Minnesota Department of **Human Services**

07 - 0161

February 1, 2007

Patrick E. Flahaven
Secretary of the Senate
231 Capitol
St. Paul, MN 55155

Dear Mr. Flahaven:

The enclosed report is in fulfillment of the Department's obligations under Laws of Minnesota, 2006, Chapter 282, article 16, section 15, subdivision 6. That law requires the Department to convene a pharmacy reform advisory committee, and to report the findings of the advisory committee to the Minnesota Legislature. The Department was not a voting member of the advisory committee.

The same law requires the Department to conduct a study to determine the average cost of dispensing Medicaid prescriptions, to report the results of that study to the Legislature, and to make recommendations to the Legislature regarding Medicaid reimbursement rates for prescription medications. The Commissioner's recommendations and the results of the study are being sent under separate cover.

In accordance with the requirements of Minnesota Statutes, we are sending six copies of the report to the Legislative Reference Library.

Sincerely,

Cal R. Ludeman

Cal R. Ludeman
Commissioner

Enclosure

Implementation of Pharmacy Payment Reform in the Minnesota Medicaid Program: Recommendations to the Legislature

Presented to:

Commissioner

Minnesota Department of Human Services

Submitted by:

Pharmacy Payment Reform Advisory Committee

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January 15, 2007

Implementation of Pharmacy Payment Reform in the Minnesota Medicaid Program

Executive Summary

The pharmaceutical market is in the midst of substantial and dynamic change. One source of change is new federal legislation, known as the Deficit Reduction Act of 2005 (DRA), that will establish new federal upper limits (FULs) for multiple source drugs under Medicaid based on the average manufacturer price (AMP).

The Pharmacy Payment Reform Advisory Committee (PPRAC) was established by the Minnesota legislature to evaluate the Minnesota impact of implementing the federal Deficit Reduction Act of 2005 and to make "recommendations to the commissioner on implementation of pharmacy reforms." The Commissioner of the Department of Human Services was to "report the findings of the study and the recommendations of the advisory committee to the legislature by February 1, 2007. More specifically, the Minnesota law requires that "the commissioner, in consultation with the advisory committee, shall make recommendations to the legislature on how to adequately adjust Medicaid reimbursement rates to pharmacies to cover the costs of dispensing and additional costs to pharmacies."

Prescription payments based on actual drug product cost and actual cost of dispensing and related additional costs can serve as a reasonable basis for pharmacy payment, if the actual costs are accurately measured and continue to be updated over time. The prescription price is a combination of a drug product and the related professional services of the pharmacist that accompany the product when it is provided to the patient. The essential components of a prescription price are: (1) the drug acquisition cost, (2) the cost of dispensing and related additional costs, and (3) a reasonable return on investment (ROI).

Beginning in 2007, the federal upper limits (FULs) for multiple source drugs will be established under Medicaid using the newly defined AMP. These FULs will cap the payment to retail pharmacies for multiple source prescriptions. The AMP, as newly defined, however, is not the same as the average price paid by a retail community pharmacy. First, the AMP does not include the operating cost of the wholesaler. Second, the AMP includes discounts and rebates provided to PBMs and mail order pharmacy, but not available to retail community pharmacies. Consequently, the new AMP is expected to be substantially below the price paid by most retail community pharmacies. When the Office of the Inspector General reviewed the DRA legislation, it recommended 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*."

The Deficit Reduction Act (DRA) provision setting the Medicaid FULs based on the drug manufacturer reported AMP is an effort to connect the payment amount for multiple source drugs to an actual price. The AMP is a reasonable starting point for estimating the acquisition cost for multiple source drug products, but it must be adjusted for the factors by which AMP is known to differ from the price that community pharmacies *actually pay* for the drug product. The FUL, however, will be established using the 'lowest AMP' among all therapeutically equivalent drug products. At the same time that Medicaid payment policy is implemented to assure 'actual' cost payment for the drug product, it is essential that the payment for the cost of dispensing and related additional costs also be adjusted to assure that 'actual' costs and expenses are paid for all components of the prescription payment.

The Pharmacy Payment Reform Advisory Committee worked in conjunction with personnel from the Medicaid program in the Department of Human Services to solicit and contract with an independent outside organization to conduct "a study to measure the average cost of filling a Medicaid prescription in the State of Minnesota." That study was performed by Myers and Stauffer LC—a public accounting firm with experience in conducting such studies for state Medicaid programs. Minnesota pharmacies were surveyed and the study had 515 of 1,065 pharmacies complete usable responses for a net response rate of 48.4%. The final report of that study was provided to the Advisory Committee on December 29, 2006.

The cost of dispensing (COD) method used for the study did not include certain additional real costs incurred by the pharmacy, but not accounted for in the baseline COD including: uncollected Medicaid copays, state and federal income tax, pharmacy return on investment, and Minnesota Wholesale Drug Tax. The Minnesota Wholesale Drug Tax is a 2% charge added on to the wholesale cost of all prescription drug purchases in Minnesota. This is a very real cost to the pharmacy and nearly all private third party programs pay this tax as an add-on to the prescription claims cost, but Medicaid does not.

Findings from the Advisory Committee's work and the cost of dispensing study are summarized below, and are followed by recommendations to the Commissioner of Human Services and to the Minnesota legislature.

Findings:

- The new upper limits (FULs) based on 250% time the lowest AMP were below the lowest pharmacy acquisition cost for more than one-half (43 of 77) of the top Medicaid multiple source drugs studied by the GAO in 2006.
- The new AMP-based FULs were 15% to 65% below the average pharmacy acquisition cost in 2006.
- Most Minnesota pharmacies (76%) had a baseline COD between $7.00 and $18.00 for 2006.
- The baseline COD for pharmacies filling Minnesota Medicaid prescriptions in 2007 is $9.88.
- The current Medicaid dispensing fee ($3.65 per prescription) is substantially below actual costs.
- Pharmacies that had a higher share of Medicaid prescriptions showed a higher average COD.
- Pharmacies with more than 10% Medicaid prescriptions had a baseline COD of $10.30 for 2007.
- The cost for Minnesota pharmacies filling Medicaid prescriptions in 2007 is $12.92.
- The cost for Minnesota pharmacies filling Medicaid prescriptions in 2007 is $12.06, if the FUL is increased by 2% to account for the Minnesota Wholesale Drug Tax.
- The cost for Minnesota pharmacies with more than 10% Medicaid prescriptions in 2007 is $13.34.

Recommendations:

Several specific changes are needed to avoid a substantial reduction in access to pharmacy services for Medicaid recipients.

- Adjustment should be made to the pharmacy payment for multiple source prescriptions at the same time as the new FULs are implemented, so that both the drug product cost and the dispensing fee will be based on actual costs.
- The Medicaid payment should be set to cover both the actual drug product costs as well as the actual cost of dispensing plus related additional costs.
- The 2007 Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be set at $12.92 per prescription to cover actual costs including the Minnesota Wholesale Drug Tax, or at $12.06 per prescription, if the FULs are increased by 2% to account for the Minnesota Wholesale Drug tax.
- The Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be adjusted each year in the future either by a cost of dispensing study or an inflation adjustment based on the CPI-All Items for urban consumers.
- To prevent substantial harm or loss of pharmacies with greater than 10% Medicaid prescriptions, the 2007 Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be set at $13.34 per prescription to cover actual costs including the Minnesota Wholesale Drug Tax, or at $12.48 per prescription, if the FULs are increased by 2% to account for the Minnesota Wholesale Drug tax.

Other recommendations identify important policy and performance measures that need to be monitored.

- Since the AMP amounts will not be known until the new FUL provisions are implemented, the actual change in payment for multiple source prescriptions under Minnesota Medicaid due to this new method for setting FULs should be evaluated after the program has begun.
- The impact on pharmacies with a higher than proportionate share (greater than 10%) of Medicaid prescriptions and those pharmacies in rural or low income areas should be monitored to avoid loss of the pharmacies most critical to Medicaid recipients.
- The Medicaid payments for multiple source prescriptions should be monitored to make sure that payment is sufficient to cover the actual pharmacy costs for dispensing these generic prescriptions. This assessment of actual costs should include cost of dispensing and related additional costs as well as actual purchase prices that are generally and currently available to retail community pharmacies for multiple source drug products.

