STATE OF MICHIGAN
IN THE SUPREME COURT
APPEAL FROM THE COURT OF APPEALS
Hons. M.J. Kelly, P.J., and Hoekstra and Stephens, J.J.

STATE OF MICHIGAN ex rel. MARCIA GURGANUS,

Docket No 146791

Plaintiff-Appellee,

v.

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN, LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION; SEARS HOLDING CORPORATION; SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & CO.; RITE AID OF MICHIGAN, INC.; PERRY DRUG STORES, INC.; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; AND WAL-MART STORES, INC.;

Defendants-Appellants.

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CITY OF LANSING and DICKINSON PRESS, INC.,

Docket No. 146792

Plaintiffs-Appellees/Cross-Appeallants,

v.

RITE AID OF MICHIGAN, INC. and PERRY DRUG STORES, INC.,

Defendants-Appellants/Cross-Appellees.

_____/

CITY OF LANSING, DICKINSON PRESS, INC., and SCOTT MURPHY, individually and On behalf of all others similarly situated,

Docket No. 146793

Plaintiffs-Appellees/Cross-Appellants,

v.

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION; SEARS HOLDINGS CORPORATION; SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & COMPANY; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; and WAL-MART STORES, INC.,

Defendants-Appellants/Cross-Appellees.

AMICUS CURIAE BRIEF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, RETAIL LITIGATION CENTER, AND MICHIGAN RETAILERS ASSOCIATION

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INTEREST OF AMICI CURIAE

The National Association of Chain Drug Stores ("NACDS") is a national not-for-profit association that represents the interests of chain community pharmacies in government affairs as well as business, regulatory, and operational matters. NACDS represents over 100 member companies that operate traditional drug stores, supermarkets, and mass merchants with pharmacies. In Michigan, NACDS has 21 member companies, operating over 1,500 pharmacies, employing nearly 140,000 people, including 5,000 pharmacists.

The National Community Pharmacists Association ("NCPA"), founded in 1898 as the National Association of Retail Druggists, represents pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies across the United States. In 2012, there were 968 independent community pharmacies in Michigan, employing more than 9,500 full-time employees, including more than 2,800 pharmacists. NCPA's members are small business entrepreneurs and multifaceted health care providers who represent a vital part of the nation's health care delivery system. NCPA's mission includes promoting the interests of its member pharmacies and the health and well-being of the public they serve.

The Retail Litigation Center, Inc. ("RLC") is a public policy organization that identifies and engages in legal proceedings that affect the retail industry. The RLC's members include many of the country's largest and most innovative retailers, including pharmacies and other retailers in regulated industries in Michigan. The member entities whose interests the RLC represents employ millions of people throughout the United States, provide goods and services to tens of millions more, and account for tens of billions of dollars in annual sales. The RLC seeks to provide courts with retail-industry perspectives on important legal issues, and to highlight the potential industry-wide consequences of significant pending cases.

The Michigan Retailers Association ("MRA") was established in 1940 as the unified voice of Michigan's retail industry. MRA's 5,000 member businesses own and operate more than 12,000 stores across the state, including pharmacies. Members range in size from single-store operations to large national and international chains.

NACDS, NCPA, RLC, and MRA (collectively, the "Amici") support Defendants' appeal to this Court because the court of appeals ruling creates the potential for broad damaging effects on the Amici's members and the Michigan consumers they serve.

Amici have a significant interest in the outcome of this appeal because the novel interpretation of MCL 333.17755(2) advocated by Plaintiffs will interfere with well-established generic drug reimbursement practices on which their members rely. The provision of the Michigan Public Health Code at issue, MCL 333.17755 (the "Substitution Statute"),[1] is aimed at regulating the substitution of brand name prescription drugs with their generic equivalents. At the time the Substitution Statute was first enacted in 1978, the current market for generic prescription drugs did not exist. The availability of generic equivalents was relatively new and most Americans paid full retail rates for prescription drugs. Today, generics account for approximately 69% of all prescription drugs dispensed in the U.S.[2] and third-party payers, such as employee benefit plans and government programs like Medicare and Medicaid, fund a great deal of the expenditure on prescription drugs.[3]

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[1] Amici will refer to Plaintiffs' interpretation of the Substitution Statute as one that imposes a ceiling. However, we note that this statute says nothing about limiting profits or setting prices. It only makes specific reference to "savings in cost."

[2] **Exhibit A**, National Community Pharmacists Association, *Cost-Saving Generic Drugs*, *available at* www.ncpanet.org/index.php/cost-saving-generic-drugs (last visited 1/6/2014).

[3] **Exhibit B**, Kaiser Family Foundation, *Prescription Drug Trends* (Sept. 2008) ("Kaiser 2008").

The Substitution Statute failed to anticipate the advent of pharmacy benefit managers ("PBMs") that negotiate and contractually set prescription drug prices paid by third-party payers (including the State of Michigan). Compliance with the statute as plaintiffs have interpreted it could require disruptive, futile changes to these sophisticated contractual arrangements, which have been adopted by the State of Michigan and the entire pharmaceutical industry. By accepting the plaintiffs' incorrect statutory interpretation, the court of appeals has introduced debilitating uncertainty to the pharmacy pricing contract terms adopted by private and governmental payers alike, and has threatened confidence in future pharmacy pricing contracts. Amici's members have a significant interest in avoiding this outcome.

As health care service providers, Amici's members also have a significant interest in the negative impact the court of appeals opinion may have on the accessibility and affordability of generic prescription drugs. An obligation imposed on pharmacies to provide "savings in cost" to the payer, at least in the manner suggested by Plaintiffs, is fraught with practical difficulties and potential negative effects on consumers.

The contractual reimbursement rates imposed on pharmacies are often very close to acquisition costs, in many instances even below acquisition costs. Many pharmacies operate on a very slim margin. According to Hoover's, the median net profit margin for publicly traded companies in "industry 446110 Pharmacies and Drug Stores (NAICS)" is only 2.63 percent.[4] Even if the statutory ceiling plaintiffs advocate did not require price adjustments for many generic drugs, if the statute were interpreted as plaintiffs suggest, pharmacies would still have to bear the cost of reconciling every prescription dispensed with this competing statutory ceiling. Given the complexity of performing this calculation at the point of sale (when costs are, in many

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[4] **Exhibit C,** *Hoovers Competitive Landscape Report* at 2.

instances, subject to retroactive adjustments), the added cost to pharmacies would be significant. Such costs would discourage dispensing of generics or would be borne by Michigan consumers. It is counterintuitive to impose on Michigan pharmacies any additional costs that may inhibit the dispensing of less expensive generic prescription drugs.[5]

Alternatively, if the pharmacies must bear that cost for themselves, reducing further their already slim profit margins, some Michigan pharmacies may not survive. As a result, Michigan consumers would lose pharmacy access and spend more acquiring prescription drugs. Those living in rural Michigan would be hit the hardest, as a retail pharmacy is a critical point of access into the health care delivery system for those in rural areas.[6] Communities with less access to pharmacies experience higher rates of prescription drug misuse (for example, discontinuing a medication due the difficulty of obtaining a refill). As a critical part of the health care delivery system, Amici's members have a significant interest in preventing this injury to the public.

Finally, the members of all five Amici have a significant interest in correcting the court of appeals ruling that private citizens may bring "false claims" lawsuits based on regulatory infractions committed to agency oversight. All of NACDS's and NCPA's members, and many of RLC's and MRA's members, operate in regulated industries subject to technical requirements for which there is deliberately no private cause of action. Replacing the careful expert oversight of administrative agencies like the Michigan Board of Pharmacy with the vagaries of any would-be private plaintiff will make Michigan a very hostile environment for businesses such as Amici's members.

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[5] *Id.* at 2 (reviewing the benefit of cheaper generics).

[6] *See* Rural Assistance Center of the U.S. Department of Health and Human Services, http://www.raconline.org/topics/pharmacy/ (last visited 1/6/14) (noting that pharmacies are "especially important in rural communities" to helping patients).

STATEMENT OF QUESTIONS INVOLVED

Amici will address the following questions, as framed by the Court in its September 18, 2013 Order:

Question 2: What is meant by the requirement that a pharmacist shall "pass on the savings in cost" when the pharmacist dispenses a generically equivalent drug product and what constitutes a violation of that requirement?

Amici: The requirement is unconstitutionally vague because a reasonable pharmacist could not interpret its meaning where the statute does not clearly define, illustrate, or explain the how to measure "savings in cost" and there is no ready measure available in the pharmaceutical industry.

Question 3: Whether this requirement is limited to transactions involving a substitution of a generic drug for a name brand drug, and in this regard, whether §17755(2) must be read in conjunction with the other subsections of MCL 333.17755?

Amici: Yes. The subsection of the statute must be read in conjunction with the surrounding subsections. The section read as a whole makes clear that subsection (2) only applies to a substitution decision made by a pharmacist. MCL 333.17755(2) does not apply when a generic drug has been prescribed.

Question 4: Whether submission of a charge for the dispensing of a generic drug that is in violation of this requirement constitutes the making of a false claim under the Medicaid False Claim Act (MFCA), MCL 400.601 *et seq.* or the Health Care False Claim Act (HCFCA), MCL 752.1001 *et seq.*?

Amici: No. A claim that runs afoul of a technical regulation on price is not *ipso facto* a "false claim." Additionally, the relator is barred from pursuing the MFCA claim because

the State would be constitutionally estopped from bringing such a claim where it has adopted "MAC" pricing for prescription drug claims made to the Michigan Medicaid program.

Question 5: Whether use of the remedies provided by the MFCA and the HCFCA is available when Part 177 of the Michigan Public Health Code, MCL 333.17701 et seq. provides administrative remedies for violations of MCL 333.17755?

Amici: No. The jurisdiction of the Michigan Board of Pharmacy over MCL 333.17755 is exclusive. There is no private cause of action under that statute.

STATEMENT OF FACTS

Amici adopt Defendants' statement of facts, with the following additions.

I. Evolution of the Prescription Drug Market

In the 35 years since MCL 333.17755 (2) was enacted, the pharmaceutical supply chain and the market forces influencing the price of prescription drugs have fundamentally changed.[7] When the Substitution Statute was enacted, very few employee benefit plans provided any prescription drug coverage. Further, prescription drug benefits through government programs were very limited.[8] As a result, most Americans paid out-of-pocket at full retail rates for prescription drugs.[9] The opposite is true today. As third-party payers began adding prescription benefits, a market developed for pharmacy benefit managers ("PBMs"). "PBMs work with third party payers (private insurers, self-funded employers and public health programs) to manage consumer drug purchases by defining which drugs will be paid for and the amounts that the pharmacy will receive and the consumer must pay out-of-pocket when the prescription is filled."[10]

II. In the Current Market, the Acquisition Cost for the Prescription Drug Cannot Be Known to the Pharmacy at the Point of Sale.

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[7] **Exhibit D**, *Declaratory Ruling of the West Virginia Board of Pharmacy* (Oct. 23, 2012) (the "Declaratory Ruling") at 8 (Finding that West Virginia's statute "was enacted in 1978 at a time when the pharmacy market in the United States was vastly different than it is today.").

[8] In 1986—eight years after the Substitution Statute was enacted—only seven-to-ten percent of all retail prescriptions were covered by managed care plans. **Exhibit E**, *Stephen W. Schondelmeyer and Joseph Thomas III, Trends in Retail Prescription Expenditures* at 134 (Health Affairs, Fall 1990).

[9] **Exhibit D**, *Declaratory Ruling* at 9 ("The contractual arrangements between pharmacies and Benefit Plans are far different than the direct-to-consumer transactions that predominated in 1978.").

[10] **Exhibit F**, Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* at 14 (March 2005) ("Kaiser 2005").

Pharmacies primarily purchase the prescription drugs they dispense from wholesalers, and, occasionally, from manufacturers.[11] However, pharmacies often negotiate with both wholesalers and manufacturers for discounts and rebates based on a variety of factors.[12] These can include cost reducing formulas based upon a pharmacy's volume of sales, market share acquired, or prompt payment.[13]

Notably, in the pharmaceutical supply chain, virtually all transactions are handled electronically using highly automated systems that process the transactions at the point of sale.[14] However, the factors that may reduce a pharmacy's cost for a particular prescription drug are in many instances applied retroactively after a drug is dispensed, and frequently are based on volume of usage. In such cases, savings can only be determined over time, resulting in price adjustments down the line. Such adjustments may be made monthly, quarterly, or on some other timetable. Consequently, current payment systems are not designed with point-of-sale cost calculations in mind.

III. PBM Pharmacy Reimbursement Contracts Set the Terms for Pharmacy Charges to and Payments from Third Party Payers and Consumers.

According to one leading report on the pharmaceutical supply chain, as of 2005, PBMs managed prescription drug benefits for as much as 57% of the U.S. population.[15] In the same year, approximately two-thirds of all prescriptions written in the U.S. were processed by PBMs.[16] in 1978 there was virtually no market for prescription benefits management, but today

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[11] **Exhibit F**, *Kaiser 2005* at 9–10.

[12] *Id.* at 2.

[13] *Id.* at 19–20.

[14] *Id.*

[15] *Id.* at 13.

[16] *Id.* at 14.

PBMs are an integral part of most consumer drug purchases, and their role continues to expand. In Michigan, and other states that have managed care Medicaid programs, prescription benefits through Medicaid are managed by a PBM.

With the advent of PBMs and government programs entering the market for prescription drugs, the manner in which those drugs are priced changed dramatically. Today, the price a consumer pays for a prescription generic drug is the result of highly complex, contractually determined and regulated pricing practices at every step in the supply chain. Third-party payers, through PBMs, use formulae to set reimbursement rates paid to pharmacies for those drugs sold to third-party beneficiaries, and they dictate what beneficiaries must pay. Pharmacies contract with PBMs to provide pharmacy services to plans by joining the PBM's pharmacy network. As a member of this network, a pharmacy must agree to the PBM's reimbursement formula for prescription drugs.

In many cases, the same PBMs that calculate and set reimbursement for private third-party payers perform the same services for government programs. Michigan's Medicaid program has adopted a managed care approach, using Michigan's Medicaid vendor, Magellan Medicaid Administration, Inc. ("Magellan"). Under state direction, Magellan uses Maximum Allowable Cost ("MAC")[17] pricing to set reimbursement for generic prescription drugs dispensed to Michigan Medicaid participants.[18] Magellan sets the MAC using its own proprietary system. The MAC is imposed on the pharmacy as a ceiling, leaving it entirely up to

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[17] "MAC is a cap set by payers on reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs." **Exhibit F**, *Kaiser 2005* at 28.

[18] **Exhibit G**, materials from Michigan Department of Community Health Medicaid Program website, at 3 ("Maximum Allowable Cost (MAC) Pricing Frequently Asked Questions").

the pharmacy to negotiate with wholesalers and manufacturers to wrestle a margin out of the reimbursement.

The market for generics is far more competitive than that for brand name drugs, "thus the prices for generic drugs change much more frequently, sometimes daily, in response to market forces."[19] The State of Michigan's MACs for generic prescription drugs are updated weekly.[20]

ARGUMENT

I. Question 2: What is meant by the requirement that a pharmacist shall "pass on the savings in cost" when the pharmacist dispenses a generically equivalent drug product and what constitutes a violation of that requirement?

A. The term "savings in cost" is unconstitutionally vague.

A statute cannot impose a mandate unless it provides fair notice of what is required:

> It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined. Vague laws offend several important values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning.

Grayned v City of Rockford, 408 US 104, 108–09; 92 S Ct 2294; 33 L Ed 2d 222 (1972), quoted with approval in *People v Howell*, 369 Mich 16; 238 NW2d 148 (1976).

MCL 333.17755(2) provides that "[i]f a pharmacist dispenses a generically equivalent drug, the pharmacist shall pass on the savings in cost to the purchaser or to the third party payment source if the prescription is covered by a third party pay contract." To comply with the statute, a pharmacist must first calculate "the savings in cost." While Plaintiffs present the issue as straightforward, in fact, given the market realities, that phrase is critically indeterminate. And plaintiffs seem to advocate for a calculation that may not be possible at the time a drug is

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[19] **Exhibit F**, *Kaiser 2005* at 17.

[20] **Exhibit G**, *Michigan Medicaid Website* at 3.

dispensed due to the complex and well-established arrangements for pharmacy rebates and other price adjustments that occur after point of sale. *See supra* at 2. A pharmacist should not have to guess at what the calculation might be and no reasonable person would understand the statute to require a calculation that cannot be made in a manner that would effectuate the statute's purpose. The defects in this language reveal the fact that MCL 333.17755(2) was really a precatory statement about consumer protection, rather than a workable mandate.

Since neither the Board of Pharmacy nor the Attorney General has ever proffered a formula to measure "savings in cost," (which itself is telling), plaintiffs guess that the required calculation is "generic price – generic acquisition cost ≤ brand price – brand acquisition cost." Second Amended Complaint, *State of Michigan, ex rel Marcia Gurganus v CVS Caremark, et al,* ¶ 34; Second Amended Complaint, *City of Lansing, et al v CVS Caremark, et al*, ¶31. The court of appeals accepted this formula without further analysis. January 22, 2013 Opinion at 16. But nothing in the statute justifies this type of calculation. Plaintiffs fail to cite any authority supporting their interpretation.

A "savings in cost" calculation that requires an accurate point of sale calculation of a pharmacy's expense associated with the drug dispensed would be incredibly difficult, if not impossible, for pharmacies, which often receive rebates, discounts, and benefits from manufacturers and wholesalers long after the drugs are dispensed. These rebates and other benefits are earned based on data that is accumulated over time, such as volume of sales or timeliness of payments. These arrangements are well-known to the government, which mandates its own manufacturer rebates, and are most common with highly competitive generic prescription drugs. In practice, rebates lower a pharmacy's net expenditure on a drug. These factors were not considered by plaintiffs or the court of appeals. The federal government has acknowledged the

fact that it is not possible to calculate an accurate real-time price for a particular drug due to "lagged price concessions" such as rebates.[21]

"[D]ue process requires standards in a statute to be 'reasonably precise' in order to ensure that individuals are not held responsible by the state for conduct that they could not reasonably understand to be proscribed." *Dep't of State Compliance & Rules Div v Mich Educ Ass'n-NEA*, 251 Mich App 110, 116; 650 NW2d 120 (2002) (*citing Sillery v Bd of Medicine*, 145 Mich App 681, 686; 378 NW2d 570 (1985); *K Mart Corp v Dep't of State*, 127 Mich App 390, 395; 339 NW2d 32 (1983)). The "standard" in MCL 333.17755(2) is not only not "reasonably precise," it is downright confusing. Plaintiffs' unsupported declaration about what the statute requires makes it no less so. Pharmacists should not have to guess at the meaning of a vague mandate that, in theory, could entail an overhaul of prescription drug pricing systems in Michigan.

Moreover, careful scrutiny of a vague statute is particularly important where, as here, it is a "statute which is enacted to protect the public health, morals, and safety" because Michigan courts will not enforce contracts, the terms of which violate such a statute. *Silver v AOC Corp*, 31 Mich App 147, 150; 187 NW2d 532 (1971); *Turner v Schmidt Brewing Co*, 278 Mich 464, 469–70; 270 NW 750 (1936); *Richardson v Buhl*, 77 Mich 632, 661; 43 NW 1102 (1889); *Cashin et al v Pliter*, 168 Mich 386, 389–90; 134 NW 482 (1912). Most prescription drugs are dispensed pursuant to the terms of contracts between pharmacies and third-party payers. Amici are not aware of any such contracts that include a requirement aligned with the vague mandate attempted in MCL 333.17755(2). Uncertainty created by the statute's vague terms creates the specter of arguments to escape contractual obligations. Given the potential for this sort of

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21 *See, eg*, 77 Fed Reg 5344, 5360, 5365 (discussing proposed rule for calculating pharmacy Medicaid reimbursement benchmark that allows for a twelve month period for smoothing out the effect of lagged price concessions.)

substitutions.[22] Like the Michigan Substitution Statute, the West Virginia law, W.Va.Code § 29A-4-1, has multiple subsections, two of which expressly address substitution decisions and a third that mandates that "[a]ll savings in the retail price of the prescription shall be passed on to the purchaser." The Board of Pharmacy ruled that the provision only reached "transactions involving the substitution of a lower cost, therapeutically equivalent, generic medication for the medication prescribed by a physician."[23]

The Michigan Substitution Statute is broken down into four subsections. The first subsection begins "[w]hen a pharmacist receives a prescription for a brand name drug product . . ." MCL 333.17755(1). A generic drug is not substituted for a brand name drug unless the prescription was for the brand name drug. Dispensing a drug as prescribed is not a substitution. Subsection (3), addressing those prescriptions for which substitution is barred, expressly incorporates subsection (1). MCL 333.17755(3). Subsection (4) is similarly expressly limited to drugs dispensed that are different from "the drug originally prescribed." MCL 333.17755(4). The statute, considered as a whole, unambiguously addresses when a substitution may be made (1), factors impacting what the pharmacist may charge when a substitution is made (2 & 4), and when a substitution may not be made (3). If the pharmacist received a prescription for a generic drug, the requirements of the statute are not triggered.

The court of appeals refused to consider the distinction between substitution decisions by a pharmacist and prescribing decisions made by a health care provider. The Substitution Statute only regulates substitutions by a pharmacist. Neither plaintiffs nor the court of appeals address the interplay of the four subsections of the Substitution Statute and, as a result, misinterpret it.

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[22] **Exhibit D**.

[23] *Id.* at 5.

III. Question 4: Whether submission of a charge for the dispensing of a generic drug that is in violation of this requirement constitutes the making of a false claim under the Medicaid False Claim Act (MFCA), MCL 400.601 *et seq.* or the Health Care False Claim Act (HCFCA), MCL 752.1001 *et seq.*?

A. Every submission in violation of MCL 333.17755(2) is not a false claim.

The MFCA and HCFCA address "false claims" made to Medicaid and private payers, respectively. Such "false claims" are commonly understood to be the product of fraud. A "false claim" to Medicaid for reimbursement for prescription drugs, for example, may include claims for drugs that were not actually dispensed (either a phantom transaction or a fraudulent substitution). A significant element of such fraud is to submit a claim knowing it is false. MCL 400.603, 752.1003; *see also* 31 U.S.C. § 3729. However, given the vagueness of MCL 333.17755 and the inability of pharmacies to determine whether there is a "savings in cost" — whatever that may be— at the point of sale, a claim submitted on that sale cannot be knowingly false. The court of appeals has opened up the entire health care industry to civil suits for claims arising from alleged errors unknowingly made, vastly expanding the legislative scope of false claims acts.

The court of appeals appears to rely on an "implied certification theory" of false claims act liability. As the court of appeals has applied this novel "implied certification theory," it means that the only proof that must be made under the MFCA or HCFCA is that the pharmacy made a claim, the calculation of which is out-of-step with any regulation affecting price or profits. That expansive interpretation of false claims act liability would expose regulated businesses in Michigan to virtually limitless liability.

Furthermore, the preambles of both the MFCA and HCFCA state that the acts are intended to reach *fraudulent* activity,[24] which is at odds with the "implied certification theory"

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[24] Preamble to the MFCA:

the court of appeals adopted. This Court should find that such a theory has no application to either the MFCA or HCFCA.

B. The Qui Tam Action Violates Due Process Because the Government Endorsed the Reimbursement Rates that the Relator Contends are False Claims.

When addressing the MFCA claim, the Court should also consider that the *qui tam* relator is estopped from pursing that claim. The *qui tam* relator stands in the shoes of the State and therefore cannot make a claim that the State would be estopped from making. Due Process estops the State from penalizing a citizen for conduct the State induced—here, charging the amounts for prescription drugs that the State adopted. Constitutional estoppel usually arises in the criminal context, where it is more commonly referred to as "entrapment." But there is no reason it would not apply with equal force to a civil action.

The origins of constitutional estoppel are discussed in *Raley v Ohio*, 360 US 423; 79 S Ct 1257; 3 L Ed 2d 1344 (1959), where state officials assured defendants that they could assert their Fifth Amendment right against self-incrimination to refuse to answer questions at a hearing

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"AN ACT to **prohibit fraud** in the obtaining of benefits or payments in connection with the medical assistance program; to **prohibit kickbacks or bribes** in connection with the program; to **prohibit conspiracies** in obtaining benefits or payments; to authorize the attorney general to investigate alleged violations of this act; to provide for the appointment of investigators by the attorney general; to ratify prior appointments of attorney general investigators; to provide for **civil actions to recover money received by reason of fraudulent conduct**; to provide for receiverships of residential health care facilities; to prohibit retaliation; to provide for certain civil fines; and to prescribe remedies and penalties." Preamble to 1977 PA 72 (MFCA) (emphasis added).

Preamble to the HCFCA:

"AN ACT to **prohibit fraud** in the obtaining of benefits or payments in connection with health care coverage and insurance; to **prohibit kickbacks or bribes** in connection with such coverage and insurance; to **prohibit conspiracies** in obtaining benefits or payments; to provide for certain powers and duties of certain state and local officers and agencies; to provide for and preclude certain civil actions; and to prescribe penalties." Preamble to 1984 PA 323 (HCFCA) (emphasis added).

before the Ohio State Legislature's Un-American Activities Commission.[25] The defendants were later charged and convicted of refusing to answer the Commission's questions. The United States Supreme Court reversed the conviction on the grounds that it violated Due Process. In Michigan, constitutional estoppel "applies when, acting with actual or apparent authority, a government official affirmatively assured the defendant that certain conduct is legal and the defendant reasonably believes that official." *People v Woods,* 241 Mich App 545; 616 NW 2d 211 (2000) (*quoting United States v Howell*, 37 F3d 1197 (CA7, 1994)). The court of appeals has recognized the applicability of this principle in the civil context:

> [E]quity prohibits the government from, on one hand, promulgating a rule and, on the other hand, denying the validity of that rule to the detriment of a person who complied with the rule. That is, the government is estopped from denying the validity of its own rule where to hold the rule invalid would work to the detriment of a private party. It makes no difference that it may have been a different department, division, bureau, or commission which promulgated the rule.

