IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF CHAIN DRUG STORES 413 North Lee Street Alexandria, VA 22314, and **NATIONAL COMMUNITY PHARMACISTS ASSOCIATION** 100 Daingerfield Rd. Alexandria, VA 22314, Plaintiffs, v. **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES** 200 Independence Ave., SW Washington, DC 20201, and **MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES**, solely in his official capacity 200 Independence Ave., SW Washington, DC 20201, and **CENTERS FOR MEDICARE AND MEDICAID SERVICES** 200 Independence Ave., SW Washington, DC 20201, and **KERRY WEEMS, ACTING ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES**, solely in his official capacity 200 Independence Ave., SW Washington, DC 20201, Defendants.	)	Case: 1:07-cv-02017 Assigned to: Lamberth. Royce C. Assign. Date: 11/7/2007 Description: TRO/PI

EXPERT REPORT OF

STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D.

I. QUALIFICATIONS AND BACKGROUND

1. I make this statement as an independent expert in pharmacy, pharmaceutical economics, and public policy. I hold the following positions and titles in the College of Pharmacy at the University of Minnesota: Head, Department of Pharmaceutical Care & Health Systems; Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics; Professor of Pharmaceutical Management and Economics; and Director of the PRIME Institute. I hold a Bachelor of Science in Pharmacy (1974, University of Missouri-Kansas City), a Doctor of Pharmacy and Residency Certificate (1977, University of Kentucky), a Master of Arts in Public Administration (1979, Ohio State University) and a Doctor of Philosophy in Administrative and Social Sciences in Pharmacy (1984, Ohio State University). A list of my professional memberships, professional activities, research activities, publications and other scholarly activities, citation of work in public media, offices held in professional and scientific organizations, university administrative and service positions, honors and awards, and civic and community activities is contained in a copy of my most recent curriculum vitae, which is attached hereto as Exhibit "1."

2. My experience related to pharmaceutical economics and public policy research spans more than 30 years. I am currently the director of the PRIME Institute at the University of Minnesota, which was established in 1991 to conduct research related to the management and economics of the pharmaceutical marketplace. Prior to accepting a position at the University of Minnesota, I directed the Pharmaceutical Economics Research Center (PERC) at Purdue University from the time the Center was established in 1986 to 1991. PERC also engaged in research related to the economics of the pharmaceutical marketplace.

3. In 1988, I was appointed by the United States Congress to the Prescription Drug Payment Review Commission, an 11-member independent Congressional commission that served as an advisory body to the U.S. Congress with respect to the outpatient drug program established by the Medicare Catastrophic Coverage Act of 1988.

4. I provided professional staff analysis for the Kentucky Drug Formulary Council, Department for Human Resources, Commonwealth of Kentucky from 1975 to 1977. The Kentucky Drug Formulary Council was the nation's first governmental body to establish a generic equivalence standard for determining whether or not brand and generic drug products could be considered as generic equivalents and, therefore, could be substituted for one another. This generic equivalence formulary preceded the FDA's Orange Book.[1]

[1] The publication commonly referred to as the "FDA Orange Book" is formally known as "Approved Drug Products with Therapeutic Equivalence Evaluations" (now in its 27th

5. As an academic researcher, my principal areas of research have included trends in the pharmaceutical marketplace at all levels, the structure and performance of pharmaceutical markets, competition between and among brand name and generic drugs, and the impact of generic competition, including generic entry into brand drug markets. I have also conducted research on medication use and expenditures by the elderly, drug coverage under health insurance plans and access and affordability of pharmaceutical products, in addition to pharmacoeconomic research and policy analysis related to all aspects of the pharmaceutical marketplace.

6. I have performed pharmacoeconomic research for many organizations, including, among others, the U.S. Centers for Medicare and Medicaid Services (CMS, formerly known as the Health Care Financing Administration (HCFA)), the U.S. Government Accountability Office (GAO, formerly known as the U.S. General Accounting Office), the U.S. Food & Drug Administration (FDA), the U.S. Congress' Office of Technology Assessment (OTA), pharmaceutical firms, professional societies, and various state governments and agencies. I have also led pharmaceutical research and policy projects at the international level for governments including Thailand, Singapore, Spain, Canada, Argentina, Venezuela, South Africa, South Korea, and Taiwan.

7. Based upon on my experience in professional consulting and academic research, I have particular expertise in economic and public policy issues in the pharmaceutical marketplace. One of the major focuses of my research and work relates to the impact and role of generic drugs and generic competition. In this context, I am well versed in assessing the economic impact of generic competition on all levels of the pharmaceutical marketplace, including on the various channels of distribution and upon consumers, the behavior of brand manufacturers faced with generic competition, and the mechanisms by which generic competition is fostered and, by contrast, impeded. I also have experience examining the impact of 'class of trade' on pricing behavior in the pharmaceutical market. Another of the major foci of my research and work relates to the reimbursement for prescription drugs under private and public insurance programs including Medicaid and Medicare. In this context, I am well versed in assessing the economic impact of reimbursement policies on all levels of the pharmaceutical market including providers, patients, and payers.

8. My research projects directly relate to general issues in the pharmaceutical market, such as drug prices, competition, generic entry, market penetration, channels of distribution and 'classes of trade,' the effects of generic competition on the market for originator drug products, and other economic and marketing issues, which also are listed in my curriculum vitae. (*See* Exhibit 1).

9. My experience includes conduct of several studies specifically for the Centers for Medicare and Medicaid Services (CMS)—the federal agency that oversees both Medicare

---

brand and generic drug products. The current version of this publication can be found on the FDA website at: http://www.fda.gov/cder/orange/obannual.pdf.

and Medicaid. Among the studies conducted for CMS (formerly HCFA) are the following:

a. *Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Outpatient Drugs Covered by Medicare* (U.S. Department of Health and Human Services, June 27, 1989, Stephen W. Schondelmeyer and Joseph Thomas);

b. *Impact of the Medicaid Drug Rebate Program on Expenditures, Utilization, and Access: Final Report* (U.S. Health Care Financing Administration, Contract # 500-92-0022, DO #3, April 1995, Stephen W. Schondelmeyer, Judy A. Johnson, Dong Churl Suh, George Wright, Ann Cherlow, Andrew Asher, Angela Schmitt, Portia DeFilippes, Jon B. Christianson, John Kralewski);

c. *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, Stephen W. Schondelmeyer and Marian V. Wrobel);

d. *Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report* (CMS Contract #500-00-0049, Task Order 1, September 19, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Susan Jureidini, Shuchita Agarwal, Rachel Sayko, A.C. Doyle);

e. *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report* (CMS Contract # 500-00-049, Task Order 1, September 26, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Shuchita Agarwal, and Janice Cooper); and

f. *Evaluation of Pharmaceutical Pricing Under Medicare Drug Card: Final Report* (U.S. Dept. of Health & Human Services, Assistant Secretary for Planning and Evaluation, Task Order Contract #100-03-0106, November 16, 2006, Stephen W. Schondelmeyer, Margaret Artz, Shriram Parashuram, Lois Olinger, and Sarah Shoemaker).

10. A list of other cases in which I have testified as an expert at trial or by deposition is attached as Appendix B to my curriculum vitae. (*See* Exhibit 1).

11. I am being compensated for my time spent working on this case at the rate of $600.00 per hour for time spent testifying, or preparing for testimony, and $400.00 per hour for all other time.

II. SCOPE OF REPORT

12. I understand that this action was initiated by the plaintiffs, the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), on behalf of their member pharmacies.

13. I have reviewed the "Complaint" filed against the United States Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), Michael O. Leavitt, Secretary of HHS, and Kerry Weems, Acting Administrator of CMS,

the defendants. The plaintiffs allege, among other things, that the final rule on AMP published on July 17, 2007 does not follow the statutory language of the Social Security Act and that the implementation of these rules would have a substantial negative impact on pharmacies throughout the United States.

14. I have reviewed numerous documents, including the relevant sections of the Social Security Act, Deficit Reduction Act of 2005, the Conference Report for the Deficit Reduction Act of 2005 (U.S. House of Representatives, 109th Congress, 1st Session, Report 109-362, December 19, 2005), the proposed rule and the preamble to the proposed rule (Federal Register, Vol. 71, No. 246, December 22, 2006, pp. 77174-77200, "42 CFR Part 447, Medicaid Program: Prescription Drugs; Proposed Rule"), the public comments related to the proposed rule, and the final rule and preamble (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245, "42 CFR Part 447, Medicaid Program: Prescription Drugs; Final Rule"). Also, I have reviewed various reports by the U.S. Government Accountability Office and the U.S. Department of Health and Human Services, Office of the Inspector General that addressed specific aspects of the Deficit Reduction Act of 2005, the prices of drug products including AMP, ASP, and other prices. I have reviewed the literature in the field of pharmaceutical economics and other related publicly available documents and sources. In addition to those sources specifically referred to in this Report, the documents I considered, received, relied upon, or created in connection with this Expert Report are listed in an attachment. (*See* Exhibit 2).

15. I have been asked to testify about the following subject matters: an overview of the pharmaceutical market including classes of trade; an overview of pharmaceutical pricing; a description of the Medicaid drug program and the Medicaid drug rebate program; and other topics related to pharmaceutical pricing and reimbursement.

16. Specifically, I have been asked to render an opinion regarding the final rule to implement AMP-based FUL pricing under the DRA of 2005 (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245, "42 CFR Part 447, Medicaid Program: Prescription Drugs; Final Rule"). I have also been asked to render an opinion regarding industry understanding and definition of various entities such as manufacturers, wholesalers, the retail pharmacy class of trade, and other providers. In addition, I have been asked to render an opinion regarding the impact of this final rule on pharmacies and access to, and provision of, prescription medications to Medicaid recipients.

17. My opinions contained herein are based upon my review of the above-described documents, as well as upon my qualifications and 30 years of experience described above. I understand that discovery may take place in this case and an administrative record will be produced, and as always with an expert report, I reserve the right to amend and update my opinions based upon additional information that may be provided to me, or that may become known to me by other appropriate means in the future.

III. SUMMARY OF FINDINGS

18. This case involves implementation of a final rule for AMP based on statutory language from the Social Security Act and CMS' promulgation of a final rule that is substantially inconsistent with the original statutory language, other federal and state statutory and regulatory language, the plain meaning or common usage of key terms, and the use of these key terms within the pharmaceutical industry.

19. The general substance of my opinions is briefly summarized here. The remainder of the report provides more detailed opinions and the bases for my opinions.

20. The bases for my opinions include documents and reports related to the final rule that I have reviewed, my education and experience as reflected in my curriculum vitae, my accumulated knowledge and understanding of the pharmaceutical industry, pharmacoeconomics, government health care policy, pharmaceutical reimbursement policies and practices, and other documents and resources broadly related to the areas of interest in this case.

21. An overview of the pharmaceutical market including classes of trade reveals that pharmacies and other providers are grouped by each manufacturer into various classes of trade based on the structure of the pharmaceutical market (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, long term care pharmacies, hospitals, physicians, etc.) and the average price paid to the manufacturer usually varies across classes of trade.

22. An examination of pharmaceutical pricing found that class of trade pricing operates based on structural criteria in the market and not necessarily economic efficiency-based criteria. Contrary to widely held perceptions, prices in the pharmaceutical market are based more on structural position than on market efficiency. The structural nature of the pharmaceutical market is due to monopoly status for single source drugs, statutorily prohibited arbitrage (i.e., as provided under the Prescription Drug Marketing Act (the PDMA)), and discriminatory pricing across structural classes of trade. Consequently, a retail pharmacy (independent, chain, mass merchandise, or food & drug store pharmacy) can not purchase at the lower prices of other classes of trade and can not obtain those lower prices through market behavior or arbitrage.

23. The AMP final rule published on July 17, 2007 (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245) promulgated definitions for key terms used in the statutory definition of AMP including "average price paid to manufacturer," "wholesaler," and "retail pharmacy class of trade." As defined in the final AMP rule, these key terms are not consistent with the original statutory language of the DRA, the Social Security Act, numerous other federal and state statutes and regulations, the plain meaning and common usage of the terms, or the use of the terms in the pharmaceutical market context.

24. The terms “class of trade” and “retail pharmacy class of trade” have a specific meaning in the context of the pharmaceutical market. The CMS final rule definition of “retail pharmacy class of trade” is in conflict with the use of this term in the pharmaceutical market.

25. CMS has re-defined the term “retail pharmacy class of trade” to encompass virtually all pharmacies and providers who dispense or administer drugs to the end consumer. This re-definition stands in stark contrast to the use of the term “retail pharmacy class of trade” in the pharmaceutical market.

26. The inclusion of different classes of trade with pricing based on different structural positions in the market will result in some pharmacies (especially traditional retail pharmacies, that is independent, chain, mass merchandise, and food & drug store pharmacies) being paid well below their actual cost. This payment inequity may result in a substantial decrease in access to care for Medicaid recipients. Moreover, because of the structural impediment of discriminatory pricing, as described above, retail pharmacies do not have access to the lower prices of these other classes of trade and will be economically disadvantaged and harmed by the overly-broad and artificial definition of the retail pharmacy class of trade as construed by CMS in the final rule.

27. CMS’ overly-broad and self-styled definition of prices to be considered in the AMP calculation has created a situation where:

- firms that are not licensed as wholesalers are called wholesalers,
- firms that are not licensed as pharmacies are called pharmacies,
- physicians, clinics, hospital outpatient, and home infusion firms are called pharmacies,
- consumers are considered as both wholesalers and pharmacies, and
- manufacturers are considered as both wholesalers and pharmacies.

28. Two government agencies have evaluated the AMP-based FULs and concluded that payments to pharmacies will decrease substantially. The GAO found that AMP-based FULs (even with the 250% multiplier applied to the lowest AMP) were below the lowest acquisition cost available to retail pharmacies for 43 of the 77 study drugs. These findings indicate that pharmacies are likely to lose money on more than one-half of the generic prescriptions subject to the new AMP-based FULs, even after the 250% multiplier is applied to the new AMP amount. A recent study by the DHHS, OIG assessed the change in FULs expected with the implementation of the new AMP-based FULs based on the final rule. The median decrease in the FUL amount was estimated to be 61%.

29. The method used by CMS to estimate the cuts in Medicaid payments was not described in sufficient detail to allow examination or evaluation. However, the reduction in pharmacy payments resulting from the final rule is expected to have a substantial incremental impact on cuts in pharmacy payments above and beyond the cuts that would have been expected had CMS used the plain meaning of the language or the

pharmaceutical market definitions of the "wholesaler" and "retail pharmacy class of trade" rather than their own greatly expanded interpretation of the statutes.