Due to the introduction of the Medicare Part D program and the shift of dual eligibles from Medicaid to Medicare, the number of fee-for-service Medicaid prescriptions in Minnesota for 2006 is estimated to have fallen by 45% to about 3.6 million prescriptions. This 2006 decline in Medicaid prescriptions amounts to about 2.1 million fewer prescriptions and about $200 million less in expenditures. Conservatively, the estimated savings to Minnesota Medicaid from the change in the FUL calculation is expected be in the range $84 million to over $160 million during the 5-year period 2007 to 2011.

About 90% of the savings expected from implementation of the DRA is expected to come from lower payments to pharmacies. Since the savings to the Medicaid program would largely be realized through lower payments to pharmacies, the Minnesota savings in Medicaid drug expenditures from the reduction of FUL payments to pharmacies could be used to provide revenue for adjusting the pharmacy payments to avoid under-payment and loss of Minnesota pharmacies. The estimated savings to Minnesota Medicaid are expected to exceed the amount needed to adequately reimburse pharmacies for actual dispensing costs of Medicaid prescriptions.

Pharmacies in Minnesota will be paid substantially less for multiple source (generic) prescriptions under the new FUL payment system. The average Minnesota Medicaid price for a prescription without a FUL (mostly brand name drugs) in 2005 was $116.41, while the average price for prescriptions with FULs (generics) was $16.78 in 2005. The greatest savings to Medicaid comes from prescribing and dispensing of generics, not from underpaying pharmacies for multiple source (generic) prescriptions. 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 may 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.

CMS analysis indicates that the new FULs would cut reimbursement so much that 350 or more Minnesota pharmacies would be significantly impacted and access for many Medicaid recipients would be disrupted. The pharmacies most affected are more likely to be in rural areas or in low income areas where there are high concentrations of Medicaid beneficiaries. These are the critical access pharmacies for the Minnesota Medicaid program and replacement of these critical access pharmacies, once lost, is not easily reversible.

This drastic reduction in Minnesota pharmacies serving the Medicaid population can be avoided by adjusting the dispensing fees to reflect actual costs at the same time as the drug product allowance (FULs) for multiple source prescriptions is adjusted based on actual costs. Because the pharmaceutical market is so dynamic and various players in the market may shift their pricing patterns and market behaviors in light of the new Medicaid payment scheme, the actual costs and the impact of the DRA on pharmacies serving Minnesota Medicaid recipients should be monitored over time to assure adequate access to pharmaceutical services.

Implementation of Pharmacy Payment Reform in the Minnesota Medicaid Program

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Implementation of Pharmacy Payment Reform in the Minnesota Medicaid Program

I. Introduction

The Medicaid drug program is in the midst of substantial and dynamic change. Prescription drugs, an optional service under Medicaid, are the program's most frequently used health benefit. Medicaid has been the fastest growing expense for most states for over 10 years. Drug program expenditures have grown at double digit rates for years and at a rate faster than the Medicaid program overall.

Contrary to the long-standing trend, Medicaid had a decline in total spending during 2006.[1] Notably, Minnesota Medicaid drug expenditures decreased by about 45% in 2006. This dramatic drop in Medicaid drug expenditures was primarily due to the January 1, 2006 implementation of the Medicare Part D prescription drug program. The Medicare Part D program was created through provisions contained in the federal Medicare Modernization Act (MMA)—the most significant change to Medicare since its inception in 1965. Under this new Medicare Part D program, the coverage of prescription drugs for dual eligibles (recipients eligible for both Medicare and Medicaid) shifted from the state-administered Medicaid program to the federally-administered Medicare program. This shift meant that about one-half of the former Medicaid drug expenditures were now covered by the new Medicare Part D program.

Another recently enacted federal law has also directed revisions to the Medicaid drug program. The Deficit Reduction Act of 2005, Pub. Law 109-171 (DRA) provided a variety of changes to Medicaid including revisions to the payment for pharmaceuticals. The DRA's primary changes to the Medicaid drug program concern: (1) revisions to, and clarification of, the definition of average manufacturer price (AMP) which serves as the basis for determination of manufacturer rebates to Medicaid, and (2) revisions to the method of establishing federal upper limits (FULs) for payments to pharmacies for multiple source (generic) drugs dispensed to Medicaid recipients. A more detailed description of the provisions of the DRA and their impact on Medicaid, as well as its beneficiaries and pharmacy providers, is provided in a later section of this report.

Implementation of the Deficit Reduction Act of 2005 permits state flexibility and at the same time creates some degree of uncertainty about the impact of the new payment rules for prescription drugs on access by Medicaid beneficiaries and payments to pharmacy providers.[2] The Minnesota legislature recognized that the change in Medicaid prescription payment methods required by the DRA would raise access and adequacy of compensation issues. Consequently, the Minnesota legislature passed a law establishing the "Pharmacy Payment Reform Advisory Committee." That Committee was appointed in June of 2006 and has conducted work and held meetings through January 15, 2007.

This report describes: (1) the formation and charge to the Pharmacy Payment Reform Advisory Committee; (2) the relevant provisions of the Deficit Reduction Act of 2005; (3) reasonable payment to pharmacies for Medicaid prescriptions subject to FULs; (4) results of a cost of dispensing study and additional costs for pharmacies; and (5) findings and recommendations for implementation of the DRA provisions within the Minnesota Medicaid program.

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[1] Dennis Cauchon, "Medicaid Spending Sees First Decline," *USA Today*, November 26, 2006.

[2] U.S. Government Accountability Office, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, December 22, 2006, GAO-07-239R Medicaid Federal Upper Limits, p.5. Within guidelines established by federal statutes, regulations, and policies, each state: (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program.

II. Pharmacy Payment Reform Advisory Committee: Members, Process and Charge

The 2006 Minnesota legislature passed a law creating the Pharmacy Payment Reform Advisory Committee (Laws of Minnesota 2006, Chapter 282, Article 16, Section 15) [See Appendix 1.]. As specified in the law, the Committee was to be composed of seven private sector members [See Appendix 2 for a list of members and their biographical information] who served without compensation. The Committee members were appointed by the Commissioner of the Department of Human Services in June of 2006 and serve until the Committee expires on January 31, 2008. The work of the Committee has been conducted during six public meetings and through individual efforts of Committee members before and after those meetings [See Appendix 3 for public meeting dates and agendas]. The Committee was staffed by personnel from the Medicaid program in the Department of Human Services.

The authorizing Minnesota legislation required that the Department of Human Services conduct a study to determine the average cost of dispensing Medicaid prescriptions in Minnesota. This study was to be conducted by an independent third-party entity. On August 7, 2006, the Department issued a request for proposals for qualified contractors to: "conduct a study to measure the average cost of filling a Medicaid prescription in the State of Minnesota." Department staff reviewed the responses and in early September selected the vendor to conduct this study. The public accounting firm of Myers and Stauffer LC was selected to conduct the study. The initial survey was sent out on October 12, 2006 with a letter of introduction from the Minnesota Department of Human Services and a letter of explanation from Myers and Stauffer. Follow-up letters to encourage pharmacies to complete the survey were sent out by Myers and Stauffer on October 24, 2006 and November 13, 2006. Also, the response date was extended by two weeks from November 17, 2006 to November 30, 2006. The Minnesota Pharmacists Association sent two letters to pharmacists expressing their support of, and encouragement to participate in, the study. These letters were sent on October 16, 2006 and November 13, 2006. The survey responses were entered, edited, and analyzed by Myers and Stauffer and a completed study report was provided to the Committee on December 29, 2006. Details of the study response and findings are discussed in a later section of this report.

The charge to the Advisory Committee was to "use the information from the cost of dispensing study and make recommendations to the commissioner on implementation of pharmacy reforms contained in title VI, chapter IV, of the Deficit Reduction Act of 2005." The charge to the Commissioner of the Department of Human Services was to "report the findings of the study and the recommendations of the advisory committee to the legislature by February 1, 2007. More specifically, the Minnesota law requires that "the commissioner, in consultation with the advisory committee, shall make recommendations to the legislature on how to adequately adjust Medicaid reimbursement rates to pharmacies to cover the costs of dispensing and additional costs to pharmacies. Reports shall include the current level of dispensing fees paid to providers for dispensing Medicaid prescription drugs and an estimate of revenues required to adequately adjust reimbursement to cover the cost to pharmacies for dispensing Medicaid prescription drugs to ensure that:

(1) reimbursement is sufficient to enlist an adequate number of participating pharmacy providers so that pharmacy services are as available for Medicaid recipients under the program as for the state's general population;
(2) Medicaid dispensing fees are adequate to reimburse pharmacy providers for the cost of dispensing prescriptions under the Medicaid program;
(3) Medicaid pharmacy reimbursement for multiple-source drugs included on the federal upper reimbursement limit is set at the level established by the federal government under United States Code, title 42, section 1396r-8(e)(5); and
(4) the new payment system does not create disincentives for pharmacists to dispense generic drugs."

