efficiencies with greater volume).

The Federal Trade Commission (FTC) reinforced these basic concepts in a letter to New York in 2011, which essentially states that reducing the effectiveness of pharmacy network contracts would result in increased costs to consumers and plan sponsors. In the words of FTC:

“By restricting a health plan’s ability to offer favorable treatment to a low cost mail order pharmacy, the Bill undercuts pharmacies’ incentives to bid aggressively for a share of that health plan’s business. Reducing those incentives is likely to raise the prices that consumers pay for the prescription drugs that their health plans cover. Some cost increases may be passed on to plan beneficiaries in the form of higher out-of-pocket prices.”¹

Proposed Legislation Would Exempt Retail Pharmacies from Key Safety and Performance Standards and Reduce the Effectiveness of Pharmacy Network Contracts

Current New York law requires that if a retail pharmacy agrees to the same reimbursement rate and—importantly—the same contractual *terms and conditions* as a mail-service pharmacy or other non-retail pharmacy, an insurer shall permit any covered prescription to be filled at that retail pharmacy and cannot impose a differential co-payment on the insured consumer if they elect to do so. The proposed state legislation would delete the key *terms and conditions* requirement. This would effectively exempt retail pharmacies from meeting the same safety and performance standards that plans require of mail-service and specialty pharmacies. In turn, this would effectively expand the applicability of New York’s current law, which would undermine volume-based pharmacy price concessions and substantially raise costs for both consumers and health plan sponsors.

How Contractual Terms and Conditions Enhance Pharmacy Safety and Performance

Terms and conditions in a typical pharmacy provider agreement relate to credentialing, drug utilization evaluation activities, clinical prior authorization requirements, quality-of-care reviews, formulary compliance, grievance resolution procedures, and other processes. Standards for these areas can differ greatly when a traditional retail drugstore is compared to a highly-automated mail-service pharmacy or a highly-credentialed specialty pharmacy.

¹ Letter to NY State Senator James Seward from the Federal Trade Commission’s Office of Policy Planning, Bureau of Competition, and Bureau of Economics. Response to request for comments on the likely competitive effects of New York Assembly Bill 5502-B, August 8, 2011.

For example, specialty pharmacies must meet many requirements to effectively handle injectable biologic medications that require refrigeration and can cost many thousands of dollars per dose. These requirements include:

- Providing round-the-clock access to pharmacists, nurses and clinicians dedicated to and specially trained with respect to the disease state treated by the drug, the specialty drug, and the drug's potential side effects
- Adhering to rigorous storage, shipping and handling standards to meet product label shipping requirements, such as temperature control, and timely deliveries of the product in optimal condition
- Performing disease-specific and drug-specific patient care management services that meet the unique needs of each patient and that incorporate multiple safeguards when dispensing and delivering the drug to ensure patient safety
- Collecting data and tracking outcomes for specific patients as required
- Managing compliance and persistency of drug regimens for patients
- Managing care within manufacturer Risk Evaluation and Mitigation strategies (REMS) program requirements, including REMS reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling

If the proposed legislation to remove the terms and conditions requirement were to pass, many retail pharmacies ill-equipped to handle any of these requirements would likely try to dispense specialty medications, which would likely reduce quality-of-care and increase non-drug medical costs, as well as compromise patient safety, which REMS are designed to address. This likely outcome is consistent with a recent national survey of 500 physicians who prescribe specialty medications which found that just 5% believed that all drugstores “have the expertise and capability to provide the different types of specialty medications to patients.”²

Likewise, high-volume mail-service pharmacies must meet a plan's performance requirements in areas related to dispensing accuracy, generic dispensing, formulary compliance, patient counseling, and prescription adherence programs. Exempting retail pharmacies from meeting these plan requirements would also result in higher costs and reduced quality of care.

Current Savings from Mail-Service and Specialty Pharmacies

A cost analysis conducted by CMS in 2013 compared mail-service pharmacies to retail pharmacies in Medicare Part D. The agency found that costs at mail-service pharmacies were 16% less than retail pharmacies across all drugs examined.³ Many studies have also shown improved patient adherence to prescription regimens with mail-service pharmacies.^{4,5,6,7}

² North Star Opinion Research, “Key Findings from the Survey of Oncologists, Neurologists, Rheumatologists, Nephrologists, and Infectious Disease Specialists Regarding Access to Specialty Medications, November 6-20, 2013.

³ Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies. Centers for Medicare and Medicaid Services, December 2013. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf>

⁴ Schmittiel et al., “Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes,” *Am J Manag Care*. 2013;19(11):882-887.

Specialty pharmacy savings could also be affected by the proposed amendment to New York's insurance law. 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.⁸ Other studies have demonstrated that specialty pharmacies save 13-23% on drug costs.^{9, 10}

Specialty pharmacies have demonstrated significantly improved patient adherence and reduced medical costs for many types of patients, including HIV, hepatitis C, cancer, transplant and multiple sclerosis.^{11, 12, 13, 14, 15, 16, 17, 18}

Impact of Proposed Legislation on Prescription Costs in New York

By eroding the effectiveness of pharmacy network contracts, the proposed state legislation is likely to substantially increase costs to consumers and plan sponsors. The effect of the legislation would not likely be a rush of retail pharmacies offering new price concessions to compete with mail-service and specialty pharmacies, but rather the undermining of price concessions offered by mail-service and specialty pharmacies based on superior economies of scale and performance in areas such as formulary compliance.

Methodology and Estimates

⁵ Zhang, L et al., "Mail-Order Pharmacy Use and Medication Adherence among Medicare Part D Beneficiaries with Diabetes," *Journal of Medical Economics*, October 2011.