Stegenga v Dep't of Treasury, 179 Mich App 307, 312; 445 NW2d 495 (1989).

Under this principle, the State—and thus the relator—should be estopped from denying that its own MAC prices for generic prescription drugs are the controlling standard for Medicaid claims, not a theoretical competing ceiling in the Substitution Statute. As a condition of participation in the Michigan Medicaid program, a pharmacy must consent to the reimbursement set by Magellan. It would be inequitable for the state to turn around and penalize pharmacies for relying on Magellan-set, state-ratified MAC prices. Due Process prevents the State from treating a claim made pursuant to its own Magellan MAC price list as a "false claim" under the MFCA. If the State is constitutionally estopped from bringing that claim, so is the relator.

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[25] *Raley, supra* at 427–31.

IV. Question 5: Whether use of the remedies provided by the MFCA and the HCFCA is available when Part 177 of the Michigan Public Health Code, MCL 333.17701 *et seq.* provides administrative remedies for violations of MCL 333.17755?

The Michigan Legislature, through the Public Health Code ("PHC"), delegated its authority to regulate pharmacists and pharmacies to the Michigan Board of Pharmacy. MCL 333.17722. The circuit court and the court of appeals ruled correctly that the jurisdiction of the Board of Pharmacy (as a division of the Department of Licensing and Regulatory Affairs ("LARA")) over the Substitution Statute is exclusive. January 22, 2013 Opinion at 9. The PHC provides a thorough framework for administrative oversight and remedies for violation of the PHC, including MCL 333.17755. The court of appeals correctly refused to infer a private cause of action where there was no evidence that the legislature intended to create one. The court of appeals also correctly determined that the administrative remedies are exclusive. "It is a general rule of law in Michigan that when a statute creates a new right or imposes a new duty having no counterpart in the common law the remedies provided in the statute for violation are exclusive and not cumulative." *Ohlsen v DST Industries, Inc*, 111 Mich. App. 580, 583; 314 NW 2d 699 (1981). There is no dispute that the requirements of MCL 333.17755 have no common law counterpart.

Despite ruling that the administrative remedies under the PHC are exclusive, the court of appeals allowed plaintiffs to proceed with false claims actions premised on the same alleged violation of the PHC. The HCFCA and MFCA are drafted to reach "false claims" submitted to health insurers and the state Medicaid program. The acts clearly are designed to address fraud perpetrated on payers of prescription drug claims. But the court of appeals expanded the reach of the false claims acts to claims that are not fraudulent, but violate a technical requirement unrelated to the claims process. According to the court, a claim in excess of the ceiling plaintiffs argue is imposed by MCL 333.17755(2) is "false" because pharmacies impliedly—not

expressly—represent by making a claim for reimbursement that the claim satisfies all other regulatory requirements. Such a wildly expansive theory of liability renders the exclusivity of administrative remedies under the PHC meaningless. For the same reasons that the court of appeals determined that the PHC does not provide a private cause of action for violation of MCL 333.17755(2), this Court should hold that the false claims acts cannot be used to circumvent exclusive administrative oversight, procedure, and remedies.

RELIEF REQUESTED

For the foregoing reasons, the Amici request that the Court REVERSE the ruling of the court of appeals and REINSTATE the orders of the circuit court dismissing these actions with prejudice.

Dated: January 7, 2014

Respectfully submitted,

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STATE OF MICHIGAN
IN THE SUPREME COURT
APPEAL FROM THE COURT OF APPEALS
Hons. M.J. Kelly, P.J., and Hoekstra and Stephens, J.J.

STATE OF MICHIGAN ex rel. MARCIA GURGANUS,

Docket No 146791

Plaintiff-Appellee,

v.

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN, LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION; SEARS HOLDING CORPORATION; SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & CO.; RITE AID OF MICHIGAN, INC.; PERRY DRUG STORES, INC.; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; AND WAL-MART STORES, INC.;

Defendants-Appellants.

/

CITY OF LANSING and DICKINSON PRESS, INC.,

Docket No. 146792

Plaintiffs-Appellees/Cross-Appeallants,

v.

RITE AID OF MICHIGAN, INC. and PERRY DRUG STORES, INC.,

Defendants-Appellants/Cross-Appellees.

/

CITY OF LANSING, DICKINSON PRESS, INC., and SCOTT MURPHY, individually and On behalf of all others similarly situated,

Plaintiffs-Appellees/Cross-Appellants,

v.

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION; SEARS HOLDINGS CORPORATION; SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & COMPANY; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; and WAL-MART STORES, INC.,

Defendants-Appellants/Cross-Appellees.

Docket No. 146793

APPENDIX

EXHIBIT A — National Community Pharmacists Association, *Cost-Saving Generic Drugs*, *available at* www.ncpanet.org/index.php/cost-saving-generic-drugs (last visited 12/16/2013).

EXHIBIT B — Kaiser Family Foundation, *Prescription Drug Trends* (Sept. 2008)

EXHIBIT C — *Hoovers Competitive Landscape Report*

EXHIBIT D — *Declaratory Ruling of the West Virginia Board of Pharmacy* (Oct. 23, 2012).

EXHIBIT E — *Stephen W. Schondelmeyer and Joseph Thomas III, Trends in Retail Prescription Expenditures* (Health Affairs, Fall 1990).

EXHIBIT F — Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* (March 2005).

EXHIBIT G — materials from Michigan Department of Community Health Medicaid Program website.

EXHIBIT A

Solutions for Plan Sponsors

Cost-Saving Generic Drugs

Community Pharmacists Can Help Maximize the Use of Low-Cost Generic Drugs

Local pharmacists are consistently cutting costs for patients, employers and other health plan sponsors by maximizing the use of less-expensive generic drugs, where appropriate.

Almost no payers are maximizing potential generic drug savings. The Generic Pharmaceutical Association (GPhA) released an independently conducted analysis showing that the savings to consumers and the U.S. health care system from the use of generic prescription drugs has risen to a current rate of $1 billion every other day—totaling $193 billion in 2011 and more than $1 trillion over the last 10 years (2002-2011). In 2011 & 2012, 6 of the 10 largest-selling brands in the U.S. will lose their patents, enabling a windfall in generic savings. It is vital that health plan sponsors fully focus their attention on maximizing this savings strategy rather than less effective strategies such as mandatory mail order.

In 2009, Medicaid had $329 million of overspending as a result of underutilizing generics. Today, 7 out of 10 prescriptions are filled with generic drugs. The average price of generic drug is about one quarter of the average brand: $35.22 vs. $137.90. And there are plenty of opportunities to embrace generics savings. Approximately 80% of FDA-approved drugs are available as generic; 2.6B prescriptions are filled with generics annually. Generics account for 69% of all U.S. prescriptions but only 16 percent of all dollars spend on drugs. Step one for health plan sponsors is to challenge pharmacy benefit managers (PBMs) to significantly increase and guarantee generic dispensing rates (GDRs) rather than simply float on the market dynamics or push mail order.

In 2010, retail pharmacies dispensed generics 72.7 percent of the time while the big three PBMs' mail order dispensing facilities had generic dispensing rates of 60.5 to 61.5 percent.

For patients, employers and health plans, that difference adds up quickly. For example, IMS Health concluded that every two percent increase in generic utilization in Medicaid programs saves taxpayers an additional $1 billion annually. More broadly, a one percentage point increase in GDR was associated with a 2.5% reduction in gross pharmacy costs, according to an analysis of plan sponsor data from 2007-2009 for approximately 14 million beneficiaries.

One explanation for this gap between the utilization of generic drugs in community pharmacies vs. mail order facilities may be the big PBMs' pursuit of brand name manufacturer rebates. Industry analyst Linda Cahn has argued in Managed Care Magazine that PBMs reap huge brand drug rebates by manipulating brand and generic drug definitions: "*...when it is in PBMs' interests to classify more drugs as generics, they magically recharacterize the drugs as generics. For example, PBMs wanting to make their generic substitution rate appear greater reclassify drugs that they invoiced as brands as generics when calculating the number of generic drugs dispensed. Similarly, if a contract calls for a PBM to pay a specified rebate 'per brand drug claim,' it can reclassify drugs that were invoiced as brands as generics for the purpose of calculating rebates...*"

Some PBM allies assert that the reason for this discrepancy in generic drug utilization is that mail order pharmacies dispense maintenance medications that often have no generic alternatives. However, total generic market share has risen significantly over the last five years, according to IMS:

- In 2006, the generic market share was just 63 percent; in 2010, it was 78 percent
- The prescription drug market available for generic substitution rose from just 70 percent in 2006 to 84 percent in 2010
- Twenty-two of the top 25 most-prescribed products in 2010 are generics, versus three brand drugs
- Within six months of brand patent loss, patients received the generic form of the drug 80 percent of the time in 2010. This compares to just 55 percent in 2006
- For patients starting therapy for chronic conditions in 2010, 3.2 million more patients started their therapy with a generic while 6.6 million fewer patients started therapy with a brand

Despite these trends, the difference between community pharmacy and mail order pharmacy generic dispensing rates remain virtually unchanged. Year after year, from 2007 to 2010, community pharmacies dispensed generics 10 to 13 percent more often than mail order.

Clearly, community pharmacies have established a generic dispensing rate that is the "gold standard" for the industry.

EXHIBIT B

THE HENRY J. KAISER FAMILY FOUNDATION

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YOUR RESOURCE FOR HEALTH POLICY INFORMATION, RESEARCH, AND ANALYSIS

September 2008

Prescription Drug Trends

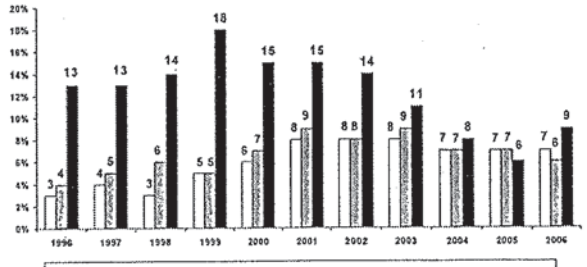
Overview

Prescription drugs are vital to preventing and treating illness and in helping to avoid more costly medical problems. Rising costs and implementation of the Medicare Part D drug benefit in 2006 have highlighted the need for a better understanding of the pharmaceutical market and for new approaches to address increasing prescription costs.

Rising Expenditures for Prescription Drugs

Spending in the US for prescription drugs was $216.7 billion in 2006, more than 5 times the $40.3 billion spent in 1990.[1] Although prescription drug spending has been a relatively small proportion of national health care spending (10% in 2006, compared to 31% for hospitals and 21% for physician services), it has been one of the fastest growing components, until recently growing at double-digit rates compared to single-digit rates for hospital and physician services. In 2006, the annual rate of increase in prescription spending was 9%, compared to 7% for hospital care and 6% for physician services[2] (Figure 1).

Figure 1: Average Annual Percentage Change in Selected National Health Expenditures, 1996-2006



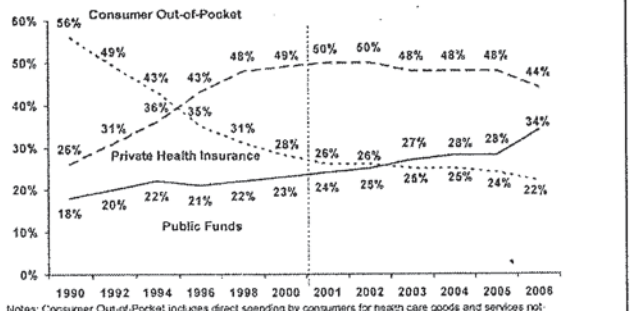
Source: Kaiser Family Foundation calculations using National Health Expenditure historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/.

Prescription spending growth slowed from 1999 to 2005 because of the increased use of generic drugs, the increase in tiered copayment benefit plans, changes in the types of drugs used, and a decrease in the number of new drugs introduced.

The growth in drug spending in 2006 resulted from 1) increased use of prescription drugs, attributed to the implementation of Medicare Part D, new indications for existing drugs, strong growth in several therapeutic classes, and increased use of specialty drugs; 2) lower rebates from drug manufacturers; and 3) changes in the therapeutic mix of drugs.[3]

The share of prescription drug expenses paid by private health insurance increased substantially over the past sixteen years (from 26% in 1990 to 44% in 2006), contributing to a decline in the share that people paid out-of-pocket (from 56% in 1990 to 22% in 2006). The government's share of expenditures remained fairly constant. However, the implementation of the Medicare Part D drug program in 2006 substantially changed the mix of funding sources, as the government's share rose from 28% in 2005 to 34% in 2006, the private insurance portion fell from 48% to 44%, and the consumer out-of-pocket share declined from 24% to 22% (Figure 2).

Figure 2: Percent of Total National Prescription Drug Expenditures by Type of Payer, 1990-2006



Notes: Consumer Out-of-Pocket includes direct spending by consumers for health care goods and services not covered by a health plan and cost-sharing amounts (coinsurance, copayments, deductibles) required by public and private health plans. It does not include consumer premium payments and cost sharing paid by supplementary Medicare policies, which are included in the Private Health Insurance category. May not add to 100% due to rounding.

Source: Kaiser Family Foundation calculations using National Health Expenditure historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/.

Within public funds, the funding shares changed from 7% Medicare and 68% Medicaid in 2005, to 53% Medicare and 26% Medicaid in 2006 (Figure 3).

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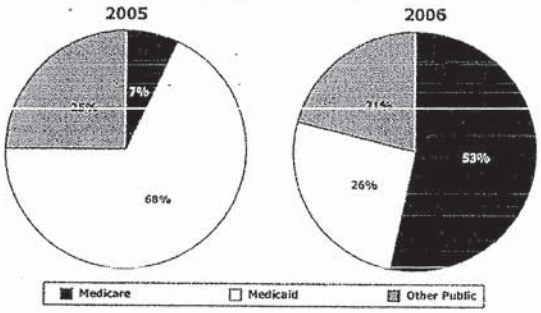
Figure 3: Distribution of Total Public Prescription Drug Expenditures by Type of Payer, 2005 and 2006



Notes: "Medicaid" includes federal and state funds for Medicaid and the Medicaid State Children's Health Insurance Program (SCHIP) expansion; "Other Public" includes other federal, state, and local expenditures and the Medicaid SCHIP program.

Source: Kaiser Family Foundation calculations using National Health Expenditures historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/.

Factors Driving Changes in Prescription Spending

Three main factors drive changes in prescription drug spending: changes in the number of prescriptions dispensed (utilization), price changes, and changes in the types of drugs used.

Utilization. From 1997 to 2007, the number of prescriptions purchased increased 72% (from 2.2 billion to 3.8 billion), compared to a US population growth of 11%. The average number of retail prescriptions per capita increased from 8.9 in 1997 to 12.6 in 2007.[4] The percent of the population with a prescription drug expense in 2005 was 59% for those under age 65, and 91% for those 65 and older; the proportions of these populations with a drug expense has changed little since 1997, when they were 59% and 86%, respectively.[5]

Price. Prescription drug prices increased at the same rate in 2006 as in 2005 (3.5%).[6] Retail prescription prices[7] (which reflect both manufacturer price changes for existing drugs and changes in use to newer, higher-priced drugs) increased an average of 6.9% a year from 1997 to 2007 (from an average price of $35.72 to $69.91), more than two and a half times the average annual inflation rate of 2.6% over the same period. The average brand name prescription price in 2007 was over 3 times the average generic price ($119.51 vs. $34.34). Of the average retail prescription price of $69.91, manufacturers received 78%, retailers received 19%, and wholesalers received 4% in 2007.[8]

Changes in Types of Drugs Used. Prescription drug spending is affected when new drugs enter the market and when existing medications lose patent protection. New drugs can increase overall drug spending if they are used in place of older, less expensive medications; if they supplement rather than replace existing drugs treatments; or if they treat a condition not previously treated with drug therapy. New drugs can reduce drug spending if they come into the market at a lower price than existing drug therapies; this can occur when a new drug enters a therapeutic category with one or two dominant brand competitors. New drug use is affected by the number of new drugs (new molecular entities) approved by the US Food and Drug Administration; approvals have fluctuated over the past decade, with 39 approvals in 1997, 27 in 2000, 20 in 2005, and 18 in 2006.[9]

Drug spending is also typically reduced when brand drugs lose patent protection and face competition from new, lower cost generic substitutes. FDA analysis shows that generic competition is associated with lower drug prices: on average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer; the second generic manufacturer reduces the average generic price to nearly half the brand name price; prices continue to fall but more slowly as additional generic manufacturers market the product. For products with a large number of generics, the average generic price falls to 20% of the branded price and lower.[10]

Approximately three-quarters of FDA-approved drugs have generic counterparts. In 2007, 21% of total prescription drug sales and 65% of total prescriptions dispensed were generic medicines. Generic sales grew 8% from 2005 to 2006.[11] Federal legislation allowing FDA approval of generic substitutes for brand name biologic drugs was introduced in 2007 but has not as yet been enacted.

Advertising. Both prescription use and shifts to higher-priced drugs can be influenced by advertising. After increasing every year since 1996, the total amount manufacturers spent on advertising declined from 2004 to 2005 (from $11.9 billion to $11.4 billion), rose to $12.0 billion in 2006, and fell to $10.4 billion in 2007. The share directed toward consumers (through advertising on

television, radio, magazines, newspapers, and outdoor advertising) decreased from 2006 to 2007 (from $4.8 to $3.7 billion), and the share directed toward physicians (through the sales activities of pharmaceutical representatives and through professional journals) also decreased (from $7.2 to $6.7 billion). Spending for consumer advertising in 2007 was over 4 times the amount spent in 1996 ($3.7 billion vs. $0.8 billion), while 2007 physician advertising was almost 2 times the 1996 amount ($6.7 billion vs. $3.5 billion).[12] The FDA and Congress are considering changes to prescription advertising rules.

Profitability. From 1995 to 2002, pharmaceutical manufacturers were the nation's most profitable industry (profits as a percent of revenues). They ranked 3rd in profitability in 2003 and 2004, 5th in 2005, 2nd in 2006, and 3rd in 2007, with profits of 15.8% compared to 5.7% for all Fortune 500 firms in 2007.[13] Prescription drug sales were $286.5 billion in 2007, an increase of 3.8% over 2006, the smallest growth rate since 1961. IMS Health attributes slower sales growth to loss of exclusivity of brand name medicines, fewer new product approvals, the leveling of year-over-year growth from the Medicare Part D program, and the impact of safety issues.[14]

Insurance Coverage for Prescription Drugs

Lack of insurance coverage for prescription drugs can have adverse effects. An April 2008 survey found that uninsured nonelderly adults (ages 18-64) are more than twice as likely as insured nonelderly adults to say that they or a family member did not fill a prescription (45% vs. 22%) or cut pills or skipped doses of medicine (38%vs.18%) in the past year because of the cost.[15]

Prescription drug coverage comes from a variety of private and public sources:

Employer Coverage. Employers are the principal source of health insurance in the United States, providing coverage for 177 million (59%) of Americans in 2007.[16] Sixty percent of employers offered health insurance to their employees in 2007, and 65% of employees in those firms are covered by their employer's health plan.[17] Other employees may have obtained coverage through a spouse. Nearly all (98%) of covered workers in employer-sponsored plans had a prescription drug benefit in 2007.[18]

Medicare. Prior to January 1, 2006, the traditional Medicare program (the federal health program for the elderly and disabled) did not provide coverage for outpatient prescription drugs. As a result, about one-quarter (27%) of seniors age 65 and older, and one-third of poor (34%) and near-poor (33%) seniors, had no drug coverage in 2003.[19] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a voluntary Medicare outpatient prescription drug benefit (known as Part D), effective January 1, 2006, under which the 44 million Medicare beneficiaries can enroll in private drug plans. These plans vary in benefit design, covered drugs, and utilization management strategies.

Department of Health and Human Services (HHS) data show that as of January 2008, approximately 90% of Medicare beneficiaries had drug coverage: 25.4 million beneficiaries had Medicare Part D drug coverage from either a stand-alone prescription drug plan (17.4 million, including 6.2 million low-income seniors and people with disabilities, known as dual eligibles, who were transferred from Medicaid drug coverage to Medicare Part D drug coverage), a Medicare Advantage drug plan (7.6 million), or other Medicare health plan types (0.4 million). Another 10.2 million beneficiaries had coverage from creditable employer or union retiree plans including FEHB and TRICARE retiree coverage. And an estimated 4.0 million beneficiaries had creditable drug coverage from the VA and other sources. About 4.6 million beneficiaries did not have creditable coverage (were not enrolled in a Part D drug plan or a source of creditable coverage).[20]

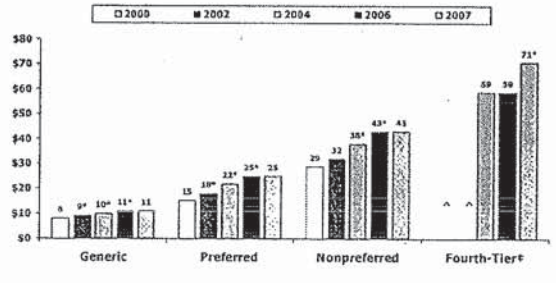
Medicaid. Medicaid is the joint federal-state program that pays for medical assistance to 60 million low-income individuals and is the major source of outpatient pharmacy services to the low-income population. All state Medicaid programs provide coverage for prescription drugs, although there are important differences in state policies with regard to copayments, preferred drugs, and the number of prescriptions that can be filled. Approximately 6 million dual eligibles were transferred from Medicaid drug coverage to Medicare Part D drug coverage in January 2006;

they represented an estimated 14% of Medicaid beneficiaries and accounted for about 45% of Medicaid prescription drug spending in FY2003.[21] Since January 1, 2006, states have been required to make payments to Medicare to help finance Medicare drug coverage for the transferred and future dual eligibles.

Responses to Increasing Prescription Costs
A variety of public and private strategies have been implemented to attempt to contain rising costs for prescription drugs, as described below.

Utilization Management Strategies. Health plans have responded to increasing prescription drug costs by excluding certain drugs from coverage, using quantity dispensing limits, and increasing enrollee cost-sharing amounts. In 2007, three-quarters (75%) of workers with employer-sponsored coverage had a cost-sharing arrangement with 3 or 4 tiers, over 2½ times the proportion in 2000 (27%).[22] Copayments for nonpreferred drugs (those not included on a formulary or preferred drug list) increased 48% from an average of $29 in 2000 to $43 in 2007. Copayments for preferred drugs (those included on a formulary or preferred drug list, such as a brand name drug without a generic substitute) increased by 67%, from an average of $15 in 2000 to $25 in 2007 (Figure 4).

Figure 4: Among Covered Workers with Three or Four-Tier Prescription Drug Cost Sharing, Average Copayments, 2000-2007



*Estimate is statistically different from estimate for the previous year shown at p<.05.
^Fourth-Tier drug copay information was not obtained prior to 2004.
Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000-2007, Exhibit 9.4, http://www.kff.org/insurance/7672/index.cfm

Discounts and Rebates. Private and public drug programs negotiate with pharmaceutical manufacturers (often using contracted organizations known as pharmacy benefit managers) to receive discounts and rebates which are applied based on volume, prompt payment, and market share. Manufacturers who want their drugs covered by Medicaid must provide rebates to state Medicaid programs for the drugs they purchase; many states have also negotiated additional rebates, known as supplemental rebates.

Several government agencies, including the Department of Veterans Affairs, the Defense Department, the Public Health Service, and the Coast Guard, participate in a program known as the Federal Supply Schedule through which they purchase drugs from manufacturers at prices equal to or lower than those charged to their "most-favored" nonfederal purchasers. In order to participate in Medicaid, another program, the Section 304B Program, requires manufacturers to provide drugs to certain nonfederal entities (such as community health centers and disproportionate share hospitals) at reduced prices. Federal legislation to expand this program was introduced in 2007 but has not as yet been enacted.

Medicaid. Historically, prescription drugs have been one of the fastest-growing Medicaid services. The Deficit Reduction Act of 2005 gave states more authority to control Medicaid drug spending through increased cost sharing for non-preferred drugs, changes in the way Medicaid pays pharmacists, allowing pharmacists to refuse prescriptions for beneficiaries who don't pay their cost sharing, and inclusion of authorized generic drugs in the calculation of "best price" for drugs. A 2006 survey of 50 states+DC found that more than half had Medicaid pharmacy cost containment measures in place in FY2006, including preferred drug lists and prior authorization programs (about 75% of states), supplemental rebates from manufacturers (about 70% of states), and state Maximum Allowable Cost programs for generic and multi-source brand drugs (about 60%); smaller proportions of states were members of multi-state purchasing coalitions (about 25%) or had limits on quantities dispensed per prescription (about 20%).[23] BY 2007, most states had already implemented many of these approaches, so new action to control drug spending slowed.[24]

The Centers for Medicare & Medicaid Services issued a rule (known as the AMP Rule) in July 2007 that would have set limits on federal government

reimbursements to states for Medicaid prescriptions; however, in December 2007, a US District Court issued a preliminary injunction against this change. Several bills have been introduced in Congress to address this issue.