III. Implementation of the Deficit Reduction Act of 2005

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 section is limited to a description of the issues raised by implementation of the DRA provisions related to definition of average manufacturer price (AMP) and the determination of federal upper limits (FULs) for multiple source drug products under Medicaid. Implications of these changes and identification of issues for the Minnesota Medicaid program will be described.

A. Average Manufacturer Price in Medicaid: Two Roles

The AMP is a 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 Deficit Reduction Act of 2005 (DRA) 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 sections on the new proposed rule for re-definition of AMP and the method for determining the FUL for drug ingredient costs of multiple source prescriptions under Medicaid.

B. Definition of AMP

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. Section 1927(k)(1) defines AMP as "the average price paid to the manufacturer by wholesalers for drugs distributed to the retail 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).

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.[3] 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 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.*"

Prior to the DRA, the AMP calculation for the 'retail class of trade' has included prices to mail order pharmacy along with the prices to other traditional retail pharmacy types (independent, chain, food and drug, and mass merchant pharmacies). AMP, as defined and used prior to the DRA, was an average price

[3] 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.

received by the manufacturer from all purchasers who are in, or distribute to pharmacies in, the retail 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.[4] 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.[5]

The Congressional Budget Office (CBO) examined the relationship of AMP to the average price paid by pharmacies. CBO found that for single source drug products the AMP was 5% below the average price paid by independent pharmacies.[6] The inter-decile range (90^{th} to 10^{th} percentile) showed that AMP ranged from 2% to 10% less than the independent pharmacy average prices. This means that if AMP was used to set the drug product cost for independent pharmacies, the pharmacy would lose 5% on average, and up to 10% in some cases, on the drug product cost reimbursement for every prescription. For multiple-source brand-name drug products the AMP was 12% below the average price paid by independent pharmacies with an inter-decile range of 2% to 27%. Finally, for multiple-source generic drug products the AMP was 32% below the average price paid by independent pharmacies with an inter-decile range of 8% to 61%.

The CMS Proposed Rule for prescription drugs under the Medicaid program implementing provisions of the DRA has proposed revisions to the definition of, and method for calculation of, AMP.[7] The Proposed Rule acknowledges that with the advent of the DRA, "AMP will serve two distinct purposes: for drug rebate liability and for payments (to pharmacies)."[8] The CMS analysis goes on to note that the drug manufacturers would benefit from a broad definition of the 'retail class of trade' that would result in a lower AMP which would lead to lower drug manufacturer rebate liabilities. At the same time, however, there is tension in the opposite direction for pharmacies from this broad definition of the retail class of trade that results in a lower AMP for use in estimating pharmacy actual acquisition costs.

To the degree that the AMP 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.

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[4] 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, that chain pharmacy experiences additional costs above the AMP similar to the operating costs a wholesaler would charge and add on to AMP.

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

[6] See Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, Table 5, p.19. The price relationships reported by the CBO were based on IMS Health data from the fourth quarter of 2003. Note that the AMP used in the CBO study included mail order pharmacy prices, but not PBM rebates and discounts as described in the CMS proposed rule for calculating the AMP when the DRA is implemented.

[7] 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.

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

CMS has chosen to align the definition of AMP, as described in the proposed rule, most closely with an accurate reflection of the revenue received by the manufacturer as characterized by the following statement: "We believe that AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer."[9] This position is reflected in the proposed factors to be included in calculating the AMP. The proposed new AMP would include: (1) discounts, rebates and other considerations to mail order pharmacies; (2) discounts, rebates and other considerations to PBMs; (3) administrative and service fees, except those which are *bona fide* fees for services at a fair market price that the manufacturer would otherwise have to purchase; (4) prices from direct patient sales such as manufacturer-sponsored patient assistance programs; (5) manufacturer "coupons redeemed by any entity other than the consumer" directly to the manufacturer; and (6) sales of authorized generics. Each of these factors included in the AMP calculation helps to assure that the AMP appropriately reflects the net revenue received by the drug manufacturer, but at the same time each of these factors represent an adjustment to AMP that moves AMP further away from the price that must be paid by a community pharmacy (i.e., an independent, chain, food and drug, or mass merchant pharmacy).

CMS justifies their definition of the retail class of trade including mail order pharmacy and PBMs based on the fact that this definition would lower the manufacturer rebate liabilities to Medicaid. This retail class of trade definition does not increase the accuracy of AMP with respect to the price paid by individual retail pharmacies.

> "We considered several options to define what prices should be included in AMP. We considered including only prices of sales to retail pharmacies that dispense drugs to the general public (e.g., independent and chain pharmacies) in retail pharmacy class of trade and removing prices to mail order pharmacies, nursing home pharmacies (long-term care pharmacies), and PBMs. This definition would address the retail pharmacy industry's contentions that an AMP used for reimbursement to retail pharmacies should only reflect prices of sales to those pharmacies which dispense drugs to the general public.
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> The exclusion of prices to mail order pharmacies, nursing home facilities (long-term care facilities), and PBMs would substantially reduce the number of transactions included in AMP. Removal of these prices would simplify AMP calculations for manufacturers because it is our understanding that certain data (e.g., PBM pricing data) are difficult for manufacturers to capture. In addition, removal of these prices would address differing interpretations of CMS policy identified by the OIG and the Government Accountability Office (GAO) due to the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP. However, such a removal would not be consistent with past policy, as specified in Medicaid Drug Rebate Program manufacturer releases 28 and 29 would likely result in a higher AMP, and would result in an increase in drug manufacturers' rebate liabilities."[10]

CMS expresses the view that AMP is intended to represent "actual prices" to the retail class of trade, but then goes on to re-define the retail class of trade as a set of buyers who admittedly[11] have substantially

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[9] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77179.

[10] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178. Releases 28 and 29 are at: (http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage).

[11] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178. CMS states in the proposed rule: "We note that even were we to incorporate this change, retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for some manufacturer price concessions."

different prices available in the market. "While there is no requirement that States use AMPs to set payment amounts, we believe the Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices of sales to the retail pharmacy class of trade."[12] Ironically, the proposed definition of "retail class of trade" will again result in an AMP that is not a price generally and currently available to the majority of the pharmacies providing prescriptions to Medicaid recipients.

C. Determination of FULs

Implementation of the DRA provides the first federal use of AMP as a factor in setting pharmacy payment for drug product costs under Medicaid. The AMP is to be used in estimating the acquisition cost for purposes of setting the federal upper limit (FUL) to be applied in aggregate[13] to State Medicaid expenditures for multiple source drug products. Prior to implementation of the DRA, the rule for setting FULs held that state Medicaid "payments for multiple source drugs identified and listed must not exceed, in the aggregate, payment levels determined by applying, for each drug entity, a reasonable dispensing fee established by the agency, plus an amount that is equal to 150% of the published price for the least costly therapeutic equivalent (using all available national pricing compendia) that can be purchased by pharmacies in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size."[14]

The DRA and proposed rule would change a number of the criteria for determining the Medicaid FUL for multiple source drugs including: (1) the price basis for calculating the FUL, i.e., AMP versus AWP or WAC; (2) the package size of the drug products whose prices would be considered in setting the FUL, i.e., all package sizes versus package sizes of 100 or the most commonly listed size; (3) the number of therapeutically equivalent drug products required for establishing an FUL, i.e., two versus three; (4) authorized generics would be counted when determining if there are two or more products listed in the national compendia, whereas they previously were not considered; and (5) two or more suppliers may include manufacturers, wholesalers, re-packagers, or re-labelers who list a drug in the nationally available pricing compendia, whereas they previously were not considered. Each of these factors will serve to increase the number of drug product groups with FULs and to lower the calculated FUL amount applied to these multiple source drug products. The proposed DRA rule would apply a multiplier of 250% of the AMP rather than the previous 150% of the published price for the least costly therapeutic equivalent. The increase in the multiplier amount appears to be more than offset by the five changes noted above that serve to lower the AMP compared to the pharmacy actual price and to lower the resulting FUL amount.