30. CMS explains "We estimate that 18,000 small retail pharmacies would be affected by this regulation. However, we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. . . Because of the lack of evidence as to the true effect, we have retained our prior conclusion, that this proposed rule is likely to have a "significant impact" on some pharmacies."[2]

31. Reduction in payments will result in substantial loss, and even closures, for a number of pharmacies. In total, the loss of 20% of all retail pharmacies would not be unexpected from payment cuts of the magnitude that will result from the final rule. If a similar proportion of all types of retail pharmacies is affected, the retail pharmacy market may see the loss of 10,000 to 12,000 pharmacies (the vast majority of which would be pharmacies in rural or inner city urban areas and with high Medicaid volumes) over the next few years.

IV. OVERVIEW OF THE PHARMACEUTICAL MARKET

32. Prescription drugs are the most widely used method for treating medical and health related conditions. In 2006, the total retail prescription sales[3] in the U.S. were reported to be nearly $250 billion. The total number of outpatient prescriptions was 3.4 billion in 2006 and with adjustment for mail order prescriptions (that is, 3 months supply per prescription counted as 3 monthly prescriptions) was equal to about 3.9 billion prescriptions (as a monthly supply). This prescription volume represents about 13 prescriptions per person per year in the United States in 2006.

33. The expenditure on prescription drugs is a substantial share of the total national health expenditures. Outpatient prescription drugs accounted for about 10.1% of national health expenditures in 2005.[4] However, when prescription drug spending in all other sectors of the national health accounts (i.e., hospitals, physicians and clinics, long term care, home health, dentists, managed care, active military and military retirees, public health service, 340B facilities, the Veterans Administration and other settings) is taken into account, the expenditure on prescription drugs is approximately 17.5% of national health expenditures.

---

2 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39233-34.

3 Total retail pharmacy sales are from data published by IMS Health as reported by the National Association of Chain Drug Stores (NACDS) in its publication titled: *The Chain Pharmacy, Industry Profile*, 2007. This estimate includes all outpatient prescriptions sold through retail community pharmacies and mail order pharmacies, but does not include medications sold through other providers such as physicians, clinics, hospital inpatient, and government programs and facilities.

4 U.S. Department of Health & Human Services (DHHS), Office of the Actuary, National Health Accounts, 2004.

34. In a broad sense, the structure of the pharmaceutical market can be described by two major features: (1) the channels of distribution for prescription drugs, or how the drug products flow through the market, and (2) the sources of payment for prescription drugs, or how the dollars flow through the market. These two structural perspectives are discussed in one of my reports for the Centers for Medicare & Medicaid Services.[5]

A. Channels of Distribution

35. First, regarding channels of distribution, there are three primary levels in the distribution channel: (1) manufacturer or marketer, (2) wholesaler, and (3) pharmacy or other provider (i.e., classes of trade). Each of these channels of distribution and its role in the market was described in my 2004 report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*.[6] Excerpts from the 2004 CMS report are provided below.

36. The role of manufacturers and marketers in the pharmaceutical market was described in my 2004 report to CMS[7] as follows:

> The manufacturer level is the starting point for prescription drugs as they begin their movement through the various channels of distribution. Any firm that manufactures or sells a prescription drug in the United States must hold a new drug application (NDA) or an abbreviated new drug application (ANDA) issued by the U.S. Food & Drug Administration (FDA). However, other firms may market a prescription drug without holding either an NDA or an ANDA, if such a firm has entered into a licensing agreement with an NDA or ANDA holder. [8]
>
> Every firm that markets a prescription drug in the United States must register with the FDA to obtain a unique national drug code (NDC) number (11-digits) for each drug product marketed. The first part of the NDC, the labeler code (5-digits), uniquely identifies the firm marketing the drug product. The second segment, the product code (4-digits), identifies a specific strength, dosage form, and formulation for a given drug product. The third segment, the package code (2-digits), identifies package sizes and package types (e.g., bulk, unit dose, or unit of use). Both the product and package codes are assigned by the firm and not by the FDA.
>
> Manufacturers or marketers, who want to be assured that the Medicaid program will cover their drug products, must sign a national drug rebate

---

5 Schondelmeyer, SW and Wrobel, MV, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, pp. 9-13.

6 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp.9-11.

7 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 9-10.

8 Drug firms can also be licensed to market a biological product under a Biological License Application or under other special circumstances.

agreement with the Secretary of the Department of Health and Human Services in order for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. Not all NDC holders participate in the Medicaid Drug Rebate program. Approximately 544 pharmaceutical companies (or labelers) currently participate in the Medicaid Drug Rebate Program.

37. The role of wholesalers and distributors in the pharmaceutical market was described in my 2004 report to CMS[9] as follows:

> Manufacturers or marketers of prescription drugs most often sell their drug products to a middleman, or intermediate level, before the drug product reaches the pharmacy or physician that will provide the drug to the patient. National wholesalers are the primary intermediate level in the channel of distribution process accounting for 45.7 percent of prescription drugs ($98.5 billion) in 2002, (see Exhibit 4) [*See* Exhibit 3A. in this report]. Other intermediate channels of distribution include chain warehouses with 32.3 percent ($69.8 billion) of the market, regional and specialty wholesalers with 9.3 percent ($20.2 billion) of the market, and group purchasing organizations that usually contract with a wholesaler to perform the distribution function on their behalf. About 12.6 percent of prescription sales by drug manufacturers are made directly to providers (e.g., physicians or hospitals) or pharmacies.
>
> The principal trade organization representing wholesalers in the United States is the Healthcare Distribution Management Association (HDMA). In 2002, the HDMA reported that there were more than 72 distributor companies operating approximately 242 distribution centers. On average, these distribution centers handle more than 21,000 different healthcare items. More than one-half of the items distributed (about 11,000) are prescription pharmaceuticals and biologics, and the additional items include "over-the-counter and herbal products, health and beauty aids, medical and hospital supplies, durable medical equipment and home healthcare items." The three largest wholesalers (Cardinal Health, AmeriSource Bergen, and McKesson) each have about 32 percent of the national market and collectively account for 97 percent of the drug sales that flow through national wholesalers and 83 percent of all wholesalers (national, regional, and specialty). Wholesalers add a markup and fees to the manufacturer's drug product cost to cover the cost of distribution and other services they provide. The total wholesaler gross margin averaged about 4.3 percent in 2002 with a range from 3.7 to 5.5 percent for the 25th and 75th percentile.[10] These costs are added to the manufacturer's drug

[9] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 9-10 (internal footnotes omitted).

[10] The gross margin for pharmaceutical wholesalers is reported annually in the publication: *HDMA Factbook, Industry Overview*. The data reported here are from 2004 as found in the 2005 edition, p.2.

product cost and passed on to the pharmacy or provider purchasing through a wholesaler.

In addition to full-line national wholesalers, there are also regional and specialty wholesalers that handle just under 10 percent of manufacturer drug sales. Regional wholesalers are usually similar to the national full-line wholesalers, but they typically have only one or a few distribution centers limited to a relatively small geographic region. Specialty wholesalers, in contrast, may have a national market presence, but instead limit the types of drug products stocked to a very narrow set. Specialty wholesalers may focus on generic drugs, biological agents, or drugs for a specific therapeutic purpose such as oncology, dialysis, or HIV therapy. Specialty wholesalers may also focus on serving certain facility types such as long term care pharmacies, home health agencies, or hospice facilities.

Group purchasing organizations (GPOs) may act on behalf of a group of providers to negotiate price with drug manufacturers. Most group purchasing organizations, however, do not ever take possession of, or handle, the drug product. Instead, GPOs often will contract with a traditional wholesaler to perform the wholesaling and distribution function on behalf of the GPO and its members.

A number of large chain pharmacies have developed and operate their own distribution centers rather than purchasing drug products through traditional wholesalers. Chain warehouses accounted for 32.3 percent ($69.8 billion) of all prescription drug sales by drug manufacturers in 2002. Chains that operate their own warehouses incur expenses similar to those seen by traditional wholesalers (range from 3.7 to 5.5 percent). When a chain pharmacy performs the warehousing function in addition to the retail distribution and counseling functions, the chain does have additional costs similar to those that a wholesaler would have added to the manufacturer's drug product cost.

38. The role of pharmacies and providers in the pharmaceutical market was described in my 2004 report to CMS[11] as follows:

The final step in the channel of distribution for pharmaceuticals comes when the pharmacist or physician provides the drug to the patient. In most cases, except for mail order pharmacies, this provision of the drug to the patient results from a face-to-face encounter with the patient. In addition to providing the drug product, the pharmacist is also responsible for taking steps to assure safe and effective drug use such as: development of a patient profile to screen for drug interactions, contraindications, and

---

The gross margin range for 2005 was reported in the 2006 edition as 4.4% to 5.1% .

[11] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 11.

duplicate therapy; counseling the patient on appropriate use; and other similar activities. The physician has similar responsibilities and, in most Part B cases, administers the drug in conjunction with other services.

There are a number of types of pharmacies and providers as shown in Exhibit 4 [*See* Exhibit 3A. in this report]. Community-based pharmacies accounted for the largest share (52.6 percent or $113.3 billion) of manufacturer prescription drug sales in 2002. Community pharmacy includes traditional chain pharmacies (e.g., Walgreen's or CVS), mass merchandise pharmacies (e.g., Wal-Mart or K-Mart), food and drug pharmacies (e.g., Kroger or Safeway), and independent pharmacies (i.e., locally-owned corner drug stores). Mail order pharmacies accounted for 13.3 percent ($28.7 billion) of manufacturer prescription drug sales in 2002.

Health plan pharmacies purchased only 1.0 percent ($2.3 billion) of all prescription drugs sold by manufacturers. These purchases were made by managed care plans (HMOs and PPOs) with their own in-house pharmacies where the health plan takes possession of drug product inventory and dispenses prescriptions directly to patients. The vast majority of managed care plans contract with a network of community pharmacies for provision of prescription drugs or with a pharmacy benefit manager (PBM) to administer the benefit for the managed care plan.

Other endpoints to the channels of distribution include: clinics and physicians' offices (1.0 percent; $2.3 billion); long term care pharmacies (4.4 percent; $9.5 billion); hospital pharmacies (15.9 percent; $34.3 billion); and government facilities and other government programs (4.4 percent; $9.6 billion).

B. Sources of Payment

39. There are three basic sources of payment for prescriptions: (1) self-pay or cash-pay individuals, (2) private third party insurance coverage, and (3) public (government) third party insurance coverage. The role of each source of payment in the prescription drug market was described in my 2004 report to CMS.

4 4llovs0175 0001 2986 02.

physitlyo n d 2 3 g o v e r n m T J 1 c a

40. The payment for prescriptions through cash or self-pay by individuals was discussed in my 2004 report to CMS[13] as follows:

> Self-pay, or cash, prescriptions represent a shrinking part of the outpatient prescription market. In 1992, more than one-half (55.6 percent) of all outpatient prescriptions were self-pay. By 1997, self-pay prescriptions had shrunk to 29.1 percent and in 2002 and 2003 they represent less than 15 percent of outpatient prescriptions. The dramatic reduction in cash pay prescriptions has also greatly reduced the pharmacy's pricing flexibility. The pharmacy has some control over setting the price for cash pay prescriptions, but it has little control over the prices paid by public and private third party programs. Although mail order programs, private PBMs and drug discount cards all claim to compare their prices against usual and customary retail prices, the disappearance of the cash pay retail prescription market renders the concept of "usual and customary retail price" almost meaningless.

41. The payment for prescriptions by private third parties (e.g., insurance and managed care) was discussed in my report to CMS[14] as follows:

> The share of outpatient prescriptions covered in part, or in whole, by private third party programs has grown substantially over the past decade from 30.1 percent in 1992 to 73.0 percent in 2002 and 2003. Most of these third party prescriptions are managed through PBMs and networks of pharmacies that have contracted to participate in these networks. Most pharmacists report that PBMs have most of the negotiating power in these networks, especially given their growing market share and the dominance of a few large PBMs.[15]

42. The payment for prescriptions through public third parties (e.g., Medicare and Medicaid) was discussed in my report to CMS[16] as follows:

> The Medicaid program is the single largest third party program (public or private) for prescription drug coverage. In 1992, Medicaid paid for 14.3 percent of all outpatient prescriptions and by 1997 the Medicaid share had dropped to 11.7 percent. The Medicaid share of outpatient prescription(s) has grown again over the last five years to 13.0 percent of outpatient prescriptions. Medicaid recipients in some states may pay modest co-payments. However, under certain circumstances if the patient can not pay the copay the pharmacy may still be required to dispense the

---

13 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12.

14 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12.

15 Radford A, Slifkin R, Fraser R, Mason M, and Mueller K, "The Experience of Rural Independent Pharmacies with Medicare Part D: Reports from the Filed, Journal of Rural Health, Vol. 23, No. 4, Fall 2007, pp. 286-293.

16 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12-13.

prescription and the pharmacy may not be able to recover the lost copay from either the patient or the Medicaid program.[17]

43. Collectively, third party prescriptions (private and government, such as Medicaid) grew from 70% of the prescription dollars and 67% of the prescriptions in 1996 to 91% of the prescription dollars and 89% of the prescriptions in 2005. With the institution of the Medicare Part D prescription drug program in 2006, the public third party share of the source of payment for prescriptions had a substantial jump with all third parties (private and public) now covering the vast majority (greater than 92%) of all prescriptions.[18] Conversely, the share of prescriptions paid for entirely by cash or the individual shrank to well under 10% of all prescriptions in 2006.

V. OVERVIEW OF PHARMACEUTICAL PRICING

44. Observation of prices in the pharmaceutical market requires an understanding of the elements, or attributes, that define a specific drug price term and an awareness of the sources of variation in price in the market.

A. Elements and Attributes of Drug Pricing Terms

45. There are several important and essential elements, or attributes, to any drug price that must be understood in order to know the meaning of a specific price for a specific drug product. These elements of a drug price were described in my report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*[19] as follows:

> * ***list or transaction***: list prices are published by manufacturers; transaction prices stem from actual transactions and hence represent both the supply and the demand side of the market;
>
> * ***level of the market involved***: drug product transactions occur at different levels in the market such as the manufacturer, wholesaler, or provider (e.g., pharmacy, physician, hospital, etc.) levels;
>
> * ***classes of trade eligible for the price***: providers are grouped by each manufacturer into various classes of trade based on the structure of the pharmaceutical market (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, long term care pharmacies, hospitals, physicians, etc.) and the manufacturer's average selling price usually varies across classes of trade;[20]

---

17 Since the implementation of the Medicare prescription drug benefit (January 1, 2006), Medicare (Parts B and D) has become the single largest third party program for prescription drugs easily surpassing the Medicaid program.