Medicare. The Medicare Part D drug benefit shifted spending from the private sector and Medicaid to Medicare, making Medicare the nation's largest public payer of prescription drugs in 2006, when Medicare spending rose to 18% of total US prescription spending from 2% in 2005.[25] Under the Medicare Part D legislation, Medicare is prohibited from directly negotiating drug prices or rebates with manufacturers, but will rely on the private Part D drug plans to negotiate these discounts/rebates. In early 2007, the 110th Congress considered but did not pass legislation to allow or require Medicare to negotiate drug prices with drug makers.

Purchasing Pools. Some public and private organizations have banded together to form prescription drug purchasing pools to increase their purchasing power through higher volume and shared expertise. Examples include joint purchasing by the Department of Defense and VA; multi-state bulk buying pools through which states purchase drugs for their Medicaid, state employees, senior/low-income/uninsured pharmacy assistance programs, or other public programs; and individual state purchasing pools.[26]

Consumers. Consumers are turning to a variety of methods to reduce their prescription costs,[27] including requesting cheaper drugs or generic drugs from their physicians and pharmacies, using the Internet and other sources to make price comparisons, using the Internet to purchase drugs, buying at discount stores, buying over-the-counter instead of prescribed drugs, buying drugs in bulk and pill-splitting, using mail-order pharmacies,[28] and using pharmaceutical company or state drug assistance programs. Over half of physicians say they frequently talk with patients about the out-of-pocket costs of medicines they prescribe, 62% say they switch patients to less expensive drugs, and 58% say they give patients office samples.[29]

Importation. The high cost of prescriptions has led some to suggest that individuals be permitted to purchase prescription products from distributors in Canada or other countries (called "importation," or "reimportation" if the drug is manufactured in the US). Although it is generally not lawful for individuals or commercial entities such as pharmacies or wholesalers to purchase prescription drugs from other countries, the government does not always act to stop individuals from purchasing drug products abroad. Importation of pharmaceutical products from Canada through Internet sales and travel to Canada totaled about $700 million in sales in 2003, or 0.3% of total US prescription sales. An equivalent amount of prescription drugs was estimated to have entered the US from the rest of the world, mostly through the mail and courier services.[30] P.L. 109-295 (enacted in 2006) allows US residents to transport up to a 90-day supply of qualified drugs from Canada to the US. Actual savings amounts, drug safety, and marketplace competition and pricing are importation issues being debated.

Outlook for the Future

HHS projects US prescription drug spending to increase from $216.7 billion in 2006 to $515.7 billion in 2017, a 138% increase in 11 years. The average annual increase in drug spending from the previous year is projected to drop from 8.5% in 2006 to 6.7% in 2007 because of a deceleration in drug price growth, and then rise to 9.6% in 2017, or an 8.2% average annual increase over the 11-year period. Drug spending as a percent of overall health spending is projected to increase from 10% in 2006 to 12% in 2017. HHS projects that over the next decade, drug spending growth will accelerate due to a leveling off of growth in the use of generic drugs, rising utilization rates, and a mild acceleration in new drugs coming onto the market.[31]

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[1] All spending amounts in this report are in current dollars (i.e., not adjusted for inflation).

[2] Centers for Medicare & Medicaid Services, National Health Expenditure Accounts, Historical, http://www.cms.hhs.gov/NationalHealthExpendData/.

[3] Aaron Catlin et al., "National Health Spending In 2006: A Year Of Change For Prescription Drugs," *Health Affairs* 27, no. 1, (January/February 2008).

[4] Kaiser Family Foundation calculations using data from IMS Health, http://www.imshealth.com (About Us, Press Room, US Top-Line Industry Data), and Census Bureau, http://www.census.gov. The per capita number may differ from the number reported at KFF's website www.statehealthfacts.org because of differing data sources which use different retail pharmacy definitions (e.g., IMS Health includes mail order, Verispan does not).

[5] Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey Component Data, "Prescription Medicines – Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment," table 2, 1997 and 2005, http://www.meps.ahrq.gov/mepsweb/.

[6] Aaron Catlin et al., "National Health Spending In 2006: A Year Of Change For Prescription Drugs," *Health Affairs* 27, no. 1, (January/February 2008).
[7] Retail prescription prices reflect the prices paid by insured and uninsured patients, and do not reflect rebates, discounts, and other payments that in effect lower the cost of prescriptions.
[8] Kaiser Family Foundation calculations using data from the National Association of Chain Drug Stores, "Industry Facts-at-a-Glance," http://www.nacds.org (based on data from IMS Health), and Consumer Price Index, US City Average, All items, from the Bureau of Labor Statistics, http://www.bls.gov.
[9] US Food and Drug Administration, http://www.fda.gov/cder/rdmt/; 2004-2007 data include new BLAs (biologic license applications) for therapeutic biologic products transferred from FDA's Center for Biologics Evaluation and Research to its Center for Drug Evaluation and Research.
[10] US Food and Drug Administration, Center for Drug Evaluation and Research, "Generic Competition and Drug Prices," http://www.fda.gov/cder/ogd/generic_competition.htm.
[11] Generic Pharmaceutical Association, http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm.
[12] IMS Health, http://www.imshealth.com (About Us, Press Room, 2007 US Top-Line Industry Data); Kaiser Family Foundation, *Prescription Drug Trends, a chartbook*, (July 2000), ex. 3.13, http://www.kff.org/rxdrugs/3019-index.cfm. The data on spending for advertising directed towards physicians excludes the retail value of drug samples left at sales visits to physicians' offices, which totaled about $16 billion in 2004, the last year such data were available online from IMS Health.
[13] Fortune 500 online, http://money.cnn.com/magazines/fortune/fortune500/2008/performers/industries/profits/index.html, and personal communication; April issues of *Fortune* magazine.
[14] "Moderating Growth Reflects Impact of Patent Expirations, Fewer Product Approvals, Maturing Medicare Part D Program, and Safety Issues," IMS Health Press Release (March 12, 2008), http://imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_83470499,00.html.
[15] Kaiser Family Foundation, Kaiser Public Opinion Survey Brief, *Economic Problems Facing Families* (April 2008), p. 4, http://www.kff.org/kaiserpolls/upload/7773.pdf.
[16] US Census Bureau, *Income, Poverty and Health Insurance Coverage in the United States: 2007* (August 2008), Table C-1, p. 61, http://www.census.gov/prod/2008pubs/p60-235.pdf.
[17] Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits 2007 Annual Survey* (September 2007), pp. 36 and 51, http://www.kff.org/insurance/7672/upload/76723.pdf
[18] Ibid, p. 134, http://www.kff.org/insurance/7672/upload/76723.pdf.
[19] Dana Gelb Safran et al., "Prescription Drug Coverage And Seniors: Findings From A 2003 National Survey," *Health Affairs*, Web Exclusive (April 19, 2005): W5-160, http://www.kff.org/medicare/med041905pkg.cfm.
[20] Kaiser Family Foundation, *The Medicare Prescription Drug Benefit*, (February 2008), http://www.kff.org/medicare/upload/7044_08.pdf.
[21] Kaiser Family Foundation calculations using data from John Holahan and Arunabh Ghosh, *Dual Eligibles: Medicaid Enrollment and Spending for Medicare Beneficiaries in 2000* (Kaiser Commission on Medicaid and the Uninsured, July 2005), 8,10,21, http://www.kff.org/medicaid/7346.cfm.
[22] Kaiser Family Foundation and Health Research and Educational Trust, op. cit., Ex. 9.1, http://www.kff.org/insurance/7672/sections/ehbs07-9-1.cfm.
[23] Kaiser Family Foundation calculations using data from Vernon Smith et al., *Low Medicaid Spending Growth Amid Rebounding State Revenues: Results from a 50-State Medicaid Budget Survey, State Fiscal Years 2006 and 2007* (Kaiser Commission on Medicaid and the Uninsured, October 2006), 39, fig. 24, http://www.kff.org/medicaid/upload/7569.pdf.
[24] Kaiser Commission on Medicaid and the Uninsured, *Few Options for States to Control Medicaid Spending in a Declining Economy* (April 2008), p. 3, http://www.kff.org/medicaid/upload/7769.pdf.
[25] Aaron Catlin et al., op.cit., ex. 4, p. 19.
[26] National Conference of State Legislatures, "Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans, 2008 edition" (Updated May 8, 2008), http://www.ncsl.org/programs/health/bulkrx.htm.
[27] Devon Herrick, National Center for Policy Analysis, *Shopping for Drugs: 2004*, National Center for Policy Analysis, Policy Report No. 270 (October 2004), http://www.ncpa.org/pub/st/st270.
[28] US mail services sales have increased 54% since 2003, though their share of total US prescription sales has increased only slightly -- 2007: $44.6 billion in sales, 16% of total prescription sales; 2003: $28.9 billion in sales, 13% of total prescription sales. IMS Health, http://www.imshealth.com (About Us, Press Room, US Top-Line Industry Data, 2007 U.S).
[29] Kaiser Family Foundation, *Prescription Drugs: Advertising, Out-of-Pocket Costs, and Patient Safety from the Perspective of Doctors and Pharmacists* (November 2006), http://www.kff.org/kaiserpolls/upload/7583.pdf.
[30] US Department of Health and Human Services Task Force on Drug Importation, *Report on Prescription Drug Importation* (December 2004), ix, http://www.hhs.gov/importtaskforce/Report1220.pdf.
[31] Sean Keehan et al., "Health Spending Projections Through 2017: The Baby-Boom Generation Is Coming To Medicare," *Health Affairs*, Web Exclusive (February 26, 2008), w145-w155.

For More Information:

In addition to the Kaiser Family Foundation reports found in the Endnotes above, this Fact Sheet (#3057-07) and the following reports are available on the Foundation's website at www.kff.org: *Trends and Indicators in the Changing Health Care Marketplace* (#7031), *Prescription Drug Trends—A Chartbook Update* (#3112), *Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature* (#7295), *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* (#7296), *Medicare Prescription Drug Benefit Fact Sheet* (#7044-08), *Medicare Payments and Beneficiary Costs for Prescription Drug Coverage* (#7620), *Resources on the Medicare Prescription Drug Benefit*, *Medicaid and Outpatient Prescription Drugs* (#1609-03), *Federal Policies Affecting the Cost and Availability of New Pharmaceuticals* (#3254), and *Retiree Health Benefits Examined: Findings from the Kaiser/Hewitt 2006 Survey on Retiree Health Benefits* (#7587). See also www.statehealthfacts.org for state-specific prescription drug utilization and sales (under Health Costs & Budgets); www.kaiserEDU.org (Prescription Drugs) for a Tutorial, Issue Modules, and SmartLinks on prescription drugs; and http://facts.kff.org/ (search for Prescription Drugs) for Fast Facts about prescription drugs.

Prepared by Janet Lundy of the Kaiser Family Foundation.

EXHIBIT C

HOOVERS™
A D&B COMPANY

Rite Aid Corporation

Camp Hill, PA United States • NYSE RADother stock tickers

Also trades as: Chicago Options: RAD; Direct Edge A: RAD; Munich: RTA; NASDAQ 2: RAD; NASDAQ CTA: RAD; National of Chicago: RAD; NYSE: RAD; NYSE Arca: RAD; OMX BX: RAD; OMX PSX: RAD;

This company is covered by Alexandra Biesada.


Alexandra Biesada has covered the retail beat for Hoover's since 2001.

Competitive Landscape

This page shows Financial Comparisons between this company, up to three competitors and Industry Medians. You can use the button at the right to select different competitors to compare with this company.

2012 Annual Sales

Save chart as:
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2012 Net Profit Margin

Save chart as:
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2012 Key Numbers

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen
Annual Sales	$26.12B	$123.13B	$469.16B	$71.63B
Employees	90,000	280,000	2,200,000	240,000
Market Cap	$1.38B	$59.52B	$231.81B	$33.76B

2012 Profitability

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen	Industry Median	Market Median1
Gross Profit Margin	27.04%	18.28%	24.87%	29.04%	22.75%	34.80%
Pre-Tax Profit Margin	(0.97%)	5.14%	5.49%	4.61%	4.30%	10.10%
Net Profit Margin	(0.68%)	3.15%	3.62%	2.91%	2.62%	6.58%
Return on Equity	--	10.24%	23.02%	12.45%	10.99%	10.58%
Return on Assets	(2.40%)	5.94%	8.57%	6.76%	5.43%	1.95%
Return on Invested Cap	--	7.40%	12.10%	10.07%	7.80%	5.68%

2012 Valuation

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen	Industry Median	Market Median1
Price/Sales Ratio	0.06	0.57	0.54	0.62	0.53	1.25
Price/Earnings Ratio	(9.55)	18.15	14.90	21.23	35.21	27.62
Price/Book Ratio	(0.62)	1.80	3.23	2.38	2.15	1.99
Price/Cash Flow Ratio	2.77	10.55	9.91	9.90	9.90	8.70

2012 Operations

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen	Industry Median	Market Median1
Days of Sales Outstanding	13.20	18.56	4.94	12.02	16.62	44.47
Inventory Turnover	5.87	9.67	8.34	6.66	7.75	6.99
Days Cost of Goods Sold in Inventory	62.20	37.73	43.76	54.79	47.11	52.25
Asset Turnover	3.54	1.89	2.37	2.32	2.07	0.30
Net Receivables Turnover Flow	27.64	19.67	73.85	30.36	21.96	8.21
Effective Tax Rate	--	38.61%	31.01%	36.94%	39.06%	28.52%

2012 Financial

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen	Industry Median	Market Median1
Current Ratio	1.75	1.44	0.83	1.23	1.44	1.44
Quick Ratio	0.46	0.57	0.20	0.40	4.42	4.92
Leverage Ratio	--	1.75	2.66	1.83	2.05	5.56
Total Debt/Equity	--	0.26	0.71	0.30	0.44	0.93
Interest Coverage	0.52	12.35	12.43	--	6.53	6.51

2012 Per Share Data

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen	Industry Median	Market Median1
Revenue Per Share	$29.35	$96.20	$138.44	$77.26	$16.86	--
Dividend Per Share	$0.00	$0.65	$1.59	$1.05	--	--
Cash Flow Per Share	$0.69	$5.21	$7.55	$4.82	--	--
Working Capital Per Share	$2.14	$4.92	($3.61)	$2.15	$3.32	$1.94
Long-Term Debt Per Share	$6.91	$7.42	$12.58	$4.30	$0.03	$0.04
Book Value Per Share	($3.05)	$30.62	$23.19	$20.02	--	--
Total Assets Per Share	$8.15	$53.54	$61.69	$35.32	$32.29	$43.38

2012 Growth

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen	Industry Median	Market Median1
12-Month Revenue Growth	3.59%	14.97%	4.97%	(0.76%)	4.88%	(3.83%)
	--	12.02%	8.28%	(21.63%)	(1.15%)	(11.71%)

	Rite Aid	CVS Caremark	Wal-Mart	Walgreen	Industry Median	Market Median1
12-Month Net Income Growthh						
12-Month EPS Growth	--	16.99%	10.57%	(17.69%)	--	--
12-Month Dividend Growth	--	30.00%	8.90%	26.67%	--	--
36-Month Revenue Growth	(0.21%)	7.64%	4.75%	4.19%	4.89%	7.10%
36-Month Net Income Growth	--	1.61%	5.85%	1.97%	20.69%	17.35%
36-Month EPS Growth	--	5.78%	10.51%	6.21%	--	--
36-Month Dividend Growth	--	28.69%	13.41%	25.99%	--	--

1 Public companies trading on the New York Stock Exchange, the American Stock Exchange, and the NASDAQ National Market.

EXHIBIT D

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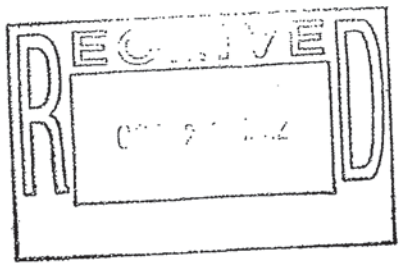

October 23, 2012

Tyler N. Williams
Dinsmore & Shohl
Huntington Square
900 Lee Street, Suite 600
Charleston, WV 25301

Re: Declaratory Ruling in the Matter of Walgreen Co. & The Kroger Co.

Dear Mr. Williams,

Please find enclosed the Declaratory Ruling in the Matter of Walgreen Co. and The Kroger Co. Thank you for your attention to this matter. Should you have any questions or concerns please feel free to contact me.

Sincerely,

David E. Potters

David E. Potters
Executive Director & General Counsel

cc: Frances A. Hughes
Michael B. Hissam

BEFORE THE WEST VIRGINIA BOARD OF PHARMACY

WALGREEN CO. and
THE KROGER CO.

DECLARATORY RULING IN THE MATTER OF
WALGREEN CO. AND THE KROGER CO.

Pending before the Board is a Petition for Declaratory Ruling filed by Walgreen Co. and The Kroger Co.[1] The Petition was filed pursuant to the West Virginia Administrative Procedures Act,[2] W. Va. Code § 29A-4-1. It seeks a declaration regarding the applicability of W. Va. Code § 30-5-12b,[3] part of the West Virginia Pharmacy Act,[4] to pharmacy reimbursement contracts entered into between Petitioners and third-party reimbursement sources such as pharmacy, medical and prescription benefit plans.[5]

1. PUBLIC HEARINGS

After having given the necessary public notice, Board President Lydia Main brought the Petition up for consideration at the Board's regularly scheduled meeting in Huntington, West Virginia on September 7, 2012. Before hearing arguments and taking evidence, Board Members Carl K. Hedrick, Jr. and Rebekah E. Hott recused themselves from the proceedings based upon their association with one or more of the Petitioners or other pharmacies that may be similarly situated. The remaining Board Members then proceeded to hear testimony from Dan Luce on behalf of Walgreen Co.[6] and arguments by counsel for both of the Petitioners.

Mr. Luce described the history of changes in the market for prescription medications over the more than three decades since Section 12b was adopted and the increased use of generic prescription medications over that period. This history is set forth in some detail below. Perhaps most notable among the factors and marketplace changes contributing to the increased use of generic drugs has been the growth in the number of Benefit Plans providing coverage for prescription medications. Mr. Luce also discussed the impact such expanded coverage afforded by Benefit Plans has had on

[1] Hereinafter referred to as "Petitioners."
[2] Hereinafter referred to as the "APA."
[3] Hereinafter referred to as "Section 12."
[4] Hereinafter referred to as the "Pharmacy Act."
[5] Hereinafter referred to collectively as "Benefit Plans."
[6] Also present at the hearing were Tracy McDaniel and Christopher Koon from The Kroger Co. Both were prepared to offer testimony supportive of that presented by Mr. Luce. Because their testimony would have been largely duplicative, it was deemed unnecessary.

reimbursement rates that pharmacies receive for dispensing such medications. All of this is set forth in greater detail below.

In addition to the foregoing, the Board had the benefit of written submissions filed by the Petitioners prior to the hearing. Those submissions, as well as the arguments heard on September 7, addressed not only the merits of the Petition but also the Board's legal authority to hear and decide the questions presented.[7] The Petitioners addressed the latter issue in response to an Opinion issued by the Attorney General after the Petition was filed.[8] In that Opinion, the Attorney General took the position that the Board not only should not but could not address the questions presented.

Following the taking of evidence and arguments of counsel, the Board considered the issues, including whether it had the legal authority to proceed. Whereupon Board Member Charles Woodcock moved that the Board issue a ruling in favor of Petitioners, which motion was seconded by Board Member Samuel Kapourales. After further discussion, the Board, based upon the record before it and considering itself otherwise sufficiently advised, unanimously approved that motion. It thereupon directed the Board's General Counsel to prepare a written ruling consistent with Mr. Woodcock's motion for presentation at the next Board meeting.

On October 9, 2012, after giving the requisite public notice, the Board reconvened to consider the draft ruling prepared by its General Counsel. Before doing so, Mr. Hedrick and Ms. Hott again recused themselves from those deliberations. That draft, appearing to fully and accurately reflect the prior motion, was thereupon approved and adopted and is hereby entered. In so doing, the Board formally approves and adopts the findings and ruling set forth herein. This ruling is binding only as between Petitioners and the Board in accordance with the provisions of the APA. It may, however, serve as guidance to others similarly situated with respect to the Board's position regarding Section 12b.

2. THE BOARD'S RULING

a. The Legislature, through the adoption of the Pharmacy Act, specifically delegated to the Board of Pharmacy the exclusive

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[7] Those submissions were made a part of the record in this matter.

[8] W. Va. Code § 5-3-1 provides that they shall give written opinions and advice upon questions of law "whenever required to do so, in writing, by . . . any . . . board . . . ." The Board made no written request for the Attorney General's Opinion as to its authority, having available to it its own General Counsel who is fully conversant with the statutory authority pursuant to which it operates. The Board is also unaware of any such written request for that Opinion having been requested by the Governor or any other executive branch officer. As such, the Board questions the basis upon which the Attorney General presumed to issue that Opinion. That said, the Board has given the substance of the Attorney General's Opinion due consideration in rendering its ruling in this matter.

authority to regulate the practice of pharmacy in the State of West Virginia;

b. By virtue of the specific authority granted it under the Pharmacy Act, the Board is authorized under the APA to issue a declaratory ruling in response to the Petition before it;

c. The Petition raises important questions regarding the scope and application of Section 12b that the Board should address;

d. At the time Section 12b was adopted, generic drugs were not in widespread use and the vast majority of prescriptions were filled by means of direct consumer purchases from individual pharmacists without the involvement of Benefit Plans, the vast majority of which did not provide coverage for prescription medication;

e. In order to encourage the use of lower cost, but therapeutically equivalent generic medications, Section 12b expressly provides that, when presented with a prescription for a brand name medication, a pharmacist shall substitute a lower cost, therapeutically equivalent generic and all savings in the retail price shall be passed on to the purchaser;

f. Concepts such as prescription drug benefit plans, Pharmacy Benefit Managers, third-party payors, and pharmacy reimbursement contracts that prevail today were largely unknown at the time Section 12b was enacted;

g. For this reason, Section 12b speaks in terms of the type of retail sales that predominated in 1978 and makes no reference to third-party transactions involving pharmacy reimbursement contracts such as predominate today;

h. Prior to the adoption of Section 12b, Congress enacted ERISA. ERISA's provisions govern pharmacy benefit plans provided by non-governmental, non-church employers or employee

organizations such as unions, a fact which the Legislature presumptively knew at the time it enacted Section 12b.

i. ERISA would preempt application of Section 12b to pharmacy reimbursement contracts entered into by such plans, a fact which the Legislature presumptively knew at the time it enacted Section 12b. *See, PCMA v. Dist. Of Columbia*, 613 F.3d 179 (D.C. Cir. 2010);

j. Extension of Section 12b to pharmacy reimbursement contracts negotiated by agencies of the State of West Virginia such as the Public Employees Insurance Agency would create the specter of pharmacies being subjected to penalties imposed by one arm of the state for complying with contracts deemed by another arm of the state to be in the best interest of those it represents;

k. Attempting to apply Section 12b to pharmacy reimbursement contracts would materially increase the administrative costs associated with the practice of pharmacy in West Virginia when compared to those of other states. Those costs would likely be passed along to Benefit Plans and, ultimately, their beneficiaries. The imposition of these added costs is contrary to the intended purpose behind Section 12b and would be contrary to the public interest and welfare the Pharmacy Act is intended to protect;

l. The Legislature has not appropriated the substantial resources that would be required to the Board to enforce the provisions of Section 12b if the Legislature truly deemed it applicable to pharmacy reimbursement contracts;

m. Since its adoption in 1978, no complaint has ever been filed with the Board pursuant to Section 12b(q) by any person, including the Attorney General of West Virginia, claiming that pharmacies in West Virginia were violating the provisions of Section 12b by complying with freely negotiated pharmacy reimbursement contracts;

n. In interpreting and applying the provisions of the Pharmacy Act, the primary goal of the Board is to ascertain and give effect to the intent of the Legislature. *See Raines Imps. v. Am. Honda Motors Co.*, 674 S.E.2d 9 (W.Va. 2009). In so doing, the Board must consider the plain language of the statute itself. *See Pilgrim's Pride Corp.* v. *Morris*, 723 S.E.2d 642 (W.Va. 2011). However, where a literal reading of a statutory enactment would compel a result at odds with its intended purpose, the Board may consider the historical context in which statute was enacted. *Public Citizens* v. *United States Dep't of Justice*, 491 U.S. 440, 455 (1989); *State ex rel. Holmes* v. *Gainer*, 447 S.E.2d 887 (W.Va. 1994). Finally, a statute should be read to afford it practical application in carrying out the purpose for which it was enacted. *Thomas* v. *South Charleston*, 148 W.Va. 577; 136 S.E.2d 788 (1964).

o. With these principles in mind and based upon all of the foregoing factors, whether considered individually or collectively, the Board is of the opinion and accordingly rules that:

(i) the provisions of Section 12b apply only to retail transactions involving the substitution of a lower cost, therapeutically equivalent, generic medication for the medication prescribed by a physician; and

(ii) they do not apply to transactions subject to pharmacy reimbursement contracts involving third-party payors as described herein; and

p. The Board is further of the opinion that should its ruling regarding the scope and application of Section 12b as reflected herein be deemed erroneous by a reviewing authority, until and unless the Legislature appropriates the resources necessary to apply Section 12b to pharmacy reimbursement contracts, the Board will exercise its prosecutorial discretion to devote such resources as it has available to it toward the pursuit of other

matters arising under the Pharmacy Act that have a true adverse impact the public health and welfare.