The DRA proposed rule would determine the AMP at the 9-digit NDC (National Drug Code) level as it has been done previously under the Medicaid Drug Rebate program.[15] This would, however, be a substantial change to the method for determining FUL amounts. The FUL amounts have historically been determined based on "quantities of 100 tablets or capsules (or, if the drug is not commonly available in

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

[13] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178. The proposed rule clarifies that "the upper limit for multiple source drugs applies in aggregate." This means that the state Medicaid program does not have to use the actual FUL for each and every specific multiple source drug product subject to an FUL, but that "the agency's payments for multiple source drugs identified and listed must not exceed, in the aggregate, payment levels determined by applying, for each drug entity, . . . an amount that is equal to 150% of the published price for the least costly therapeutic equivalent . . ."

[14] *Code of Federal Regulations*, Part 447.332(b).

[15] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77177. "We are proposing to use the currently reported 9-digit AMP for calculating the FUL. Changing the current method of calculating the AMP would require manufacturers to make significant changes to their reporting systems and have an unknown effect on the calculation of rebates in the existing Medicaid Drug Rebate Program."

quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size."[16] Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000, or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. One of the most popular generic drugs (i.e., generic ranitidine 150 mg tablets) comes in a package size as large as 40,000 tablets per drum. The proposed rule, however, seems to misunderstand the economic impact of excess inventory when it comments "The resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent that it does have an impact, it would encourage pharmacies to buy the most economical package size."[17] "Second, pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices."[18]

The lowest AMP for a given group of two or more therapeutically equivalent drug products will serve as the basis for establishing the FUL. The lowest AMP will then be multiplied times 250% to actually set the FUL. Several explanations are given for this 250% factor including: (1) adjustment for the effect from inclusion of larger package sizes in the AMP calculation;[19] (2) certain multiple source drug products may not be widely available at the reported AMP either across all regions or to all types of pharmacy purchasers; and (3) some generic products will have an AMP that is substantially below the price of all other therapeutically equivalent drug products.[20]

For quite some time prior to the DRA, the FULs were established based on the lowest published price (AWP or WAC) when three or more 'therapeutically equivalent' drugs were on the market.[21] The proposed rule follows the DRA requirement that an FUL be established when therapeutic equivalence has been determined for "two or more" drug products. The "FUL will be set when at least two suppliers (e.g., manufacturers, wholesalers, re-packagers, or re-labelers) list the drug in a nationally available pricing compendia (e.g., *Red Book*, *First DataBank*, or *Medi-Span*)."[22] Thus, the number of drug product groups that will have FULs under the proposed new DRA rule will be substantially broadened from the current number of FULs. At present there are about 500 drug product groups with an established FUL. Under the proposed new rule, the number of drug product groups with FULs could grow to 3,000 or more.[23]

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[16] See *Code of Federal Regulations*, Part 447.332(b).

[17] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193. "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. Although it is clear that the effects will be small on the great majority of pharmacies, whether chain or independent, we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."

[18] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193.

[19] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77187. "We expect that because the AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent it does have an impact, it would encourage pharmacies to buy the most economical package size."

[20] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77188.

[21] The term 'therapeutically equivalent drugs' is used in the proposed rules to mean "drugs that are identified as A-rated in the current edition of the FDA's publication, "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (including supplements or successor publications)." See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77187.

[22] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77187.

[23] Analysis of data on FULs, state MACs, commercial MACs, and other pricing data provided through personal communication with George Saunders, Pharm.D., Vice President, Professional Services, AmeriSourceBergen, e-mail on June 28, 2006 and an excel file titled "FUL vs Comm MAC vs State MAC 10052005.xls".

Minnesota also has State MACs or FULs for 734 drug product groups, although this still represents less than one-fourth of the total drug product groups expected to have FULs under the proposed rule.[24]

Historically, the FULs have been updated periodically which meant 2 to 4 times a year and sometimes not even that frequent. The DRA-driven proposed rule would require manufacturer's to report the AMP on a monthly basis to CMS and CMS to post these AMPs on a public website. The DRA statutes state that the AMP-based FULs were to be implemented on January 1, 2007. Since the DRA proposed rule was not issued until mid-December 2006, the legislated timeline was not possible. CMS will receive and respond to comments on the proposed rule within a 60-day period. After that time CMS is likely to implement the final rule and begin collecting manufacturer AMP data. With processing time for both the drug manufacturers and CMS, the first published AMPs and FULs under the propose new rule are not likely to be available until summer of 2007.

D. Impact of DRA on Medicaid and Pharmacy Providers

The impact of DRA for Medicaid and pharmacy providers is in opposite directions. First, AMP has been re-defined and its calculation method will change substantially. The new AMP will be used as the basis for determining drug manufacturer rebates under Medicaid. AMP will also be used to set the Medicaid FULs 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.

CMS commentary on the proposed rule indicates that the States, collectively, are expected to receive about $3.5 billion over a five-year period. At the same time, "the State administrative costs associated with this regulation are minor as States currently pay based on a FUL for drugs subject to that limit, determine their drug reimbursement rates, and collect claims information on physician-administered drugs."[25]

AMP has been revised to more closely represent the actual net revenue that a given drug manufacturer receives from a specific drug product. These revisions address concerns expressed by the OIG and others about variation in the methods used by drug manufacturers to calculate and report AMP data to CMS. However, the decisions that move AMP closer to the drug manufacturer's actual net revenue (and price per unit) serve to move AMP further away from the actual acquisition cost to retail pharmacies (and especially independent and chain pharmacies). The AMP includes discounts and rebates to both mail order pharmacy and PBMs. Retail community pharmacies (independents and chains) do not have access to these discounts and rebates.[26]

The AMP data is not 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."[27] The GAO conducted an analysis of this relationship using the highest expenditure and highest use drugs for Medicaid. 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."[28] For the 27 drug products with the highest expenditures, the AMP-based FULs averaged 65% below the average retail pharmacy acquisition cost.

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[24] Minnesota Medicaid has 734 drug product groups with State MACs which includes the 496 drug product groups with FULs. The number of State MACs in Minnesota compared to other states ranks 24th with the largest number of State MACs being nearly 1,400 in Washington. See George Saunders, AmeriSourceBergen, e-mail on June 28, 2006 and excel file titled "FUL vs Comm MAC vs State MAC 10052005.xls".

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

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

[27] See GAO, *Medicaid Outpatient Prescription Drugs*, December 22, 2006, p.2.

[28] See GAO, *Medicaid Outpatient Prescription Drugs*, December 22, 2006, p.4.

For the 27 drug products with the highest number of prescriptions, the AMP-based FUL averaged 15% below the average retail pharmacy acquisition cost. And, for the 23 drug products with high expenditures and high use, the AMP-based FUL 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 loose money on more than one-half of the generic prescriptions subject to the new AMP-based FULs.

The Regulatory Impact Analysis section of the CMS proposed rule notes that "Retail pharmacies would be affected by this regulation as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs."[29] The regulatory impact analysis goes on to say that "The savings to the Medicaid program would largely be realized through lower payments to pharmacies." The effect of lower FULs is expected to be $800 million in 2007 and will increase to about $2 billion annually by 2011 with a total savings of $8.04 billion over 5 years. The New York Times observed that "90 percent of the savings would come from pharmacies."[30]

The estimated savings to Minnesota Medicaid from the change in the FUL calculation is $84.4 million over the 5-year period 2007 to 2011, just for the drug products that already have FULs.[31] This savings would come from decreases in the payments to pharmacies for multiple source prescriptions with FULs. The reduction in generic payments would be about 35% in 2007, 51% in 2008 and would reach 67% in 2009 to 2001 (See Exhibit 1). These reductions in Minnesota if evenly spread across all pharmacies in the state would mean a loss of more than $7,500 in 2007, $12,500 in 2008, and would grow to more than $20,800 in 2011. In reality, however, these losses will not be spread evenly across Minnesota pharmacies, but will disproportionately affect those pharmacies serving the largest number of Minnesota Medicaid recipients.