⁶ Hermes M., et al., "Adherence to Chronic Medication Therapy Associated with 90-Day Supplies Compared with 30-Day Supplies," *Journal of Managed Care Pharmacy*, 2010, 16:141-142.

⁷ Duru, K et al., "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," *The American Journal of Managed Care*, January, 2010.

⁸ Kaiser Commission on Medicaid and the Uninsured, "Managing Medicaid Pharmacy Benefits: Current Issues and Options," September 2011.

⁹ Medco Health Solutions, "Specialty Pharmacy: Future Evolution of Service and Value," Presented at PCMA Specialty Pharmacy Symposium, May 2008.

¹⁰ 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.

¹¹ Miller S., "Personalizing the Specialty Business. Presentation at the PCMA Specialty Pharmacy Business Forum," April 04, 2012.

¹² Visaria J and Frazee S., "Role of Pharmacy Channel in Adherence to Hepatitis C Regimens," *Am J Pharm Benefits*. 2013;5(1):17-24.

¹³ Tang J, and Faris R., "Exploring the Impact of Dispensing Channel on Medication Adherence Among Multiple Sclerosis Patients," Presented at the 14th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), May 2009.

¹⁴ 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):479-86.

¹⁵ Tan et al., "Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis," *Adv Ther*. 2011 Jan;28(1):51-61.

¹⁶ Specialty Pharmacy News, June 2013, Volume 10, Number 6.

¹⁷ Tschida et al., "Outcomes of a Specialty Pharmacy Program for Oral Oncology Medications," *Am J Pharm Benefits*. 2012;4(4):165-174.

¹⁸ 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

This economic analysis assumes that the proposed amendment to NY insurance law (*i.e.*, *deleting the requirement that the pharmacy has to agree to the same terms and conditions as mail-service or other non-retail pharmacies*) would effectively eliminate the savings currently being generated by mail-service pharmacies and specialty pharmacies for the commercial fully insured and individual markets impacted by the legislation. The following important assumptions were also incorporated into the analysis:

- CMS findings that prescriptions filled at mail-service pharmacies cost 16% less than the same prescriptions filled at retail pharmacies.¹⁹
- Visante estimates that specialty pharmacies save 10% of specialty drug costs vs. retail pharmacies, plus an equal amount of “non-drug medical/hospital cost savings.”
- The proposed amendment will affect commercial fully insured and individual insurance but not self-insured commercial insurance, Medicare, or Medicaid.

Applying these assumptions to create an estimated cost of the Legislation

1. Total U.S. outpatient prescription drug expenditures for 2016 are projected to be \$325 billion,²⁰ with \$234 billion being traditional (non-specialty) prescription drugs and \$91b being specialty medications.²¹ For the 10 year period 2016-25, total outpatient drug expenditures are estimated at \$4.2 trillion, with \$2.6 trillion in spending on traditional medications and \$1.6 trillion in spending on specialty medications.
2. The projected expenditures for specialty medications above capture only the approximate 50% of specialty expenditures that flow through the pharmacy benefit (potentially available for retail pharmacies). The other 50% flow through the medical benefit (physician offices, clinics, hospitals).²²
3. Nationally, approximately 13% of traditional outpatient drug expenditures flows through mail-service pharmacies in the commercial/private insurance market.²³
4. NY accounts for approximately 6.5% of U.S. drug expenditures, and 26% is in the commercial fully insured and individual insurance markets that would be impacted by the legislation.^{24 25 26}

¹⁹ Centers for Medicare and Medicaid Services, “Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies,” December 2013. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf>

²⁰ CMS National Health Expenditures (NHE), Prescription Drugs, Projected 2015, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>

²¹ Visante estimate based on published data from IMS Health and PBM Drug Trend Reports

²² EMD Serono Specialty Digest™, 7th edition

²³ IMS Health, Channel Distribution by Non-Discounted Spending (U.S.) http://www.imshealth.com/depoyedfiles/imshealth/Global/Content/Corporate/Press%20Room/2012_U.S./Channel_Distribution_by_Non-Discounted_Spending_U.S.pdf

²⁴ US Census 2013 <http://www.census.gov/popest/data/state/totals/2013/index.html>

²⁵ Kaiser Family Foundation, Health Insurance Coverage of the Total Population 2014, <http://kff.org/other/state-indicator/total-population/#>

5. Therefore, the subset of drug expenditures in New York in 2016 that could potentially be affected by this legislation is \$500 million (\$5.8 billion over 10 years) for traditional non-specialty mail-service and \$1.5 billion for specialty pharmacy (\$27 billion over 10 years). These sum to \$2 billion in combined traditional and specialty expenditures potentially impacted by the New York legislation in 2016, and \$33 billion over 10 years.
6. Potential “Lost Savings” from Mail-Service Pharmacy and Specialty Pharmacy
 - a. Mail-Service: Estimated savings of 16% = \$82 million in 2016 (\$0.9 billion over 10 years).
 - b. Specialty: Estimated savings of 10% drug spend (\$154m in 2016, \$2.7b over 10 years) + equal amount medical offset (\$154m in 2016, \$2.7b over 10 years) = \$308m in 2016 (\$5.4 billion over 10 years).
 - c. Therefore, total potential “annual cost” of the legislation (based on “lost savings”) could be up to \$390 million in 2016 or \$6.3 billion over 10 years.

²⁶ MEPS, Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and State: United States, 2013
http://meps.ahrq.gov/mepsweb/data_stats/summ_tables/insr/state/series_2/2013/tiib2b1.htm