3. DISCUSSION

a. The Board's Authority

Because the Attorney General's Opinion raises questions regarding its legal authority to issue the requested declaratory ruling, the Board believes it necessary and appropriate to first address that question. The Petition was filed in accordance with the APA. In § 29A-4-1, the APA provides that:

> On petition of any interested person, an agency may issue a declaratory ruling with respect to the applicability to any person . . . or state of facts of any . . . statute enforceable by it.

Here, Petitioners seek a declaratory ruling with respect to the applicability of Section 12b to certain stated facts detailed in the Petition. Given that they operate pharmacies in West Virginia, Petitioners are clearly subject to the provisions of Section 12b and are, therefore, "interested parties" under the APA and entitled to seek the requested declaratory ruling. The only remaining question then is whether the Pharmacy Act is enforceable by the Board. Notwithstanding the Attorney General's assertions to the contrary, the Board's authority to enforce the Pharmacy Act is incontrovertible.

The State Legislature is vested with the authority to regulate the pharmacy profession, among other professions, in order to ensure the health, safety and welfare of the general public. *See, e.g., State ex rel. Barker* v. *Manchin,* 167 W.Va. 155, 279 S.E.2d 622 (W. Va. 1981). Absent a specific delegation of that authority to the executive branch, it is a matter of "fundamental law" that neither the Governor (through his executive agencies and boards) nor the Attorney General may impinge upon that power. *Id.* at 630. *See also, State ex rel. State Bldg. Cmm'n* v. *Bailey,* 151 W.Va. 79, 150 S.E.2d 449 (W. Va. 1966).

The Legislature, through the Pharmacy Act, delegated its authority to regulate pharmacists and pharmacies to this Board exclusively. *See,* W. Va. Code § 30-5-2(e)(1). It granted no other agency, board or executive branch officer, including the Attorney General, any such regulatory authority. Because of the Legislature's exclusive delegation of authority, this Board – and this Board alone – is charged with determining who may engage in the practice of pharmacy and operate pharmacies within our borders, as well as whether the privilege of practicing pharmacy should be revoked or suspended as a result of a failure to abide by the provisions of the Act. W. Va. Code §§ 30-5-5, 30-5-7, and 30-5-19. *See also, Barker.*279 S.E.2d at 630; *Coll* v. *Cline,* Syl Pt. 2, 320 W. Va. 599, 505 S.E.2d 662 (W. Va. 1988), *Mountaineer Disposal* v. *Dryer,* Syl Pt. 3, 156 W.Va. 766, 197 S.E.2d 111 (W. Va. 1973).

More specifically, the Legislature expressly authorized this Board to investigate and adjudicate complaints filed against pharmacists and pharmacies for alleged violations of Section 12b and to impose such penalties and take such other actions as are appropriate when it finds that Section 12b has been violated. No other agency or executive branch office is vested with any similar authority. W. Va. Code §§ 30-5-12b(q), 30-5-12b(r). In order to properly discharge this responsibility, the Board is implicitly, if not explicitly, authorized to interpret and apply Section 12b. The Attorney General's arguments to the contrary defy common sense and, if adopted, would frustrate the very purpose of the Act itself.

Given the Legislature's specific and exclusive delegation to the Board of the authority to regulate the practice of pharmacy in West Virginia, the Board finds that it has the legal authority – indeed the legal duty – to issue a declaratory ruling as to the scope and applicability of Section 12b of the Pharmacy Act. W. Va. Code § 29A-4-1. Because the Petition raises important questions regarding Section 12b, the answers to which may have significant impacts upon the manner in which the practice of pharmacy is conducted in West Virginia, the Board is of the opinion that those questions should be answered through the issuance of a declaratory ruling.

In so ruling, the Board rejects the Attorney General's assertion that declaratory rulings issued pursuant to W. Va. Code § 29A-4-1 are limited to factual situations unique to the person requesting that ruling. The plain language of W. Va. Code § 29A-4-1 requires only that the declaratory ruling go to the question of the applicability of the statute to a state of facts, nothing more. To adopt the Attorney General's reading of W. Va. Code § 29A-4-1 would require the Board to rewrite the statute by inserting requirements that do not appear within its text. This is something that the Attorney General himself acknowledges is improper under the rules governing statutory construction.

The Board also rejects the Attorney General's contention that the Board should stay its hand with respect to the Petition in light of civil actions the Attorney General previously filed against Petitioners (and others) in Boone County, West Virginia.[9] In those actions, the Attorney General has sought to enforce Section 12b as he interprets its provisions.[10] In urging the Board to stay its hand pending the outcome of those actions, the Attorney General presupposes that the Legislature vested

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[9] The Board has been advised that the Circuit Court dismissed the Attorney General's claims against Walgreen and various other defendants on the grounds that venue was improper in Boone County. His claims against the Kroger Co. and Rite Aid remain pending, however.

[10] He has done so based upon the provisions of W. Va. Code § 30-5-23 which provide that "the Board of Pharmacy or any person . . . may apply to a court having competent jurisdiction over the parties and the subject matter for a writ of injunction to restrain repetitious violations of the provisions of this article." An application for injunctive relief under this section necessarily presupposes that there has been a prior finding by the Board of "repetitious violations" of the Pharmacy Act. *See* W. Va. Code § 30-5-12b(r). It does not and cannot mean that any "person" is entitled to apply for injunctive relief whenever, in their individual judgment, the Pharmacy Act has been violated on a repetitious basis. To so interpret § 30-5-23 would destroy the uniform regulation of the practice of pharmacy in West Virginia that the Pharmacy Act was intended to accomplish.

him with concurrent authority to enforce the provisions of the Pharmacy Act in general and Section 12b specifically. With all due deference, the Attorney General's presupposition is incorrect.

As previously noted, the Pharmacy Act is not enforceable by the Attorney General. The Legislature delegated no such authority to him and he is not vested with any such authority by virtue of the common law. *State ex rel. Manchin* v. *Browning*, 120 W. Va. 779, 296 S.E.2d 909 (W. Va. 1982). *See, e.g., State ex rel. Barker* v. *Manchin*, 167 W.Va. 155, 279 S.E.2d 622 (W. Va. 1981); *see also, State ex rel. State Bldg Comm'n* v. *Bailey* 151, W.Va. 79, 150 S.E.2d 449 (W. Va. 1966).[11] Moreover, the Attorney General did not initiate his civil suits in Boone County at the Board's request or in his capacity as the Board's legal counsel. The Attorney General neither consulted with the Board regarding the advisability of such action nor solicited the Board's view as to the proper scope and application of Section 12b. Instead, he chose to act unilaterally and, in so doing, impinge upon the authority delegated to the Board. Given this, the Board is not required to and should not, as a matter of policy, stay its hand in deference to the Attorney General's civil litigation.[12]

Being mindful of the responsibilities vested in this Board by the Legislature regarding the regulation of the practice of pharmacy in West Virginia as well as the applicable rules of statutory construction, the Board now turns to Section 12b and the specific questions presented by the Petition.

b. History of Section 12b

Consistent with the testimony of Mr. Luce and the submissions of the Petitioners, it is clear that Section 12b was enacted in 1978 at a time when the pharmacy market in the United States was vastly different than it is today. Generic drugs had only recently been introduced to the market and were not in widespread use. Pharmacies and pharmacists had considerably more flexibility in setting the retail prices for prescription medications than they do now. Most people for whom prescription medications

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[11] *See also, Securities Investor Protection Corp.* v. *Barbour*, 421 U.S. 412 (1975). That case involved the question of whether an entity other than the Securities and Exchange Commission was entitled to institute certain proceedings under SIPA. In concluding that it could not, the Supreme Court noted that Congress created the SEC to solve a public problem and provided it with substantial supervisory and enforcement powers to do so. This statutory scheme "ordinarily implies that no other means of enforcement was intended by the Legislature." That would yield only to "clear contrary evidence of legislative intent." *Id. at* 419, quoting *Passenger Corp.* v. *Passenger Assn.*, 414 U.S. 453, 458 (1974).

[12] The Board recognizes that its authority to issue declaratory rulings is not without boundaries. In issuing such rulings, it must, for example, do so in accordance with established rules governing the construction of statutes. In order to ensure that it has done so, moreover, its rulings are subject to review by the Circuit Court of Kanawha County. W. Va. Code § 29A-4-1; W. Va. Code § 29A-5-2. As the West Virginia Supreme Court has made clear, however, the reviewing court is not to address the question *de novo*. Rather, it must defer to the Board's reading of the statute, even if it might have construed it statute differently, so long as the Board has reached its decision in accordance with the applicable rules of construction. *West Virginia Health Care Cost Review Auth. v. Boone Mem'l Hosp.*, 196 W. Va. 326, 472 S.E.2d 411 (1996). This deference reflects the judicial branch's recognition of the proper role of the executive branch and the fact that the resolution of questions such as those presented here often encompass not just questions of law, but also questions of public policy that executive agencies, as opposed to the Courts, are best equipped to address. *Pauley v. Beth Energy Mines*, 561 U.S. 680 (1991); *Wyeth* v. *Levin*, 129 S.Ct. 1187, 173 L. Ed.2d 51, 2009 LEXIS 1774, 2009 WL 529172 at 11 (Mar. 4, 2009).

were prescribed paid 100% of the cost of their prescription medications out of their own pockets. And, people were generally unaware of the availability of less expensive, generic drugs or their ability to request that their physicians prescribe such medications in lieu of more costly brand name drugs.

Faced with this reality and the pressures that increasing costs were having upon individual consumers of prescription drugs, the Legislature enacted Section 12b. It was clearly intended to encourage the substitution of less expensive, therapeutically equivalent generic medications for more expensive, brand name drugs whenever such an equivalent was available. It did so by authorizing pharmacists to exercise their professional judgment to make such substitutions and requiring that the cost savings resulting from that substitution be passed along to the consumer/patient.

After the enactment of Section 12b, the pharmacy market underwent a dramatic and fundamental change. Employers began offering pharmacy benefit plans to their employees in ever increasing numbers. As a result, the vast majority of prescription medications today are covered by such plans. As the number of such plans grew, they began using the services of pharmacy benefit managers (PBMs) to negotiate contracts for pharmacy services with independent pharmacy groups, chains, and individual pharmacists. Today, those contracts are often multi-state or nationwide in scope. Moreover, it is now common for PBMs to represent multiple plans. As a consequence, they bring to their negotiations the aggregated purchasing power of those plans and all of the individual participants in those plans.

Pharmacy benefit plans are, and have been from the outset, under pressure to manage their expenses and hold down costs passed along to employers and beneficiaries. In order to do so, they increasingly rely on PBMs. PBMs, in turn, compete for the business of these plans based upon their ability to negotiate contracts that provide for pharmacy services at the lowest possible cost. This has resulted in contracts with Petitioners and other pharmacies throughout West Virginia and the nation that require the substitution of lower cost and therapeutically equivalent generic drugs for prescribed name brand medications and for the reimbursement of the pharmacies dispensing those medications at rates substantially below what would otherwise be charged at retail. Those requirements and reimbursement rates govern the entire spectrum of medications covered by these plans. Pharmacies agree to those requirements because of the anticipated number of prescriptions they will fill over the life of the contract, numbers that could not necessarily be achieved in the absence of such a contract

Thus, market forces that were not present (and could not reasonably have been anticipated) in 1978 are, today, causing generic medications to be dispensed in far greater numbers and at lower costs than was the case when Section 12b was enacted. The contractual arrangements between pharmacies and Benefit Plans are far different from the direct-to-consumer transactions that predominated in 1978. They are also far more complex, involve parties with relatively equal bargaining power, and result in agreements that serve the interests of the beneficiaries of these plans. It is against this background that the Board must determine whether Section 12b is applicable to prescriptions

dispensed pursuant to these types of contracts and, if so, how it is to be applied as a practical matter in order to advance the purposes of the statute.

c. Employee Retirement Income Security Act ("ERISA")

In assessing the scope and application of Section 12b, the Board has also been mindful of ERISA. ERISA was enacted to, among other things, "avoid a multiplicity of [State] regulation[s] [and] . . .permit the nationally uniform administration of employee benefit plans." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 657 (1995). In order to achieve this uniformity, ERISA expressly preempts "State laws insofar as they . . . relate to employee benefit plans." 29 U.S.C. § 1144(a). "A law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan." *Shaw v. Delta Air Lines*, 463 U.S. 85, 96-97 (1983).

ERISA plans are defined to include both pension or welfare plans provided to employees by employers (other than church or governmental employers) and employee organizations. A "welfare plan" is a plan, fund, or program which is established or maintained by an employer (or by an employee organization, or by both) to provide medical or related benefits. ERISA §3(1). This would include pharmacy benefit plans provided by non-governmental, non-church employers as well as unions and other employee organizations in West Virginia.

Thus, ERISA covers virtually all Benefit Plans offered by private, non-church employers and employee organizations throughout the state. It does so in order to ensure that such plans can be administered in uniform manner on a multi-state or nationwide basis without having to be tailored to meet differing state laws and regulations. Nominally, Section 12b would require plans operating in West Virginia to price generic drugs in the particular manner set forth therein and, as a consequence, preclude those plans from entering into pharmacy service contracts on a uniform nationwide or multi-state basis to the extent those contracts did not incorporate the provisions of Section 12b. That is antithetical to the stated goal of ERISA.

ERISA was enacted in 1974, well before Section 12b. As such, the Legislature was presumptively aware of the scope and preemptive nature of the federal law when it adopted Section 12b. It is unlikely, therefore, that the Legislature intended Section 12b to apply in a way that would clearly be preempted by ERISA. Regardless, it is clear that, if Section 12b were deemed to apply to plans governed by ERISA, Section 12b would be preempted and have no force or effect as to such plans.

The United States District Court for the District of Columbia reached that exact same conclusion in *PCMA v. Dist. Of Columbia*, 613 F.3d 179 (D.C. Cir. 2010). There, the District of Columbia sought to compel compliance with the provisions of a local statute that, like Section 12b, required pharmacies within the District to substitute lower-priced, therapeutically equivalent generics for high-priced brand

named drugs and pass along the financial savings occasioned by that substitution. The court found that the statute in that case ran afoul of ERISA and the "free hand" it was intended to afford plan administrators to "structure their plans in [the District] precisely as they would elsewhere." *Id.* at 80 (quoting *Pharm. Care Mgmt. Ass'n v. Rowe,* 429 F.3d 294, 303 (1st Cir. 2005)). The statute did so by "improperly inject[ing] state regulation into an area exclusively controlled by ERISA." *Id.* at 85. As such, the court enjoined enforcement of the District's statute.

Accordingly, the Board finds that Section 12b, even if it were deemed to apply to third party payor contracts, would not be enforceable with respect to any contract entered into by Petitioners that relates to a plan covered by ERISA.[13]

d. Government-Employer Benefit Plans

That then leaves government and church sponsored Benefit Plans if Section 12b was deemed to cover pharmacy reimbursement contracts. Such government sponsored plans would include the welfare plans offered state workers through the Public Employee Insurance Agency ("PEIA"). The question, then, becomes: If Section 12b cannot apply to non-governmental plans because of the preemptive effect of ERISA, did the Legislature nevertheless intend Section 12b to apply to pharmacy reimbursement contracts negotiated by or on behalf of PEIA and other similar governmental organizations for the benefit of state workers, retirees and their beneficiaries?

PEIA, for example, utilizes the services of a PBM in the same way as private employers. That PBM negotiates pharmacy reimbursement contracts on PEIA's behalf with pharmacy groups and chains using the substantial bargaining power that PEIA has because it represents such a large pool of state workers and beneficiaries. Given its bargaining power, PEIA, through its PBM, is able to negotiate not only which generic drugs will be substituted for which name brand prescriptions but also the reimbursement rates for those medications. Only when PEIA is satisfied with the agreed upon medications to be dispensed and the reimbursement rates it will pay pharmacies for that service are those pharmacies permitted access to its beneficiaries.

If Section 12b applies to those contracts, and if the reimbursement rates negotiated by PEIA do not comport with the requirements of Section 12b *with respect to every single drug covered by PEIA's contract,* that contract would likely be deemed void. Moreover, any pharmacy group or chain that, in good faith, agreed to the terms of such contracts and accepted reimbursements in accordance with its terms, would find itself subject to potential fines and enforcement actions – actions instituted by one arm of the State for accepting the reimbursements agreed to and paid by another arm of the State.

[13] Section 12b does not apply to prescription medications dispensed under the Medicare or Medicaid programs. In this regard, the Board notes that even the Attorney General in his civil actions does not allege violations of Section 12b with respect to these programs and seeks no relief for substituted prescription transactions under these programs.

The absurdity of this scenario is self-evident. In essence, a pharmacy or pharmacist would be punished for simply honoring its contract with a state agency or department – a contract that the state agency or department determined to be in the best interest of workers and retirees to whom it provides prescription drug coverage. It is difficult for the Board to see how application of Section 12b in such a manner would serve the interests the Legislature intended to advance when it enacted the statute in 1978. This is particularly true where the agency or department charged with providing benefits of this type is not compelled to agree to the contractual terms it did and has not complained to the Board about that contractual arrangement.

e. <u>The Practical Application of Section 12b</u>

Added to the foregoing is the question of how Section 12b can, as a practical matter, be applied as the Attorney General interprets it to pharmacy benefit contracts that set reimbursement rates to be paid pharmacies for medications dispensed pursuant to that contract. Gone are the days when drug manufactures sold generic drugs to wholesalers and wholesalers sold them to pharmacies at standard mark-ups. The nature of today's market is such that prescription medications are often purchased in bulk by large pharmacy chains or groups pursuant to a variety of contractual arrangements involving discounts and retroactive rebates. PBMs themselves negotiate with generic drug manufactures in order to secure rates for medications included in their formularies that are lower than might otherwise be the case.

Thus, determining what, for example, a pharmacy's cost is for a particular branded medication and the generic drug substituted for it on the particular day when a prescription was filled is something that is not easily determined. Moreover, those cost figures, once determined, would then have to be compared to the negotiated reimbursement rates agreed to by the pharmacy and applicable third party payor for other generic substitutes to determine whether the medication required to be dispensed was the lowest retail cost, effective brand that was in stock. This, in turn, would require data regarding the medications that each pharmacy had *in stock* on the particular day and time each and every substituted generic drug was dispensed. And then, in order to determine whether the cost savings on any given generic substitution transaction was passed on to a given patient on a given prescription on that given day would require creation, for each generic substitution transaction, a non-existent "shadow" transaction, in which the same patient with the same pharmacy benefit coverage on the same day received the prescribed brand name drug instead of the substituted generic drug. Absent that shadow transaction, it would be impossible to determine the true cost savings on any generic transaction because there would be no benchmark brand drug transaction against which to measure the "savings."[14]

[14] Given the discounts and associated rebates that are a part of this pricing, that determination alone would take resources well beyond those provided the Board by the Legislature.

Requiring pharmacies located in West Virginia to compile and maintain such data would impose an obvious and significant burden upon them with all the attendant costs. Those costs would either have to be absorbed by the pharmacies, making the practice of pharmacy in West Virginia less attractive when compared to our sister states, or, in the alternative, passed on in the form of higher reimbursement rates for prescription medications paid by Benefit Plans operating in West Virginia. Neither outcome serves to promote the public welfare and health of West Virginia residents or advance the goal of providing affordable prescription drugs for all residents of West Virginia.

Beyond this, the simple fact is that Board does not have the administrative resources that would be required to gather and analyze the data necessary to determine compliance with Section 12b if it were deemed applicable to pharmacy reimbursement contracts. It would take a veritable army of inspectors and auditors to review the myriad of real and shadow transactions involved and the data related to each such transaction. Data would have to be reviewed first to determine whether the medication in question was dispensed in substitution for a brand name drug. If so, given that Section 12b speaks in terms of retail prices, it would then be necessary to determine whether that generic carried the lowest retail price of the therapeutically equivalent generic in stock at the pharmacy when the prescription was filled. Then, the actual generic substitution transaction would have to be compared to the shadow brand name drug transaction in order to determine whether or to what extent the cost savings resulting from the generic drug transaction were passed on to the patient.

Even if the focus were not on retail prices, but instead were limited to the reimbursement rates to which the pharmacy was contractually entitled for dispensing a generic in substitution for a higher priced, brand name medication, the task becomes no easier. The Board's auditors would have to determine what the reimbursement rate was under the particular contract involved. It would then have to determine whether the formulary for that plan recognized other generics as appropriate, alternative (or even preferred) substitutes for that branded product, and, if so, what the reimbursement rate for each alternative was. Each of these determinations would have to be replicated every time a generic drug was dispensed in substitution of a branded product, as would a new "shadow" brand drug transaction, since plan formularies frequently change in terms of approved and preferred generics.

In the more than 30 years that Section 12b has been the law, the Board has not received a single complaint from any source, including the Attorney General, that pharmacies are violating Section 12b by dispensing generic medications pursuant to negotiated pharmacy reimbursement contracts. The Board interprets this to mean that there is not a problem that demands a solution, and particularly not a solution that would undermine the Legislature's objectives of the Pharmacy Act. The Board also interprets the absence of such complaints to mean that the resources that would be needed to enforce Section 12b, <u>if</u> it were deemed applicable to pharmacy reimbursement contracts, could and

should be better allocated toward pressing concerns that are having a negative impact on the public health and welfare.

Accordingly, even if Section 12b can be read to apply to pharmacy reimbursement contracts, which the Board concludes it should not, the Board will, in the exercise of its prosecutorial discretion, elect not to enforce Section 12b in this manner unless and until the Legislature indicates its disagreement with the Board's determination and appropriates the funds necessary to extend the ambit of Section 12b to such contracts. To do so would divert scarce and valuable resources from more pressing concerns while at the same time driving up the administrative costs associated with the practice of pharmacy with no discernable benefit to the residents of West Virginia.

f. The Plain Language of Section 12b

The backdrop against which Section 12b was adopted, ERISA's preemptive effect, the specter of pharmacies being held in violation of state law for accepting reimbursements for medications dispensed pursuant to contracts negotiated by state entities, the vast resources that would be required to enforce Section 12b were it deemed applicable to such contracts, and the total absence of any suggestion that the high cost of prescription medications today is the product of pharmacy reimbursement contracts negotiated by or on behalf of Benefit Plans, all suggest that Section 12b was never intended to be applied to such contracts. The plain meaning of the language of Section 12b confirms that.

First, lest there be any doubt, Section 12b is, by its express terms, limited to transactions involving the substitution of a therapeutically equivalent generic drug for a higher priced medication prescribed by a treating physician. It does not apply where there is no such substitution. To conclude otherwise would require the Board ignore the language of statute itself.

Second, Section 12b speaks in terms of "retail" prices paid by "purchasers" of prescription medications. "Retail" prices are commonly defined as prices established in connection with the sale of goods in small batches directly to the consumers of those goods. That Section 12b speaks in such terms is not surprising given the fact that the market for prescription medications in 1978 involved precisely that type of direct retail transaction between the pharmacists and patients.

Conversely, Section 12b makes no reference to "reimbursement rates," "PBMs," "Third Party Payors," "Prescription Benefit Plans," or "Plan Beneficiaries." This, too, is not surprising given that these were largely unknown concepts at the time the Legislature adopted Section 12b. As a result of the emergence of Benefit Plans, PBMs, and third-party payors, pharmacies today are reimbursed for prescription medications in the vast majority of transactions, not on the basis of "retail" prices, but instead on the basis of contractually negotiated reimbursement rates predicated upon volume dispensing.

Accordingly, the Board concludes that Section 12b was not enacted and does not apply to prescriptions dispensed pursuant to contracts negotiated with Benefit Plans, third-party payors, state or other such entities.

Trying to twist the language of Section 12b to fit situations involving pharmacy reimbursement contracts with third party payors would, in the view of the Board, be inconsistent with accepted rules governing statutory construction. Moreover, doing so would not further the goals of Section 12b, but, instead, frustrate them. It would disrupt the provision of pharmacy services in West Virginia by voiding most if not all existing reimbursement contracts to the extent doing so was not preempted by ERISA. This, in turn, would serve to distinguish West Virginia as an outlier in terms of the manner in which the practice of pharmacy is regulated. None of this would serve to aid the orderly regulation of the practice of pharmacy in this state, or the operation of pharmacies, Benefit Plans or, most importantly, their beneficiaries.

IT IS SO RULED This 9th day of October, 2012.

THE WEST VIRGINIA BOARD OF PHARMACY

EXHIBIT E

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DataWatch

Trends In Retail Prescription Expenditures

by Stephen W. Schondelmeyer and Joseph Thomas III

Few would question the value of appropriately used prescriptions to the U.S. health care system. The economics of prescription drugs, however, has undergone increased legislative scrutiny recently, with the now repealed Medicare Catastrophic Coverage Act of 1988 and the proposed Pharmaceuticals Access and Prudent Purchasing Act of 1990. In this DataWatch, we present a review of trends in retail prescription expenditures to provide some substance to the debate about these economic issues.

National Health Spending Trends

Pharmaceutical products and services represent an essential component of health care. Appropriate drug therapy is one of the most cost-effective therapeutic modalities known to modern medicine.[1] The 1988 expenditures for drugs and medical sundries were $41.9 billion.[2] In contrast, only $8.8 billion was spent in 1970 and $1.7 billion in 1950 for this category. This drug and medical sundries category has diminished considerably as a percentage of national health expenditures since 1950, when drugs accounted for 13.6 percent of expenditures. By 1970, the percentage had declined to 11.8 percent, and in 1988, drugs were responsible for 7.8 percent of national health expenditures. Prescription and over-the-counter drugs combined represent approximately 1 percent of gross national product (GNP) in the United States.