Bruce T. Roberts, executive vice president of the National Community Pharmacists Association, said "The new limits on Medicaid reimbursement will be way below what drugstores typically pay for those drugs." He went on to say that "The proposed rules would have the perverse effect of discouraging the use of generics."[32] 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."[33] "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."[34] The 18,000 pharmacies affected by the DRA implementation account for about one-third of the community pharmacies in the United States. Based on CMS' analysis, these changes would have a significant impact on about 350 of the 1,078 pharmacies in Minnesota.

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[29] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77192.
[30] Robert Pear, "U.S. Is Proposing to Cut Medicaid's Drug Payments," *New York Times*, December 18, 2006.
[31] The number of drug product groups with FULs is expected to nearly double and the Minnesota Medicaid 5-year savings would also double to about $160 million over the 5-year period.
[32] See *New York Times*, December 18, 2006.
[33] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193.
[34] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193.

IV. Reasonable Payment to Pharmacies

Prescription drugs are the most frequently used health service in Medicaid. Payment for prescriptions involves a high volume of relatively low dollar value claims. Nationwide, the Medicaid program covered about 600 million prescriptions and spent nearly $40 billion in 2005. In Minnesota, the Medicaid fee-for-service system covered nearly 5.8 million prescriptions and spent $440 million in 2005. The average payment per Medicaid prescription was $66.84 for the U.S. and $67.89 for Minnesota in 2005. Due to the introduction of the Medicare Part D program and the shift of dual eligibles from Medicaid to Medicare, the number of fee-for-service Medicaid prescriptions in Minnesota for 2006 is estimated to have fallen by 45% to about 3.6 million prescriptions. [See Exhibit 2.]

The majority of the growth in Medicaid drug program expenditures over the past decade has come from growth in the average prescription price with utilization growth accounting for a lesser share of the increase in expenditures. However, the majority of the prescription price growth has come from increases in drug product cost while dispensing fees have held steady, or even gone down in constant dollars, over the same time period.[35] States have routinely set the dispensing fees for pharmacies, but have allowed the drug manufacturer prices to grow relatively unfettered. Obviously setting the dispensing fee and the pharmacy payment amount is not an effective means for moderating growth rate in manufacturer drug product prices or Medicaid drug program expenditures. Not only have the drug product prices grown substantially in recent years, but concern has also developed about the list price (e.g., AWP or WAC) of drug products in comparison with the actual transaction prices (e.g., AMP or ASP). The reported list prices of drug manufacturers often differ considerably from actual transaction prices. While the relationship of the list price and the actual price for single source brand name drug products are usually predictable, the list price to actual price relationship for generic drug products varies widely.[36, 37]

The Deficit Reduction Act (DRA) provision setting the Medicaid FULs based on the drug manufacturer reported AMP is an effort to connect the payment amount for multiple source drugs to an actual price. Payment of the actual price for a drug product is "the appropriate conceptual basis for the payment policy."[38] At the same time that Medicaid payment policy is implemented to assure 'actual' cost payment for the drug product, it is essential that the payment for the cost of dispensing and other costs also be adjusted to assure that 'actual' costs and expenses are paid. *Prescription payments based on actual drug product cost and actual cost of dispensing and related additional costs can serve as a reasonable basis for pharmacy payment*, if the actual costs are accurately measured and continue to be updated over time. If, however, the payment method sets the prescription payment amount for either drug product cost or cost of dispensing and related additional costs, below the actual costs, the potential for problems with Medicaid beneficiary access to pharmacy services will be greater. Pharmacies are likely to be unwilling to provide prescriptions when the total payment falls short of the total actual drug product costs and the costs of dispensing and other costs.[39]

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[35] Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Final Report, Abt Associates, Inc., CMS Contract #500-000-0049, Task Order 1, August 30, 2004, pp 4-6. Also, see Exhibits 2 and 3.

[36] Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, Publication No.2703, January 2007, Table 2, p.19.

[37] Marian V. Wrobel, Stephen W. Schondelmeyer, Shuchita Agarwal and Janice Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost*, Final Report, Abt Associates, Inc., CMS Contract #500-00-0049, Task Order 1, September 26, 2005, p.55.

[38] See Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, August 30, 2004, p.16.

[39] See Wrobel, Schondelmeyer, et al, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost*, September 26, 2005, p.56.

A. Essential Components of Pharmacy Payment

The payment to a pharmacy for a prescription can be broken down into several types of costs. The essential components of a prescription price are: (1) the drug acquisition cost, (2) the cost of dispensing and related additional costs, and (3) a reasonable return on investment (ROI). These components and their relationships are shown in the following equation:

$$\text{Prescription Payment Amount} = \underbrace{\overbrace{\text{Drug Acquisition Cost}}^{\text{COGS}} + \overbrace{\text{Cost of Dispensing}}^{\text{Breakeven Cost}}}_{\text{Gross Margin}} + \text{ROI}$$

The drug acquisition cost is commonly referred to as the cost of goods sold (COGS). The prescription price less the COGS is known as the Gross Margin (that is, the cost of dispensing plus the return on investment. The 'breakeven cost' is the sum of the drug acquisition cost and the cost of dispensing.

Minnesota Medicaid payment policy takes advantage of market-based pricing by requiring pharmacies to report their usual and customary price and by paying that price if it is lower than the established formula for pharmacy payment. The established Medicaid payment formula for prescriptions appears to be, but really is not at just a single rate (i.e., a dispensing fee or $3.65 and product costs paid as AWP-12%). Policy-makers often focus on this formula as a single rate and assume that all prescriptions are paid on that basis. Actually the payments to pharmacies for prescriptions are based on the 'lower of' several criteria as follows:

- the pharmacy's usual and customary price; or the
- the estimated acquisition cost (EAC) plus a reasonable dispensing fee, where the EAC is determined by the characteristics of the drug product as follows:
    - the federal upper limit (FUL) for multiple source drugs with a published FUL;
    - the state maximum allowable cost (State MAC) for multiple source drugs with a published State MAC; or
    - the average wholesale price (AWP) less a certain percent for all other drugs.

In Minnesota, the prescriptions with FULs account for about 40% of all prescriptions and about 9% of total drug payments.[40] Prescriptions for drugs with state MACs are estimated to account for another 10% to 15% of prescriptions. The usual and customary price is estimated to be the pricing basis for between 5% and 15% of Minnesota Medicaid prescriptions. Finally, the payment of prescriptions at AWP – 12% plus a $3.65 dispensing fee is estimated to account for the payment method for only 25% to 40% of the Medicaid prescriptions.

B. Drug Product Cost

The drug product cost payment is the single largest part of the cost of most prescriptions. On average, the drug product cost accounts for about 70% to 75% of the total prescription price. Ideally, the drug product cost allowance under Medicaid would be based on the actual transaction price for each and every prescription. Tracking the millions of transactions to accomplish this, however, would be impractical. For that reason, Medicaid has for decades relied upon the concept of 'estimated acquisition cost'. The 'estimated acquisition cost' with respect to Medicaid prescription payment policy is defined as: "an

[40] Minnesota Medicaid data as reported in *Survey of the Average Cost of Filling a Medicaid Prescription in the State of Minnesota*, Myers and Stauffer, December 2006, p.10.

estimate of the price generally, and currently, paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers."[41]

The actual acquisition cost (AAC) for prescription drugs has historically been estimated for both Medicaid and the private market by using the list price known was average wholesale price (AWP). AWP is a list price represented as the price a pharmacy would pay the wholesaler for the drug product. The actual prices pharmacies pay the wholesaler are known to be substantially below the AWP. For example, for single source brand name drug products the Congressional Budget Office and others have found that the actual average purchase price is 83% of AWP or AWP less 17%.[42] The relationship between AWP and AAC is considered to be fairly predictable, constant, and reliable.

In contrast, the relationship between AWP and AAC for multiple source drug products is quite variable across drug products and over time. The AAC may range from 17% to more than 95% less that the AWP. The Medicaid program realized that AWP was not the best estimate of AAC for multiple source drugs, but it did not have a practical way to know the AAC or transaction prices. The development of the Medicaid Drug Rebate Program in 1991 did create the average manufacturer price (AMP) which was the actual revenue received by the manufacturer when selling its drug product to a wholesaler, pharmacy, or other provider. The use of the AMP, however, was limited, until the passage of the DRA, to use only for purposes of operating the manufacturer rebate program. The DRA has re-defined the AMP and will make the AMP publicly available on a monthly basis.

