NATIONAL CENTER FOR POLICY ANALYSIS

New Drug Plan Regulations Protect Pharmacies, Harm Consumers

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Compared to hospital and physician care, drug therapy is by far the most cost-effective way to treat most diseases and health conditions. Americans spend twice as much for physician care and three times as much on hospital care as they do for drugs. And drug therapy often eliminates, lessens or delays the need for more invasive treatments such as surgery or inpatient care.

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Executive Summary

Drug plans and drug benefits have become widespread. An estimated 220 million Americans obtain their drugs through a managed plan. Some drug plans are integrated with health coverage, while others — such as the Medicare Part D plans — are stand-alone plans. Drug plans use a variety of techniques to control costs. Large national pharmacy benefit managers (PBMs) are able to negotiate lower prices from manufacturers because they have multiple clients, and therefore possess far more bargaining power than individual firms. PBMs also negotiate with pharmacies, and assemble networks of preferred pharmacies willing to provide the most value for consumers' dollars. The process is highly competitive: PBMs compete for the rights to manage health plan members' drug benefits; drugstores compete to attract drug plan members needing a prescription filled; drug makers compete to ensure their drugs go into members' prescription pill bottles. The process is also often antagonistic — involving intense negotiation, competitive bidding and fierce price competition.

The degree to which drug benefits are managed efficiently has significant effects on consumers' cost-sharing and premiums. For most Americans, a trip to the pharmacy incurs little out-of-pocket cost:

- One-fourth (23 percent) of retail prescriptions are fully covered by insurers and require no copayment by the patient.
- An additional one-third (34 percent) cost the patient $5 or less.
- The cost-sharing for more than three-fourths of prescriptions (78.6 percent) is $10 or less.

Considering the benefits of safe and affordable prescription drugs, lawmakers are unwise to impose stifling regulations on drug plans, boosting costs to consumers and employers. These regulatory initiatives purportedly "protect consumers," but are actually designed to protect local pharmacies from competition. State regulations reducing competition often boost the profits of local stakeholders. These profits generally come at the expense of insurers, employers, pharmacy benefit managers and consumers.

Drug Plan Regulations Harm Consumers

Harmful Drug Plan Regulations. PBMs reduce premiums by contracting with qualified pharmacies offering competitive prices. Pharmacies and other suppliers excluded from the network (due to price or quality considerations) lobby sympathetic politicians to force PBMs, health plans, drug plans and insurers to do business with noncompetitive pharmacies, which increases costs to consumers. Recent legislative proposals — some that passed and some that didn't — would weaken or prohibit these agreements health plans negotiate with pharmacy networks.

These regulations have tilted the playing field further away from free market competition and are likely to continue. Failed legislative agendas designed to benefit special interests have a way of coming back year after year. Some examples of bad regulations include:

Banning Preferred Pharmacy Networks. Increasingly, drug plans have experimented with exclusive or "preferred" pharmacy networks as leverage to negotiate lower drug prices from pharmacies competing to become exclusive network drug providers. The Federal Trade Commission (FTC) has argued time and time again — in numerous reports and opinions issued on specific state proposals — that *any willing pharmacy* laws banning such networks lead to higher drug prices and higher premiums.

Limiting Mail-Order Pharmacies. One self-serving regulation that harms consumers is designed to protect local pharmacies from having to compete with highly efficient mail-order pharmacies. These restrictions often prohibit drug plans from offering members a financial incentive (a discount) for using a health plan's preferred pharmacy or its mail-order option.

Inhibiting Specialty Networks. Highly advanced specialty drugs and biological agents are supplanting the pills, capsules and elixirs Americans relyied on during the past century. Specialty drugs are very expensive, costing thousands to tens of thousands of dollars per month — creating a gold rush among firms vying to provide these lucrative services.

Well-managed, exclusive specialty pharmacy networks allow manufacturers to track drugs that require specific or complex dosing and laboratory monitoring. FDA monitoring requirements favor tightly controlled networks for safety reasons. Moreover, the Federal Trade Commission (FTC) agrees exclusive networks are an effective means of cost control. Regulations that inhibit drug plans from establishing highly efficient, preferred specialty networks also make it more difficult to ensure the integrity of these drugs.

Obstructing Competitive Bidding. With the cost of advanced therapies growing to previously unimaginable levels, health plans and PBMs have increasingly turned to competitive bidding in order to negotiate better deals with drug makers and retail pharmacy chains. This often means the lowest bidder of a competitive auction wins the near-exclusive right to dispense a particular medication. And in a healthy marketplace, competition for a coveted place on a formulary encourages bidders to offer their best deals — to avoid the loss of potentially lucrative business.