Health care expenditures have consistently grown faster than the rest of the U.S. economy for several decades. As Exhibit 1 shows, health care

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Exhibit 1
Consumer Price Index Of Selected Health Items, Annual Percent Change, 1980-1989

Year	All items	All medical care	Physician services	Hospital room	Prescription drugs
Annual percent change					
1980	13.5%	11.0%	10.5%	13.1%	9.2%
1981	10.3	10.7	11.0	14.9	11.4
1982	6.2	11.6	9.4	15.7	11.6
1983	3.2	8.8	7.8	11.3	11.0
1984	4.3	6.2	6.9	8.3	9.6
1985	3.6	6.3	5.9	5.9	9.5
1986	1.9	7.5	7.2	6.0	8.6
1987	3.6	6.6	7.3	7.2	8.0
1988	4.1	6.5	7.2	9.3	8.0
1989	4.8	7.1	7.3	10.3	8.7
Average annual percent change					
1970–1989	6.4	8.1	8.1	10.7	6.6
1970–1979	7.1	7.8	8.0	11.2	3.6
1980–1989	5.5	8.3	8.0	10.2	9.6
1982–1988	3.8	7.6	7.4	9.1	9.5

Source: U.S. Department of Commerce, *Statistical Abstract of the United States*, 1990.

costs inflated at twice the rate of the consumer economy during 1982 to 1988. Prescription drugs were the highest-inflating component of the health care sector during this period, with prices increasing at two and one-half times the rate of inflation in the general consumer economy. This strong inflation in drug prices during the 1980s deserves further study to determine the factors responsible.

Retail Prescription Spending

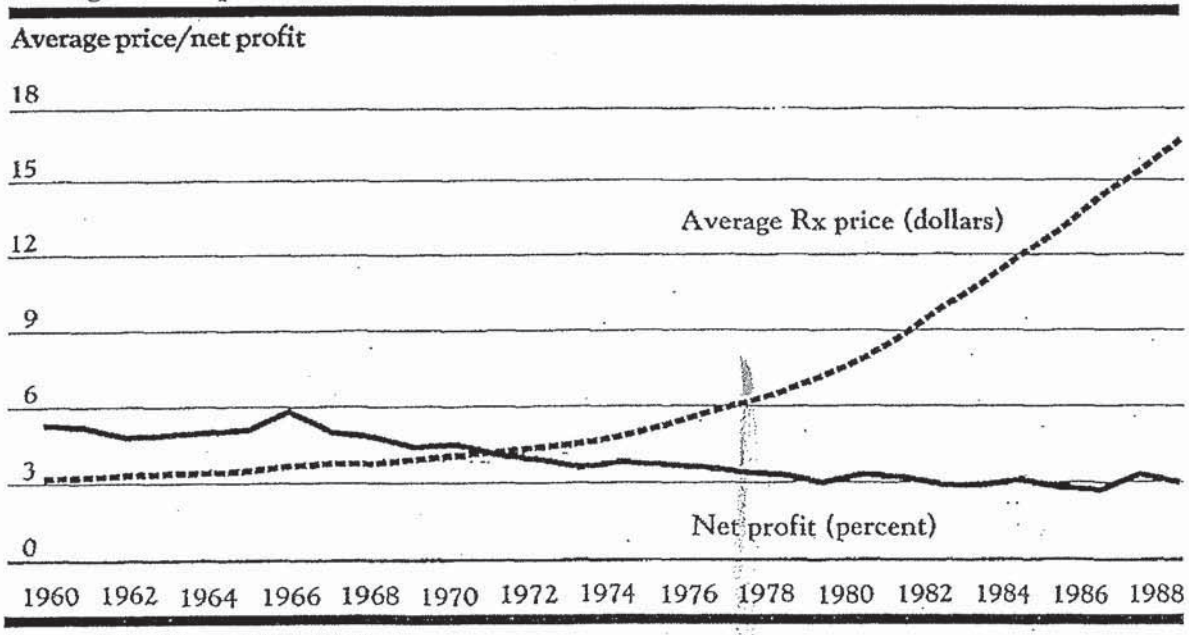
The nation's consumers purchased more than 1.73 billion prescriptions in 1989 from retail (chain and independent) pharmacies for a total expenditure level of $28.2 billion.[3] Retail prescription expenditures have increased nearly threefold from $9.7 billion in 1980 and more than sevenfold from $4.0 billion in 1970. The number of retail prescriptions consumed by the American public has shown modest change in the past decade, increasing only 18 percent over the 1.47 billion prescriptions dispensed in 1980 and 62 percent over the 1.07 billion prescriptions dispensed in 1970. Retail outpatient prescriptions represent approximately 70 to 75 percent of the total prescription drug market in the United States.[4] Prescription drugs are also distributed through hospitals, practitioners' offices, and various government facilities.

The elderly (age sixty-five and over) represented 12.4 percent of the

U.S. resident population in 1988, yet they accounted for 34.3 percent of retail prescription expenditures. The average price for all retail prescriptions was $16.31 in 1989, up from $6.62 in 1980 and $3.77 in 1970.[5] The average prescription price differed little between chain and independent pharmacies in 1989 ($16.31 and $16.30, respectively). When the average prescription price is adjusted for differences over time in the purchasing power of the dollar, the average prescription in 1985 cost the consumer less than the average prescription in 1960 ($11.70 versus $11.28 in 1985 constant dollars).[6] However, the 1985 constant dollar value of the average prescription has increased 25 percent since 1985. Despite growth in the average retail prescription price, the profitability of retail independent pharmacies has been declining over the past three decades. The average independent pharmacy in 1965 had 5.8 percent net profit (before taxes); by 1986, this had declined to 2.7 percent (Exhibit 2).[7]

Over the past four decades, the number of retail community pharmacies has held relatively constant at about 55,000 units.[8] The number of independent pharmacies has been steadily decreasing, while the number of chain pharmacies has been increasing. In 1950, 92 percent of all pharmacies were independents; by 1970, the percentage had slipped to 87 percent; and in 1989, 64 percent of all retail pharmacies remained as independents. Independent pharmacies dispensed 62 percent (1.08 billion) of retail prescriptions in 1989, while chain pharmacies dispensed 38 percent (0.65 billion).

Exhibit 2
Average Prescription Price And Pharmacy Net Profit, 1960–1988



Source: Lilly Digest, 1961–1989.

New Channels Of Prescription Distribution

About 7 to 10 percent of all retail prescriptions in 1986 were covered, or paid for directly, by managed care plans.[9] These managed care prescription programs have accounted for much of the growth in private third-party coverage of prescriptions. Patients who receive prescriptions through managed care and other third-party programs are often "channeled" to certain providers of prescriptions and other pharmaceutical services. Channeling allows the purchaser of health care products and services to buy in volume to improve administrative efficiency and often to obtain discount prices. Patients may be channeled by employers, insurance companies, health maintenance organizations (HMOs) or preferred provider organizations (PPOs), physicians, hospitals, nursing homes, various types of organizations (such as the American Association of Retired Persons), urgent care centers, and others. When a "patient channel" is formed for directing the prescriptions of a defined group, several alternatives are available for providing prescriptions. Many managed care enrollees are served through contracts with community pharmacies, but others are served by an in-house pharmacy at the managed care site.[10] Prescriptions for ambulatory patients may be obtained on a contractual basis with individual independent or chain pharmacies, a network of pharmacies, hospital outpatient pharmacies, mail order pharmacies, and other types of pharmacies. In the managed care environment, all of these pharmacies may be in direct competition with each other.

Choice of a specific channel, or panel of preferred pharmacy providers, may be made by one corporate decisionmaker for an entire channel of patients. Often these decisions lock patients into one or a few preferred providers for one year or more. Contracts for serving patient channels may develop without public notice, and a given pharmacy may suddenly lose 10 to 30 percent or more of its customer base.[11] Not only does such an event disrupt the pharmacy's economic base, but it also significantly disrupts the patient's continuity of pharmaceutical care.

Contracted pharmacies may be engaged through either open or closed panels or networks. Open panels allow participation by all pharmacies in a given market area that meet certain standards regarding level of service and that are willing to accept the offered contractual terms for participation and reimbursement. Closed panels limit pharmacy participation exclusively to those that are members of a defined network, or even a single chain of pharmacies, covering the market area. One study reported that professional fees for third-party plans open to all pharmacies were "virtually identical to those for closed plans."[12]

Several other distribution methods have developed or shown renewed

strength in recent years. Mail order prescription plans have captured about 6 percent of the outpatient prescription market and are expected to continue growth into the 1990s.[13] Physician dispensing for a profit has surged in some areas, with 1 to 2 percent of the outpatient prescription market.[14] Despite popular belief to the contrary, recent evidence suggests that neither mail order nor. physician-dispensed prescriptions cost consumers less than similar prescriptions from community pharmacies. For example, the average charge per day's supply of medication from mail order pharmacies was $0.58, while community pharmacies' charges averaged $0.56 per day's supply in 1988.[15] Urgent care centers and surgicenters have established dispensaries (some with and some without a pharmacist), and many hospitals have activated and expanded outpatient pharmacies and ambulatory care clinics. Another means of direct distribution is via employer-owned pharmacies at the worksite to provide both convenience and hands-on cost management. A corporate-owned pharmacy may be supported by as few as 1,500–2,000 employees and 3,500–5,000 total enrollees, including spouses and dependents.

The organizational structures of pharmacies are changing. For instance, pharmacies have formed networks in more than twenty-five states to facilitate access of independent and small chain pharmacies to the contracted, managed health care market. Advantages of such networks include network administration, benefit contracting, volume purchasing, and cooperative marketing. State professional organizations have formed many of the pharmacy networks, with others formed by wholesalers, groups of pharmacists, insurance companies, and for-profit corporations. These pharmacy networks strive for economies of scale and efficiency, while still maintaining autonomy for the individual member pharmacies.

Retail pharmacists have formed, and joined, retail pharmacy buying groups to increase buying power with pharmaceutical companies. More than one-half of all independent pharmacies in 1988 participated in one or more drug buying groups.[16] Retail pharmacy buying groups have had moderate success in improving their purchasing power for generic drug products. They have, however, achieved little leverage in obtaining contractually discounted prices on single-source, patent-protected drug products. Nearly all manufacturers have refused to participate in such programs with respect to their single-source products.[17]

Hospital buying groups and some HMOs have been able to negotiate lower prices on both multiple- and single-source products. Part of their success is due to their control over prescribing and dispensing practices. Typically, these health care settings establish physician- and pharmacist-approved guidelines for both generic and therapeutic product interchange. Through a pharmacy and therapeutics committee, a formulary

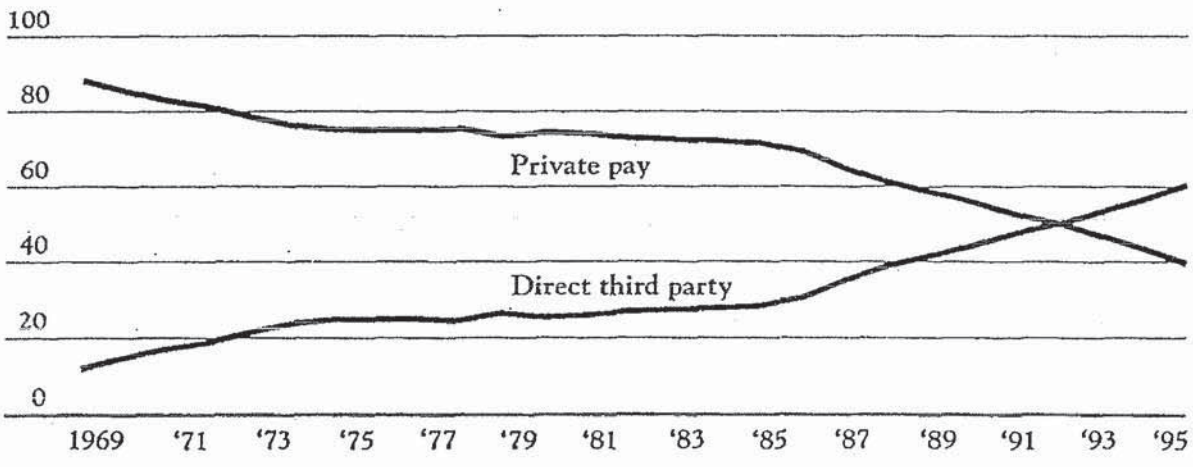
of acceptable substitute products is defined, and these products are forced to compete on price through a bid purchasing or negotiation process.

Changes In Prescription Payment Source

The retail prescription market has experienced a significant shift in the source of payment for prescriptions. Private-pay (out-of-pocket) prescriptions have been declining, and direct third-party pay prescriptions have been on the increase (Exhibit 3). A review of this change is essential for understanding the impact of third-party payment on retail prescrip tion expenditures.

Private-pay prescriptions. Private-pay prescriptions are those for which a cash or charge payment for the price of the prescription is made at the time of dispensing. These out-of-pocket expenses are borne solely by many consumers, while other consumers may be reimbursed for these prescriptions under an indemnity insurance plan or may count such prescription charges against an annual deductible. Private-pay (also known as out-of-pocket) prescriptions were the most prevalent payment source in 1989, representing 58.5 percent of all prescriptions dispensed in community pharmacies.[18] In 1969, private-pay customers purchased 88.1 percent of all retail prescriptions dispensed. By 1995, private-pay customers are expected to be less than 40 percent of the retail prescription market due to growth in third-party coverage.[19]

Exhibit 3
Percentage Of Prescriptions Sold At Retail, By Payment Source, 1969–1995



Source: American Druggist, May 1979–1990; and projections from Purdue University, Pharmaceutical Economics Research Center.
[a]Projections.

Third-party prescriptions. Direct-payment third-party prescriptions are those for which the pharmacist must complete a reimbursement form, either manually or electronically, and submit the form to a third party for payment. Most third parties have predetermined payment limits for prescriptions filled on behalf of their patients. The payment amounts are usually less than what the pharmacist would charge a cash-paying customer, even though filling a third-party prescription requires considerably more effort. In 1988, it cost the average chain pharmacy $5.14 to dispense private-pay prescriptions and $6.39 to dispense third-party prescriptions.[20] This additional cost is due primarily to personnel and other administrative expenses for processing third-party claims. Direct third-party prescriptions rose from 11.9 percent of all retail prescriptions in 1969 to 41.5 percent in 1989.[21] Historically, independent pharmacies have had a higher percentage of prescriptions filled under third-party contracts than have chain pharmacies, although chains have significantly closed the gap in the past few years (41.7 percent versus 41.2 percent, respectively, in 1989).

An estimated 7 19 million third-party prescriptions were filled in 1989. Medicaid, the federal/state insurance program for the nation's poorest citizens, covered 18.9 percent of all retail prescriptions dispensed in 1989.22 Medicaid prescriptions totaled more than 23.5 percent of all prescriptions dispensed in independent pharmacies and only 11.2 percent of those in chain pharmacies. Among all third-party prescriptions in independent pharmacies, Medicaid prescriptions outnumbered private third-party prescriptions (by a ratio of 4:3) while in chain pharmacies the reverse was true: private third-party prescriptions outnumbered Medicaid prescriptions (by a ratio of 3:1). The rate of third-party volume growth in chains has surpassed the growth rate in independents, with chains making their strongest gains among private third-party prescriptions since 1985.

Economic Transformation Of Retail Pharmacy

As the proportion of third-party prescriptions rises, retail prescription prices will be less influenced by a competitive consumer market and more dominated by private and government third-party reimbursement policies. Retail prescription prices under both private and governmental third-party contracts are usually predetermined by one or more specific limits or formulae, so that third-party reimbursement to the pharmacy is a regulated, prospective payment. In this new economic environment, retail pharmacies will experience changes nearly as dramatic as the advent of diagnosis-related groups (DRGs) for hospitals. With prospective pay

ment limits defined before a prescription is dispensed, the pharmacy becomes a cost center, rather than a profit center. Neither a retail pharmacy's revenue nor its profit can be increased simply by raising prescription prices. Additionally, increases in manufacturers' drug product prices to the pharmacy without corresponding changes in payment by third parties will result in a direct reduction of the pharmacy's operating margin.

Successful pharmacies in this new economic environment must: (1) achieve efficient operating volumes (for instance, greater than 30,000 prescriptions per year); (2) minimize operating expenses; (3) maximize personnel efficiency; (4) monitor and control, to the degree possible, the acquisition cost of drug products (through buying groups, generic substitution, and effective formulary programs); and (5) improve the satisfaction and health of the patient. Most patients under third-party programs pay the same price (or copayment) for a prescription no matter which pharmacy they may choose to have fill their prescription. When price is not a factor, -what factors will influence pharmacy choice? Patients are likely to choose the pharmacy where they are treated as an individual and where a pharmacist is available to answer their questions about medications. Thus, competition in a third party–dominated prescription market will be on the basis of service rather than price.

A Framework For Managing Drug Expenditures

Both the channels of distribution and the payment sources in the retail prescription market are experiencing significant change. As prescription drug expenditures continue to grow at a rate substantially above the general inflation rate, purchasers will look for means to understand and manage the growth in drug expenditures. The following framework discusses disaggregation of factors contributing to growth in total expenditures. This framework is then used to analyze changes in Medicaid expenditures between 1982 and 1988. Many of the patterns seen in the retail prescription market are also found in the Medicaid drug program.

Total drug expenditures are determined by multiplying the number of eligible persons (population effect) times the number of prescriptions per person (intensity effect) times the cost per prescription (inflation effect), plus administrative costs. "Population" effects are concerned with a change in the number of persons eligible for a given plan. For example, a change in the definition of poverty or in the number of persons meeting a set poverty level may increase the number of persons eligible for Medicaid. "Intensity" measures the amount of product or service provided per

person, thereby eliminating the influence of population growth on the total number of prescriptions. Intensity may contribute to changes in expenditures because of changes in the need for medications (either more or less illness); changes in prescribing patterns among physicians; changes in drug benefit design (such as copayments) or scope of coverage (such as open or closed formulary); or changes in other factors.

"Inflation" can occur for a number of reasons, including retail prescription price inflation, manufacturer drug product price inflation, and pharmacists' professional fee inflation. The average price per prescription may also increase as new or improved drug products are introduced into the market as substitutes for older, lower-priced products.

Finally, the total expenditures for a given drug program may be affected by the administrative costs of the program. Because of their high number volume and low dollar value, prescription claims are perhaps the most expensive type of third-party claim to process and administer in proportion to the total dollar value of the benefit delivered. Pharmacy claims accounted for about 57 percent of the number of claims submitted to a state Medicaid program, but only 7 percent of the dollar volume of claims paid.[23] More than ninety-two pharmacy claims were needed in 1984 to collect $1,000 versus only 1.5 nursing home claims or 2.7 hospital claims.

Medicaid Drug Expenditures

Medicaid's national drug expenditures in fiscal year 1988 were $3.29 billion, an increase of 9.7 percent over 1987 (Exhibit 4). Between 1982 and 1988, Medicaid drug spending more than doubled (105.6 percent). Factors affecting this growth in drug spending include population, intensity, and inflation. Regarding population, approximately two-thirds of Medicaid beneficiaries (15.3 million) received drug benefits in 1988. From 1982 to 1988, the number of total Medicaid recipients increased 12.3 percent, and the number of Medicaid drug recipients increased 11.7 percent.

Intensity effects increased by 12.5 percent for Medicaid during 1982–1988. Total Medicaid recipients averaged 9.6 prescriptions per person per year in fiscal year 1988, compared to 7.0 prescriptions per year for the average U.S. civilian.[24] Increased health care need based on the lower socioeconomic status of Medicaid recipients is not surprising but may deserve further examination.

Inflation effects (cost per prescription) may include changes in manufacturers' drug product price, in pharmacists' professional fee, and in the general economy's inflation rate. The average Medicaid prescription

Exhibit 4
Medicaid Drug Expenditures And Recipients. Fiscal Years 1982–1988

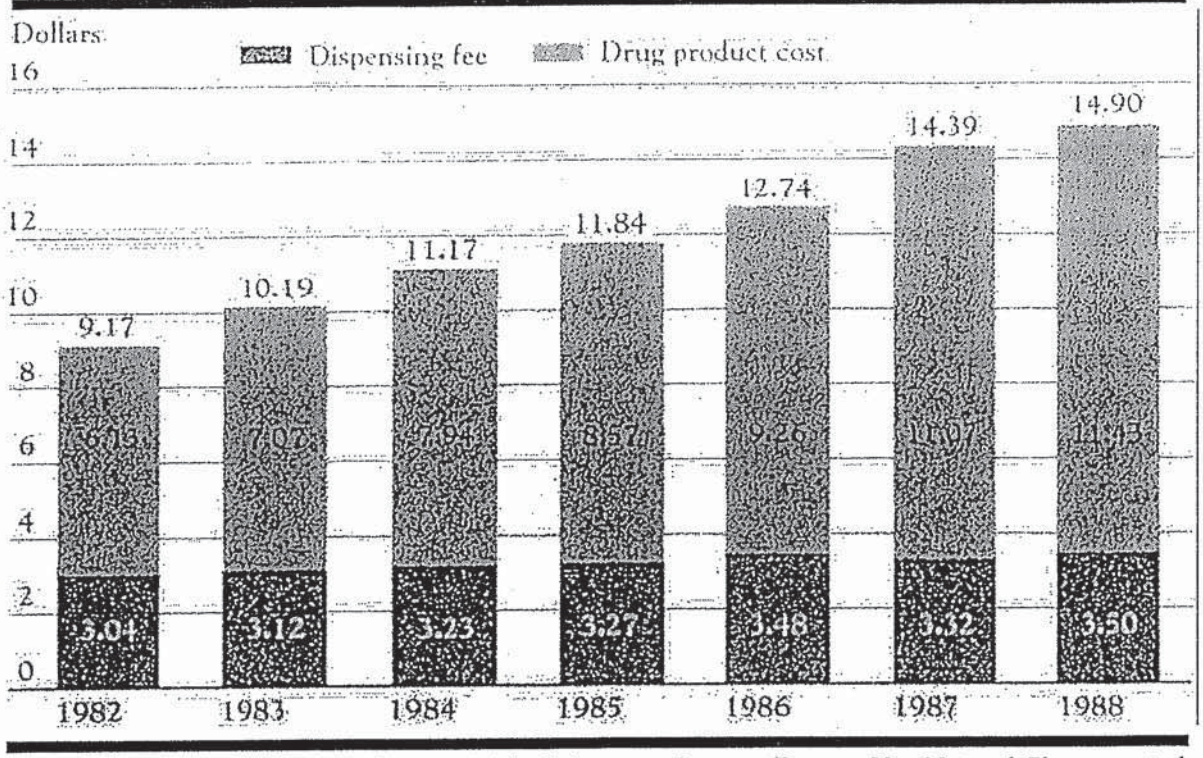
Indicator	1982	1983	1984	1985	1986	1987	1988	Percent change 1982–88
Total drug expenditures								
Drug expenditures (billions of dollars)	$1.60	$1.77	$1.98	$2.32	$2.69	$3.00	$3.29	105.6%
Annual percent change	–	10.7%	11.8%	14.5%	13.9%	11.5%	9.7%	
Percent of total expenditures	5.4%	5.5%	5.8%	6.1%	6.5%	6.6%	6.7%	24.1%
Annual percent change	–	1.9	5.5	5.2	6.6	1.5	1.5	
Population effects								
Drug recipients (millions)	13.7	13.7	14.0	13.9	14.7	15.1	15.3	11.7%
Annual percent change	–	0.1%	2.4%	−0.6%	5.6%	2.7%	1.3%	
Total program recipients (millions)	20.4	19.9	20.3	20.2	22.4	23.2	22.9	12.3%
Annual percent change	–	−2.2%	1.7%	−0.2%	10.8%	3.6%	−1.3%	
Intensity effects								
Prescriptions per drug recipient per year	12.8	12.7	12.6	14.0	14.4	13.8	14.4	12.5%
Annual percent change	–	−0.5%	−0.3%	10.9%	2.3%	−4.2%	4.3%	
Prescriptions per total recipient per year	8.6	8.7	8.8	9.7	9.4	9.0	9.6	11.6%
Annual percent change	–	11.1%	9.6%	6.0%	7.6%	13.0%	3.8%	
Inflation effects								
Average price per prescription	$9.17	$10.19	$11.17	$11.84	$12.74	$14.39	$14.93	62.8%
Annual percent change	–	11.1%	9.6%	6.0%	7.6%	13.0%	3.8%	

Source: *Phamaceutical Benefits under State Medical Assistance Programs* (Reston, Va: National Pharmaceutical Council, 1983–1989).

charge in 1982 was $9.17 and grew to $14.93 by 1988, a six-year increase of 62.8 percent. In contrast, the average retail prescription price in 1988 was $15.19, up 67.5 percent from 1982.

Inflation in the price per prescription appears to be the major force contributing to increased expenditures in the Medicaid drug program. When broken down to its components, the inflation factor showed that expenditures per prescription for the drug product increased 86.5 percent, and pharmacists' professional fees increased 15.1 percent. In comparison, general inflation (the CPI–all items) over the same period showed an increase of 26.9 percent. The cost of the drug product component increased more than three times as much as general inflation between 1982 and 1.988. Pharmacists' professional fees under Medicaid increased at nearly one-half the rate of change in the overall CPI and at less than one-fifth the rate of change in manufacturers' drug product prices. Exhibit 5 shows the prescription price components of Medicaid.