18 NACDS, *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2007. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for 1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006.

19 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 13-14.

20 The "retail class of trade" is open to the general public and is made up of independent, chain, mass

* ***type of drug product***: drug products may be grouped by their patent and exclusivity status into three broad groups that have different pricing patterns such as single source (patent and exclusivity protected brands), innovator multiple source (off-patent brands), and non-innovator multiple source (generics or branded generics) drug products;

* ***adjustments to price that have or have not been taken into account***: the invoice price for drug products may not reflect all adjustments to prices such as discounts, rebates, purchasing allowances or other forms of economic consideration;

* ***source of the price information***: price information can be collected from different sources such as the manufacturer, wholesaler, provider, or a third party program;

* ***effective time when price is available***: manufacturers determine when and how much the price of a drug product will change and the providers' costs are affected by price changes immediately upon implementation of a price change. The timing of when third party programs update their price reimbursement files (e.g., immediately or based on retrospective data) can have a substantial impact on providers; and

* ***relationship to other prices***: AWP and WAC are primarily used as benchmark prices rather than as actual transaction prices, but most other types of prices, discounts, rebates, and methods of third party reimbursement are expressed in relationship to one of these benchmark prices (AWP or WAC).

B. Determining Acquisition Costs

46. In 2004, at the request of CMS, I conducted a study of methods to estimate acquisition costs for pharmaceuticals.[21] This study set forth several criteria that would assist in determining the validity and reliability of the estimation method. Ideally, the method used for determining "estimated acquisition cost" should produce cost information for each drug product with prices that are: accurate and reliable, generally and widely available, current and up-to-date, transparent and accessible, adequate compensation to providers and pharmacies, incentives for pharmacies and providers to supply drugs, and incentives for key parties to provide data. For purposes of this report, three of these criteria are especially critical in this case: (1) the concept of generally and

---

merchandise, and food & drug pharmacies. "The Retail Perspective audit (formerly U.S. Drugstore) is a continuing monthly audit designed to measure, in projected dollars and units, pharmaceutical products purchased by independent pharmacies, chain store pharmacies, and food and drug store pharmacies in all 50 states." (*Retail Perspectives, Appendix A: IMS Audit Information*, 2006.)

[21] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 18-19.

widely available, (2) adequate compensation for pharmacies and providers, and (3) differentiation by class of trade.

47. The concept of "generally and widely" available prices was described in my 2004 CMS report[22] as follows:

> **Generally and Widely Available**
> Any price list used by the Medicaid or Medicare program should reflect 'generally and widely available prices,' that is, any provider paid according to the payment policy should be able to procure drugs at the published payment amount.

48. The role of "adequate compensation to providers and pharmacies" was described in my 2004 CMS report[23] as follows:

> **Adequate Compensation to Providers and Pharmacies**
> While the drug product component of the payment policy should be based on actual acquisition costs, the payment policy as a whole should adequately compensate providers for the storage, handling, dispensing, and administration of prescription drugs and for their professional services. This is essential to ensure that beneficiaries have access to quality care, without triggering perverse incentives. At present, the margins, or spreads, between drug product payment amount and actual acquisition cost may compensate providers (physicians and pharmacies) for deficiencies elsewhere in the payment system. If and when the method for estimating acquisition costs is altered, it may be desirable to reconsider the payment policy as a whole.

49. The importance of separately estimating prices by "class of trade" was described in my 2004 CMS report[24] as follows:

> **Estimated Separately by Class of Trade**
> Because actual acquisition costs vary by class of trade, the estimation methodology must take into account these differentials in order to generate drug product payments that are both accurate and reflect generally and widely available prices. For example, when a drug manufacturer sets lower prices for one class of trade (e.g., physicians) versus another class of trade (e.g., community pharmacies), the result is that the average of the prices across these two classes of trade will overpay the class with the lower price (physicians) and will under pay the class with the higher price (pharmacies). In addition to class of trade differences, drug product prices may differ for other reasons such as geographic or regional (urban versus rural) variations. A payment policy that does not account for different

[22] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 19.
[23] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 20.
[24] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 19.

> acquisition costs by class of trade, or other factors, may preclude certain providers from the market for reasons beyond their control. For providers within the same class of trade, the concept of 'generally and widely available prices' is appropriate and helpful to assure that a wide spectrum of physicians or pharmacies will be willing to participate in the program.

C. Class of Trade and Variation in Drug Prices

50. Drug prices will typically vary over time. Other sources of variation at any specific point in time may be related to: (1) the type of purchaser (i.e., also referred to as classes of trade), (2) the type of drug product, and (3) geographic variation.

51. The type of purchaser of a drug product may determine the price level that is available to that purchaser. The role of purchaser type was described in my 2004 report to CMS[25] as follows:

> Nearly all drug manufacturers divide the channels of distribution into groups known as 'classes of trade'. The 'classes of trade' at the broadest level are the groups identified on the pharmacy-provider level of the channels of distribution chart (Exhibit 4) [*See* Exhibit 3A. in this report] including: chain pharmacies, mass merchandise pharmacies, food and drug pharmacies, independent pharmacies, mail order pharmacies, health plan and HMO (in-house) pharmacies, long term care pharmacies, hospital pharmacies, physicians and clinics, government facilities, and other settings. [26] The structural differences in actual prices charged to each of these 'classes of trade' can differ considerably and appear to be arbitrary and are usually unrelated to volume of drug product purchased.[27]
>
> In most markets, when one buyer can purchase a product at a lower price than other purchasers, there is the potential for arbitrage. That is, the buyer with access to the lower price is able to purchase the product at the low price and resell it, at a profit, to the party without access to the lower price. This drives down the price differentials both directly (because the high-price buyers get lower prices) and indirectly (because manufacturers no longer gain from the differential pricing and hence desist from the practice). This practice of arbitrage across classes of trade is explicitly

---

25 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 16-17.

26 The "retail class of trade" is open to the general public and is made up of independent, chain, mass merchandise, and food & drug pharmacies. The "retail class of trade" is open to the general public and is made up of independent, chain, mass merchandise, and food & drug pharmacies. "The Retail Perspective audit (formerly U.S. Drugstore) is a continuing monthly audit designed to measure, in projected dollars and units, pharmaceutical products purchased by independent pharmacies, chain store pharmacies, and food and drug store pharmacies in all 50 states." (*Retail Perspectives, Appendix A: IMS Audit Information*, 2006.)

27 Wrobel MV, Schondelmeyer SW, Agarwal S, and Cooper J, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report* (CMS Contract # 500-00-049, Task Order 1, September 26, 2005).

> prohibited by re-sale limitations established in the pharmaceutical marketplace by the Prescription Drug Marketing Act of 1988.
>
> Both the monopoly position of patent (or exclusivity) protected drug products and the prohibition on arbitrage enable drug firms to use 'discriminatory pricing', which seeks to maximize the price to each individual buyer or group of similarly situated buyers. There are sometimes volume discounts within a class of trade, but volume does not usually explain the difference in price across classes of trade. A physician purchasing drug product direct from the manufacturer will usually get one of the lowest prices in the market, especially for drug products administered in the physician's office, while independent and chain community pharmacies often pay the highest prices in the market. This pattern occurs even when the chain pharmacy purchases far more volume (millions of dollars) nationally than an individual physician purchases in a year (i.e., hundreds or thousands of dollars). Volume may get one physician a better price than another physician. Volume, however, does not explain why a chain pharmacy pays a higher price, even though it purchases a substantially larger volume of a drug product than an individual physician typically purchases. The structural barriers of monopoly position and statutory prohibitions on price arbitrage mean that the purchasers who get the lowest price in the market are not necessarily the most efficient purchasers in the market. Because class-of-trade differentials exist and are outside of the control of the purchaser, an accurate approach to estimating actual acquisition costs must take into account the class of trade pricing practices of drug firms. . .

52. In 2005, I completed a study at the request of CMS which examined the relative prices across various classes of trade.[28] In conducting this study, I relied upon data from IMS Health's Retail Perspective and Provider Perspective databases[29] for the year 2004. This analysis of prices across classes of trade showed that prices differed across the structural classes of trade and that the classes of trade with the largest volume did not necessarily have the lowest prices. The "class of trade" pricing practices of pharmaceutical companies are considered proprietary and confidential and are not usually disclosed.

53. In summary, class of trade pricing operates based on structural criteria in the market and not necessarily efficiency-based criteria. In other words, the purchaser with the largest volume of purchases may not be the purchaser with the lowest purchase price. In a market based on efficiency, a given entity can engage in behaviors that increase its efficiency and thus lowers price. Contrary to widely held perceptions, prices in the pharmaceutical market are based more on structural position than on economic

---

[28] Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report*, September 26, 2005.

[29] IMS Health, Retail Perspective, Appendix A, IMS Audit Information, pp. A-52 to A-58, 2006. Also, see IMS Health, Provider Perspective, Appendix A, IMS Audit Information, pp. A-46 to A-51, 2006.

efficiency. The structural nature of the pharmaceutical market is due to monopoly status of single source drugs, statutorily prohibited arbitrage (i.e., the PDMA), and discriminatory pricing across structural classes of trade. Consequently, a retail pharmacy (independent, chain, mass merchandise, or food & drug store pharmacy) can not purchase at the lower prices of other classes of trade and can not obtain those lower prices through market behavior or arbitrage.

54. A purchaser cannot change its structural position (i.e., a chain pharmacy cannot become a hospital without losing the very character of the entity).

VI. THE MEDICAID DRUG PROGRAM

55. Overall, Medicaid drug expenditures accounted for 15.3% of total outpatient drug expenditures in the U.S. in 2004. The number of Medicaid prescriptions represented 13.6% of all outpatient prescriptions in 2004.[30] Medicaid outpatient prescription drug expenditures in the U.S. were $32.1 billion in 2005.[31]

56. Medicaid has historically been the single largest payer for prescription drugs in the United States—although with the advent of the Medicare Part D prescription drug program in 2006 that role has now been supplanted.

57. Over the past 15 years, Medicaid ultimately paid for approximately 10% to 15% of outpatient drug purchases in this country. The advent of the Medicaid program in 1965 and the Medicare Part D prescription drug program in 2006 has extended coverage and expanded the number of prescriptions dispensed. Both Medicaid and Medicare have enabled large populations of Americans to have increased access to prescription drugs through government financed and subsidized programs. These government drug programs have provided access to prescription drugs to many people who could not have afforded the drugs before, thus increasing total sales for drug manufacturers.

---

[30] NACDS, *The Chain Pharmacy Industry Profile*, annual edition, 2005. Data was from NDC Health (a health care information company) for 2004.

[31] NACDS, *The Chain Pharmacy Industry Profile*, annual editions from 2004 to 2005. Data was from NDC Health (a health care information company) from 2004 to 2006.

A. Medicaid Drug Reimbursement

58. The State Medicaid programs reimburse for covered pharmaceutical products through various formulas that are designed to estimate the acquisition cost of the drug product to the provider submitting the claim for reimbursement. Medicaid programs, then, determine the amount to pay on a specific claim for prescription pharmaceuticals by setting an amount intended to compensate the provider for the estimated acquisition cost of the drug product plus an additional amount, also set by the applicable Medicaid reimbursement method, to compensate the provider for profit and overhead related to the cost of dispensing prescriptions and counseling patients.

59. The setting of payments for prescription drugs is also critical to providing access to prescriptions and pharmaceutical care. For example, the Medicaid program wants to ensure that enough community-based pharmacy providers open to the general public choose to participate so that patients will have access to the drug products they are prescribed within a reasonable distance from the patient's home or work. (42 U.S.C. § 1396a(a)(30)(A)).

B. Medicaid Drug Rebate Program and AMP

60. The term AMP was first introduced as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) which established the Medicaid Drug Rebate program (Section 1927 of the Social Security Act). A drug manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) in order for the manufacturer's drug products to be covered outpatient drugs eligible for Federal Medicaid funding. Each drug manufacturer with a rebate agreement must report the AMP to CMS on a quarterly basis (and now under the final rule on a monthly basis). Section 1927(k)(1) defines AMP as "the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." The AMP is then used as the basis for calculating the per unit rebate amount that a drug manufacturer owes to CMS. The States then multiply the unit rebate amount times the number of units dispensed to determine the total rebates owed by the manufacturer in a given period (quarter).

61. Over time since 1991, the methods for calculating or determining AMP have been found to be unclear and incomplete. The DRA required that the Office of the Inspector General (OIG) review the manner in which AMP is determined and recommend appropriate changes. The OIG found that different manufacturers define and calculate AMP in different ways.[32] One of the major points of confusion in calculating AMP was the treatment of pharmacy benefit manager (PBM) rebates. Another source of confusion was the treatment of sales to pharmacies of drug products that are used for Medicaid patients or for patients under State Pharmaceutical Assistance Programs. Other issues raised were concerns over administrative and service fees, lagged price concessions, the

[32] Office of Inspector General, Department of Health and Human Services, *Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005,* OIG A-06-06-00063, May 2006.

frequency of AMP reporting (monthly versus quarterly), and AMP restatements. The OIG also recommended to the Secretary that CMS "*encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs*."

C. The Social Security Act and Deficit Reduction Act of 2005

62. The Deficit Reduction Act of 2005 (DRA) addresses a number of changes to the Medicaid program including the method and amount of payment for certain prescription drugs under Medicaid. This report provides a description of the certain issues raised by implementation of the statutory provisions related to definition of average manufacturer price (AMP) and its role in the determination of federal upper limits (FULs) for multiple source drug products under Medicaid.

1. Average Manufacturer Price in Medicaid: Two Roles

63. The AMP is a manufacturer-reported transaction price that serves two functions in the Medicaid program: (1) AMP is one of the basic price points used for determining the amount of rebates that drug manufacturers must pay to the Medicaid program, and (2) AMP will serve as the new base price for determining the FULs for payments to pharmacies for multiple source prescription drugs provided to Medicaid recipients. The Social Security Act as amended by the Deficit Reduction Act of 2005 included provisions related to both of these functions of AMP. A brief discussion of the background of these two functions is provided here, followed by comments on the final rule which re-defines AMP and describes the method for determining the FUL for drug ingredient costs of multiple source prescriptions under Medicaid.