Drug benefits managed efficiently help make most medications affordable to most patients. Blatant protectionism through restrictive drug plan regulations may be touted as consumer protections, but more often than not they benefit local pharmacy service providers at the expense of consumers.

About the Author

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Introduction

Three-fourths of physician visits in the United States result in prescription drug therapy.[1] Drug plans cover much of these costs, and patients typically pay only about 14 percent out of pocket, on average.[2]

Health coverage with integrated drug benefits has become widespread, as have the calls on state lawmakers to impose stifling regulations on drug plans and the firms that manage them.

These regulatory initiatives purportedly "protect consumers," but are actually designed to protect local pharmacies from competition. In the process, these regulations intentionally weaken the ability to efficiently manage prescription drug benefits.

Drug manufacturers, retail pharmacies that dispense drugs to patients, and firms that manage drug benefits — all compete for the right to serve health plan members. State regulations reducing competition in favor of local interests often boost the profits of local pharmacies (and sometimes drug makers). But these profits generally come at the expense of insurers, employers, pharmacy benefit managers and consumers.

Background. Compared to hospital and physician care, drug therapy is by far the most cost-effective way to treat most diseases and health conditions. Consider: Americans spend twice as much on physician care (often simply to obtain a prescription) as they do on drugs, and three times as much on hospital care.[3] [See Figure I.]

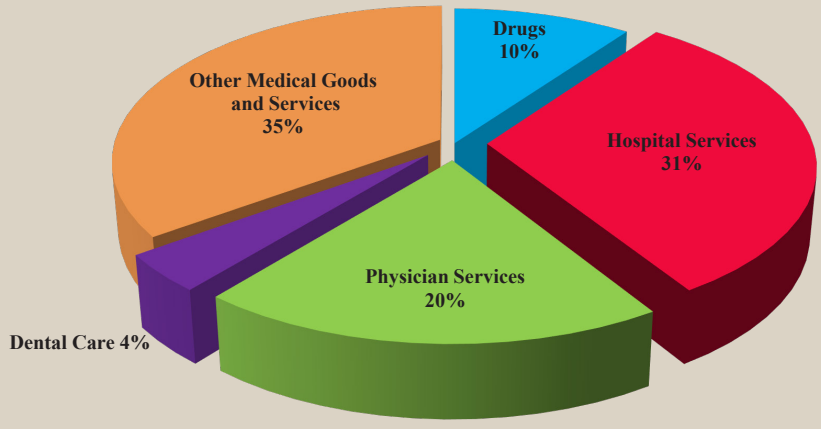
- More than 60 percent of Americans take a prescription drug in any given year, including 90 percent of all seniors.[4]
- An estimated 3.9 billion retail prescriptions were filled in 2013 — about 12 per person in the United States, on average.[5]
- U.S. residents spend about $329 billion annually on prescription therapies,[6] a significant increase from the $40 billion spent on prescriptions just over two decades ago.[7]
- Americans consume an additional $36 billion in nonprescription medications each year.[8]

Drugs represent the greatest bargain in the U.S. health care system. Drug therapy often eliminates, lessens or delays the need for more invasive treatments such as surgery or inpatient care. Drugs are also convenient. Most patients prefer medication over surgery to treat significant health problems.

Drug Plans Benefit Consumers. Nowadays most health plans include some drug benefits. An estimated 70 percent of Americans belong to a drug plan, and relatively few patients are unable to afford their medications. According to industry data, nearly one-fourth (23 percent) of retail prescriptions are fully covered by insurers and require no copayment by the patient. An additional one-third (34 percent) cost the patient $5 or less. And three-fourths (78.6 percent) cost the patient $10 or less.[9] [See Figure II.]

Why is drug therapy so affordable for most American consumers — including seniors with multiple prescriptions? Arguably, much of the reason has to do with competition. [See the sidebar: "Competition Benefits Consumers."] Health plan sponsors often employ PBMs, large

Figure I
Drug Spending as a Proportion of All Health Care Expenditure
(2012)



Source: "National Health Expenditures by Type of Service and Source of Funds, CY 1960-2012," Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services, page last modified January 7, 2013. Available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE201.zip

firms that specialize in designing and managing drug benefits. Drug plan sponsors — including insurers, employers, Medicare Part D drug plans and many state Medicaid programs — contract with PBMs because these specialized firms work more efficiently than health insurers or employers alone.

PBMs use a variety of techniques to control costs for their clients and enrollees. With multiple clients, large national PBMs can negotiate lower prices from manufacturers, and therefore possess far more bargaining power than individual firms. They also negotiate with pharmacies and build preferred pharmacy networks.