Exhibit 5
Medicaid Prescription Price Components, 1982–1988



Source: *Pharmaceutical Benefits under State Medical Assistance Programs* (Reston, Va.: National Pharmaceutical Council, September 1989).
Note: Dispensing fee covers pharmacy operating expenses and profits. Drug product cost covers both manufacturers' and wholesalers' charges.

Medicaid Drug Reimbursement Policies

The differential growth of drug product costs and dispensing fees is not surprising when one examines Medicaid drug reimbursement policies. Pharmacy reimbursement is established by the state Medicaid agency and must be accepted by a pharmacy as a condition of participation in the program. In most states, pharmacy reimbursement is a single flat fee per prescription dispensed. State Medicaid programs frequently freeze dispensing fees for three to five years at a time, and in some cases such fees have remained frozen for as long as ten years.[25] The average fee paid by Medicaid to participating pharmacies grew from $3.04 in 1982 to $3.50 in 1988. Medicaid agencies have limited dispensing fees to an average annual growth rate of 2.4 percent (1982 to 1988), which is far below the average rate of growth in the general economy (CPI–all items, 3.8 percent).

Reimbursement for the drug product component of a prescription is also paid to the pharmacy rather than to the manufacturer. Payment for the drug product component of Medicaid prescriptions usually differs

for single-source (patent-protected) products and multiple-source (generically available) products. The amount the pharmacy is paid for single-source products is typically based on the list price established by the manufacturer. This list price is not negotiated with the manufacturer, and, if it is limited, the limit is on pharmacy reimbursement and not manufacturers' revenue. The amount the pharmacy is reimbursed for multiple-source products in most states is determined by an upper limit established by the Medicaid program. If the pharmacist should happen to use a manufacturer's product that costs more than the upper limit, the pharmacy reimbursement will be reduced; however, this limited reimbursement does not affect what the pharmacist has already paid the manufacturer for the drug product. In other words, there are no limits on single-source drug product prices, and the limits on multiple-source drug product prices affect the pharmacy and not the drug manufacturer. In the absence of measures to moderate or limit drug product price increases at the manufacturer level, the drug product component of the average Medicaid prescription has grown from $6.13 in 1982 to $11.43 in 1988. This amounts to an average annual growth rate of 11.1 percent. Given the Medicaid drug reimbursement policies and actual expenditure patterns, it is hard to argue that dispensing fees are to blame for the doubling of Medicaid drug program expenditures over the past six years.

Faced with limited budgets for Medicaid, state Medicaid administrators and public policy decisionmakers have been looking for ways to reduce or control program outlays. Since prescription drug expenditures have been one of the fastest-growing components of the Medicaid budget, reducing drug program expenditures has been a high priority for state Medicaid programs in recent years. Comparison of prices paid by Medicaid with prices paid by other purchasers for similar drugs reveals that Medicaid usually pays the highest price in the market, despite the fact that state Medicaid programs pay for 12 to 20 percent of all retail prescriptions in their respective states.

Directions For Public Policy

There are limited resources to pay for entitlement programs, which are growing faster than the revenue bases that support them. This will require increased competition among health care providers and increased scrutiny of health care utilization and costs by program managers. Leveling off the rate of inflation in all sectors of the health care market is a far more critical issue than onetime or notch savings in the level of health expenditures. Prescription drug product prices have been singled out for scrutiny because of their strong inflation rate over the past decade.

Growth in drug expenditures has brought retail and manufacturer pricing practices to the forefront of the public policy agenda. Prescription drug programs, however, will not escape the growing pressure for cost management that has already been imposed upon hospital and physician payment systems.

Accurate identification of the underlying causes of drug expenditure growth are necessary and will require federal research support targeted toward cost management of effective drug therapy. The problems identified will require targeted legislative and regulatory proposals aimed squarely at the root problem and not the symptom. For example, manufacturers' drug product price inflation cannot be managed through pharmacy reimbursement policies because the pharmacist has little control over manufacturers' prices. The primary driving force for drug program expenditure growth appears to be inflation in the cost of the drug product component of a prescription and will require solutions aimed at the factors influencing drug product cost. Increases in drug prices by a manufacturer may occur for a variety of reasons, including inflation in the cost of production and raw materials, growth of research and development costs, expansion of the sales force, and increased marketing and advertising expenditures. Also, the drug product component of the prescription price may increase because of growth in the use of newer, higher-cost products versus older, lower-cost products. A careful assessment of the underlying factors contributing to growth in the drug product cost component of the prescription price is necessary so that solutions that may be imposed do not unduly restrain innovation in the pharmaceutical industry.

Several proposals have been made for addressing manufacturers' drug product prices under state Medicaid programs, including Sen. David Pryor's (D-AR) Pharmaceuticals Access and Prudent Purchasing Act (PAPPA), an Office of Management and Budget (OMB) proposal, and plans prepared by several pharmaceutical manufacturers.[26] All of these proposals offer some type of rebate to the state Medicaid agency as a means for decreasing expenditures on prescription drugs. In most cases, the rebate is based on the lowest or "best" price to any customer.

Rebates will provide a onetime notch in expenditure growth and may prolong by one year (from six years to seven years) the time needed for Medicaid drug program expenditures to double again. However, a simple rebate system will not slow the rate of drug expenditure growth after the first year's savings have been realized. Any meaningful effort at reducing drug program expenditures under Medicaid, or any other drug program, should involve measures that influence the rate of growth and not just the level of expenditures.

In addition, third-party programs should assure that the limited resources available are used efficiently to improve the health of covered patients. For example, expenditures on necessary drug therapy may be able to reduce spending for other, more costly health care services such as physician office visits, emergency room visits, or hospital admissions. Management of program expenditures should focus not only on the cost of inputs (such as manufacturer rebate programs for lowering drug prices), but also on the cost of achieving desired patient outcomes. Third-party programs must begin to evaluate drug expenditures in the context of their contribution to the total cost per health care outcome.

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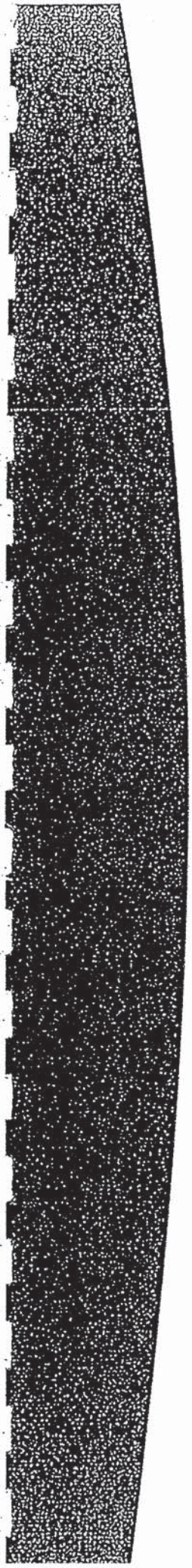
EXHIBIT F



THE HENRY J. KAISER FAMILY FOUNDATION

Follow The Pill:
Understanding the U.S. Commercial Pharmaceutical Supply Chain

Prepared for The Kaiser Family Foundation by:

The Health Strategies Consultancy LLC

March 2005

Table of Contents

I. Executive Summary

The pharmaceutical supply chain is the means through which prescription medicines are delivered to patients. Pharmaceuticals originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by pharmacy benefit management companies (PBMs); dispensed by pharmacies; and ultimately delivered to and taken by patients. There are many variations on this basic structure, as the players in the supply chain are constantly evolving, and commercial relationships vary considerably by geography, type of medication, and other factors.

The intent of this paper is to demystify the U.S. pharmaceutical supply chain. The first section of the paper describes each of the key players (i.e., industry segments) involved in the process of supplying prescription drugs to consumers. The section begins with a discussion of what each player does and the role that it plays in the flow of pharmaceuticals from manufacturer to patient. The second section of the paper describes the financial relationships between each of these key players and how the dollars flow between and among the segments, including the consumer.

Highlights from this paper about the key players and their financial relationships include:

Pharmaceutical Manufacturers:

- A relatively few large, multinational firms comprise the bulk of the brand pharmaceutical manufacturing industry today – the 10 largest pharmaceutical corporations, as measured by U.S. sales, accounted for almost 60 percent of total U.S. sales in 2004.
- Pharmaceutical manufacturers have the most influence over pharmaceutical prices, assessing expected demand, future competition, and projected marketing costs to establish the wholesale acquisition cost (WAC), which is the baseline price at which wholesale distributors purchase drug products. Discounts and rebates may be applied, based on market share, volume, and prompt payment.

Wholesale Distributors:

- The wholesale distribution industry has consolidated in the last 30 years, with the number of wholesale distributors in the U.S. declining from approximately 200 in 1975 to fewer than 50 in 2000. The top 3 wholesale distributors account for almost 90 percent of the wholesale market.
- Wholesale distributors typically sell drugs to pharmacies at WAC plus some negotiated percentage. They may facilitate discounts negotiated between manufacturers and other customers.

Pharmacies:

- Although comprising a small overall percentage of total prescriptions filled (approximately 6.1 percent in 2004), mail-order pharmacy sales were the fastest-growing sector of the U.S. prescription drug retail market in 2004, increasing by 18 percent over the previous year.

- Pharmacies may negotiate with manufacturers or wholesalers for discounts and rebates based on volume sales or market share, and they may negotiate with PBMs for inclusion in their networks and for their reimbursement (drug cost plus dispensing fee).

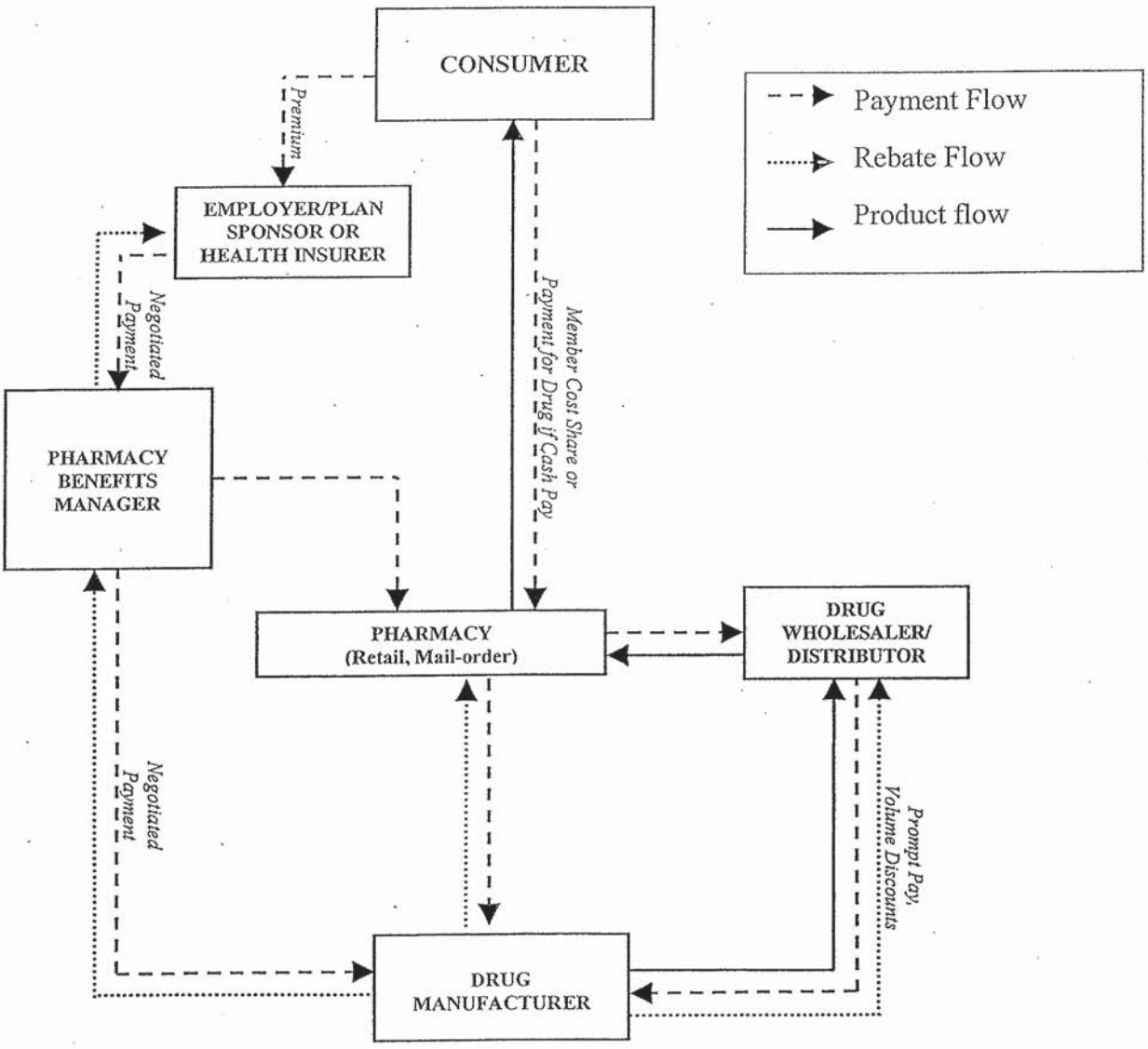
Pharmacy Benefit Managers (PBMs):

- Approximately two-thirds of all prescriptions written in the U.S. are processed by a PBM.
- PBMs may achieve savings for their customers by negotiating discounts and through cost containment programs, including use of formularies and cost sharing.

The Appendix briefly describes: (A) special pricing rules applicable to Medicaid and some other federal programs, and (B) the roles physicians, large employers, and health plans have in the pharmaceutical supply chain.

The pharmaceutical supply system is complex, and involves multiple organizations that play differing but sometimes overlapping roles in drug distribution and contracting. This complexity results in considerable price variability across different types of consumers, and the supply chain is not well understood by patients or policymakers. Increased understanding of these issues on the part of policymakers should assist in making rational policy decisions for the Medicare and Medicaid programs.

Exhibit 1. Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain



Source: The Health Strategies Consultancy LLC

II. The Flow of Goods from Manufacturers to Consumers in the U.S. Pharmaceutical Supply Chain

Pharmaceutical Manufacturers

Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs (e.g., Pfizer, Merck, and Novartis) and manufacturers of generic drugs (e.g., Mylan, Roxane, and Barr). There are a few pharmaceutical companies that participate in both the branded and generic parts of the industry, and both models focus on the manufacturing and packaging of pharmaceutical products, but there are other important differences. Most brand manufacturers devote a portion of their expenses to the scientific research and development of new drug therapies. Generic drug manufacturers typically do not develop new drug therapies, but instead manufacture generic compounds that compete directly with the original branded version of a drug once the brand product's patent protection has expired.

Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly to government purchasers, such as the Veterans Administration, AIDS Drug Assistance Programs (ADAPs), and Vaccines for Children (VFC), which typically receive the largest price discounts. In a few rare cases, a manufacturer may distribute drugs directly to a self-insured employer with an on-site pharmacy, but the typical employer-sponsored plan does not follow this path. Wholesale distributors are the manufacturers' largest purchasers. Very few drugs are distributed directly to consumers.

At the most basic economic level, a pharmaceutical manufacturer supplies a quantity of its products that is equal to the demand for its products from consumers/patients (of course, consumer demand in this market is expressed through the medium of a prescribing physician or other licensed health care provider). Manufacturers also play roles in stimulating demand for drug products through underwriting clinical studies designed to demonstrate the value proposition of pharmaceutical treatments compared to one another or compared to no clinical treatment at all; by engaging in the promotion and marketing of products to health care providers (including health plans and PBMs) and direct-to-consumer advertising; and by administering patient assistance programs that provide the firm's products at nominal cost to low-income consumers.

Manufacturers also play an important role in ensuring the safety of the pharmaceutical supply chain by producing informational labeling for prescribers and consumers that is consistent with the terms and conditions of a drug's approval by the U.S. Food and Drug Administration (FDA), and by using electronic bar-coding technology on drug packaging that may be used to track individual production lots, and to prevent prescribing errors.

Overview of Pharmaceutical Manufacturing Industry

Pharmaceutical manufacturing is a large global industry. In 2003, worldwide pharmaceutical industry sales totaled $491.8 billion, an increase in sales volume of 9 percent over the preceding year.[1] The U.S. represents the largest single national market for pharmaceuticals, accounting for 44 percent of global industry sales in 2003, or a total of $216.4 billion, which was an increase of approximately 12 percent from the previous year's figure.[2]

After a decade of significant mergers and acquisitions by drug companies, a relatively few large, multinational firms comprise the bulk of the brand pharmaceutical manufacturing industry today. The ten largest pharmaceutical corporations, as measured by U.S. sales, accounted for almost 60 percent of total U.S. sales in 2004:

Exhibit 2. Top 10 Pharmaceutical Corporations by U.S. Sales, 2004

Rank	Corporation	U.S. Sales ($ Billions)	% Growth Over Previous Year	% Market Share
1	Pfizer	$30.7	5	13.1
2	GlaxoSmithKline	18.8	1	8.0
3	Johnson & Johnson	16.2	7	6.9
4	Merck & Co.	15.0	8	6.4
5	AstraZeneca	11.3	12	4.8
6	Novartis	10.2	7	4.3
7	Sanofi-Aventis	10.0	13	4.3
8	Amgen	9.5	23	4.1
9	Bristol-Myers Squibb	9.2	-4	3.9
10	Wyeth	8.2	11	3.5
	Total, Top 10	139.1	--	59.3

Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891374,00.html

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[2]IMS Health, "IMS Reports 11.5 Percent Dollar Growth in '03 U.S. Prescription Sales," February 17, 2004, accessed at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_44771558,00.html. Prescription sales figures reported by IMS Health represent manufacturer prices.

When measured by prescription volume, the "top 10" list is similar but not identical, as a few generic drug manufacturers appear on the list:

Exhibit 3. Top 10 Pharmaceutical Corporations by Total U.S. Dispensed Prescriptions, 2004

Rank	Corporation	U.S. Prescriptions (Millions)	% Growth Over Previous Year	% Market Share
1	Pfizer	360.7	-4	10.2
2	Novartis	225.5	-2	6.4
3	Teva*	221.2	7	6.3
4	Mylan Labs*	215.2	4	6.1
5	Watson*	175.6	7	5.0
6	GlaxoSmithKline	138.8	-13	3.9
7	Merck & Co.	129.5	3	3.7
8	AstraZeneca	100.4	11	2.9
9	Johnson & Johnson	95.6	-9	2.7
10	Abbott	91.5	-4	2.6
	Total, Top 10	1754.0.		49.8

* Generic drug manufacturers

Source: IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913574,00.html

Exhibit 4 provides a description of the generic pharmaceutical market:

Exhibit 4. Top 10 Generic Manufacturers by Total Global Sales, 2003

Rank	Corporation	Global Sales ($ Millions)	% Growth Over Previous Year
1	Sandoz	$4,004.0	
2	Teva Pharmaceutical Industries Limited	3,276.4	30.1
3	IVAX Corporation	1,420.3	18.6
4	Mylan Laboratories Inc.	1,269.2	15.0
5	Alpharma Inc.	1,297.3	4.8
6	Andrx Corporation	1,046.3	35.7
7	Barr Pharmaceuticals, Inc.	902.9	-24.1
8	Par Pharmaceutical Companies, Inc.	661.7	73.4
9	American Pharmaceutical Partners, Inc.	351.3	26.6
10	Eon Labs, Inc.	329.5	34.9

Source: Hoover's, Inc. Hoover's Online, accessed 1/03/2005.

To convey the size of the pharmaceutical manufacturing industry from the perspective of individual products, the following tables present data on the biggest selling pharmaceutical products in the United States in 2004, measured by prescriptions dispensed and by sales in dollars. Exhibits 5 and 6 are for individual drug products, while Exhibits 7 and 8 are for broader therapeutic classes of drugs.

Exhibit 5. Top 10 Products by Total U.S. Dispensed Prescriptions, 2004

Rank	Product	Manufacturer	Prescriptions (Millions)	% Growth Over Previous Year	% Market Share
1	Lipitor	Pfizer	74.8	9	2.1
2	HYCD/APAP	Mallinckrodt	49.5	12	1.4
3	Synthroid	Abbott	47.4	-5	1.3
4	Norvasc	Pfizer	38.3	5	1.1
5	Toprol-XL	AstraZeneca	35.0	18	1.0
6	Zoloft	Pfizer	33.1	1	0.9
7	Zocor	Merck	29.6	1	0.8
8	HYCD/APAP	Watson	29.0	-2	0.8
9	Albuterol	Warrick	26.8	0	0.8
10	Amoxicillin	Teva	26.2	-5	0.7

Source: IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913594,00.html

Exhibit 6. Top 10 Products by U.S. Sales, 2004

Rank	Product	Manufacturer	U.S. Sales ($ Billions)	% Growth Over Previous Year	% Market Share
1	Lipitor	Pfizer	$7.7	14	3.3
2	Zocor	Merck	4.6	4	1.9
3	Prevacid	TAP	3.8	-5	1.6
4	Nexium	AstraZeneca	3.8	23	1.6
5	Procrit	Ortho Biotech	3.2	-3	1.4
6	Zoloft	Pfizer	3.1	8	1.3
7	Epogen	Amgen	3.0	-4	1.3
8	Plavix	Sanofi-Synthelabo	3.0	33	1.3
9	Advair Diskus	GlaxoSmithKline	2.9	26	1.2
10	Zyprexa	Eli Lilly	2.8	-10	1.2

Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2-28-05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69890133,00.html

Exhibit 7. Top 10 Therapeutic Classes by Total U.S. Dispensed Prescriptions, 2004

Rank	Therapeutic Class	Total Prescriptions (Millions)	% Growth over Previous Year	% Market Share
1	Codeine	157.6	5	4.5
2	SSRIs/SNRIs	147.4	4	4.2
3	ACE Inhibitors	143.8	5	4.1
4	HMG-COA Reductase Inhibitors (Statins)	139.8	11	4.0
5	Beta Blockers	120.6	7	3.4
6	Proton Pump Inhibitors	93.1	-2	2.6
7	Thyroid Hormone, Synthetic	90.0	6	2.6
8	Calcium Blockers	88.4	0	2.5
9	Seizure Disorders	84.8	7	2.4
10	Oral Contraceptives	82.5	-3	2.3

Source: IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68914714,00.html

Exhibit 8. Top 10 Therapeutic Classes by U.S. Sales, 2004

Rank	Therapeutic Class	U.S. Sales ($ Billions)	% Growth Over Previous Year	% Market Share
1	HMG-COA Reductase Inhibitors (Statins)	$15.5	12	6.6
2	Proton Pump Inhibitors	12.5	-3	5.3
3	SSRIs/SNRIs	11.0	1	4.7
4	Antipsychotics, Other	9.1	12	3.8
5	Seizure Disorders	8.2	19	3.5
6	Erythropoietins	8.0	8	3.4
7	Antiarthritics, COX-2 Inhibitors	5.3	0	2.3
8	Calcium Channel Blockers	4.4	1	1.9
9	Angiotensin II Antagonists	4.4	24	1.9
10	Ace Inhibitors	3.9	-5	1.7

Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891394,00.html

Wholesale Distributors

Wholesale distributors purchase pharmaceutical products from manufacturers and distribute them to a variety of customers, including pharmacies (retail and mail-order), hospitals, and long-term care and other medical facilities (e.g., community clinics, physician offices and diagnostic labs). Some wholesalers sell to a broad range of potential clients while others specialize in sales of particular products (e.g., biologic products) or sales to particular types of customers (e.g., nursing homes).

Exhibit 9. Wholesale Distribution Industry

In 2004, the wholesaler distributor industry is valued at approximately $212 billion in annual U.S. sales. The following three wholesalers represent 88% of the market:

1) McKesson

- Merged with health-care software giant HBO & Co. in 1998
- Rolling 12-month sales as of September 2004: $72.2 billion; Market Share: 34.1%

2) Cardinal Health

- From 1999 – 2002, Cardinal merged with many other wholesalers including Allegiance Corporation and Bindley Western Industries
- Rolling 12-month sales as of September 2004: $63.3 billion; Market Share: 29.9%

3) AmerisourceBergen

- Began operations in August 2001 following merger of AmeriSource Health Corporation and Bergen Brunswig Corporation
- Rolling 12-month sales as of September 2004: $52.4 billion; Market Share: 24.8%

Source: *GICS Sub-Industry Revenue Share (09/04/2004).*

In the past, wholesalers limited their operations to a traditional distribution function. They provided the link between manufacturers and pharmacies (and other entities, e.g., government sites and physicians) by warehousing products and managing inventory. While "traditional" distribution services remain the cornerstone of the business, the industry has developed a more comprehensive list of services in response to the evolving

marketplace. Today, wholesale distributors provide a number of specialized services, including specialty drug distribution, drug repackaging, electronic order services, reimbursement support, and drug buy-back programs.[3]

The wholesale distribution industry has gone through significant change and consolidation in the last 30 years, due in part to the increasing pressures to lower costs. Between 1975 and 2000, the number of wholesale distributors in the U.S. declined from approximately 200 to fewer than 50.[4] The top three wholesale distributors, McKesson, Cardinal Health, and Amerisource-Bergen, account for almost 90 percent of the entire wholesale drug market.[5]

This consolidation has forced the industry to change its revenue model, evolving its core distribution business into a low-margin enterprise that makes money by maximizing economies of scale, creating physical efficiencies in the distribution system (such as "just-in-time" deliveries to customers), and realizing financial efficiencies (such as retaining discounts for prompt payment). The industry has also extended and augmented its business model by moving into specialty pharmacy and disease management services.