2. Historical Definition of AMP

64. AMP was an average price received by the manufacturer from wholesalers who distribute to pharmacies in the retail pharmacy class of trade. Thus, AMP is based on transaction prices and is not a list price like the average wholesale price (AWP) or the wholesale acquisition cost (WAC). However, the average price received by the manufacturer is not the same as the average price paid by a pharmacy. The operating cost of the wholesaler, if one is used, as well as other costs of acquisition experienced by the pharmacy, need to be taken into account when estimating the pharmacy's acquisition cost.[33] The CBO report found that independent pharmacies use wholesalers for about 98% of their purchases, while wholesaler purchases accounted for 85% in mail order pharmacies, 53% in food stores with pharmacies, and 25% in chain pharmacies.[34]

---

[33] The state of Minnesota has a wholesale drug tax which adds 2% on to the wholesale price paid by all pharmacies or purchasers at the wholesale level. Also, if a chain of pharmacies purchases drug products direct from the manufacturer and operates its own wholesale distribution centers, which chain pharmacy experiences additional costs above the AMP similar to the operating costs a wholesaler would charge and add on to AMP.

[34] Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, Publication No.2703, January 2007, Table 2, p.6.

65. The statutory definition of the term Average Manufacturer Price (AMP) is "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." (*See* Social Security Act § 1927(k)(1), 42 U.S.C. § 1396r-8(k)(1)).

66. To the degree that the AMP calculation contains factors that lower the AMP below the most efficient acquisition cost available to a specific pharmacy, that pharmacy will be faced with losing money or refusing all prescriptions whose drug product payment amount is based on an inadequate and unadjusted AMP. Since the average price for revenue to the manufacturer is not the same as the average acquisition cost to the pharmacy as noted above, the AMP can be more accurately focused on only one of these two purposes (manufacturer rebates or pharmacy payments) and use of AMP for the other purpose will require adjustments and estimation.

VII. DEFINITION OF AMP IN THE STATUTE AND FINAL RULE

67. This statutory definition of AMP, then, establishes a three part test that can be used to determine if specific types of drug prices, and related price concessions, should be included in calculation of AMP: (1) What price was paid to the manufacturer? (2) Was the payer a "wholesaler?" and (3) Was the drug purchased for distribution to the "retail pharmacy class of trade?" In order for a price to be included in the AMP calculation, all three conditions must be met, that is, the price must be "paid" to the manufacturer, the purchaser must be a "wholesaler" and the drug must be distributed to the "retail pharmacy class of trade."

68. The AMP final rule published on July 17, 2007 (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245) promulgated definitions for key terms used in the statutory definition of the AMP including "average price paid to manufacturer," "wholesaler," and "retail pharmacy class of trade." As defined in the final AMP rule, these key terms are not consistent with the original statutory language of the Social Security Act and DRA, numerous other federal and state statutes and regulations, the plain meaning and common usage of the terms, and the use of the terms in the pharmaceutical market context.

69. The CMS final rule for prescription drugs under the Medicaid program implementing provisions of the DRA has included revisions to the definition of, and method for calculation of, AMP.[35] The final AMP rule acknowledges that with the advent of the DRA, "AMP will serve two distinct purposes: for drug rebate liability and for payments (to pharmacies)."[36] The CMS analysis goes on to note that the drug manufacturers would benefit from a broad definition of the "retail pharmacy class of trade" that would result in a lower AMP which would lead to lower drug manufacturer

[35] Centers for Medicare & Medicaid Service, Department of Health and Human Services, 42 CFR Part 447, CMS-2238-P], RIN 0938-A020, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Vol. 71, No. 246, December 22, 2006, pp. 77174-77200.

[36] CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178.

rebate liabilities. At the same time, however, there is tension in the opposite direction for pharmacies from this broad definition of the retail pharmacy class of trade that results in a lower AMP for use in estimating retail pharmacy actual acquisition costs.

70. For each of the key terms a summary is presented stating the essential elements defining that term based upon information from various sources which are examined and compared including: (1) federal and state statutory and regulatory definitions, (2) the plain meaning or common usage of these terms, (3) the use of these terms within the pharmaceutical market, and (4) the definitions and provisions in the final AMP rule.

A. Definition of Price Paid to the Manufacturer

71. The meaning of the term "average price paid to the manufacturer" can be understood by examining the elements essential to defining the term as found in federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context.

1. Price Paid to Manufacturer: Essential Elements

72. Based upon federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context, a test for the "average price paid to the manufacturer" can be constructed using the following essential elements. For each pharmacy or provider setting each of the following questions should be examined. Regarding the "average price paid to the manufacturer":

(1) Is the manufacturer paid a price for the drug?
(2) Are the drugs "covered outpatient drugs"?
(3) Are there discounts or other price considerations that should be included in AMP?
(4) Are there discounts or other price considerations that should be excluded from AMP?
(5) Are rebates, or other price considerations, compensation for *bona fide* services?

2. Price Paid to Manufacturer: Federal and State Statutes and Regulations

73. The "average price paid to the manufacturer" is limited to covered outpatient drugs. Drugs provided in certain settings are not included among "covered outpatient drugs." (42 U.S.C. §1396r-8(k)(3)) However, CMS has included these non-covered drugs in the calculation of AMP. Drugs provided "incident to," or in connection with, physician services, hospital outpatient services, or renal dialysis services are not covered outpatient drugs.

3. Price Paid to Manufacturer: Plain Meaning and Common Usage

74. The plain meaning of the term "price" is the "amount of money given or set as consideration for the sale of a specified thing;" "the terms for the sake of which

something is done or undertaken;" or "the cost at which something is obtained."[37] "Paid" is the "past simple or past participle of pay." The "price paid" then is the amount being, or having been, given for the good or service.[38]

75. "Average" has the plain meaning of being "a single value (as a mean, mode, or median) that summarizes or represents the general significance of a set of unequal values." The "average is the quotient obtained by dividing the sum total of a set of figures by the number of figures." Synonyms for average include: mean, median, norm, or "something that represents a middle point."[39]

76. The average can be estimated as a simple arithmetic mean of a set of numbers or in this case, prices. This average is calculated by adding the total amount paid for all units and dividing by the number of units purchased. If the price data reported and summed is accurate, this will yield an "average price."

4. Price Paid to Manufacturer: Use in the Pharmaceutical Market Context

77. In the pharmaceutical market, it is common for the amount on invoices (e.g., manufacturer to wholesaler, wholesaler to pharmacy, etc.) to be a benchmark price or an invoice price (e.g., AWP, WAC, or sometimes referred to as a list or catalog price), but not the actual amount paid, or to be paid, for the drug product.[40]

78. The AWP and WAC prices are benchmark prices from which discounts, rebates and other price concessions are negotiated between manufacturers and wholesalers, and between manufacturers and private payers.[41]

79. Benchmark prices and invoice prices require adjustment for discounts and other economic considerations in order to determine the "price paid" to the manufacturer. The other forms of economic consideration have to be evaluated to determine which actually lower the price of the drug product versus those that are compensation for some type of *bona fide* service.

80. Rebates paid to a pharmacy benefit manager (PBM) may be for services provided such as formulary placement or preferred status, market share movement, or other types of services related to operation of a drug benefit plan. Rebates paid after the fact on mail order prescriptions through a PBM may be for *bona fide* services, rather than a reduction in price paid to the manufacturer.

---

37 Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/price, accessed on October 23, 2007.

38 Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=58172&dict=CALD, accessed on October 23, 2007.

39 Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/average, accessed on October 23, 2007.

40 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 25.

41 Academy of Managed Care Pharmacy, *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 3.

5. Price Paid to Manufacturer: Final AMP Rule

81. As noted above, the AMP means "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." The final rule specifies that in calculating the AMP, the calculation shall "include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation." (AMP Rule § 447.504 (a)). Notably, the final rule definition, as quoted above, does not explicitly mention rebates, even though rebates are included in the calculation of the AMP.

B. Definition of Wholesaler

82. The meaning of the term "wholesaler" can be understood by examining the elements essential to defining the term as found in federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context.

1. Wholesaler: Essential Elements

83. The term "wholesaler" has been examined by reviewing federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context. There are several elements that emerge as distinguishing features of the term "wholesaler" in the context of the pharmaceutical market:

(1) Is this entity or type of entity a wholesaler or licensed as a wholesaler?
(2) Does this wholesaler or entity purchase drug product from manufacturers?
(3) Does this entity sell to pharmacies, providers or other entities that dispense or administer prescription drugs to the end consumer?
(4) Does this entity sell directly to the consumer?
(5) Does this entity sell to entities that are in the retail pharmacy class of trade?
(6) Can the sales of this entity to the "retail pharmacy class of trade" be identified as distinct from sales to other purchasers?

2. Wholesaler: Federal and State Statutes and Regulations

84. There are numerous statutory and regulatory definitions of drug wholesalers including definitions related to the Federal Food, Drug & Cosmetic Act and the Prescription Drug Marketing Act (PDMA). Federal law requires every drug wholesaler to be licensed in a state. Also, nearly every state either through its dangerous drug act, its pharmacy practice act, or both has a statutory definition of a wholesaler. There is considerable uniformity among the various state laws and the federal statutory and regulatory language with respect to the definition of a "wholesaler." The Healthcare Distribution Management Association (HDMA, the national trade association for drug

wholesalers) provided comments to CMS on the proposed rule and recommended that CMS follow the definitions of wholesaler and wholesale distribution as already set forth in statutes related to the Prescription Drug Marketing Act of 1988. (21 CFR 203.3(cc)) (HDMA, Comments on the Proposed Rule, pp. 8-9). Also, AmerisourceBergen (one of the top three drug wholesalers) recommended in comments to the proposed rule that CMS "should follow PDMA and FDA definitions of wholesale distributor and distribute."

85. Moreover, 42 U.S.C. §1396r8(k)(5) defines wholesaler and specifically excludes manufacturers from the definition.

86. According to the regulations promulgated by HHS pursuant to the Prescription Drug Marketing Act of 1988, "wholesale distribution means distribution of prescription drugs to persons other than a consumer or a patient . . . " (21 CFR 203.3(cc)) The definition describes "wholesale distribution" as excluding sale, purchase, or trade by or for: (1) intracompany sales, (2) group purchasing organizations, (3) charitable organizations, (4) among health care entities under common control, (5) emergency medical reasons, (6) pursuant to a prescription by a provider, (7) distribution of samples by a manufacturer's representatives, (8) blood components intended for transfusion, (9) drug returns by a hospital, health care entity or charitable institution, or (10) sale of minimal quantities by a retail pharmacy to licensed practitioners for office use.

87. At least 42 states have a statutory or regulatory definition of "wholesale distribution" that is similar, or identical, to the definition put forth in federal regulations.[42] Six of the 8 remaining states have very brief definitions of wholesaler or wholesale distribution, but none of these include sales to consumers. The other two states do not have a definition of these terms. Clearly, federal and state statutes and regulations explicitly exclude sales from manufacturers to consumers as a wholesale distribution function.[43]

88. Also, distribution directly to consumers does not fit within the meaning of distribution to "the retail pharmacy class of trade." In fact, provision of a prescription drug to a consumer is "dispensing," rather than "distribution." Consequently, prices paid by consumers to manufacturers or wholesalers are not within the plain meaning of "the average price paid to the manufacturer . . . by wholesalers for drugs distributed to the retail pharmacy class of trade."

---

[42] At least 42 states have substantially the same definition of wholesaler as is found in the Prescription Drug Marketing Act of 1988. Those states are Alabama, Alaska, Arkansas, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

[43] Colorado and other states have statutes and regulations that define "wholesaler" as "a corporation, individual, or other entity with facilities in this state that buys drugs or devices for resale or distributes drugs or devices to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers." (Colo. Rev. Stat. Ann. §12-22-102(34) (for pharmacy practice generally)).

3. Wholesaler: Plain Meaning and Common Usage

89. The term "wholesaler" has the plain meaning of being a merchant middleman that sells commodities in quantity to retail merchants. Merriam-Webster's Online Dictionary describes "wholesale" as "the sale of commodities in quantity usually for resale (as by a retail merchant)." This definition involves "sale of commodities" for "resale." Also, the definition distinguishes that a wholesaler sells to, but is not the same as, "a retail merchant." In addition, the term "wholesaler" is used to describe "a merchant middleman who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users mainly for resale or business use." In this case, the common language definition describes a wholesaler as "a merchant middleman" who sells chiefly to retailers.[44]

90. Another reputable dictionary defines the term "wholesale" as an adjective (or adverb) related to "the selling of goods in large amounts at low prices to shops and businesses, rather than the selling of goods in shops to customers."[45] Practical usage examples cited by this dictionary are: "wholesale prices," "a wholesale supplier/business," and "We only sell wholesale, not to the public." The entry for "wholesale" ends by recommending that one "compare (wholesale to) retail." This reference to "compare to retail" indicates that wholesale is distinct from retail.

4. Wholesaler: Use in the Pharmaceutical Market Context

91. Wholesalers are middle men who buy drugs from manufacturers and sell those drugs to pharmacies, providers, and other entities that in turn sell the drugs to the ultimate consumer. Drugs may be distributed from manufacturers to pharmacies and providers by several pathways including: (1) through a national, regional or specialty wholesaler, or warehouse; (2) through a chain warehouse, or (3) through direct sales to pharmacies or providers. Wholesalers, according to the pharmaceutical market structure, are highlighted in Exhibit 3D. In 2000, wholesalers accounted for about 56.0% of manufacturer prescription drug sales, chain warehouses represented 23.3% of manufacturer sales, and direct purchases by providers and pharmacies were 15.0% of manufacturer sales.[46]

92. There is a national association of wholesale drug distributors now known as the Healthcare Distribution Management Association (HDMA) and, formerly known as the National Association of Wholesale Druggists. Active membership in this trade association requires the following qualification: "The primary business of the distributor

---

[44] Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/wholesale, accessed on October 23, 2007.

[45] Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=90438, accessed on October 23, 2007.