A health plan responsible for reimbursing health care providers has an incentive to encourage the use of appropriate drugs, because skimping on drug therapies often leads to higher medical costs. Thus, it makes sense for health plans to coordinate with PBMs to manage chronic diseases, to analyze the effectiveness of drugs and to track patient compliance.[10] PBMs also consult with health plan sponsors to determine which drug therapies to include in their formularies, and to encourage enrollees to use cost-effective alternatives. Within the same therapeutic class, multiple drugs with vastly different costs may be available. They also check for drug interactions and inappropriate or duplicate prescriptions. Finally, PBMs assemble pharmacy networks, contract with mail-order pharmacies and process payments.

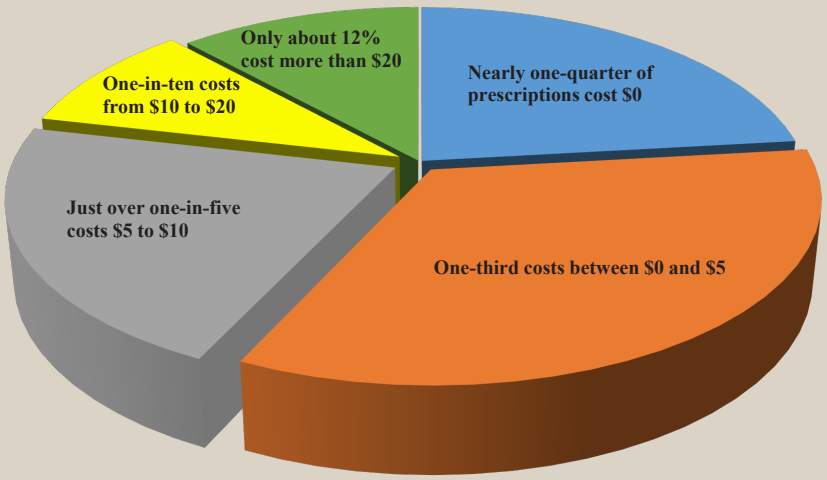
Harmful Drug Plan Regulations

Health plans reduce premiums by contracting with qualified pharmacies offering competitive prices. Pharmacies and other suppliers excluded from the network (due to price or quality considerations) lobby sympathetic politicians to force employee health plans, PBMs and insurers to do business with them — boosting costs to consumers. Recent legislative proposals — some that were passed and some that were not — would weaken or prohibit the agreements PBMs negotiate with pharmacy networks.[11]

During a flurry of industry lobbying and ill-advised legislative activity in recent years:

- In early 2014, the Centers for Medicare and Medicaid Services proposed a ban on exclusive "preferred networks," where seniors are offered lower cost-sharing in return for patronizing a preferred pharmacy network. Many industry observers believed the proposal was due to lobbying by pharmacy trade groups that preferred to avoid competitive bidding for inclusion as a network provider.[12]
- The state of California debated and narrowly avoided perverse regulations in 2014. Assembly Bill 2418 would have forced health plans to use unqualified pharmacies to administer the most advanced, specialty drug therapies and made it harder to offer discounts for mail-order drug delivery to enrollees' homes.
- The New York State legislature was debating similar bills (S.3995-B and A.5723-B) in committee when the 2014 legislative session ended.
- In early 2015, Colorado Senate bill 15-123 was introduced to prohibit PBMs from offering financial incentives (for instance, lower-cost sharing)

Figure II
What Americans Pay for a Prescription



Source: "Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013," IMS Institute for Healthcare Informatics, April 2014.

to fill costly specialty drugs at designated network pharmacies or mail-order pharmacies.[13]

Had they passed, these proposals would have driven up consumer costs. The consulting firm Visante estimated the regulatory changes proposed in California would have cost residents nearly $1.8 billion in 2015 — a 10-year cost of $31 billion.[14] Similar regulations would have cost New Yorkers nearly $392 million a year, climbing to $6 billion over a decade.[15]

These legislative cash-grabs began as early as 2011, when a Mississippi initiative transferred regulatory authority over PBMs and drug plans from the state insurance commissioner to the board of pharmacy. State pharmacy boards are generally composed of pharmacists or pharmacy trade association members who sympathize with local pharmacy interests over health plans, PBMs and consumers.[16] A similar initiative failed a year later in Oregon.[17] In a February 2015 ruling, the U.S. Supreme Court recognized that state regulatory boards sometimes become captives of the industry they regulate. This means such boards' decisions reflect the interests of the industry rather than the public. These captured regulatory bodies often exceed their legislative mandate. In *North Carolina State Board of Dental Examiners v. Federal Trade Commission*, the Supreme Court found that when boards are not adequately supervised by the legislature, their actions often diminish competition. This is further evidence that extending authority over drug plans and pharmacy benefit managers to state pharmacy boards is a bad idea. The Federal Trade Commission (FTC) holds the same opinion. However, since 2012, many poorly-conceived pharmacy regulations have passed in Arkansas,[18] Pennsylvania,[19] New York State[20] and numerous other states.[21]