The AMP is a reasonable starting point for estimating the acquisition cost for multiple source drug products, but it must be adjusted for the factors by which it is known to differ from the price that community pharmacies actually pay for the drug product. CMS has chosen to align the definition of AMP, as described in the proposed rule, most closely with an accurate reflection of the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer. Therefore, the relationship of the AMP must be adjusted for certain factors to provide an accurate reflection of the actual price paid by community pharmacies. As identified previously in this report, the AMP as defined by the DRA proposed rule differs from the community[43] pharmacy actual acquisition cost in the following ways:

- Wholesaler Operating Margin. AMP does not include the wholesaler operating cost and margin, estimated to be about 3.75%, on average, with a middle range of 3.3% to 5.1%.[44]

- PBM & Mail Order Discounts & Rebates. AMP does include price concessions given to PBMs and mail order and acknowledged by CMS not to be available to community

[41]National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, 2005/2006, p.E-13. 'Estimated acquisition cost' was defined in 1987 as "an estimate of the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers." National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1987, p.21.

[42]See Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, Table 5, p.4. The price relationships reported by the CBO were based on IMS Health data from the fourth quarter of 2003. Also, see Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, August 30, 2004, pp 14-15.

[43] 'Community pharmacy' as used here means a pharmacy where any patient can walk in to a brick and mortar facility in the community such as an independent pharmacy, a chain pharmacy, a food and drug pharmacy, or a mass merchant pharmacy.

[44] Health Care Distribution Management Association, *2005-2006 HDMA Factbook, Industry Overview*, p.2, see Table 1.

pharmacies.[45] The AMP was found by CBO to be 32% below the average price paid by independent pharmacies for multiple source drugs and ranged from 8% to 61% across various multiple source drug products.[46] The data used for the CBO estimate already included mail order prices in the AMP, but it did not include PBM rebates. A rough estimate is that PBMs account for about one-half of all prescriptions in the outpatient market and receive about a 5% to 6% rebate on those prescriptions so that the net effect of inclusion of PBM rebates in the AMP is to reduce the overall AMP by an additional amount of 2.5% to 3.0%. The combined effect of PBM and mail order prices being included in the AMP means that on average the AMP is 35% below the average price paid by community pharmacies.

- Manufacturer-sponsored Patient Assistance Programs & Coupons. The new AMP definition includes the prices of drug product sold to consumers under manufacturer-sponsored patient assistance programs or coupons redeemed by the consumer from anyone other than 'directly' from the manufacturer. The exact amount of such sales and coupons is not known. There have been suggestions that manufacturer-sponsored patient assistance programs provide as much as 5% of the prescriptions in a given year. As a conservative estimate the effect of these programs is expected to reduce AMP by about 1%.

- Usual Package Size versus the 9-digit NDC Level . The FULs used by the Medicaid program prior to the DRA proposed rule have determined estimated acquisition cost based on the price for the "package size most frequently purchased by providers."[47] The AMP under the new DRA proposed rule will be calculated at the 9-digit NDC level (i.e., without regard to package size) so that the price will be a weighted average price across all package sizes. Some drug products, however, come in package sizes intended only for purchase by facilities that will repackage and re-label the drug product to meet their own needs. These package sizes may range from 5,000 up to 40,000 tablets or capsules per drum and the price may be 2% to 10% below the price for a 'common package size' such as 100s. Inclusion of all package sizes in the AMP may reduce the AMP by 1% to 3% below the price that a community pharmacy would pay to buy the drug product.

- Authorized Generics. An NDA holder that markets, or licenses the marketing, of another version of a drug product other than the original brand name drug product prior to the expiration of the patent and market exclusivity is said to be selling an 'authorized generic'. The new AMP definition includes the prices of authorized generics as well as the price of the original brand name drug product. While the inclusion of authorized generics is understandable in terms of measuring the net revenue impact on the manufacturer, this provision may cause a less than efficient change in the purchasing

[45] See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178. CMS states in the proposed rule: "We note that even were we to incorporate this change, retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for some manufacturer price concessions."

[46] See Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, Table 5, p.19. The price relationships reported by the CBO were based on IMS Health data from the fourth quarter of 2003. Note that the AMP used in the CBO study included mail order pharmacy prices, but not PBM rebates and discounts as described in the CMS proposed rule for calculating the AMP when the DRA is implemented.

[47] National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, 2005/2006, p.E-13. 'Estimated acquisition cost' was defined in 1987 as "an estimate of the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers." National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1987, p.21.

behavior of generics by pharmacies. If the authorized generic is launched prior to the time when other generics can enter the market, the authorized generic will derive the 'first mover' advantage in the generic market. This means that the first generic (i.e., authorized or pseudo-generic) will be able to fill the wholesale and retail pipeline. Virtually every wholesaler and retailer will have to have at least one bottle of the generic on the shelf as soon as the authorized generic is introduced so as not to lose money under Medicaid from the lower reimbursement. On the one hand that is good, but then when other generic drug products do reach the market and usually at substantially lower prices, the pharmacy will still have a supply of the higher cost 'authorized generic' and the pharmacist may be hesitant to switch generic products on a frequent basis so as not to concern or confuse the patients with a pill that is a different color every time the prescription is filled. There is likely to be an economic impact from this effect, but for purposes of this report that impact has not been estimated. The issue is, none-the-less, an important consequence of the new definition of AMP.

These adjustments to the new AMP and to the new FULs based on the new AMP need to be made before such AMPs and FULs are used as a basis for payment for multiple source prescriptions by a State Medicaid program. The above impact of the cited factors is based on the effect of those factors on the prices of multiple source drug products. Each of the above factors would also be expected to have an economic impact on the new AMP versus the actual pharmacy cost of drugs other than multiple source drugs. However, the magnitude of that impact would be expected to be different for single source drugs than it is for multiple source drugs as reported here.

C. Cost of Dispensing

The operating costs in the prescription department of a pharmacy are commonly referred to as the 'cost of dispensing' (COD). The prescription price is a combination of a drug product and the related professional services of the pharmacist that accompany the product when it is provided to the patient. As a part of its charge from the Minnesota legislature, the Pharmacy Payment Reform Advisory Committee worked in conjunction with personnel from the Medicaid program in the Department of Human Services to solicit and contract with an independent outside organization to conduct "a study to measure the average cost of filling a Medicaid prescription in the State of Minnesota." That study was performed by Myers and Stauffer LC—a public accounting firm with experience in conducting such studies for state Medicaid programs. The final report of that study was provided to the Advisory Committee on December 29, 2006.[48]

The State of Minnesota had 1,065 eligible pharmacies that received the survey and 515 pharmacies provided usable responses. This resulted in a net response rate of 48.4%. Thirteen of the responding pharmacies were specialty pharmacies that had a very different COD and they were excluded from the rest of the analysis unless otherwise noted.[49] The data collection for itemizing the data solicited by the survey is provided in the COD Study report. The data analysis procedures and calculation methods were reviewed by the Advisory Committee and in general were considered acceptable. There were discussions about the appropriateness of certain allocation methods or about the inclusion of certain types of costs. Some of these issues are discussed elsewhere in this report and some are described in other published

[48] Myers and Stauffer LC, *Survey of the Average Cost of Filling a Medicaid Prescription in the State of Minnesota*, December 2006. A copy of the study is available by contacting the Medicaid pharmacy program, Department of Human Services, State of Minnesota.

[49] The 13 specialty pharmacies had an unweighted average COD of $59.18 with a standard deviation of $40.96 compared to an unweighted average COD of $11.25 for all other pharmacies with a standard deviation of $6.71.

documents critiquing COD methodologies.[50] Overall, the survey and resulting data were considered to be well done and the reported baseline COD is reflective of actual costs experienced by Minnesota pharmacies.

The COD is a dollar amount that reflects the actual amount of allocated costs needed to fill and dispense a prescription. The COD in pharmacies may vary for a variety of reasons including the prescription volume in the pharmacy, the percent of prescriptions covered by third parties or Medicaid or Medicare, the geographic location (i.e., urban versus rural versus suburbs), and other factors such as differences in rent and salaries. The data collected was for the most recent complete fiscal year for each pharmacy and the responses were adjusted to standardize all responses to represent the midpoint (June 30, 2006) of 2006. The baseline COD found for Minnesota pharmacies ranged from a low of $4.09 per prescription to a high of over $150.00 per prescription. The majority of the pharmacies (76%) had a baseline COD ranging between $7.00 and $18.00.