[46] The IMS Health publication *DDD Annual Class-of-Trade Analysis*, 2000 reported that NWDA member warehouse accounted for 48.0% of the pharmaceutical purchasers from manufacturers in 2000, while non-NWDA warehouse accounted for 8.0%, chain warehouse accounted for 23.3% and direct sales from manufacturer to provider or pharmacy represented 15.0% of pharmaceutical purchasers from manufacturers.

must be to purchase or receive pharmaceutical and health-related products in bulk quantities, inventory the products, distribute them in individual package quantities, and provide other value-added services including information technology to its suppliers and healthcare providers."[47] The HDMA reported that in 2006 there were 40 HDMA corporate (wholesale) distributor members and they operated 147 distribution centers. The HDMA member wholesale distributors were reported to have accounted for 48% of manufacturer prescription drug sales in 2000, while non-member wholesale warehouses distributed 8% of manufacturer prescription sales.[48]

93. Federal law requires that a wholesaler be licensed in at least one state. Every state requires every wholesaler to be licensed by at least one state in order to distribute prescription drugs in the state.[49]

94. Based on the pharmaceutical market context, a wholesale drug distributor can be identified by the role it serves in the market. A wholesale distributor is an entity that purchases drugs from a manufacturer and distributes those drugs to pharmacies, providers, and other entities that may provide drugs to the end-consumer. These wholesale distributors may be independent firms in the market or they may be a vertically integrated corporate division of a firm operating at a different level in the market. Some drug companies operate warehouses that sell drugs direct to pharmacies, providers, and other purchasers. Also, many chain pharmacies operate their own drug warehouses through facilities that distribute drugs to the chain's own retail pharmacies. Another indicator of being a wholesale distributor is whether or not an entity holds a state license as a wholesale drug distributor.

---

47 The definition of an active member in the Healthcare Distribution Management Association was reported on the associations website at http://www.healthcaredistribution.org/membership/member_companies.asp) and viewed on October 24, 2007.

48 The IMS Health publication *DDD Annual Class-of-Trade Analysis*, 2000 reported that NWDA member warehouse accounted for 48.0% of the pharmaceutical purchasers from manufacturers in 2000, while non-NWDA warehouse accounted for 8.0%, chain warehouse accounted for 23.3%, and direct sales from manufacturer to provider or pharmacy represented 15.0% of pharmaceutical purchasers from manufacturers.

49 Many states require both in-state and out-of-state wholesale distributors or warehouses to be licensed by the state.

5. Wholesaler: Final AMP Rule

95. The final AMP rule as published in the Federal Register[50] states "*Wholesaler* means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not re-label or repackage the covered outpatient drug." (To be codifed in 42 CFR § 447.504 (f)) Clearly, this promulgated definition of "wholesaler" is overly broad because it encompasses virtually any purchaser who buys from the manufacturer. Wholesalers as defined by the final rule are highlighted in Exhibit 3E. The definition in the final rule is much broader than the statutorily specified definition of "wholesaler" or the commonly accepted use of the term in the pharmaceutical market. (*Compare* Exhibits 3D. and 3E.)

C. Retail Pharmacy Class of Trade

96. The meaning of the term "retail pharmacy class of trade" by Congress and the industry can be understood by examining the elements essential to defining the term as found in federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context.

1. Retail Pharmacy Class of Trade: Essential Elements

97. The term "retail pharmacy class of trade" has been examined by reviewing federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context. There are several essential elements that emerge as distinguishing features of the term "retail pharmacy class of trade" in the context of the pharmaceutical market:

(1) Is this entity a pharmacy or licensed as a pharmacy?
(2) Is a licensed pharmacist present at the entity at all times it is open?
(3) Does this entity sell to the end consumer?
(4) Does this entity sell to the "general public" (i.e., all patients) or a limited population of patients (e.g., an enrolled population)?
(5) Is this entity a "provider" (i.e., physician, clinic or hospital) rather than a "pharmacy"?
(6) Has the entity been identified and distinguished from a retail pharmacy in other statutes or regulations?
(7) Is this entity a hospital, other institutional facility, or managed care plan?
(8) Is this entity eligible to provide covered outpatient drugs?
(9) Is this entity in the structurally-defined "class of trade" known as the "retail pharmacy classes of trade" (i.e., independent, chain, mass merchandise, or food & drug store pharmacies)?

98. The AMP final rule has included entities from many different channels by which prescription drugs can be distributed to consumers. This final rule for calculating AMP

[50] Federal Register, Vol. 72, No. 136, July 17, 2007, p.39241.

includes prices paid by entities that are "non-retail" settings, entities that are "not a licensed pharmacy," and entities that "do not serve the general public."

2. Retail Pharmacy Class of Trade: Federal and State Statutes and Regulations

99. The use of the terms "retail pharmacy" and "pharmacy" in federal statutory language can be instructive as to the industry's view of the meaning of the term "retail pharmacy class of trade." Several examples showing how the term "retail pharmacy" is used in statutes in relation to other entities that sell prescription drugs are described below.

100. A Congressional study of drug purchasing and billing activities of various health care systems was mandated as part of Public Law 101-508 (§4401(d) of Pub.L. 101-508, as amended Pub.L. 104-316, Title I, § 122(i), Oct. 19, 1996, 110 Stat. 3837 (1)(A)). That law required that "The Comptroller General shall conduct a study of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the Medicaid program. The study shall compare the ingredient costs of drugs for Medicaid prescriptions to these facilities and plans and the charges billed to medical assistance programs by these facilities and plans compared to retail pharmacies." The language here lists separately "hospitals, other institutional facilities, and managed care plans" and then requires that the prices of these entities be "compared to retail pharmacies." This enumeration of purchaser types and request for their comparison to retail pharmacy prices indicates that Congress viewed retail pharmacy as not including the enumerated entity types—that is, "hospitals, other institutional facilities, and managed care plans."

101. When defining the term "covered outpatient drug" for the Medicaid program the regulation identifies certain drugs not covered when they are provided as part of, or as incident to and in the same setting as, any of the following: (A) inpatient hospital services; (B) hospice services; (C) dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs; (D) physicians' services; (E) outpatient hospital services; (F) nursing facility services and services provided by an intermediate care facility for the mentally retarded; (G) other laboratory and x-ray services; and (H) renal dialysis. (42 U.S.C. § 1396r-8 (k)(3)) Some of these settings for which prescriptions are not covered under Medicaid have been included in the promulgated final AMP rule as prices that should be included in calculating the AMP. Prescription drugs provided through the settings listed above are not covered by Medicaid and these settings are not part of the "retail pharmacy class of trade."

102. The Social Security Act as amended by the DRA (used in the Medicaid drug rebate program) includes regulations describing prices to be considered when determining the "best price." The type of entities whose prices are included in determining the "best price" is an extensively enumerated list as follows: "(1) Prices to wholesalers; (2) Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs; (3) Prices to

providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies); (4) Prices available to non-profit entities; (5) Prices available to governmental entities within the United States; (6) Prices of authorized generic drugs; (7) Prices of sales directly to patients; (8) Prices available to mail order pharmacies; (9) Prices available to outpatient clinics; (10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements; and (11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity." (42 CFR §447.505) Note that this list includes "prices to any retailer" and proceeds to list ten other entity types whose prices are also to be included in determining the "best price." The existing best price regulations considered ten other categories of entities to be distinct from "prices to any retailer." Now, a different section of the final AMP rule has taken the term "retail pharmacy class of trade" and defined it to encompass most or all of these ten distinct entities.

103. Federal statutes and regulations have recognized that the prices paid by retail pharmacy are different from, and can be compared to, prices for hospitals, other institutional facilities, and managed care plans. A number of provider and distribution entities that have been included in the final AMP rule definition of "retail pharmacy class of trade" are excluded from coverage under Medicaid. The inclusion of these excluded prices in calculating AMP is unwarranted. The history of statutory and regulatory recognition of retail pharmacy as distinct from many other providers and distributors of prescription drugs is contrary to the overly broad definition of the "retail pharmacy class of trade" as published in the final AMP rule. Moreover, because of the structural impediment of discriminatory pricing as described above, retail pharmacies do not have access to the lower prices of these other classes of trade and will be economically disadvantaged and harmed by the overly-broad and artificial definition of the retail pharmacy class of trade as construed by CMS in the final rule.

104. In the Medicare Part D program, CMS defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy." (42 C.F.R. § 423.100, the Medicare Part D prescription drug program regulations). This definition of retail pharmacy is clearly more consistent with the use of the term "retail pharmacy" than is the CMS interpretation which re-writes the statutory criteria of the Social Security Act in the final rule.

105. The terms "retail" and "retail pharmacy" are terms defined in state statutes and regulations. The states, and not the federal government, are responsible for defining the term "pharmacy" and for licensing pharmacies. CMS cannot by the stroke of its pen re-define "pharmacy" or "retail pharmacy" to be different from the definition of these terms in the states, individually or collectively. State boards of pharmacy are responsible for licensure of pharmacies (entities that dispense, compound, prepare, and administer prescription drug products). In every state, a pharmacy must be licensed and a licensed pharmacist must be present at the entity in order to dispense prescription medications

within the state. Across the states there are many types (or categories) of pharmacy licenses such as a "retail pharmacy" license, hospital (or institutional), charitable clinic, long term care, nuclear, mail order, HMO, and other types of pharmacy licenses.[51] The fact that each type of pharmacy is issued a unique license type indicates that "retail pharmacy" is distinct from, and not inclusive of, the other types of pharmacies for which specific licenses are available and required. Many of the entities whose prices are included in the definition of AMP are not licensed as retail pharmacies, and some may not be licensed as a pharmacy of any type, or even have a licensed pharmacist present at the entity during normal business hours.

106. The use of the word "pharmacy" in the federal statutory language defining how AMP will be calculated carries special meaning. In every state an entity must be a "licensed pharmacy" in order to dispense and administer medications to the end consumer. In fact, it is illegal for any entity not licensed as a pharmacy by the state to call itself a "pharmacy" or a "drug store." This would imply that only entities that are licensed pharmacies should be taken into account in calculating the AMP which is to be "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail *pharmacy* (emphasis added) class of trade." (*See* Social Security Act §1927(k)(1) 42 U.S.C. § 1396r-8(k)(1)).

3. Retail Pharmacy Class of Trade: Plain Meaning and Common Usage

107. "Retailer" is defined by the Cambridge Advanced Learner's Dictionary as "a person, shop or business that sells goods to the public."[52] Another dictionary source uses the term "retail" to have a plain language meaning "to sell in small quantities directly to the ultimate consumer" and the term "retailer" to mean "to sell at retail."[53]

108. "Public" means "relating to, or involving, people in general, rather than being limited to a particular group of people."[54] Public also means "of, relating to, or affecting all the people" or "relating to people in general." Additionally, public means "accessible to or shared by all members of the community."[55]

109. Both the dictionary definitions, above, and the CMS final AMP rule describe "retail" as selling or providing drugs "to the general public." (42 CFR § 447.504 (e)) This stipulation that retail means a firm that "sells or provides the drugs to the general public," means that merely selling to the end consumer is not sufficient to define a retail pharmacy or the "retail pharmacy class of trade."

---

51 *Survey of Pharmacy Law*, National Association of Boards of Pharmacy, 2007, pp. 49-50.

52 Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=90438, accessed on October 23, 2007)

53 Merriam-Webster's Online Dictionary, http://www.merriam-webster.com/dictionary/retail, accessed on October 23, 2007.

54 Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/public, accessed on October 23, 2007.

55 Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=public*1+0&dict=A, accessed on October 23, 2007.

110. Therefore, to be included in the plain meaning of "retail pharmacy" or CMS' definition of the "retail pharmacy class of trade" it is not sufficient to dispense prescriptions to a limited group of patients, such as members of a particular health plan. Instead, to be included in the "retail pharmacy class of trade" a pharmacy must dispense prescriptions to any customer who chooses to use the pharmacy. In other words, the dictionary and plain meaning of retail means selling or providing goods or services to the ultimate consumer and that the goods and services are accessible to all people in the community.

111. Another component of the plain meaning of the term "retail pharmacy class of trade" is the word "pharmacy." A pharmacy is an entity that is licensed by the state to dispense prescription medications.

4. Retail Pharmacy Class of Trade: Use in the Pharmaceutical Market Context

112. The term "class of trade" has a specific meaning in the context of the pharmaceutical market. IMS Health (a pharmaceutical market research firm) tracks nearly the entire universe of pharmaceutical sales throughout the United States at all levels in the market. The sales from manufacturers to wholesalers and direct sales to virtually every other type of pharmacy, provider and other entity type are tracked for every prescription drug product. IMS Health and pharmaceutical companies in the United States group the sales of their products according to the type of purchaser. This grouping system for pharmaceutical purchasers is called the "class of trade" system and IMS Health uses a uniform set of "classes of trade" across all pharmaceutical firms. The class of trade of a given purchaser is a function of various "structural" criteria such as type of entity (e.g., pharmacy versus hospital versus clinic); type of ownership (e.g., for profit versus non-profit); and type of financing (e.g., private versus government). The detailed Outlet Subcategory Codes for the class of trade system are presented in a document maintained by DDD, a division of IMS Health.[56] (*See* Exhibit 4). Notice that this coding scheme groups outlets by their description and definitions of the type of facility. However, nowhere in this document is the volume of business of any given class of trade presented. In other words, "class of trade" has a specific structural meaning in the pharmaceutical market and the classes of trade are differentiated by structural and not economic efficiency criteria.

113. The pharmaceutical market structure involves several distinct groups of players including: (1) manufacturers, marketers, and distributors; (2) wholesalers and warehouses; (3) retail pharmacies; (4) mail service pharmacies; (5) outpatient providers; and (6) institutional providers. (*See* Exhibit 3C.)

114. The "Retail Perspective" is an IMS Health data product that describes the "retail pharmacy class of trade" as including the following types of pharmacies: (1) independent pharmacies, (2) chain pharmacies, (3) food & drug store pharmacies, and (4) mass merchandise pharmacies (sometimes combined with chain pharmacy data). The

---

[56] IMS Health, DDD Outlet Subcategory Codes, Updated October 2002.

retail pharmacy class of trade, according to the pharmaceutical market structure, is highlighted in Exhibit 3F. Data from the "retail pharmacies open to the general public" is collected by IMS Health by a common method and is reported separately from other pharmaceutical sales data.[57] (*See* Exhibits 5 and 6). Retail pharmacies typically carry a full line of drug products including chronic and acute medications, oral and topical medicines, insulin, vaccinations and other biologicals, etc. In contrast, many of the other entities, force-fitted into the "retail class of trade" definition by CMS, do not carry a full line of drugs but only a limited supply of drugs for special patient populations such as dialysis patients, home infusion patients, long term care patients, etc.