The backers of the California and New York State initiatives insisted the proposals would protect consumers, but in fact, they would have had the opposite effect. Indeed, the regulations would have tilted the playing field away from healthy competition and toward protecting local businesses. And these kinds of

Success of Medicare Part D

Approximately 36 million seniors and disabled individuals are enrolled in drug plans known as Medicare Part D. Satisfaction with these drug plans averages about 90 percent to 95 percent.

Medicare drug plans vigorously compete for seniors' patronage. Under the Medicare Modernization Act of 2003, the plans use a variety of techniques to keep premiums affordable, including tiered formularies, preferred pharmacy networks and mail-order drug suppliers. PBMs negotiate prices with drug manufacturers and distributors, and contract with pharmacy network providers to secure seniors the lowest possible drug prices.

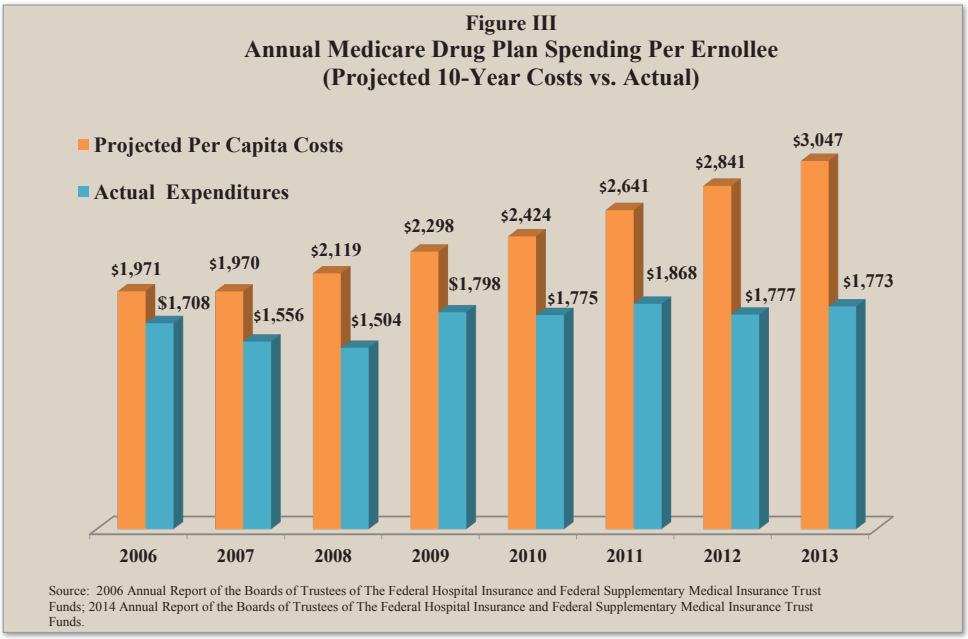
Though subsidized by Medicare, the premiums seniors pay are a function of the plan they choose — and ultimately of total program expenditures. Premiums have remained relatively stable because competition among drug plans has kept spending far lower than projected. As Figure III shows:

- Nearly a decade ago, the Medicare Trustees projected the per capita cost of Medicare drug benefits would be $1,971 in 2006, rising to $3,047 by 2013.
- However, the actual per capita cost in 2013 was only $1,773 — nearly 42 percent lower than initial projections.

Competition Benefits Consumers

An estimated 220 million Americans belong to a health plan that provides medications through a managed drug plan, utilizing drug companies, pharmacy benefit managers (PBMs) and pharmacies to provide benefits to consumers. The process is highly competitive: PBMs compete for the right to manage health plan members' drug benefits; drugstores compete to attract drug plan members filling a prescription; and drug makers compete to ensure their drugs are in enrollee prescription pill bottles.

The process is often antagonistic — involving intense negotiation, competitive bidding and price competition. The degree to which drug benefits are managed efficiently has a significant effect on consumers' cost-sharing and premiums.



regulatory activities seem likely to continue. Failed legislative agendas designed to benefit special interests have a way of coming back year after year.