There are several measures of central tendencies that communicate the typical COD across the sample of Minnesota pharmacies. These include: (1) the unweighted mean or straight average, (2) the weighted mean using the annual number of Medicaid prescriptions as the weight factor, (3) the unweighted median, and (4) the weighted median using the annual number of Medicaid prescriptions as the weight factor. Each of these measures provides important information about the value and dispersion of the COD across Minnesota pharmacies. For simplicity, however, this report will use the Medicaid-weighted mean when reporting COD values unless otherwise noted. The COD for Minnesota pharmacies based on various pharmacy characteristics were also reported by the Myers and Stauffer study (See Exhibits 3 and 4). Summary results for the mid-2006 baseline COD are presented below:

- The baseline COD for pharmacies filling Minnesota Medicaid prescriptions in 2006 was $9.59.
- Pharmacies that had a higher share of Medicaid prescriptions showed a higher average COD.
- Pharmacies with more than 10% Medicaid prescriptions had an average COD of $10.00.
- Pharmacies with more than 15% Medicaid prescriptions had an average COD of $10.56.
- Pharmacies with the highest volume had an average COD of $9.03.
- Hospital pharmacies had an average COD of $10.37.
- Long term care or institutional pharmacies had an average COD of $9.86.
- Chain pharmacies had an average COD of $9.97
- Independent pharmacies had an average COD of $8.46.
- Urban pharmacies had an average COD of $9.87.
- Rural pharmacies had an average COD of $8.99.
- More than 75% of Minnesota pharmacies would be covered by a baseline COD of $12.00.
- More than 85% of Minnesota pharmacies would be covered by a baseline COD of $13.00.

[50] *Elements of a Pharmacy Dispensing Fee*, Issue Brief, National Association of Chain Drug Stores, October 2004. See also, *Medicaid Rx Costs Participating Providers More than Private, Third Party Rx Programs*, Issue Brief, National Association of Chain Drug Stores, July 2005. And also, *Estimating the Costs of Dispensing Prescription Drugs Within a Chain Pharmacy*, The Center for Pharmacoeconomic Studies, The University of Texas at Austin, Summer 2005.

All of the baseline COD numbers reported above are actual costs for the midpoint of 2006. The actual costs are expected to increase each year and therefore need to be adjusted each year to reflect actual COD. The baseline COD data reported above was adjusted from mid-2006 to mid-2007 and later years using the same method as that used by Myers and Stauffer for standardizing the fiscal years across Minnesota pharmacies.[51] The Minnesota baseline COD will be $9.88 in 2007, $10.17 in 2008, $10.48 in 2009, and $10.79 in 2010. The baseline COD for a pharmacy with greater than 10% Medicaid prescriptions will be $10.30 in 2007 and will grow to $11.26 by 2010.

If the Medicaid prescription payments are to be based on actual costs (i.e., actual drug product cost and actual COD), then the COD, and dispensing fee, for prescriptions provided to Medicaid recipients should be based on actual costs. A COD study could be done every year to determine actual costs. Alternatively, a COD study could be done every 4 years and revised each year with an inflation adjustment multiplier.

D. Additional Costs to Pharmacies

The Advisory Committee examined the costs factors included and excluded in the COD reported by Myers and Stauffer. There were certain factors not included in the overall average COD reported by Myers and Stauffer that the Advisory Committee wanted to examine and consider for inclusion in the calculated COD. Among the business related costs and factors not included in the reported COD were: (1) accounts receivable carrying costs, (2) inventory carrying costs, (3) limit on owner's labor cost, (4) allocation of costs based on OTC drug products dispensed to Medicaid recipients, (5) advertising and marketing costs, (6) contributions, (7) uncollected Medicaid copays, (8) bad debts, (9) net profit after taxes (return on invested capital), and (10) Minnesota Wholesale Drug Tax.

Accounts Receivable Carrying Costs & Inventory Carrying Costs. The cost of capital is an important cost of doing business. Any firm, including a community pharmacy, must have working capital that is either invested capital or borrowed capital. The major uses of working capital are inventory carrying costs and accounts receivable. The typical independent pharmacy in 2004 had more than $260,000 in inventory and sales of about $3.6 million.[52] Most community pharmacies today have over 90% of their prescription paid for by third parties. Some third party claims processors pay their claims on a timely bases (i.e., a few days to a week), while other may take several weeks to months to pay accounts receivable. An unpaid prescription claim is a situation where the pharmacy has purchased the drug product from the wholesaler—has given the drug to the patient and now is waiting to re-collect the money already spent. The inventory carrying costs are a necessary and real part of a business. One of the fastest ways to lose money operating a drug store is to carry excess inventory. The Advisory Committee believes that these are real costs of the business, but did not have a reliable estimate of the cost per prescription.

Limit on Owner's Labor Cost. The method for applying a limit on owner's labor cost applied by Myer's and Stauffer appears to be a reasonable approach if the assumption that the excess labor cost is profit being taken out by the owner. The adjustment made by Myers and Stauffer was "tied to the number of prescriptions dispensed by owner pharmacists (based on the logarithmic regressions performed on number of prescriptions dispensed by employee pharmacists and employee pharmacists salaries)." The Advisory Committee was concerned that this method of applying the limit did not take into account the fact that owners usually work longer hours than employee pharmacists, and those longer hours worked by the owner could have accounted for some or all of the owner's salary above the arbitrary limit applied. Owners may perform relevant work to Medicaid participation (e.g., claims submissions and review and

[51] The COD data was adjusted for inflation going forward using an estimate of the CPI-All Items for urban consumers. The rate of 3% was assumed for CPI-All in 2007 and 2008.

[52] National Community Pharmacists Association, *2005 NCPA-Pfizer Digest*, October 2005, pp.6-7.

reconciliation of claims rejections) in addition to dispensing prescriptions. In 2004 owner pharmacists averaged 48.4 hours worked per week while staff pharmacists averaged 42.7 hours worked per week.[53] The Myers and Stauffer study determined that this factor contributed $0.01 per prescription to the pharmacy COD. This factor had a low impact on the cost of dispensing number derived (i.e., a $0.01 decrease), so the Advisory Committee chose to make no adjustment to the COD at this time.

COD Allocation for OTC Meds Dispensed to Medicaid Recipients. The Minnesota Medicaid program does cover selected over-the-counter drug products. The cost allocation formulae used by Myers and Stauffer did not apply any cost allocation to the COD for the space, inventory, and management that were necessary to support sale of the OTC drug product to Medicaid recipients. This cost was not estimated by Myers and Stauffer and the Advisory Committee did not attempt to develop an estimate. The Advisory Committee, however, felt that this cost was worth mentioning from a conceptual and validity standpoint.

Advertising & Marketing Expense. None of the advertising and marketing expense of the pharmacy was assigned to the Medicaid COD. The reference cited by Myers and Stauffer for excluding advertising is the "Medicare Provider Reimbursement Manual." This manual refers primarily to hospital cost reporting principles. This reference "does not seem directly relevant as 'pharmacies' are NOT 'Medicare providers'.[54] These advertising expenses may have included costs related to listings in yellow pages,

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[53] David Mott, et. al., *Pharmacist Participation in the Workforce: 1990, 2000, and 2004*, Journal of the American Pharmacists Association, May/June 2006, Vol. 46, No. 3, pp e-14-e22, see Table 3.