115. Data from "Mail Service Pharmacies" is collected by IMS Health separately from the retail pharmacy data included in the "Retail Perspective". (*See* Exhibit 7). Although mail service pharmacy data is sometimes grouped with the retail classes of trade, mail service pharmacy data is collected by different methods and is almost always reported separately from retail pharmacy data.[58] In general, mail service pharmacies constitute retail pharmacies with limited distribution or special populations. The largest mail service pharmacies serve enrolled and special populations (e.g., PBM-owned mail service pharmacies serve the members of an insured group being served by a given PBM, also there are mail service pharmacies for special populations such as the Federal TriCare program for military dependents and retirees) and are not open to the general public.

116. The "Provider Perspective" is an IMS Health data product that describes the following classes of trade as "non-retail providers": (1) clinics (i.e., physician's offices, group practices, and specialty clinics), (2) healthcare plans (staff model HMOs, hospitals, and clinics), (3) home health agencies, (4) long term care settings, (5) non-federal hospitals, (6) federal hospitals, and (7) miscellaneous (i.e., prisons, universities, and others). (*See* Exhibit 8). Note that this report refers to the Provider Perspectives classes of trade as "non-retail."

117. Market trend analysis information is published by IMS Health in an annual volume titled *DDD Annual Class-of-Trade Analysis*.[59] (*See* Exhibit 9). In general, IMS Health divides the various classes of trade into two broad categories: (1) retail and (2) providers (or sometimes referred to as "non-retail"). These two broad groups form the basis of market data products known as the Retail Perspective™[60] and Provider Perspective™.[61] These two data products provide manufacturers and others with market volume and market share data through the various channels of distribution for their drug products in the pharmaceutical market.[62] (*See* Exhibits 5 and 8). Although mail service pharmacy is sometimes listed under the retail sector, mail service pharmacy, as noted

---

57 U.S. Chain and Independent Pharmacies, Mass Merchandisers, Proprietary Stores and Foodstores with Pharmacies, IMS Health, March 2006.

58 Mail Service Sales, IMS Health, 2006.

59 IMS Health, DDD™ Class of Trade Report, 2003, p. 13. (*See* Exhibit 9).

60 IMS Health, Retail Perspectives. (*See* Exhibit 6).

61 IMS Health Provider Perspectives. (*See* Exhibit 8).

62 IMS Health, DDD® Class of Trade Report, 2003. (*See* Exhibit 9).

above, is a distinct class of trade from other retail pharmacies and does not serve the general public, but rather an enrolled and limited segment of the public.

118. Several comments noted that the CMS proposed, and now final, rule definition of "retail pharmacy class of trade" was in conflict with the use of this term in the pharmaceutical market. The CMS response to these comments makes it clear that

however, are not always consistent with the original statutory language. For example, the definition and rules related to "wholesaler" includes many entities and related price transactions that are not generally considered to be wholesalers by other federal and state statutes and regulations, that are not consistent with the plain meaning of the term based on dictionary definitions, and that are not consistent with the use of the term in the pharmaceutical market context.

123. Similarly, the promulgated definition and rules related to the "retail pharmacy class of trade" includes many entities that are not generally considered to be retail pharmacies. The retail pharmacy class of trade as defined in the final rule includes many types of providers who are clearly not in the "retail pharmacy class of trade" as the term is commonly and routinely used in the pharmaceutical market.

124. Also, the final rule definitions create confusion about the definition of a "wholesaler" versus entities within the "retail pharmacy class of trade." The final regulation essentially declares that all entities in the retail pharmacy class of trade are also wholesalers as well as retailers.

125. The final rule has re-defined several key terms such as "manufacturer," "wholesaler," and "retail pharmacy class of trade," to have meanings contrary to that found in other federal and state statutes and rules, contrary to that found in the plain language and common usage of the terms, and contrary to that found in the use of the terms in the pharmaceutical market.

126. This re-definition of key terms will have a substantial and material impact upon the definition and calculation of the Average Manufacturer Price (AMP) and the amount of payment that pharmacies and other providers will receive from Medicaid for generic medications provided to recipients.

127. Examination of the entities whose prices are to be included in the AMP calculation according to the final rule is compared below with the statutory language describing the AMP and its calculation, with the plain meaning or common usage of key terms, and with the use of the key terms within the pharmaceutical market.

128. The following examples from the final rules involve prices paid by non-wholesalers to manufacturers, drugs distributed to non-retailers, or both.

1. Sales to Other Manufacturers Who Act As Wholesalers (42 CFR §447.504 (g)(2))

129. Certain manufacturers sell their drug products to another manufacturer who serves merely as a wholesaler or distributor. These "other manufacturers" may then sell the drug product to retail pharmacies, other outlets, or other entities that may or may not distribute drugs to the end consumer or the general public.

130. This category of transactions (e.g., sales to other manufacturers) should not be included in AMP because: (1) the Social Security Act excludes manufacturers from the

definition of wholesaler, (2) the entities may not be licensed as wholesalers, and (3) the sales may not be for distribution to the "retail pharmacy class of trade."

131. Inclusion of this group of entities in effect defines "other manufacturers who act as a wholesaler" as both a "wholesaler" and a "retail pharmacy." So in this case, the same firm is a manufacturer, a wholesaler, and a pharmacy, even though the firm may not be licensed as either a wholesaler or a retail pharmacy. Since these firms are not necessarily licensed as wholesalers, they are not wholesalers. And, since these firms are not necessarily licensed as pharmacies, they are not pharmacies. Additionally, there is no indication that these sales of drugs must be distributed to the "retail pharmacy class of trade."

2. Direct and Indirect Sales to Hospital Outpatient Pharmacies, Clinics and "Affiliated Entities" (42 CFR §447.504 (g)(3))

132. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) these entities are not often licensed as retail pharmacies, (4) these entities primarily serve the hospital's or health system's own patients, but do not serve the general public, and (5) the manufacturer can not distinguish whether the drugs sold will be used for inpatient or outpatient purposes.

133. Hospital outpatient pharmacies, clinics, and affiliated entities clearly are not wholesalers. The sales in this category bypass the wholesaling function. While hospital pharmacies may be licensed as a pharmacy, most states designate "hospital pharmacies" as distinct from "retail pharmacies." The statute defining AMP referred to: sales for "distribution to the retail pharmacy class of trade." The statute does NOT read: sales for "distribution to the *hospital* (emphasis added) pharmacy class of trade." Clinics may dispense drugs under the authority of the physicians who practice in the clinic without having a licensed pharmacy in the clinic. Likewise, "affiliated entities" related to hospital and health systems are not necessarily licensed as pharmacies.

134. The entities enumerated in (42 CFR §447.504(g)(3)) are able to purchase drug products at lower prices than other classes of trade including the retail class of trade (i.e., independent, chain, mass merchandise, and food & drug pharmacies). Clinics, for example, were able to purchase a Medicaid-weighted market basket of patented brand name drug products at 30.5% below AWP in July 2004, while the retail class of trade were only able to purchase the same market basket of Medicaid-used drugs at about 20.2% below AWP.[63] This difference in prices was due to the structurally defined classes of trade and the manufacturer's practice of price discrimination across classes of trade and sustained by the statutory prohibition of arbitrage (PDMA) across, and within, classes of trade.

[63] Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report*, CMS, September 26, 2005, p. 47.

135. The general public can not obtain prescription drugs from these entities. Sale of drugs provided at the lower prices for these classes of trade is limited to patients who meet the "own use" criteria for the facility—that is, the patient is one who is being treated by providers affiliated with the facility. A person from the general public being treated by a provider not affiliated with the entity is not supposed to be able to walk into the facility with a prescription and have that prescription filled. Consequently, these entities do not serve the "general public," but rather only those persons being treated by providers affiliated with the facility.

136. In a related matter, hospital outpatient pharmacies are not open to the general public. These pharmacies may dispense only to hospital patients (inpatient or outpatient) by providing outpatient services in a manner that is integrated with inpatient pharmacy services. (Medicare Hospital Conditions of Participations, 42 CFR §482.54)

137. When a sale is made to one of these entities (i.e., hospital outpatient pharmacies, clinics, and affiliated entities), the manufacturer can not distinguish whether the drugs sold will be used for inpatient or outpatient purposes.

3. Sales at Nominal Prices to "Any Entity" (42 CFR §447.504 (g)(4))

138. This category of transactions should not be included in AMP because: (1) most of the entities encompassed by "sales at nominal prices to any entity" are not licensed as wholesalers, and (2) most of the entities encompassed by "sales at nominal prices to any entity" are not licensed as retail pharmacies.

139. Sales at "nominal prices" exist in the market for two primary purposes. First, to provide drug products to charitable (non-profit) organizations at an extremely low cost. Many of the charitable organizations that may be dispensing drugs are not licensed wholesalers or licensed pharmacies. For this reason alone these sales do not meet the statutory test for inclusion in the calculation of AMP.

140. In addition, nominal prices are not "negotiated" or awarded based on economic efficiency, but rather are provided by a manufacturer for promotional purposes. If the drug company can get doctors in the hospital to prescribe their oral medication, through lower (i.e., nominal) prices, then when the patient is discharged to the outpatient market, the patient will be on a chronic medication that generates a much greater revenue for the manufacturer for the rest of the time the patient continues to use the medication.

141. Nominal prices are rarely, if ever, provided to wholesalers for drugs distributed to traditional "retail pharmacy class of trade" entities. Therefore, the inclusion of nominal prices in AMP will assure that the resulting AMP will be below the price to the retail pharmacy class of trade for reasons that are not related to market efficiency and below the price that is attainable by the actions of retail pharmacies.

4. Direct Sales to Retail Pharmacies (42 CFR §447.504 (g)(5))

142. This category of transactions should not be included in AMP because these entities are generally not licensed as wholesalers.

143. Retail pharmacies are not wholesalers. The sales in this category bypass the wholesaler function.

5. Sales and Discounts to PBMs for their Mail Order Pharmacies (42 CFR §447.504 (g)(6))

144. Pharmacy benefit management companies (PBMs) are defined as "organizations that manage pharmaceutical benefits for managed care organizations (MCOs), other medical providers, or employers. PBMs contract with clients who are interested in optimizing the clinical and economic performance of their pharmacy benefit. PBM activities may include some or all of the following: benefit plan design, creation/administration of retail and mail service networks, claims processing, and managed prescription drug care services such as drug utilization review, formulary management, generic dispensing, prior authorization (PA), and disease and health management."[64] PBMs do not, generally, purchase, take possession of, or dispense prescription drugs to their covered members, except in the case where the PBM owns their own mail order pharmacy.

145. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) these entities serve only the PBM enrolled patients and not the general public.

146. This category involves mail order pharmacies that are affiliated with a PBM. These pharmacies do not generally function as, and are not generally licensed as, wholesalers.

147. Mail order pharmacies usually serve enrolled members in a PBM or insurance program and not the general public. Also, mail order pharmacies get differential prices compared to traditional retail pharmacies (i.e., independent, chain, mass merchandise and food & drug pharmacies). Mail order pharmacies paid on average 27.9% below AWP for a Medicaid-weighted market basket of drugs in July 2004. In contrast, traditional retail pharmacies paid on average 20.2% below AWP for the same market basket of drugs. The difference in this payment is due primarily to the structural class of trade pricing used by drug manufacturers to carry out their discriminatory pricing scheme supported by patent monopolies and a prohibition on arbitrage (PDMA) across various settings in the pharmaceutical market. Inclusion of prices to mail order pharmacies in the AMP

64 Pharmacy benefit management companies are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 55.

calculation will mean that the AMP will be lower than the actual acquisition cost for entities in the traditional retail pharmacy class of trade.

148. PBM rebates are typically based on factors such as market share movement, preferred formulary status, or other services. The rebates are compensation for the service provided, and are not a discount to the price. Absent transparent information on rebates and the basis for those rebates, it is not possible to determine what portion of a rebate is attributable to price versus other *bona fide* services. Manufacturers do not know when rebates paid to PBMs are for drugs dispensed by mail or by the retail pharmacy class of trade.

149. The PBM rebates are not passed on to the pharmacies in the retail pharmacy network. PBM rebates may reduce the health plans' costs, but typically do not reduce the cost to the pharmacy. The inclusion of PBM mail order rebates in the final rule is in conflict with past policy announced in Medicaid Releases No. 28 & 29.[65]

6. Sales To Mail Order Pharmacies (42 CFR §447.504 (g)(9))

150. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," and (3) these entities typically serve only the PBM or insured enrolled members and not the general public.

151. These mail order pharmacies do not generally function as, and are not generally licensed as, wholesalers.

152. Mail order pharmacies usually serve enrolled patient populations in an insurance program and not the general public. Moreover, except in very rare circumstances, these mail order pharmacies do not typically serve Medicaid recipients.

153. Mail order pharmacies get differential prices compared to traditional retail pharmacies (i.e., independent, chain, mass merchandise, and food & drug pharmacies). Mail order pharmacies paid on average 27.9% below AWP for a Medicaid-weighted market basket of drugs in July 2004. In contrast, traditional retail pharmacies paid on average 20.2% below AWP for the same market basket of drugs.[66] The difference in this payment is due primarily to the structural class of trade pricing used by drug manufacturers to carry out their discriminatory pricing scheme supported by patent monopolies and a prohibition on arbitrage (PDMA) across various settings in the pharmaceutical market. Inclusion of prices to mail order pharmacies in the AMP

---

[65] The Medicaid Releases are memoranda from CMS to drug manufacturers that contain every instruction issued by CMS to participating drug companies related to the National Drug Rebate Agreement. A complete archive of these Medicaid Releases can be found on the CMS Medicaid website at: http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp.

[66] Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report*, CMS, September 26, 2005, p. 47.

calculation will mean that the AMP will be lower than the actual acquisition cost for entities in the traditional retail pharmacy class of trade.

154. Rebates paid to mail order pharmacies are based on factors such as market share movement, preferred formulary status, or other services. The rebates are compensation for the service provided, and not a discount to the price. Absent transparent information on rebates and the basis for those rebates, it is not possible to determine what portion of a rebate is attributable to price versus other *bona fide* services.

7. Sales Directly To Patients (42 CFR §447.504 (g)(7))

155. This category of transactions should not be included in AMP because: (1) patients are not licensed as wholesalers, and (2) patients are not licensed as pharmacies and are not in the retail pharmacy class of trade.

156. Furthermore, federal and state statutes and regulations explicitly exclude sales from manufacturers to consumers as a wholesale distribution function.[67] Also, distribution directly to consumers does not fit within the meaning of distribution to "the retail pharmacy class of trade." Consequently, inclusion of prices paid by patients directly to manufacturers is not within the plain meaning of "the average price paid to the manufacturer . . . by wholesalers for drugs distributed to the retail pharmacy class of trade."