Banning Efficient Pharmacy Networks. Increasingly, health plans and PBMs have experimented with exclusive or "preferred" pharmacy networks as leverage to negotiate lower drug prices from pharmacies competing to become exclusive network drug providers.[22] Opponents of this practice argue "open" pharmacy networks offer enrollees more choices and more convenience, and promote competition. However, PBMs counter that the "preferred pharmacies" in exclusive networks have agreed to deeper discounts in return for the business.[23]

When PBMs create pharmacy networks, they negotiate the lowest possible prices. Negotiated prices are the result of bargaining power — the ability of the drug plan to deny business to a firm if their bid isn't favorable. However, so-called "any-willing-provider" and "retail-choice" laws are designed to reduce pharmacy benefit managers' bargaining power and protect less-efficient pharmacies from competition.[24] The Federal Trade Commission has argued time and time again — in numerous reports and opinions issued on specific state proposals — that these laws lead to higher drug prices and higher premiums.[25] In a recent letter to the Centers for Medicare and Medicaid Services, the FTC wrote:[26]

> "The proposed any willing pharmacy provisions threaten the effectiveness of selective contracting with pharmacies as a tool for lowering costs. 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. Evidence suggests that prescription drug prices are likely to rise if Prescription Drug Plans (PDPs) are less able to assemble selective pharmacy networks. The proposed provisions may also hinder the ability of plans to steer beneficiaries to lower-cost, preferred pharmacies and preferred mail order vendors through financial incentives or other terms."

A recent letter to the chair of the Health & Human Services Committee of the Colorado Senate from the Academy of Managed Care Pharmacy explained that health plans can minimize administrative costs and maintain quality by partnering with selective pharmacy networks.[27] A *Health Affairs* study found laws that restrictions on exclusive pharmacy networks boost administrative costs about 43 percent, by expanding the number of entities able to submit claims to the health plan.[28] Fraud is an additional consideration: When PBMs are forced to reimburse any drug store that submits a claim, fraudulent claims become more likely.

Obstructing Mail-Order Pharmacies. The same any-willing-pharmacy regulations protect local pharmacies from competition with highly efficient mail-order pharmacies. These restrictions often prohibit PBMs from offering drug plan members a financial incentive (a discount) for using a health plan's preferred pharmacy or its mail-order option.

PBMs encourage patients to use mail-order pharmacies for maintenance medications because

they lower costs and boost compliance. Some PBMs will only reimburse patients for maintenance medications filled through a mail-order pharmacy.[32] Alternatively, they may limit the number of times a patient can refill a prescription at a retail pharmacy, after which the patient must obtain those drugs through the mail. More commonly, plans offer lower cost-sharing to encourage enrollees to patronize pharmacies that have negotiated lower prices. For instance, many plans offer lower copayments for mail-order dispensing (or charge higher deductibles for retail purchases).

Many states have passed laws designed to benefit local community pharmacies by prohibiting PBMs from rewarding members who use the mail-order option.[33] In 2011, New York State passed Assembly Bill 5502, making it illegal to charge less for mail-order drugs. The law required to reimburse for prescriptions purchased at either local or mail-order pharmacies without consumers incurring additional PBMs cost-sharing or fees. A well-known drug plan consultant explained the issue rather succinctly:

> "Imagine that your local bookstore owner lobbied your state Senate to pass a law preventing you from buying a book less expensively via Amazon.com. You would immediately recognize that the bookstore was trying to protect its business at your expense. This is precisely what has happened for prescription drugs in New York."[34]

These efforts continue. In early 2015, Colorado Senate bill 15-123 was introduced to prohibit health plans from offering financial incentives (that is, lower-copays) to fill costly specialty drugs at designated network pharmacies or through a PBM's mail-order pharmacy.[35]

Consider: In the retail sector, stores often use price competition to attract customers. They entice consumers with low prices, sales, discounts or rebates. Why would a lawmaker want to prohibit PBMs from offering state residents a discount for using a preferred pharmacy? Because low cost-sharing is used to steer business to firms that agree to the lowest price. Without a financial incentive, drug plan members would have no reason to utilize a low-cost mail-order pharmacy (or a preferred local pharmacy). Likewise, without the threat of losing business, brick and mortar pharmacies have less reason to agree to low prices (or low dispensing fees).

In addition, the mail-order pharmacy may be out of state. State lawmakers typically sympathize with local businesses. Thus, banning discounts for utilizing mail-order pharmacies is a form of protectionism to benefit local businesses.[36] While state residents denied a discount for using mail-order may not realize they are paying higher prices, local pharmacies know they stand to benefit, and they lobby legislatures to restrict competition with out-of-state mail-order pharmacies. The Lewin Group, a consulting firm that analyzes public policy proposals, calculated that a nationwide any-willing-provider requirement would boost prescription mail-order pharmacy costs.