Pharmacies

Pharmacies are the final step on the pharmaceutical supply chain before drugs reach the consumer/patient. Pharmacies purchase drugs from wholesalers, and occasionally directly from manufacturers, and then take physical possession of the drug products. After purchasing pharmaceuticals, pharmacies assume responsibility for their safe storage and dispensing to consumers. Pharmacy operations include maintaining an adequate stock of drug products, providing information to consumers about the safe and effective use of prescription drugs, and facilitating billing and payment for consumers participating in group health benefit plans.

Pharmacies also serve as a vital information link between PBMs, drug manufacturers, and wholesale distributors. Unlike most other sectors of the health care delivery system in the U.S., the pharmaceutical supply chain is highly automated and virtually all claims transactions are handled electronically, rather than on paper. Since they are the final point of sale for pharmaceuticals and the interface between the supply chain and the consumer, pharmacies generate the prescription drug claims information that PBMs, as well as heath plans, employers, governments, and other payers, rely upon to measure consumer activity. Other types of information, both quality-focused (e.g., drug-drug interaction warnings) and utilization management-based (e.g., formulary compliance

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[3] Drug buy-back programs are offered by manufacturers and are facilitated by wholesale distributors. Buy-back programs are intended to minimize the financial risk that pharmacies must assume in stocking products by allowing them to sell unused products or products with near-term expiration dates back to the manufacturer.

[4] Goldman Sachs Industry Report: Health Care Technology & Distribution, February 27, 2003.

[5] Standard & Poor's, *GICS Sub-Industry Revenue Share,* September 4, 2004.

messaging) can originate from other parts of the supply chain, in particular from PBMs, to the pharmacy as a prescription is being dispensed. As the final actor in the supply chain, it is up to the pharmacy to take action based on the information provided. For example, the pharmacy is expected to contact the prescribing physician if the drug prescribed is not on the patient's health plan's formulary or if a lower-cost therapeutic alternative is available.

There are several types of pharmacies, including independent pharmacies, chain drug stores, pharmacies in supermarkets and other large retail establishments, and mail-order pharmacies. Most pharmacies purchase their drug supply from a wholesale distributor, although in some cases, large institutional and retail chain pharmacies, specialty pharmacies, and mail-order pharmacies obtain drugs directly from a manufacturer. These organizations can deal directly with manufacturers because they already possess the operational infrastructure necessary to bypass wholesalers – warehousing facilities, distribution vehicles, and inventory control systems. Once a pharmacy takes possession of the drug products, it distributes the products to physicians or directly to consumers. In addition, there are specialty pharmacies, which specialize in the distribution of high-cost and more complex drug therapies (e.g., self-injectable drugs and biologics).

In 2003, there were 55,000 community retail pharmacies, including 19,000 independent drug stores, 21,000 chain drug stores, and 16,000 pharmacies in supermarkets and other retail merchants.[6] In 2004, there were 3.5 billion prescriptions dispensed in the United States through community pharmacies, including about 1.8 billion filled at chain drug stores, 780 million filled at independent pharmacies, and 470 million filled in supermarkets. Another 214 million prescriptions were filled through the mail.[7]

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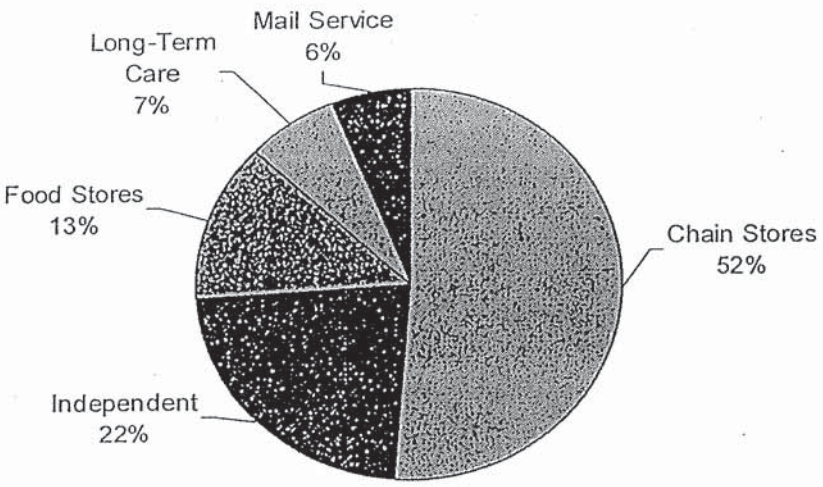
[6] National Association of Chain Drug Stores, http://www.nacds.org/user-assets/PDF_files/Retail_Outlets2003.pdf.

[7] IMS Health, National Prescription Audit™Plus, January 2005, accesses 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html

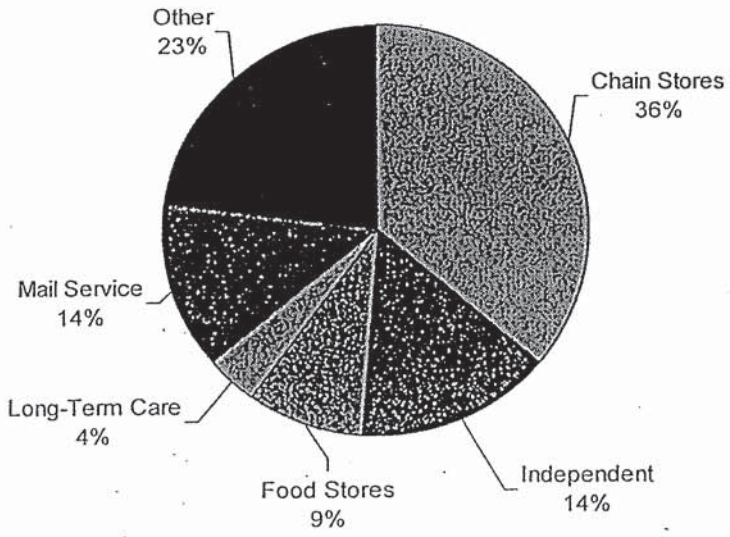
Exhibits 10 and 11 depict the distribution of pharmaceuticals in the U.S. through the various types of "retail" pharmacy channels:

Exhibit 10. Number of Prescriptions by Pharmacy Distribution Channel, 2004



Note: Represents total dispensed prescriptions, including insulin dispensed through chain, food store, independent, long term care, and mail service pharmacies.
Source: IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html

Exhibit 11. Drug Sales by Pharmacy Distribution Channel, 2004



Note: Represents wholesale prices. Sales include prescription products only.
Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html

Like all other parts of the pharmaceutical supply chain, the pharmacy industry has gone through significant consolidation as well as diversification of its businesses over the past five to ten years. Several retail pharmacy chains have merged, primarily as a way to gain buying power for use in negotiations with drug manufacturers and wholesale distributors.

As shown in Exhibit 12, Walgreens, CVS, and Rite Aid were the top three retail pharmacy chains based on market capitalization:

Exhibit 12. Top 5 Retail Pharmacy Chains in the U.S., By Market Capitalization

Rank	Pharmacy Chain	2004 Market Cap
1	Walgreens Company	$35.2 bil.
2	CVS Corporation	$16.1 bil.
3	Rite Aid	$2.6 bil.
4	Longs Drug Stores	$0.7 bil.
5	Duane Reade	$0.4 bil.
	Total for Industry	$103.0 bil.

Source: Health Strategies Consultancy analysis of Pharmacy/Drug Store Industry based on market cap data obtained from Dow Jones (factiva.com)[8]

In addition to traditional retail pharmacy services, consumers have increasingly been using specialty and mail-order pharmacies over the past several years. Growth in the use of these types of pharmacies is expected to increase rapidly for the foreseeable future, as more payers adopt the view that these specialized retail distribution channels can be important components of their strategies to manage the rate of growth in their pharmacy benefit expenditures. Residents of long-term care facilities (LTC) rely almost exclusively on dedicated LTC pharmacies.

- ***Specialty pharmacies*** serve patients with chronic diseases by dispensing high-cost biotechnology drugs. Specialty pharmaceuticals typically are administered by injection or infusion (intravenously), and often, are administered by a clinical professional in a doctor's office. The diseases treated with specialty pharmaceuticals range from relatively common conditions, some of which are treated with multiple drug therapies, such as HIV/AIDS, multiple sclerosis, cancer, and rheumatoid arthritis, to rare diseases that are treated with a single drug therapy, such as hemophilia and growth hormone deficiency. The specialty pharmacy industry today is dynamic, with new companies entering continuously. Types of firms in the market range from publicly-traded stand-alone firms to subsidiaries of PBMs, retail pharmacies, and home health companies.[9,10]

[8] Market capitalization is the value of a company's outstanding shares of stock, which is measured by multiplying the number of shares outstanding by the current share price. Speaking very generally, the larger the market capitalization, the more financially stable the company.

[9] Credit Suisse First Boston, "Pharmacy Benefit Managers and Specialty Pharmacies: Initiating Coverage," July 14, 2003, p. 22.

[10] Raymond James & Associates, Inc., "Specialty Drug Distribution," July 16, 2002, p. 3.

- *Mail-order pharmacies* receive prescriptions by mail, fax, phone, or Internet at a central location; process the prescription in large, mostly automated centers; and mail the prescribed drugs back to the consumer. An aging population, convenience, and the recent upswing in pharmaceutical treatments for common chronic ailments, such as diabetes and depression, are some of the driving forces behind the rapid growth in the use of mail-order pharmacies.[11] While representing a small overall percentage of total prescriptions filled (approximately 6.1 percent in 2004[12]), mail-order pharmacy sales remained the fastest-growing sector of the U.S. prescription drug retail market in 2004, increasing by 18 percent over the previous year.[13] The majority of mail-order facilities are owned and operated by PBMs, and a number of the large retail pharmacy chains also own mail-order pharmacies.[14]

- ***Long-term care pharmacies***, sometimes called institutional pharmacies, are a third type of specialized retail pharmacy. Long-term care pharmacies address the special needs of nursing homes, providing packaging for controlled administration (called unit-dose supply or bubble packs), and special services that are more extensive than those provided by retail pharmacies. These special services include: quality assurance checks, emergency drug kits and medication carts, regular and emergency (24-hour-a-day) delivery services, and in-service training programs for nurse aides, nurses, and other professional nursing facility staff. Four national chains provide the bulk of institutional pharmacy services to nursing homes: Omnicare, PharMerica, NeighborCare, and Kindred Healthcare. In 2003, these four chains served over two-thirds of all nursing home beds and had collective revenues of more than $6 billion.[15] The two largest national long-term care pharmacies, Omnicare and PharMerica (which is a subsidiary of AmerisourceBergen, a wholesale distributor), provide drugs to over half of the nursing home beds in the United States. Omnicare is the largest provider with over $3 billion in 2003 revenues.[16]

Pharmacy Benefit Managers (PBMs)

According to one leading report on the PBM industry, PBMs currently manage prescription drug benefits for as much as 57 percent of the U.S. population,[17] and the

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[11] National Health Policy Forum, *The ABCs of PBMs*, October 1999.
[12] IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html
[13] IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2/28/05, at http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html
[14] California Health Care Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.
[15] Long-Term Care Pharmacy Association, 2003.
[16] Omnicare Annual Report, 2003.
[17] Atlantic Information Services (AIS), Inc., *A Guide to Drug Cost Management Strategies (2nd Edition)*, 2004, p. 329. AIS states that its data are based on a quarterly survey that the firm has been using to track all publicly-traded and privately-held PBMs since 2000.

National Association of Chain Drug Stores estimates that approximately two-thirds of all prescriptions written in the U.S. are processed by a PBM.[18] While not a direct link in the physical supply chain for pharmaceutical products (PBMs in most instances do not take possession or control of prescription drugs), PBMs have become an integral part of most consumer drug purchases. PBMs work with third party payers (private insurers, self-funded employers and public health programs) to manage consumer drug purchases by defining which drugs will be paid for and the amounts that the pharmacy will receive and the consumer must pay out-of-pocket when the prescription is filled.

PBMs have evolved over the last three decades from basic claims administrators to more complex organizations offering a wide range of prescription drug management tools. In addition to offering their basic services – claims processing, record keeping, and reporting programs – PBMs offer their customers a wide range of services including drug utilization review, disease management, and consultative services. PBMs also assist clients with establishing their benefit structure. Options for plan design include: developing and maintaining a prescription drug formulary; developing a network of pharmacy providers; and providing mail order fulfillment services. A PBM's core services and tools include:

- ***Formularies:*** PBMs use formularies to negotiate deeper price discounts with manufacturers, set cost-sharing levels to influence beneficiary utilization rates, and encourage beneficiaries to use a mix of preferred or lower-cost covered products.

- ***Rebates:*** PBMs negotiate with pharmaceutical manufacturers for rebates on products selected for the formulary. Rebate amounts are based on the contracts negotiated between the PBM and plan sponsors and the PBM and manufacturers. Typically, contracts are structured so that PBMs retain a portion of the rebate in exchange for developing the formulary and negotiating with manufacturers.

- ***Pharmacy Networks:*** Pharmacy networks consist of pharmacies that have agreed to dispense prescription drugs and provide pharmacy services to a health plan's enrollees under specified terms and conditions. Pharmacy networks can be broad or narrow. These networks allow PBMs to lower prescription drug prices by negotiating the reimbursement rate and dispensing fee with pharmacies.

- ***Mail-Order Pharmacy Service:*** Almost all PBMs offer mail-order pharmacy service, especially targeted toward individuals with chronic medical conditions who take maintenance medications. The medications are dispensed typically in 90-day amounts per prescription, as opposed to the usual 30-day supply per prescription dispensed by a retail pharmacy. PBMs are able to lower the cost of pharmaceuticals to consumers and payers by using mail-order services to more successfully drive market share for particular products, based on the terms of

[18] Ibid., p. 331.

contracts negotiated with pharmaceutical manufacturers (e.g., encouraging generic and branded therapeutic substitution and other forms of managing formulary compliance), and (relative to the typical retail pharmacy operation) by automating dispensing processes.

- ***Claims Adjudication:*** All PBMs use a real-time, point-of-sale system linked to retail and mail-order pharmacies and distribution centers. This process provides verification of coverage, formulary restrictions, drug interactions, and individual co-pay information. This process also provides prescription drug information back at the PBM data warehouse, where it can be used for customized reporting and quality-focused clinical and intervention programs.

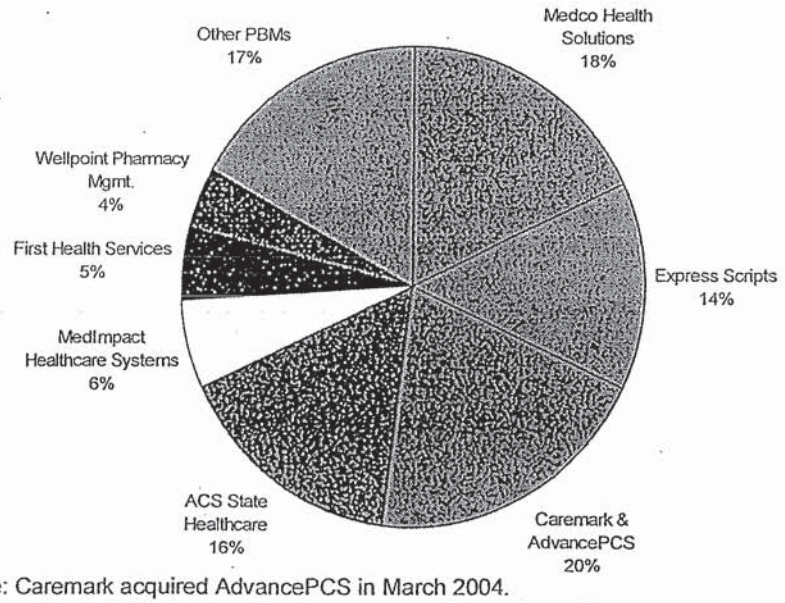
- ***Generic and Therapeutic Substitution:*** Generic substitution promotes the shift from brand to chemically equivalent generic drugs as a cost savings device. Therapeutic interchange programs promote the use of preferred drugs (i.e., drugs on a plan's formulary) that are determined to be clinically similar.

- ***Quality-Focused Programs:*** PBMs develop programs that provide disease management, compliance strategies, and other clinical expertise promoting the safe, educated use of prescription drugs.

PBMs generally do not take physical possession of prescription drugs when performing their core pharmaceutical management functions. However, in their mail-order and specialty-pharmacy businesses, PBMs buy drugs from wholesalers or manufacturers and dispense them directly to patients in a manner similar to other pharmacies.

During the 1990s, there was a great deal of jockeying within the PBM market, a highly penetrated market compared to just a decade ago. In order to remain competitive, PBMs have merged and acquired new businesses. Most recently, in March 2004, Caremark acquired AdvancePCS; in 2001, Express Scripts acquired National Prescription Administrators; in 2000, Medco Health Solutions acquired Provantage; and in 1998, Express Scripts acquired Value Rx. As shown in Exhibit 13, the PBMs that controlled the most market share measured by prescriptions per year in 2003 were Medco Health Solutions, ACS State Healthcare, AdvancePCS/Caremark, and Express Scripts.[19]

Exhibit 13. PBM Market Share by Number of Prescriptions per Year, 2003



*Note: Caremark acquired AdvancePCS in March 2004.
Source: AIS, *A Guide to Drug Cost Management Strategies*, 2nd Edition (2004), Fig. 12.13.

[19] Atlantic Information Services, Inc., *A Guide to Drug Cost Management Strategies*, 2nd Edition, 2004.

III. The Flow of Money and Key Financial Relationships in the U.S. Pharmaceutical Supply Chain

The flow of money between manufacturers and end-users is more complex than the physical distribution of drugs. The manufacturer typically interacts with three primary entities when dealing with price: wholesale distributors, retail pharmacies, and pharmacy benefit managers. Pharmaceutical manufacturers negotiate separate contracts with these entities and offer various discounts and rebates based largely on the entities' varying ability to influence the quantity of drugs that are sold. This section looks at these financial relationships and charts the flow of funds among the key players, starting with manufacturers, who play by far the most important role in establishing prices.

Pharmaceutical Manufacturers

Manufacturers have the most influence over pharmaceutical prices. They develop algorithms to account for expected demand for the product, future competition for the product, and projected marketing costs, and use those algorithms to establish the "wholesale acquisition cost" (WAC), which is the baseline price at which wholesale distributors purchase products. After the WAC is established, the average wholesale price (AWP), or the retail list price, is established either by the manufacturer or by one of the companies that publishes price compendia. The AWP, and sometimes the WAC, is listed in drug compendia published by a small number of private firms, such as the Red Book, published by Thomson Medical Economics, and First DataBank. The AWP has two purposes: (1) it is often used by public and private third-party payers as the basis for reimbursement, and (2) it often serves as the base price for negotiations between manufacturers and private sector purchasers of drugs (e.g., health plans, pharmacy benefit managers, self-insured employers, etc.).

The negotiation process and the price points on which negotiations are based are different for brand and generic manufacturers. Brand manufacturers typically offer discounts based on a percentage of AWP or WAC, depending upon the purchaser. End purchasers can typically acquire brand drug products for a price in a range of AWP minus 5 to 40 percent, depending upon their purchasing power or that of their designated agent, such as a PBM. Generic pharmaceutical manufacturers operate in a more aggressive and dynamic negotiation environment than brand manufacturers and thus the prices for generic drugs change much more frequently, sometimes daily, in response to market forces. The most common kinds of discounts and rebates include: retroactive rebates based on market share (i.e., rebates paid by the manufacturer to the pharmacy or PBM based on its ability to direct consumers to certain products); volume discounts (discounts that are triggered when predetermined sales volume targets are met); and "prompt pay" discounts (discounts that are triggered when the purchaser reimburses the manufacturer in an expedited fashion).

Pricing for prescription drugs purchased and dispensed by certain federal programs, including Medicaid and the Veterans Administration, are subject to special rules which

generally result in those programs getting lower prices than other purchasers. These rules are outlined in the Appendix.

PRICING TERMS DEFINED

- *Average Manufacturer Price (AMP)*: The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP was a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available. (See Appendix for additional discussion of pharmaceutical pricing in Medicaid).
- *Average Sales Price (ASP*: The weighted average of all non-Federal sales to wholesalers net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to ASP.
- *Average Wholesale Price (AWP)*: Although not defined in statute, AWP is recognized as retail list price (sometimes referred to as a "sticker" price) and is currently used by some public and private third-party payers as the basis for reimbursement (e.g., AWP minus 5 or 25 percent). AWP has been widely criticized as a price that is (1) not reflective of the true market price, and (2) easily manipulated. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to average sales price (ASP).
- *Estimated Acquisition Cost (EAC)*: EAC is a state Medicaid Agency's best estimate of the price generally paid by pharmacies for a particular drug.
- *Maximum Allowable Cost (MAC)*: MAC lists are designed to cap reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing for drugs on a MAC list.
- *Wholesale Acquisition Cost (WAC)*: The price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. Publicly disclosed or listed WAC amounts may not reflect all available discounts.

Wholesale Distributors

Wholesale distributors purchase drugs from manufacturers. For branded products, the purchase price is fairly uniform, with little negotiation on the part of the wholesale distributor. The distributor typically purchases branded products for a discounted rate off of WAC. Examples of discounts for branded products include volume discounts, prompt pay discounts, and discounts related to the sale of short-dated products (because the wholesaler is assuming a risk that the product will expire before it can be resold). The wholesale distributor then sells the product to its end consumer, typically a pharmacy, at WAC plus some negotiated percentage.

For generic products, the purchase price is highly variable, largely depending upon competition in the class and the ability of the wholesale distributor to drive market share or increase the volume sold. In this case, wholesale distributors play a larger role in the negotiation of the price of the product. The price to the end consumer also is highly elastic depending upon the negotiated contracts with the retail pharmacies.

In some cases, the wholesale distributor may facilitate discounts negotiated between manufacturers and other customers. For example, wholesaler A may distribute drugs to pharmacy B based on negotiations between pharmacy B and manufacturer C. Although wholesaler A directly distributes the drugs to pharmacy B, it plays a minimal part in pricing negotiations for these drugs. In this case, wholesalers use an important pricing mechanism, *chargeback*, which allows them to carry products destined for customers paying very different prices to manufacturers. The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then "charges back" the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler's cost of goods (WAC).

Pharmacies

Payment for prescription drugs flow from the pharmacy to the manufacturer according to a negotiated contract involving manufacturers, PBMs, and pharmacies. Retail pharmacies negotiate with manufacturers for discounts and rebates based on the pharmacy's ability to sell specific volumes of certain drugs or achieve a certain share of a specified market. As discussed in the wholesale distributor section, pharmacies may be able to negotiate discounts with manufacturers that are more substantial than the wholesale distributor's cost. In these instances, the wholesale distributor facilitates the discount and "charges back" the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler's cost of goods (WAC). Pharmacies also negotiate with PBMs for inclusion in a PBM's pharmacy network and for reimbursement for the cost of the drug plus dispensing fees.

Manufacturers may offer volume discounts on selected drugs to pharmacies when they achieve predetermined market share targets. These discounts provide an incentive for pharmacists to work with patients and physicians to switch products from a prescribed non-preferred drug to a preferred drug.

Pharmacies contract with PBMs to join their pharmacy network. This structure provides pharmacies with guaranteed, stable reimbursement from private payers and access to a greater number of customers. The network consists of a group of retail and independent pharmacies and serves to offer plan members with lower prescription drug costs. As part of the pharmacy network contract, retail pharmacies must agree to a guaranteed reimbursement formula for prescription drugs. For brand-name medications, the reimbursement formula is usually determined by subtracting a negotiated percentage from the drug's AWP and adding the dispensing fee. For generic drugs, reimbursement may be determined in the same way as for a brand drug (for less competitive generic drug classes), but more often is based on an amount specified referred to as the maximum allowable cost (MAC).

Smaller retail stores, such as independent pharmacies and smaller retail chains, either purchase directly from wholesalers – at a price significantly higher than retail pharmacies – or join group-purchasing organizations (GPOs). As members of a GPO, small

pharmacies receive the benefits of volume purchasing by leveraging their combined purchasing power to negotiate discount pricing from wholesalers or even in some cases from manufacturers. Some of these groups further reduce their costs through direct rebate deals offered by manufacturers.

Mail-order and specialty pharmacy services are increasingly becoming a more attractive and demanded option for health plan sponsors and other payers seeking to rein in pharmaceutical expenditures for their members. Mail-order and specialty pharmacies are able to generate increased savings by driving market share, streamlining the distribution chain, and automating drug dispensing processes.

- ***Specialty Pharmacy:*** Most specialty pharmacy providers manage the cost of specialty pharmaceuticals by negotiating directly with manufacturers and by running quality-focused programs intended to improve patient care and lower costs. Large PBMs or retail pharmacy chains own a number of the specialty pharmacies, and in some cases these entities are able to negotiate greater discounts with manufacturers.[20] Nearly all specialty pharmacies also administer programs designed to enforce patient compliance. Industry representatives claim that these programs save the patient and health plan money by averting acute incidences.

- ***Mail-Order Pharmacy:*** In 2000, the U.S. Department of Health and Human Services estimated that mail-order pharmacies were able to generate savings between two and 35 percent compared to retail pharmacies.[21] Representatives from the mail-order industry attribute these savings to their ability to "manage" prescriptions because the majority of mail-order prescriptions are filled in 90-day units (the equivalent of three prescriptions).[22] The considerable lead time associated with filling a 90-day prescription gives the pharmacists and other clinical staff at a mail-order pharmacy the time to analyze whether the prescribed drug is on the client's (i.e., insurer's or health plan's) approved formulary, if there is a generic equivalent available, and if there are any potential interactions of the prescribed drug with other medications the member's physician or physicians may have also prescribed.