157. Certain drugs are distributed through specialty pharmacies that never really purchase the drug and maintain it in inventory. Rather, the drug remains under the ownership of the manufacturer until the drug is sold to a patient. This constitutes direct sales to the patient by the manufacturer.

158. Manufacturers hire certain distributors to provide services related to these direct sales to the patient. However, these distributors never purchase the drug nor maintain it in their inventory. Rather, the drug remains under of the ownership of the manufacturer until the drug is sold to a patient. Therefore, these distributors can not be considered wholesalers.

[67] Colorado and other states have statutes and regulations that define "wholesaler" as "a corporation, individual, or other entity with facilities in this state that buys drugs or devices for resale or distributes drugs or devices to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers." (Colo. Rev. Stat. Ann. §12-22-102(34) (for pharmacy practice generally)).

8. Sales to Outpatient Facilities (42 CFR §447.504 (g)(8))

159. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) some, but not all, of these entities may be licensed as pharmacies, (4) these entities may serve a health system's own patients, but they do not serve the general public, and (5) the manufacturer can not distinguish whether the drugs sold will be used for inpatient or outpatient purposes.

160. This category of transactions may include: clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers. These entities do not function as, and are not licensed as, wholesalers. In general, these entities are not licensed as a pharmacy. These entities are not part of the traditional retail pharmacy class of trade.

161. Unlike traditional retail pharmacies (i.e., independent, chain, mass merchandise, and food & drug store pharmacies), these providers (entities) generally provide drugs "incident to" providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home. Drugs provided as "incident to" the provider visit are not covered drugs under the Medicaid program. Therefore, it is not proper to include these prices in the calculation of AMP.

9. Sales to Home Infusion Providers (42 CFR §447.504 (g)(10))

162. Home infusion providers are entities "specializing in supplying members with home-infusion therapy medications and supplies."[68]

163. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) many of these entities are not licensed as pharmacies, and (4) these providers do not serve the general public.

164. Medicare Part D regulations specify that …"home infusion pharmacies" are not "retail" pharmacies, and are excluded from the definition of "retail" pharmacies due to the "ongoing clinical monitoring, care coordination and home infusion nursing that is provided by staff of, or affiliated with, the home infusion therapy provider." (42 C.F.R. § 423.120)

165. Most specialty and home infusion pharmacies are located in industrial areas, where there is little, if any, general consumer traffic.

[68] Home infusion providers are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 52.

10. Sales To Specialty Pharmacies (42 CFR §447.504 (g)(11))

166. A specialty pharmacy is a "pharmacy that dispenses generally low-volume and high-cost medicinal preparations to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex, and potentially life threatening. These therapies often require specialized delivery and administration."[69]

167. This category of transactions should not be included in AMP because: (1) the entities are not wholesalers or licensed as wholesalers, (2) the sales are not be for distribution to the "retail pharmacy class of trade," and (3) these entities typically serve an enrolled, or insured, population of patients, but do not serve the general public.

168. Most specialty pharmacies are located in industrial or warehouse business districts, where there is little, if any, consumer traffic from the general public.

169. Specialty pharmacies do not function as wholesalers, and they are not usually licensed as wholesalers.

170. Specialty pharmacies are not retail pharmacies within the "retail pharmacy class of trade" and they do not serve the general public. These specialty pharmacies serve a small, and usually enrolled, patient population with unique medication needs. Specialty pharmacies do not usually have a store-front capacity for serving walk-in clientele.

11. Sales To Home Health Providers (42 CFR §447.504 (g)(12))

171. Home health providers are entities that provide patient care services at the patient's home including assistance with activities of daily living and medication administration and use. These services are often delivered by visiting nurses or other health providers.

172. This category of transactions should not be included in AMP because: (1) the entities are not wholesalers or licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) these entities are not usually pharmacies or licensed as pharmacies, and (4) these entities serve a small specialized group of patients, but can not and do not serve the general public.

173. Home health providers do not function as wholesalers and are not licensed as wholesalers. Home health providers do not function as retail pharmacies, and are not licensed as retail pharmacies.

174. Home health providers serve a specialized group of patients with special medical and service needs, but do not dispense prescriptions to the general public. There

[69] Specialty pharmacies are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 56.

usually is no store-front location for home health providers to interface with the general public in a manner that would allow dispensing of prescriptions to the general public or Medicaid recipients.

12. Sales to Physicians (42 CFR §447.504 (g)(13))

175. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not be for distribution to the "retail pharmacy class of trade," (3) physicians are not licensed as pharmacies, and (4) physicians may dispense for their own patients, but can not dispense drugs to the general public.

176. Physicians are not wholesalers and are not usually licensed as wholesalers. Physicians are not retail pharmacies and are not licensed as a pharmacy or retail pharmacy.

177. A manufacturer's drug product sales to physicians are not for "distribution to the retail pharmacy class of trade."

178. Physicians may serve the medication needs of their own patients, but they do not serve the medication needs of the general public.

13. Rebates, etc. "Associated With" Sales of Drugs to the Retail Pharmacy Class of Trade (42 CFR §447.504 (g)(14))

179. This category of transactions should not be included in AMP because the rebates are not prices paid to manufacturers by wholesalers.

180. Rebates paid by manufacturers and associated with sales of drugs to the retail pharmacy class of trade are based on factors such as moving market share for a specific generic drug. These rebates are compensation for the service provided, and not a discount to the price. Absent transparent information on rebates and the basis for those rebates, it is not possible to determine what portion of a rebate is attributable to price versus other *bona fide* services.

14. Sales of Drugs Reimbursed By 3rd Party Payers (42 CFR §447.504 (g)(15)), (but not related discounts (42 CFR §447.504 (h)(23))

181. Third party payers are "public or private organization(s) (such as Blue Cross and Blue Shield, Medicare, Medicaid, commercial insurer, self-insured employer, Taft-Hartley Trust, or Multiple Employer Trust) that pay for or underwrite coverage for health care expenses for an individual or group. The individual enrollee generally pays a premium for coverage in all private and some public health insurance programs, and the

organization pays claims on the patient's behalf."[70] Third party payers do not, generally, purchase, take possession of, or dispense prescription drugs to their covered members.

182. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution into the retail pharmacy class of trade. Third party payers are not wholesalers, or licensed as wholesalers. Also, third party payers are not retail pharmacies, or licensed as pharmacies.

15. Manufacturer Patient Assistance Programs, in some circumstances (42 CFR §447.504 (h)(15))

183. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

184. Consumers receiving prescriptions through a manufacturer patient assistance program are not wholesalers or part of the retail pharmacy class of trade. Manufacturer patient assistance programs do no affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's patient assistance program. The pharmacy is merely a pass through entity.

16. Manufacturer Coupons (42 CFR §447.504 (h)(15))

185. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

186. Consumers receiving coupons are not wholesalers or part of the retail pharmacy class of trade. At most, coupons could be included only if they affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's coupons. The pharmacy is merely a pass through entity.

17. Manufacturer Vouchers are included in some circumstances (42 CFR §447.504 (h)(16))

187. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

[70] Third party payers are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 56.

188. Consumers receiving vouchers are not wholesalers or part of the retail pharmacy class of trade. At most, vouchers could be included only if they affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's voucher. The pharmacy is merely a pass through entity.

189. Manufacturer's vouchers may be used as a promotional tool to increase the prescribing and dispensing of a given drug. These manufacturer vouchers may also be used to deliver a charitable benefit to a certain limited set of persons, but these vouchers are not available to the general public.

190. CMS has previously held that vouchers do not need to be included in best price or AMP calculation if there is no net income to the wholesaler or pharmacy from participation in the program.

18. Manufacturer Discount Cards are Included in Some Circumstances (42 CFR §447.504 (h)(17))

191. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

192. Consumers receiving prescriptions through a manufacturer discount card program are not wholesalers or part of the retail pharmacy class of trade. Manufacturer discount card programs do no affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's discount card program. The pharmacy is merely a pass through entity.

19. Rebates, Discounts, and Other Price Concessions (42 CFR §447.504 (i))

193. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler.

194. For example, this provision appears to include certain fees paid to group purchasing organizations (GPOs). GPOs are not wholesalers, but rather serve as a broker or middleman between manufacturers and hospitals or other providers. GPOs rarely, if ever, take possession of the drug product. GPOs are not typically wholesalers or licensed as wholesalers.

20. Lagged Price Concessions – 447.510(d)(2), 447.502 (definition).

195. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

196. CMS' response to lagged price concessions says "Lagged price concessions are not limited to discounts or rebates offered to wholesalers." (Federal Register, Vol. 72, No. 136, p. 39210). If the lagged price concession was offered to any entity other than a wholesaler, then the lagged price concession is not part of the "price paid by the wholesaler."

E. "Adequate Documentation" Issue (42 CFR §447.504 (g)(1))

197. CMS modified the final rule at § 447.504(g)(1) to state that "where the manufacturer can identify with adequate documentation that subsequent sales from the wholesaler are to an excluded entity, the manufacturer can exclude such sales from AMP." This provision creates an opportunity for manufacturers to favor their own economic interests to the detriment of Medicaid and the retail pharmacies that serve Medicaid recipients.

198. According to the final rule, all sales are included in the AMP calculation unless there is adequate documentation to prove that the price should not be included in AMP. By lowering the AMP, the manufacturer can reduce the amount of rebate it has to pay to the Medicaid drug program. Therefore, manufacturers have an economic interest in avoiding documentation of sales (at higher prices) that they wish to exclude from the AMP calculation.

199. A prudent manufacturer, acting in accordance with the provisions of the final rule will likely not have adequate documentation, and not have an interest in developing adequate documentation, for prices and sales that raise the AMP and thus the manufacturer's rebate liability. In particular, drug manufacturers usually lack adequate documentation to demonstrate whether PBM rebates are for mail order or retail pharmacy network prescriptions.

VIII. "In The State" versus Nationally Available

200. The Social Security Act has a definition of "multiple source drug" that says a drug does not constitute a multiple source drug in a particular State unless two or more equivalent drug products are "sold or marketed in the State." The statute explains that "a drug product is considered to be sold or in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in the State." (*See* Social Security Act § 1927(k)(7), 42 U.S.C. § 1396r-8(k)(7)).

201. The final AMP rule, however, contradicts this statutory language in three principal ways: (1) the statute requires that the drug be "sold or marketed in the State" while the final rule has substituted the requirement that the drug must be "sold or marketed in the United States;" (2) despite specific statutory language mandating that a drug price can only be used to set an FUL if it "appears in a published national listing of average wholesale prices selected by the Secretary," the final rule does not mandate use of any listing of prices or drug availability in the market; and (3) the final rule fails to ensure that FULs are applied in each State

IX. Web Site Posting of FULs and AMPs

206. The AMP information collected pursuant to the final rule will be posted by CMS on a web site for each drug product and will be updated monthly. In general, transparency of price information is usually a good thing for consumers and for the market. However, when disclosed information is complex, confusing, or even inaccurate the transparency loses its value or even becomes counterproductive.

207. In the case of the AMP data that would be collected and posted under the final rule, the data would be confusing and not constructive in encouraging an efficient market with pricing pressure in the right places. There would be two primary types of users for the data on the website: (1) consumers and (2) third party payers. Consumers examining the website would in all likelihood be looking for information to make an informed decision based on the expected cost of their prescription from the pharmacy. Instead, what the consumer would find is prices paid to manufacturers by wholesalers (and non-wholesalers) for drugs by a collection of various pharmacy and provider types, some of which the consumer is totally unaware of, and from which the consumer can not even buy a prescription as an individual. The "retail pharmacy class of trade" defined by the final rule is not reflective of either the structure of the pharmaceutical market from the perspective of the supply side (i.e., manufacturers, wholesalers, and pharmacies and providers) or from the perspective of the demand side (i.e., consumers and the place where they usually get their prescriptions filled—independent, chain, mass merchandise, and food & drug store pharmacies).

208. The prices that would be posted would not be directly applicable at the consumer level—that is, the prices posted (i.e., AMP) would not be prices that could be expected for the prescription the consumer is planning to purchase. The individual consumer can not even purchase a prescription from many of the providers whose price data has been defined by CMS as being in the "retail pharmacy class of trade." Absent this clarity in information and applicability to the 'real' price that will be charged for a prescription, consumers will: (1) blame the pharmacy for charging a price different than what is posted on the web site, (2) ignore the website as irrelevant or too complex, (3) get frustrated when the web site price is found to be wrong, or (4) some combination of the above.

209. The second group that may use the web site and information posted there, would be third party programs looking for pricing information to serve as a benchmark for determining a reasonable payment level for pharmacies delivering their prescription drug benefit. The broad and detached definition of the "retail pharmacy class of trade" in the final rule muddles the actual data from various distinct groups (actual classes of trade) of purchasers in a manner that renders the actual data nearly useless in reflecting the structure and pricing patterns that are functional in the pharmaceutical market. Most third party programs deliver their prescription drug benefit through a large network of retail pharmacies (that is, independent, chain, mass merchandise, and food & drug store pharmacies). Therefore, they need a price benchmark that can serve as an appropriate and reliable reflection of the prices being paid by these pharmacies for prescription drugs.

Instead, however, the final rule 'piles on' so many other drug purchaser types, who have different prices and who serve different special groups of patients, that the 'average' price has very little meaning for the 'retail pharmacy' network serving the third party's drug program recipients.

210. Once the FULs based on AMP, as defined in the final rule, are published on the web site, other third parties are likely to adopt the Medicaid FULs, or even the brand and generic AMPs in some manner, and use them for their reimbursement caps within their own drug benefit program. Use of this benchmark price by other third parties will further reduce payments to retail community pharmacies and will squeeze their margins. The private market has historically observed new payment methods adopted by Medicare and Medicaid and, after determining their effect, the private market has adapted these new payment methods for their own use. The maximum allowable cost (MAC) method for capping the payment for generic drug products was first created by Medicaid in the 1970s, but is now widely used by virtually all (public and private) third party drug programs.

X. Economic Impact of DRA on Medicaid Access and Pharmacy Providers

211. The economic impact of the final rule on Medicaid reimbursement has two major effects: (1) it will reduce Medicaid drug program expenditures and (2) it will subsequently reduce payments to pharmacies and other providers. Moreover, AMP has been re-defined and its calculation method will change substantially upon implementation of the final rule. The new method for calculating the AMP will affect (i.e., reduce, in general) the amount of rebates collected from manufacturers under the Medicaid program. The new AMP will continue to be used as the basis for determining drug manufacturer rebates under Medicaid.