Retail-choice and any-willing-pharmacy laws drive up costs for drug plan members and plan sponsors. These anticompetitive regulations are obviously not in consumers' best interest.

In early March 2015, legislation was introduced in Arkansas (Senate Bill 688) that would increase the administrative tasks and burdens of drug plans and PBMs when pharmacies serve health plan members. The proposal went from a senate bill to law in about one month.

Drugs by Mail

Drug store chains sell the most medications. However, mail-order pharmacy drug delivery now accounts for nearly one-fifth of the retail market. All told, about 217 million prescriptions were filled by mail in 2013. This is down sharply from 264 million in 2010, as more states began restricting PBM mail-order initiatives.[29] High-volume mail-order pharmacies benefit from economies of scale and low overhead (no need for expensive retail real estate). Mail-order pharmacies purchase drugs in large quantities, are highly automated and make fewer errors than walk-in pharmacies.[30] Mail-order pharmacies offer the lowest cost-sharing on prescription drugs for patients with chronic conditions. Patients also have the convenience of mail delivery right to their homes.[31]

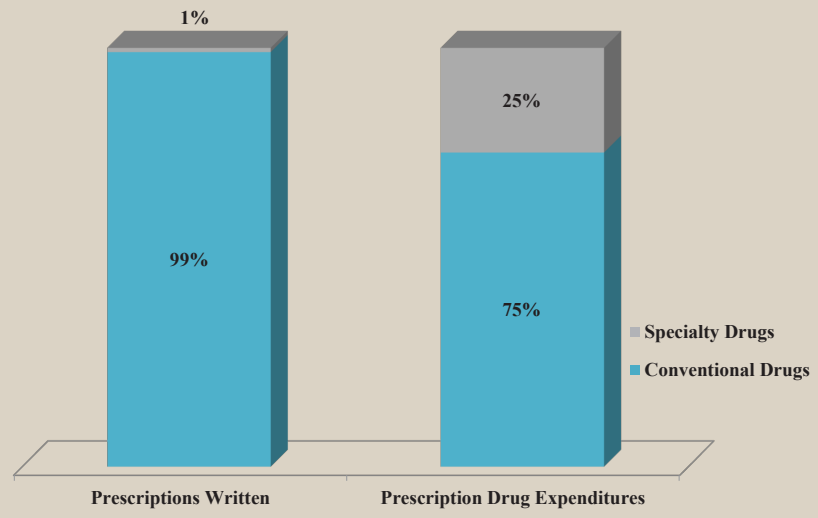
Among other things, the new law allows a pharmacy that has contracted with a PBM to refuse to fill a prescription for a drug that is unprofitable, while filling prescriptions that are profitable. The law also prevents drug plans from paying higher reimbursements to an affiliated pharmacy — even if it provides better services or higher quality.

At first glance these requirements may not seem problematic, but they could have dire consequences. Pharmacy owners could purposely refuse to fill selected prescriptions as a bargaining tactic. For example, rather than decide to participate or not participate, drugstores could fill customers' prescriptions for some drugs, but purposefully send them away for others — using drug plan members as pawns in a game to force higher reimbursements. In addition, this law makes it harder to contract for value-added services, like diabetic counseling or other forms of patient education, in return for higher fees.

The authors purposely exempted state employee health plans from the regulations, which boosted support among legislators and allowed supporters to claim it would cost the state budget nothing. However, it will cost state residents. Had they not exempted state employees, proponents would have had to admit the bill would boost costs for tax-payers, employees and consumers.

Ensuring Safe and Efficient Specialty Networks.[37] As newer therapies are developed, highly advanced specialty drugs and biological agents are supplanting the pills, capsules and elixirs Americans relied on during the past century. Increasingly, physicians are using highly-advanced specialty drugs to treat rare diseases and disorders that, only a few years ago, had no effective treatment. These conditions include cancer, multiple sclerosis, HIV, hepatitis C, rheumatoid arthritis and infertility. These newer, specialty drugs require a level of experience and expertise many old-fashioned drugstores simply do not possess. Stocking and dispensing specialty drugs often involves handling very fragile biological agents, that require complex distribution channels.

Figure IV
Prescription Drug Utilization in 2012



Source: "Specialty Therapy Class Forecast 2012," Research and New Solutions Lab, Express Scripts Drug Trend Report, March 5, 2013. http://lab.express-scripts.com/insights/industry-updates/~/media/07e71c2358f244678d1812c80e273014.ashx

What Is a Specialty Drug?