- ***Long-Term Care Pharmacy:*** LTC pharmacies have long-term, almost exclusive contracts with nursing homes to provide medications and services for residents. LTC pharmacies capture a large volume of customers in this way. LTC pharmacy chains have developed formularies and use them in many states that do not have Medicaid preferred drug lists (PDLs) applicable in the nursing home setting. The large LTC pharmacy chains negotiate rebates with manufacturers in exchange for

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[20] Berg, Kevin I. "Health Care Industry Report: The Down Low," *First Albany Corporation* 6 (2003): 1-153.

[21] Department of Health and Human Services, *Report to the President: Prescription Drug Coverage: Spending Utilization and Prices*, April 2000.

[22] California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

moving market share on their formularies. In addition to receiving rebates, many pharmacies are reimbursed at higher rates than acquisition costs, because they purchase drugs through wholesalers and group purchasing organizations.

Pharmacy Benefit Managers (PBMs)

Although PBMs are a relatively unknown entity to the end consumer, they play a fundamental role in negotiating the price that is ultimately paid for the product through their relationships with other entities in the supply chain.

PBMs contract with health plans to manage their prescription drug costs. Each contract is different between health plans and PBMs; however, there are generally three basic components of the payment negotiated between PBMs and their sponsors. First, PBMs receive payment for the services they provide. These services may include claims adjudication processing and disease management services. Second, PBMs typically assume some type of performance risk in the contracts they negotiate. Performance metrics can include: customer service (e.g., adequacy of pharmacy networks, timeliness of reporting), clinical quality measures (e.g., the number of people averted from taking inappropriate medications), and cost management techniques (e.g., the number of generic substitutions made in a given time period). Third, PBMs also retain a portion of rebates they secure from manufacturers.

PBMs do not typically assume full insurance risk for drugs. This type of risk is assumed when an insurer takes full or partial financial responsibility for claims incurred under a specified benefit. Insurance risk can further be segmented into three sub-categories: price, utilization, and selection risk. PBMs do not typically guarantee either the unit prices of drugs, the volume of drugs (utilization) or the kinds of patients that sign up for the drug plan (selection). Insurance risk for drugs is often assumed by self-insured entities in the context of a full medical benefit. For an entitiy to assume insurance risk, the entity must demonstrate that it has adequate financial reserves, be licensed and overseen by state insurance regulators, and be prepared for underwriting cycles.

While performance risk arrangements are very common for PBMs, insurance risk arrangements are not. During the mid-1990s, some PBMs experimented with risk contracts. ValueHealth, PCS, and Medco had contracts in which the PBM assumed full insurance risk. The contracts typically contained actuarial carve-outs for new biotechnology products and unexpected changes in demographics, but put the PBM at risk for other drug utilization and cost. Many of these contracts were with large manufacturing clients who were self-insured, concerned about drug spending, and bid out the pharmacy benefit competitively to multiple vendors. The experience was uniformly negative from the PBM perspective. The PBMs consistently lost money because they under-estimated the development and diffusion of new technology. Many were able to negotiate out of these contracts, but some contracts persisted until the late 1990s. Most, if not all, are now gone.

PBM relationships with manufacturers are governed under guidance from the Department of Health and Human Services (HHS) Office of the Inspector General, and subject to oversight by the Department of Justice for compliance with federal anti-kickback statutes. PBMs are further regulated in many states under consumer protection statutes. In recent years, some industry practices, for example switching of medications and associated pricing issues, have come under scrutiny by state Attorneys General and the Department of Justice. Allegations have also included accepting undisclosed incentives from pharmaceutical manufacturers, not passing manufacturer rebates through to plan sponsors, and driving beneficiaries unnecessarily to mail-order services for the benefit of the PBM. False Claim Act lawsuits also have been filed by the federal government and several states. Medco Health Solutions settled in April 2004 with twenty State Attorneys General on a case involving therapeutic interchange and price disclosure. While this legal scrutiny has focused on a few industry practices, the typical business practices of PBMs have also been heavily scrutinized by plan sponsors, such as health plans and self-insured employers. Further guidance from the HHS Office of the Inspector General on PBM operations and safe harbors under the anti-kickback statute is expected.[23]

According to a January 2003 study conducted by the federal Government Accountability Office (GAO), PBMs achieved significant discounts for drugs purchased at retail pharmacies (in comparison to cash-paying customers) and offered even greater discounts for their mail-order services.[24] However, cost savings are largely driven by how restrictive or open the cost-containment programs are. This is a point usually negotiated between the health plans and PBMs. For example, open formularies (where consumers are free to access all prescription drugs) typically yield lower cost savings than closed formularies (where consumers are limited to certain drugs). Cost sharing differences by the type of formulary also increase members' sensitivity to prescription drug costs and provides an incentive to use lower-cost or preferred products on the formulary. Common private-sector, cost sharing tools include flat copayments, percent copayments with a minimum/maximum dollar amount, and front-end deductibles with a benefit maximum and/or stop loss.[25]

- ***Manufacturer-PBM Relationship:*** As discussed above, the relationship between manufacturers and PBMs is centered around inclusion of a drug on a plan's formulary and the PBM's ability to increase a manufacturer's market share for certain drugs through inclusion or exclusion on a formulary. Manufacturers pay rebates to PBMs retroactively based on the PBM's ability to meet both of these goals. These rebates are passed in whole or in part back to the employer. According to the California HealthCare Foundation, PBMs are often able to secure rebates of 5-25 percent for branded drugs.[26]

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[23] For more information about the Medco settlement, see *The Pink Sheet*, May 3, 2004, pages 22-30.
[24] U.S. Government Accountability Office, "Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," GAO-03-196, January 2003.
[25] Joanne Sica, "Managing prescription drug costs," *Employee Benefits Journal*, March 2001, pp. 35-40.
[26] California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

- ***PBM-Pharmacy Relationship:*** As discussed above, PBMs negotiate with pharmacies for drug reimbursement and dispensing. The pharmacies negotiate for inclusion in a PBM's pharmacy network. There is often significant tension between the two entities because (1) in general, pharmacies are reimbursed by PBMs at levels below uninsured cash-paying customers and other government payers, like Medicaid, and (2) pharmacies are often required to perform more administrative tasks when filling a prescription for a PBM customer.

IV. Conclusion

Pharmaceuticals are a vital part of patient care, and their importance will only grow as the population ages and pharmaceutical innovation continues. Understanding current pharmaceutical issues (including the sources of prescription drugs, pricing and discounts, cost containment methods, and brand/generic questions) requires knowledge about the various actors in the supply chain. State and federal policymakers increasingly are looking to private sector financing strategies to shape the ways in which individuals with public coverage receive medications. Passage of the Medicare Modernization Act of 2003 (MMA) makes knowledge about the pharmaceutical chain even more important as the large public Medicare program and its beneficiaries begin to access the chain, and pharmaceutical chain entities make changes in response to the new coverage.

The pricing of prescription drugs and the flow of money among the various links in the pharmaceutical supply chain is more complex than the physical distribution of drugs through the chain. This complexity can result in substantial variations in what different purchasers pay for the same drugs. As we have shown, the price of prescription drugs paid by the consumer is determined by a constellation of negotiated contracts between manufacturers, PBMs, wholesale distributors, pharmacies, and plan sponsors. The price charged by each entity in the chain is largely driven by the ability of contracting entities to sell specific volumes of certain drugs or achieve a certain share of a specified market. It is also affected by the value each entity brings to the subsequent actors in the supply chain.

Rapid increases in spending on pharmaceuticals in recent years have led policymakers to more closely scrutinize drug pricing and the relationships among key actors in the marketplace, and the greatly enhanced federal role in the market brought about through the MMA will only intensify public interest in these areas. Experiences with the Medicare price comparison website for the drug discount card has increased consumer and government interest in internet-based price comparisons. The price differences highlighted by these and other analyses lead to questions about the basis for these pricing differentials. Medicare's activities to detect and remedy fraud and abuse will also require continued oversight and need for transparency and fiscal accountability. Public policy discussions regarding transparency and price disclosure are thus likely to continue to be active over the coming years.

V. Appendix

This Appendix briefly describes: (A) special pricing rules applicable to Medicaid and some other federal programs, and (B) the roles physicians, large employers, and health plans have in the pharmaceutical supply chain.

A. Special Pricing Rules Applicable to Federal Programs

Several federal programs that are significant purchasers of prescription drugs have special rules for pricing.

Medicaid

Federal rules require that states pay for brand name prescription drugs based on the lower of (1) the estimated acquisition cost (EAC) of a drug (the method most states use); or (2) the usual or customary charge to the public. Most Medicaid programs use a drug's AWP to calculate the EAC, generally AWP minus some percentage. An additional limit, known as the Federal Upper Limit (FUL), applies to the purchase of generic drugs. Manufacturers who want to have their drugs covered by Medicaid also must provide rebates to state Medicaid programs. For brand name drugs, the basic rebate is the larger of (1) 15.1% of the AMP (the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies; the AMP is usually lower than the AWP); or (2) the difference between the AMP and the lowest price the manufacturer offers to most other purchasers. An additional rebate is required if the price of brand name drugs rises faster than the change in Consumer Price Index. Rebates for generic drugs are calculated by multiplying the AMP by 11%.

Department of Veterans Affairs, Department of Defense, Public Health Service, Coast Guard

The Department of Veterans Affairs (VA) administers a program known as the Federal Supply Schedule (FSS), through which the VA and certain other government agencies can purchase prescription drugs at prices that are equal to or lower than the prices that drug manufacturers charge their "most-favored" private customers. In addition, manufacturers must sell brand-name drugs to these agencies at a minimum of 24% off the AMP (known as the federal ceiling price).

Section 340B Drug Pricing Program

Section 340B of the Public Health Service Act requires drug manufacturers, as a condition of having their drugs covered by Medicaid, to provide prescription drugs to certain nonfederal entities (public and disproportionate share hospitals, community health centers, certain grantees of Federal agencies, and health centers that serve migrant, homeless, public housing, and Native American populations)

at prices that are equal to or below the AMP reduced by the applicable Medicaid rebate percentage.

B. The Role of Physicians, Employers and Health Plans in Supply Chain

Physicians

Physicians play an important role in the pharmaceutical supply chain. They are the first to interact with the consumer (i.e., patient), the end-user in the supply chain. Doctors typically diagnose a patient's illnesses and prescribe a medication. The physician is also responsible for ensuring the appropriate quantity and dosage of the prescribed medication. If the prescribed drug is not covered under the patient's health plan, the physician may have to submit additional information substantiating the necessity of the specific medication for the treatment of the injury or illness. This is called "prior authorization." Once a drug is prescribed, patients typically fill prescriptions at their local retail pharmacies. In some cases, the physician may administer the drug in their office (e.g., chemotherapy).

Historically, patient compliance with whatever treatment the doctor ordered was assumed as part of the physician-patient relationship; increasingly, however, patients are becoming more proactive in their interaction with physicians, particularly in the area of prescription drug treatment decisions. Greater access to health information (fueled, in part, by widespread use of the Internet), the loosening of "direct-to-consumer" (DTC) advertising restrictions on drug manufacturers, and a general increase in the public's awareness of health care issues have helped transform many once-passive patients into inquiring and demanding consumers.[27] This trend has affected physician choices of specific medications prescribed and the modes of delivery used, and it has increased the complexity of the information transmitted to physicians and consumers. Now more than ever, physicians and patients/consumers play a large role in driving the market demand for pharmaceuticals.

Large Employers

Large employers that self insure their employees for health benefits generally negotiate contracts with PBMs (and sometimes with specialty pharmacy companies as well) to provide pharmaceutical coverage to employees. Employers exercise control over the supply chain through the contracts they set with PBMs. The contracts govern the prices of pharmaceuticals paid by the employer, the cost sharing to the insured population, the type of formularies that will be applied, the network standard for pharmacies, and what types of drug utilization review will be applied. Employers pay PBMs either on an administrative services basis, or by

[27] *Health Affairs*, March/April 2000.

allowing the PBMs to retain a portion of manufacturer rebates. Employers retain audit rights to exercise oversight of PBM operations.

Health Plans

Health plans employ the use of a range of strategies to manage prescription drug benefits, most of which involve the use of a PBM or PBM-like strategies. There are a few remaining plans that compensate pharmacies on a fee-for-service basis, but plans are using this method less frequently, as it does not allow for use of cost-containment strategies to lower prescription drug costs. More commonly, plans do one of the following: (1) outsource management to an external PBM, (2) operate their own PBM, or (3) outsource claims administration only. Notable exceptions include certain group models, such as that of Kaiser Permanente, which has maintained control of pharmaceutical procurement. Kaiser streamlines the distribution process by purchasing pharmaceuticals from manufacturers and dispensing the medications to consumers at on-site pharmacies.

Regardless of the strategy used, health plans often influence the cost-containment strategies utilized by PBMs. For example, managed care organizations may negotiate a more restrictive formulary or more competitive pharmacy networks. Managed care companies a greater ability to enforce formulary compliance and to drive consumers to a smaller number of pharmacies.

VI. Key Acronyms and Glossary of Key Terms

AMP – Average Manufacturer Price
ASP – Average Sales Price
AWP – Average Wholesale Price
EAC – Estimated Acquisition Cost
MAC – Maximum Allowable Cost
PBM – Pharmacy Benefit Manager
WAC – Wholesaler Acquisition Cost

Average Manufacturer Price (AMP) – The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP was a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available.

Average Sales Price (ASP) – The weighted average of all non-Federal sales to wholesalers net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to ASP.

Average Wholesale Price (AWP) – A national average of list prices charged by wholesalers to pharmacies. AWP is sometimes referred to as a "sticker price" because it is not the actual price that larger purchasers normally pay.

Estimated Acquisition Cost (EAC) – EAC is a state Medicaid Agency's best estimate of the price generally paid by pharmacies for a particular drug

Maximum Allowable Cost (MAC) – MAC is a cap set by payers on reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing for drugs on a MAC list.

Medicaid Best Price – The lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts, or other pricing adjustments, excluding nominal prices. Best price is a variable used in the Medicaid rebate statute to calculate manufacturer rebates owed to State Medicaid agencies. Prices charged to certain governmental purchasers are statutorily excluded from best price including prices charged to the Veterans Administration, Department of Defense, Indian tribes, the Federal Supply Schedule, State Pharmaceutical Assistance Programs, Medicaid, Public Health Service "340B" entities, and Medicare Part D prescription drug plans (starting in 2006). Best price data are reported by manufacturers to CMS, but are not publicly available.

Reference Pricing – System of fixed reimbursement for pharmaceuticals, in which the government or other third party payers establish a level at which they are willing to reimburse "interchangeable" products. Manufacturers may charge above the reference price, but patients must pay the excess cost.

Wholesale Acquisition Cost (WAC) – The price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. Publicly disclosed or listed WAC amounts may not reflect all available discounts.

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Michigan Department of Community Health Medicaid program

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MPPL Drug List

MPPL Drug List	Last Modified
MPPL Introduction	04/09/2008
MPPL and Coverage Information	02/28/2013
Michigan Preferred Drug List – Summary Document (Effective 02/05/2013)	01/11/2013
MPPL and PDL Changes (Effective 07/20/2011)	06/30/2011
MPPL Drug List	**Last Modified**

Other Drug Information

Other Drug Information	Last Modified
Quantity Limitation Information	11/10/2011
Copay Information	11/01/2010
ABW County Plan Carveout	10/16/2012
Health Plan Carveout	10/16/2012
Anti-ulcer Medication Policy – Definition of High Dose	01/10/2008
NOTICE on fluoxetine 40 mg coverage	01/10/2008
Maintenance Drug List	01/10/2008
Part D covered and excluded drugs 04/19/2006	08/12/2009
Other Drug Information	**Last Modified**

Other Drug Information	Last Modified
Quantity Limits on Acetominophen Products	07/16/2010
Drug coverage for PlanFirst! can be viewed at: www.michigan.gov/medicaidproviders Under >> Billing and Reimbursement >> Provider Specific Information >> Family Planning	not available
Compound Exclusion List	05/10/2007
Drug Classes and Products Covered for the MOMS Program	10/18/2012
FAQ's for Drug Manufacturers	07/16/2010
Additional Information on Billing Medicare/Medicaid COB Claims	08/04/2005
Dose Optimization Program	03/31/2010
Clinical Alerts	not available
Other Drug Information	**Last Modified**

Secure Personnel

MAGELLAN MEDICAID ADMINISTRATION

Maximum Allowable Cost (MAC) Pricing Frequently Asked Questions

What is a State Maximum Allowable Cost program?

State MAC programs are modeled after the Centers for Medicare & Medicaid Services (CMS) Federal Upper Limit (FUL) program. The intent is to provide a maximum price the state will pay for a given generic pharmaceutical irrespective of its package size or manufacturer. The Michigan MAC program is designed to promote the efficient purchasing of generic pharmaceuticals within the Department of Community Health's pharmacy provider network to ensure that the Medicaid program is a prudent payer of prescription drugs.

How are the drugs selected for inclusion on the MAC list?

"AB" rated generic drugs that have more than one generic manufacturer are selected for inclusion on the Department's MAC list. Other considerations are included such as market availability, drug shortages, obsolete or terminated status, CMS rebate status, and the clinical practicality of generic interchange.

How are market prices researched?

Prices are researched using wholesaler information (prices and availability). At least two wholesalers conducting business within the State of Michigan are included in this analysis. In addition, industry data, such as published pricing information, and information provided by Michigan pharmacies is used to review and assess the MAC program and to ensure that established MAC prices reflect current pharmaceutical market conditions.

How are MAC prices set?

The State of Michigan uses a vendor to set the MAC prices. The vendor uses a proprietary algorithm that computes the MAC price.

Where are the MAC list and prices located?

All information is posted at the vendor's Michigan Medicaid website:
https://michigan.fhsc.com/MAC/MacInfo.asp

This includes

- Monthly MAC List
- Weekly MAC Price Update List
- MAC Price Research Request Form
- MAC Pricing Request Form

How do providers request a MAC pricing review?

Providers may request a MAC price review by filling out the *MAC Price Research Request Form* and submitting it to the vendor. All inquiries must be accompanied by actual invoices from the providers wholesaler for consideration. All efforts will be made to respond to requests within two business days.

What should I do if I'm unsatisfied with the initial MAC pricing review response and believe the price is incorrect?

Providers should submit a second price review request with documentation supporting why they believe the price is incorrect and warrants re-review. Providers can also contact the State MAC Department (see contact information below) to request additional assistance including a more detailed explanation of the review determination.

Whom should I contact if I have questions?

The State of Michigan welcomes providers' questions, comments, and input regarding the Medicaid MAC program. Providers are encouraged to contact the State's vendor, Magellan Medicaid Administration, regarding

- Changes in product availability
- Questions or concerns regarding MAC prices
- Questions concerning drugs included on the MAC list
- How to obtain a copy of the MAC list

Magellan Medicaid Administration, Inc.
Attn: State MAC Department
Mail: 4300 Cox Road, Glen Allen, VA 23060
Fax: (888) 656-1951
E-mail: StateMACProgram@MagellanHealth.com

Michigan Department of Community Health

MDCH

Jennifer M. Granholm, Governor
Janet Olszewski, Director

MICHIGAN PHARMACEUTICAL PRODUCT LIST (MPPL)

INTRODUCTION

Michigan Pharmaceutical Product List (MPPL) provides specific pharmacy coverage information for billing the Michigan Department of Community Health (MDCH) fee-for-service programs: Medicaid, Children's Special Health Care Services (CSHCS), Maternity Outpatient Medical Services (MOMS), Adult Benefits Waiver (ABW) [formerly State Medical Program (SMP)] and Plan First! It applies to drug products billed by retail and long-term care (LTC) pharmacies that are enrolled as Medicaid Provider Types 50. The MPPL is to assist you in the pre-point of sale (POS) decision making only. POS is your most reliable source of information regarding coverage parameters. The drug products listed are not necessarily covered for all programs. The presence of a particular drug product in this file **does not guarantee payment**. Changes to drug product coverage may occur between postings of this document.

The MPPL lists drug products alphabetically and specifies coverage parameters such as prior authorization, age, and sex requirements. Covered drug products include both prescription and prescribed over-the-counter (OTC) drugs where applicable. Every effort is made to list a drug product under its generic name with a reference to the brand name.

Drug products listed on the MPPL are reimbursable based on the parameters listed and if they are manufactured by a Centers for Medicare Medicaid Services (CMS) approved labeler or medically necessary. **Note: If the MDCH is informed that a drug product availability prevents the use a rebatable national drug code (NDC), the MDCH will consider the coverage of the most cost effective alternative.**

The MPPL does not apply to drug products used:

- *In an Inpatient Hospital Setting*
- *In an Outpatient Hospital Emergency Room or Clinic Setting*
- *In a Physician's Office or a Clinic Setting*
- *For Persons enrolled in Medicaid Health Plans (MHPs) or County Health Plans (CHPs)*
- *In Mental Health Hospital LTC Units and Medical Care Facilities with In-house Pharmacies*

Drug product coverage not individually listed within the MPPL are:

- *X1B – Diaphragms*
- *X1B - Artificial Tears Ophthalmic. Solution [Maximum Allowable Cost (MAC) = 0.41650/ml]*

DRUG LIST ABBREVIATIONS AND REMARKS:

The following drug list abbreviations and remarks indicate conditions of coverage for a specific drug product.

Abbreviation	Meaning of Abbreviation
#	Prior Authorization (PA) Required. (Refer to prior approval instructions)
CC	Covered only for CSHCS Program
EFFECTIVE DATE	First Date the Drug Product Is Covered or Recent MAC Price Change.
EQ	MAC Price Established. (Override must be obtained for reimbursement above the MAC rate.)
HIV	HIV Drug Products that are part of MHP and CHP Carve-Out
INJ	Injectable Drug Products Covered for Home Infusion and LTC Beneficiaries
P1st	Drug Products that are payable under Plan First! Program
NCC	Drug Products Not Covered for CSHCS Program
NOSMP	Drug Products Not Covered for ABW Program (formerly SMP)
NOLTC	Drug Products Not Reimbursed to Pharmacies for LTC beneficiaries.
PSY	Drug Products that are part of MHP and CHP Psychotropic Carve-Outs.
REMARKS	Examples: 1) For 10 Years of Age and Under Only (The drug product will not be reimbursed for beneficiaries 11 years old and over). 2) No PA for 6-17 Years of Age (PA is required for beneficiaries 5 years old and under as well as 18 years old and over). 3) PA for 30 Years of Age & Over (PA is not needed for beneficiaries 29 years old and under). 4) Reproductive Females Only (Prenatal vitamins are covered during the ante and postpartum term and not as a daily multiple vitamin).
UNIT	Units Are Either EACH, ML OR GM. (The billing quantity listed on the invoice must be based on the unit listed for the drug. **Note: When the unit is each, bill the quantity based on the dosage form. An exception is an antihemophilic drug, which must be billed per Antihemophilic Factor Unit (AHF). Humate has a unit of each, the dosage form is vial, but the remarks state use AHF units.)**

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Michigan Department of Community Health

Benefit Plan Co-pay Information

Group ID	Description	Coverage	Co-pay
INCARCE	Incarcerated Medicaid patients	No coverage	No coverage
SHPDUAL	Health Plan with Medicaid and CSHCS	Standard	No Co-pay
CSHCSCAID	Children's Special HealthCare Services with Medicaid	Standard with Children's special health	No Co-pay
SHP5ONLY	Health Plan with CSHCS	Select mental health and antiviral	No Co-pay
CSHCS5ONLY	Children's Special HealthCare Services	Standard with Children's special health	No Co-pay
HPHKFULLCAID	Health Plan with Medicaid	Select mental health and antiviral	$3.00 Brand $1.00 Generic
HKFULLCAID	Healthy Kids Medicaid	Standard	$3.00 Brand $1.00 Generic
FULLREFCAID	Full Refugee Medicaid	Standard	$3.00 Brand $1.00 Generic
HPFULLCAID	Health Plan Full Medicaid	Select mental health and antiviral	$3.00 Brand $1.00 Generic
FULLCAID	Full Medicaid	Standard	$3.00 Brand $1.00 Generic
MOMS	Maternity Outpatient Medical Services	Pregnancy related medications	No Co-pay
EMERREFCAID	Emergency Refugee Medicaid	Standard	$3.00 Brand $1.00 Generic
HKEMERGCAID	Healthy Kids Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
EMERGCAID	Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
SMPCOP	Adult Benefit Waiver-County Plan Coverage	Select mental health and antiviral	$1.00
SMPFULL	Adult Benefit Waiver	Standard	$1.00

Michigan Department of Community Health

Benefit Plan Co-pay Information

Group ID	Description	Coverage	Co-pay
SMPEMERG	Adult Benefit Waiver - Emergency	Standard	$1.00
HPTMACAID	Health Plan Full Medicaid	Select mental health and antiviral	$3.00 Brand $1.00 Generic
HPTMAPLUS	Health Plan Full Medicaid	Select mental health and Antiviral	$3.00 Brand $1.00 Generic
TMAPLUSFULL	Full Medicaid	Standard	$3.00 Brand $1.00 Generic
TMACAID	Full Medicaid	Standard	$3.00 Brand $1.00 Generic
TMAEMERG	Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
TMAPLUSEMERG	Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
FAMILYPLAN	Family Planning Waiver	Pregnancy prevention and related medications	No Co-pay
QMB	Qualified Medicare beneficiary	Medicare Part B covered drugs	No Co-pay