212. The new AMP will also be used for the first time to set the Medicaid FUL payment limits to pharmacies for multiple source drug products. Other changes have been made to the method of identifying drug product groups that will be subjected to an FUL. The final AMP includes discounts and rebates to both PBM owned and stand alone mail order pharmacies. CMS acknowledged that pharmacies within the retail pharmacy class of trade (independents, chains, mass merchandise, and food & drug store pharmacies) do not have access to these discounts and rebates.[72]

213. Prior to 2007, the AMP data has not been publicly available so that "retail pharmacies cannot determine what the relationship will be between AMP-based FULs and the prices pharmacies pay to acquire these drugs."[73] The GAO conducted an analysis of this relationship using the highest expenditure and highest use drugs for Medicaid. I have reviewed this analysis and find it to be a reasonable estimate given the limited data available. GAO found that the AMP-based FULs were "lower than the average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs."[74] For the 27

[72] CMS, *Medicaid Program; Prescription Drugs*, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178.
[73] GAO, *Medicaid Outpatient Prescription Drugs*, December 22, 2006, p.2.
[74] GAO, *Medicaid Outpatient Prescription Drugs*, December 22, 2006, p.4.

drug products with the highest expenditures, the AMP-based FULs averaged 65% below the average retail pharmacy acquisition cost. For the 27 drug products with the highest number of prescriptions, the AMP-based FULs averaged 15% below the average retail pharmacy acquisition cost. And, for the 23 drug products with high expenditures and high use, the AMP-based FULs averaged 28% below the average retail pharmacy acquisition cost. The AMP-based FULs (even with the 250% multiplier applied to the low AMP) were below the lowest acquisition cost available to retail pharmacies for 43 of the 77 study drugs. These findings indicate that pharmacies are likely to lose money on more than one-half of the generic prescriptions subject to the new AMP-based FULs, even after the 250% multiplier is applied to the new AMP amount.

214. A more recent study by the DHHS, OIG assessed the change in FULs expected with the implementation of the new AMP-based FULs based on the final rule.[75] I have reviewed the methods of this study and find them to be a reasonable basis for analyzing the expected impact of the final rule. The median decrease in the FUL amount was estimated to be 61%. OIG found that 492 of 521 drugs under review (94%) would experience a decrease in the FUL amount, even after the 250% multiplier for AMP. Nearly two-thirds of the drugs (334 of 521) would have a decrease in excess of 50% and 90 of the 521 drugs would have a decrease of greater than 90%. Importantly, OIG found that oese -ytophLsld have

mordoureasion of tin treimbursee FUL eavehdt stantl 43 of

Program; Prescription Drugs, Proposed Rule, *Fed. Reg*., Dec. 22, 2006, p. 77192.). The estimates examined a five-year period with partial-year cuts for 2007 and full-year savings estimates for the years 2008 to 2011. Across the total period 2007 to 2011 the total federal and state savings resulting from Section 6001—Federal Upper Payment Limits and Other Provisions, a savings of $8.04 billion is expected. The payment cuts were to phase in during 2007 and 2008, but reached their full amount in 2009 to 2011. By the year 2011, the annual payment cuts were expected to be $2.14 billion.

217. The $8.04 billion over 5 years (now actually 4 years; i.e., 2008-2011) was estimated by CMS to be the payment reduction to Medicaid from the change in the FUL calculation according to the proposed rule.[78] A number of changes were made to the AMP calculation method in the final rule published by CMS when compared with the proposed rule published by CMS. For example, providers from several channels of distribution were added to the CMS-defined retail class of trade definition to be used for purposes of calculating the AMP and FUL payment rates. The sales to outpatient facilities, clinics, surgical centers, ambulatory care centers, dialysis centers, mental health centers, home infusion providers, specialty pharmacies, home health care providers, and physicians were clarified or added to the list of sales included in AMP. These additional sales added to the AMP are, for the most part, sales that occur at a lower price than for the traditional retail pharmacy class of trade (i.e., independent, chain, mass merchandise, and food & drug store pharmacies). A study I conducted for CMS in 2005 found that clinics could purchase single source drugs at an average of 30.5% less than AWP, while traditional retail pharmacies average a purchase price of only 20.2% below AWP for the same market basket of drug products.[79]

218. The final rule's addition of sales to these other settings is likely to lower the AMP even further than the originally proposed rule would have. There should have been additional price cuts from adding these lower-priced sales to the AMP calculation, however, the estimated savings reported in the final rule were identical to the savings reported in the proposed rule. This would suggest the CMS did not bother to update their savings estimate in the final rule.

219. The CMS comments attempt to minimize the effect on retail pharmacy from the AMP and FUL changes in the final rule. CMS cites that "total retail prescription sales in the United States, including chain drug stores, independent drug stores and supermarkets totaled about $200 billion in 2006."[80] Actually the total outpatient prescription sales in 2006 including independent, chain, mass merchandise, food & drug, and mail order pharmacy were estimated to have been $258.0 billion and for the traditional retail class (excludes mail order) the 2006 prescription sales were about $206 billion.[81] When projected forward to 2011 using a conservative growth rate of 5% per

---

78 See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg*., Dec. 22, 2006, p. 77192.

79 Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report*, CMS, September 26, 2005, p. 47.

80 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39233.

81 Wolters Kluwer Health Pharmaceutical Source Audit Suite, data accessed 6/21/06 as reported in NACDS, *The Chain Industry Profile*, 2007, pp. 67-68.

year,[82] the annual sales will be over $263 billion in 2011 and will total about $1,197 billion for the 5-year period 2007 to 2011. (*See* Exhibit 12). Since the 2007 savings will not be realized, the impact of this new rule will be felt over the four year period 2008 to 2011. The total sales from 2008 to 2011 are expected to be about $981 billion. When comparing the $8.04 billion in expected savings over 4-years to the total prescription sales of $981 billion, the savings represent about 0.6% of the prescription revenue in the United States. From this estimate, CMS concludes "Thus, the effect of this rule will be to reduce retail prescription drug revenues by less than one percent." Assuming the CMS estimate of the impact is correct, this is a true statement, but it is not a fair characterization of the impact this revenue loss will have on retail pharmacies.

220. Medicaid outpatient drug expenditures in 2006 dropped to about one-half of their level in 2005, due to the advent of the new Medicare Part D drug program. Consequently, Medicaid outpatient drug expenditures in 2006 were about $19.6 billion compared to $32.2 billion in 2005.[83] Medicaid outpatient drug expenditures from 2008 to 2011 are expected to be about $93.1 billion. The Medicaid reduction in payments to retail pharmacies from the new AMPs and FULs is estimated to be $7.25 billion for the years 2008 to 2011. (*See* Exhibit 12). This total reduction in payments from 2008 to 2011 amount to a reduction of total Medicaid prescription expenditures of 7.8%. This means that on average pharmacies will be paid 7.8% less for each Medicaid prescription. Again, assuming the CMS estimate of the impact is correct, retail pharmacies will experience a substantial 7.8% reduction in revenue from Medicaid prescriptions.

221. Not only will the reduction in payments from the final rule come from retail pharmacies and the Medicaid prescriptions that they dispense, but this reduction will actually come from the generic prescriptions with FUL limits. CMS estimated that 8.3% of total Medicaid drug expenditures were for drugs with FUL limits.[84] For the years 2008 to 2011, the Medicaid expenditures on FUL drug products would be about $9.20 billion. The total reduction from implementation of the new AMP-based FULs will come exclusively from these generic prescriptions. The 4-year reduction of $7.25 billion represents a 78.7% reduction in payments for FUL-paid generic prescriptions. (*See* Exhibit 12). In other words, the reduction in payments to retail pharmacies will be more than 75% of the current payment rate for generic prescriptions. This represents a *very substantial reduction* in payments to retail pharmacies for generic drug products dispensed to Medicaid recipients.

222. As described above, the reduced payments by Medicaid would come from decreases in the payments to pharmacies for multiple source prescriptions with FUL payment limits. The reduction in generic payments would be about 65% in 2008 and would average greater than 80% in 2009, 2010, and 2011. These reductions in pharmacy payments, if spread evenly across all pharmacies in the United States would mean a loss of more than $22,500 per pharmacy in 2008, $32,300 per pharmacy in 2009, and would

---

82 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39233.

83 Wolters Kluwer Health Pharmaceutical Source Audit Suite, data accessed 6/21/06 as reported in NACDS, *The Chain Industry Profile*, 2007, pp. 67-68.

84 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39236 and 39238.

grow to more than $37,000 per pharmacy in 2011. In reality, however, these losses will not be spread evenly across U.S. pharmacies, but rather will be distributed across pharmacies in proportion to the number of Medicaid recipients served. Those pharmacies serving the most Medicaid recipients will be the pharmacies most affected by these payment cuts.

223. The AMP-based FULs, as described in the final rule, will result in payments to pharmacies that are below the pharmacy's actual costs for many generic prescriptions. I agree with the statement of Steven C. Anderson, President and CEO of the National Association of Chain Drug Stores, who warned of "dramatic under-reimbursements to community pharmacy as a result of the rule." [85] After examining the payment rates that are expected, I also agree with the comment of Bruce T. Roberts, executive vice president of the National Community Pharmacists Association, who said "The new limits on Medicaid reimbursement will be way below what drugstores typically pay for those drugs." Because pharmacies will face a real loss on many generic prescriptions, they will be less inclined to encourage use of generic prescriptions when a brand name prescription would pay their full cost. Again, I agree with the assessment of Bruce T. Roberts when he said that "The proposed rules would have the perverse effect of discouraging the use of generics."[86]

224. CMS explains "we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. . . Because of these uncertainties, we have concluded that this proposed rule is likely to have a "significant impact" on some pharmacies."[87] "We estimate that 18,000 small retail pharmacies would be affected by this regulation. However, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries."[88] These 18,000 pharmacies affected by the implementation of the final rule would account for about one-third of the traditional retail community pharmacies in the United States.

225. Pharmacies, on average, will be paid substantially less for multiple source (generic) prescriptions under the new FUL payment system. The effect, however, will not be even across all pharmacies. Those pharmacies most likely to be affected by the final rule AMP-based FULs are those who serve a large share of Medicaid recipients (e.g., greater than 15% of their patients are Medicaid recipients) and those with a limited number of prescriptions per day due to a geographically limited patient population (e.g., chain or independent pharmacies in rural areas).

226. Reduction in payments will result in substantial losses, and even closures, for a number of pharmacies. The new payment method reduces pharmacy payments without a significant lowering of expenses; therefore, the reduced payments will result in lower

---

85 "AMP Makes Things Tougher for Rx," *Chain Drug Review*, July 23, 2007.
86 *New York Times*, December 18, 2006.
87 CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193.
88 CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193.

net profit before taxes for retail pharmacies. In 2001, the NCPA-Pharmacia Digest reported that 13% of independent pharmacies had an operating loss, 28% had a net profit of less than 2%, 33% had a net profit between 2% and 5%, and 26% had a net profit of 5% or more.[89] Many of these pharmacies are already economically vulnerable and the changes due to the final rule reductions in payments for generic prescriptions are expected to have a significant impact on the pharmacy's long term viability. The majority of pharmacies already operating at a loss (13%) are likely to be closed within 1 to 3 years of the final rule implementation. Additionally some portion of pharmacies in the next two profit level categories (i.e., less than 2%, and 2% to 5%) are expected to be seriously harmed from the final rule cuts. Even if only 10% to 20% of the pharmacies with low net profit (before taxes) become unsustainable and go out of business, that would be 7% to more than 15% of pharmacies, in addition to the 13% already operating at a loss, that may cease to exist. In total, the loss of more than 20% of all retail pharmacies would not be unexpected from payment cuts of the magnitude in the final rule. If a similar proportion of all types of retail pharmacies is affected, the retail pharmacy market may see the loss of 10,000 to 12,000 pharmacies (the vast majority of which would be pharmacies in rural or inner city urban areas) over the next few years.

227. The majority of pharmacies will not be able to make up the lost revenue on sales elsewhere in the pharmacy as suggested by CMS.[90] In fact, a statement made by CMS in the proposed rule is factually wrong. That statement was "Actual revenue losses would be even smaller for two reasons. First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales." Actually, in 2006, the average independent pharmacy derived 98.1% of its sales from prescriptions and the traditional chain pharmacy received 70.9% of its revenue from prescription sales. These pharmacies can not make up losses from 98.1% and 70.9% of their revenue by increased sales in the 1.9% or 29.1% non-prescription side of their pharmacy.[91]

228. Pharmacies faced with these dire economic choices would either refuse to serve Medicaid recipients, or even cease to exist as viable businesses.

229. The loss of a few thousand pharmacies in the United States, especially in rural and inner city areas, would be disruptive to access for many Medicaid recipients.[92] (*See* Exhibit 10). These pharmacies are most likely to be those in rural areas or in low income areas where there are high concentrations of Medicaid beneficiaries. These are the critical access pharmacies for the Medicaid program and the replacement of these critical access pharmacies, once lost, is not easily reversible.[93] (*See* Exhibit 11).

---

89 2002 NCPA-Pharmacia Digest, National Community Pharmacists Association, p. 31.

90 CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg*., Dec. 22, 2006, p. 77192.

91 NACDS, *The Chain Pharmacy Industry Profile*, 2007, p. 51.

92 National Rural Health Association, Protecting Rural Beneficiaries with a Medicare Prescription Drug Benefit, 2003, p.3.

93 Rural Pharmacy Preservation Act, Minnesota Pharmacists Association, 2005. Minnesota loses 38 pharmacies per year; 10-12 of those community pharmacies are not replaced. From July 2004 to February 2005, Minnesota lost 22 pharmacies.

230. Pharmacies are likely to be unwilling to provide prescriptions when the total payment falls short of the total actual drug product costs and the actual costs of dispensing and related additional costs. Pharmacies can be expected to refuse Medicaid recipients because the payments based on the new FUL reimbursement levels are too low, unless an adjustment is made to assure adequate total payments.

231. CMS, in a comment to the final rule, suggests that pharmacies can take steps to mitigate the effect of the sales loss by lowering (acquisition) costs. CMS stated "Actual revenue losses will be even smaller because pharmacies have the ability to mitigate the effects of the rule by changing purchasing practices. The 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs." (FR 39233, final rule) Unfortunately, CMS' suggested mitigation is

Dated: Nov. 13, 2007

STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D.