Advanced drug therapies are expensive. The cost of specialty medications may range from tens of thousands of dollars to hundreds of thousands annually. Some specialty therapies cost $1,000 per day; some cost $1,000 per pill. And while specialty drugs comprise only about 1 percent of prescriptions written, their costs account for about one-fourth of all prescription drug spending.[38] [See Figure IV.]

The actuarial consultancy Milliman projects this spending to increase to $235 billion by 2018.[39] Specialty pharmacy per-unit costs are rising about seven times as fast as overall pharmacy costs.[40] In just a few short years — before the end of the decade — specialty drug therapies could grow to nearly half of all drug expenditures.[41]

And the number of drugs that fall into this category is growing. Specialty drugs comprise a significant portion of the new drugs. [See Figure V.] A little over two decades ago, about 10 specialty drugs were available; today there are more than 300.

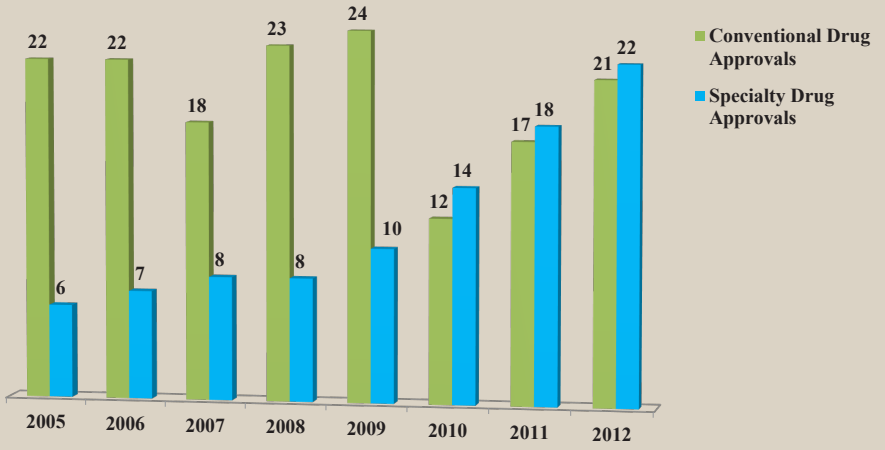
The U.S. Food and Drug Administration recently approved its first biosimilar drug in 2015. These biologically similar drugs are less costly than biotech drugs already in existence. Biotech drugs are drugs derived from living organisms rather

than made using a chemical recipe as is the case with traditional pills and capsules. A PBM may encourage enrollees to ask their doctors to seek out cost-saving biosimilars when appropriate, and reduce enrollees' cost-sharing as an incentive. However, the process is not as simple as merely substituting a generic drug for a name brand drug whose patent has expired. Because follow-on biosimilars are similar, rather than chemically identical, PBMs need to work with specialty pharmacies and doctors closely to identify where cost-saving opportunities exist. However, many specialty drugs have no close substitutes, rendering efforts to control costs by encouraging generic substitution largely ineffective. Due to these medications' high cost and fragile nature, pharmacy benefit managers must carefully manage their distribution, procurement and dispensing. As more specialty drug therapies enter the market, are increasingly relying on exclusive networks and formulary management.

Pharmacies that supply specialty drugs are much more highly involved in patient care than typical retail drugstores that merely dispense drugs. For instance, many biological agents require sophisticated logistical planning — including climate-controlled shipping and meticulous storage — with specific protocols and documentation. Patients prescribed specialty drugs and biological agents require extensive monitoring, risk evaluation, mitigation strategies for side effects and diagnostic support by a physician.

Physicians are best qualified to evaluate the expertise and capabilities of the specialty pharmacy providers

Figure V
Share of Drug Approvals



Source: "Medical Cost Trend: Behind the Numbers, 2014," PricewaterhouseCoopers Health Research Institute, June 2013, Figure 6.

their patients patronize. In a recent survey, two-thirds of the physicians agreed that "some" traditional pharmacies are competent to handle and dispense specialty medications, but three-fourths also agreed that "most" pharmacies do not possess the expertise and capability to manage complex drugs.[42]

Tightly controlled pharmacy networks also allow better tracking by manufacturers of drugs that require special handling (such as refrigeration), specific or complex dosing, and lab monitoring, which the FDA sometimes requires as a condition of drug approval.[43] FDA monitoring requirements favor tightly controlled networks for safety reasons. Moreover, the FTC agrees narrow networks do a good job of controlling costs, whereas any-willing-provider laws could raise costs for consumers.[44]

Regulations that inhibit PBMs from establishing the most efficient preferred network for specialty drugs also make it more difficult to ensure the integrity of those networks. The more entities that drug plans must reimburse, the greater the likelihood a firm could cut corners with drugs that have been mishandled, mislabeled — or are counterfeit. Because specialty drugs are extremely costly, unethical medical (and drug) providers trying to boost their profit margins have a financial incentive to ignore warning signs that a product is suspect.

Early in 2015, Maryland, West Virginia and Texas debated legislation requiring PBMs to work with any willing specialty pharmacy. This is unwise. As the Federal Trade Commission has repeatedly stated, these regulations harm consumers by jacking up prices. These provisions aren't intended to benefit patients; rather they're intended to benefit specialty drug providers who would otherwise have to compete for the privilege of being included in the specialty network.

Competitive Bidding: Choice versus Access. With the cost of advanced therapies growing to unimaginable levels, health plans and PBMs have increasingly turned

to competitive bidding in an attempt to negotiate better deals with drug makers and retail pharmacy chains. This often means the lowest bidder of a competitive auction wins the near-exclusive right to dispense certain specialty drugs. Some stakeholders have criticized the use of contracts won through competitive bidding as overly restrictive for patients.[45] Yet this is how firms compete in a healthy marketplace: Competition for a coveted place on a formulary encourages bidders to offer their best deals — to avoid the loss of potentially lucrative business.

The debate about exclusive networks and exclusionary formularies can be simplified to this: Which is more important, the choice of a wide range of drug therapies, or access to affordable drug therapies?[46] Understandably, drug makers argue "choice" is more important. And it is true that some therapies may work more successfully for one patient than another. However, PBMs argue that if two similar therapies have to compete against each other to become the preferred therapy on a formulary, the incentive for drug makers is to compete vigorously.

An example of this competition is Gilead Sciences' breakthrough hepatitis C therapy, Sovaldi. When Sovaldi was approved in 2014, Gilead priced the therapy very high — a retail price of $1,000 per dose. At $1,000 per day, a 12-week course of treatment would cost about $84,000. Insurers and drug plans bristled at the exceptionally high price.[47] But PBMs could do little to negotiate a lower price. Drug maker Gilead claimed Sovaldi had an effective cure rate of above 90 percent of those who adhere to the therapy.[48] This was far more effective than the hepatitis C therapies then available, and far cheaper than a liver transplant.[49]

Within months of its approval, Gilead announced it would begin offering steep discounts and rebates for Sovaldi — nearly halving the price of the drug to some customers.[50] Makers of the competing drug AbbVie also began offering steep discounts to win exclusive contracts. What led to these steep discounts? The answer is: market-based competition.[51] Shortly after Sovaldi's approval, two similar drugs (one of which was also a Gilead product) were also approved by the FDA. Once there were multiple drugs available (with more in the pipeline), the firms that pay for health care (and manage drug benefits) could begin negotiating with multiple drug makers and require competitive bidding to win the right to be the preferred drug on the formulary.

Competition Lowers Prices. Whereas the retail price for a 12-week course of treatment with Sovaldi would cost $84,000, large PBMs can now expect costs 25 percent to 40 percent lower due to competition (~$50,000 to $65,000). Drug plan members who arbitrarily decide to get their pills at a nonpreferred pharmacy rather than using their drug plans' mail order option could potentially cost their employer (or insurer) thousands more.

Some large pharmacy benefit managers have announced they will investigate the use of contests to negotiate down the cost of other very costly specialty drugs, including a new class of cholesterol-reducing drugs and drugs to treat cancer.[52] These contests ultimately benefit customers by making premiums more affordable.

Conclusion. An estimated 220 million Americans get their drugs through a health plan, or a drug plan managed by a PBM. Efficiently managed drug benefit plans have positive effects on consumers' cost-sharing and premiums, and help make most medications affordable to most patients. Though restrictive drug plan regulations are often touted as consumer protections, they are designed to beneficial local pharmacy service providers at the expense of consumers. Residents of states contemplating such regulatory proposals should tell their elected representatives to resist these initiatives and allow competition to thrive. A better way to ensure desirable outcomes is to promote a competitive environment where health and PBMs partner with the pharmacy networks that can ensure the best possible care at the best possible price.

Notes

1. "National Ambulatory Medical Care Survey: 2010 Summary Tables," National Center for Health Statistics.
2. "National Health Expenditure Projections 2012-2022," Centers for Medicare and Medicaid Services, 2012, Table 11. Available at http://tinyurl.com/kzsnqyo.
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