[54] A footnote in the Myers and Stauffer report (p.15) explains the exclusion for advertising expense as follows:
"[13] The exclusion of most types of advertising expense is consistent with Medicare cost reporting principles. See Provider Reimbursement Manual, CMS Pub. 15.1, Section 2136.2. "Costs of advertising to the general public which seeks to increase patient utilization of the provider's facilities are not allowable."" The reference cited by Myers and Stauffer for excluding advertising is the "Medicare Provider Reimbursement Manual." This manual refers primarily to hospital cost reporting principles. This reference "does not seem directly relevant as 'pharmacies' are not 'Medicare providers'. First, pharmacies are not "providers" in the sense that the term is used under Medicare. Second, this COD study is being done in reference to 'Medicaid' and not 'Medicare'. Myers and Stauffer is by inference asserting that the cost principles for 'providers' (i.e., hospitals) under Medicare apply to estimating the advertising costs for a COD study for 'pharmacy vendors under Medicaid', but there is no statute or regulation that directly states "pharmacy vendors" are subject to the hospital cost reimbursement principles. Second, in support of the Advisory Committee's comments, PBMs, and other types of organizations, do contract directly with Medicare for Part D PDPs and are more appropriately referred to as 'Medicare providers' than are 'community pharmacies.' Yet, the cost principles in the Medicare "Provider Reimbursement Manual, CMS Pub. 15.1, Section 2136.2." referred to by Myers and Stauffer are not applied to PBMs or other firms that are Medicare Part D PDP providers. If the 'cost principles' of Medicare are not even applied to other 'providers' of prescription drugs in Medicare, it seems like a much greater stretch to argue that the principles apply to the COD for a prescription drug vendor that is 'not a provider' and who is serving 'Medicaid' recipients and not Medicare beneficiaries. Also, managed care organizations do contract directly with Medicaid for Medicaid Managed Care to provide comprehensive, capitated care to Medicaid recipients (i.e., as of June 30, 2005 65.93% of Minnesota Medicaid recipients were in Medicaid Managed Care Organizations, see National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, 2005/2006, p.2-31). Again, the 'cost principles' in the Medicare "Provider Reimbursement Manual, CMS Pub. 15.1, Section 2136.2." referred to by Myers and Stauffer are not applied to these 'Medicaid' contractors who provide prescription drugs. Since other contractors with Medicare and Medicaid who provide prescription drugs are not subjected to the 'cost principles' of the Medicare "Provider Reimbursement Manual" cited, there appears to be little justification to argue that these cost principles apply to pharmacy vendors under Medicaid. Additionally, all drug manufacturers sign a national rebate agreement with the Secretary of the Department of Health and Human Services in order for their drug products to be covered under Medicaid. As part of that agreement, each manufacturer is required to report the price (the sum of their costs including advertising, marketing and profits, among other costs) to CMS on a quarterly basis. The Medicaid program then is paid rebates by the drug firm based on statutes and regulations that govern the Medicaid Drug Rebate program. Neither the old nor the new AMP definition excludes marketing and advertising expense from the AMP, or from the amount that drug companies are paid for their drug products.

consumer and neighborhood publications and other places that would make Medicaid recipients aware of the pharmacy, its location, hours, and services. Other pharmaceutical organizations providing products and services to Medicaid and Medicare do include these expenses in the price they are paid including managed care organizations, PBMs, other Medicare Part D PDPs, and drug companies. Neither the old nor the new AMP definition excludes marketing and advertising expense from the AMP or from the amount that drug companies are paid for their drug products. Drug companies, on average, spend over 30% of their total revenue on 'sales, marketing, and general administration.'[55] The Myers and Stauffer report estimated that the cost of advertising and marketing to a Minnesota pharmacy was $0.26 per prescription. The Advisory Committee believes that some share of this expense should be allocated because Medicaid recipients benefit from some of the advertising and marketing effort, and also because other organizations that contract with Medicare and Medicaid for prescription drugs (i.e., managed care organizations, PBMs, and drug companies) spend much larger amounts and shares on advertising expense and these costs are fully funded by the Medicaid and Medicare programs."

Contributions & Bad Debt. The Myers and Stauffer report indicated that contributions accounted for about $0.043 per prescription and bad debt represented $0.092 per prescription, but these amounts were not included in the Medicaid COD. The Advisory Committee felt that on principle some share of bad debt should be included in the COD. Practically, however, the data was not collected in a manner to facilitate easy allocation to Medicaid. Therefore, the Advisory Committee does not recommend addition of any expense from bad debt into the COD.

Another expense for which data was not clearly reported in a consistent manner was uncompensated care. A number of pharmacies provide medication to patients at times when the patient can not pay and these acts of charity are similar to the uncompensated provided by hospitals.[56] Also, recall that during January and February of 2006 the Medicare Part D program rolled out and hit a number of problems related to enrollment, eligibility and coverage. The pharmacists of Minnesota provided the prescriptions needed by the seniors who came to their pharmacy, often without any certainty that they would ever get paid by anyone, let alone Medicare for providing these prescriptions. The exact cost to Minnesota pharmacies from providing prescriptions during this time of uncertainty and then getting paid weeks to months later, it at all, is not known. This uncompensated service, and related prescriptions, by Minnesota pharmacists is an example of the commitment Minnesota pharmacists have for serving the needs of their patients.

Uncollected Medicaid Copays. Multiple source (generic) prescriptions under Medicaid are subject to a $1.00 copay and brand name prescriptions are subject to a $3.00 copay. The pharmacy can attempt to collect the copay, but historically the pharmacy is not permitted to refuse providing the medication to the patient if they can not pay the copay amount. A research study using Medicare Current Beneficiary Survey data from 38 states found that "pharmacies in copay states failed to collect anything from patients for one of every three Medicaid prescriptions."[57] This is a very real cost to the pharmacy that is directly related to the Medicaid program. There does not appear to have been any accommodation of this uncollected copay in the Myers and Stauffer report. The Advisory Committee recommends a conservative assumption that 20% of the $1.00 generic copays go uncollected resulting in a contribution of $0.20 per prescription to the total Medicaid COD for multiple source prescriptions with an FUL.

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[55] Tom Scully, Wall Street's View of Pharmaceutical Manufacturers, Centers for Medicare & Medicaid Services, January 10, 2003, p. 21.

[56] Minnesota Department of Health, *Minnesota Hospitals: Uncompensated Care, Community Benefits, and the Value of the Tax Exemptions*, January 2007.

[57] Bruce Stuart and Christopher Zacker, "Who Bears the Burden of Medicaid Drug Payment Policies?" *Health Affairs*, Vol. 18, No. 2, March/April 1999, pp. 201-212.

Reasonable Return on Investment or Net Profit. The Myers and Stauffer report did not include any net profit or return on investment for the pharmacy. The market-based system of health care depends upon some level of net profit as a necessary incentive for pharmacies to enter, and remain in the market, and to provide Medicaid recipients an appropriate level of access to pharmacy services. The average independent pharmacy net operating margin (net profit before taxes) in 2004 was 3.6%.[58] For chain pharmacies, the average net profit margin before taxes for 2005 was 4.55%.[59] The weighted average net operating margin based on the mix of independent and chain pharmacies in Minnesota is 4.2%.[60] The Advisory Committee recommends using the more conservative independent pharmacy net operating margin of 3.6% to represent the minimum reasonable return on investment.

The COD survey reported that for those pharmacies reporting a cost of goods sold, the Medicaid weighted average drug product cost per prescription was $41.74 and the Medicaid weighted average baseline COD was $9.59. The sum of the COD ($9.59) and the drug product cost ($41.74) provides an estimate of the price per prescription without tax ($51.33). This prescription price without tax ($51.33) can then be divided by 0.964 (that is, 1.00 minus 0.036, the net operating margin) to derive an average prescription price of $53.25. The net operating dollar margin is calculated as the net operating margin percent (3.6%) times the average prescription price ($53.25) and yields a net operating dollar margin of $1.92. The Advisory Committee recommends adding the net operating dollar margin of $1.92 to the baseline COD.

Allowance for a reasonable return on investment is essential to ensure that proper incentives exist for pharmacies to enter the market, and to remain accessible to Medicaid patients. Other business entities involved with Medicaid and Medicare in the drug distribution and use system are allowed a net operating margin in their rate structure with Medicaid and Medicare including Medicaid managed care organizations, PBMs, and drug companies. With respect to drug companies, neither the old AMP nor the new AMP excluded net operating margin (profit) from the drug product cost for drug companies or from the cost structure and compensation to PBMs. Branded drug firms have averaged net income of about 20% before taxes and interest expense of about 6% in recent years.[61]

Minnesota Wholesale Drug Tax. The Minnesota Wholesale Drug Tax is a 2% charge added on to the wholesale cost of all prescription drug purchases in Minnesota. This is a very real cost to the pharmacy that is paid through the wholesaler to the state Department of Revenue. Nearly all other private third party programs pay this tax as an add-on to the prescription claims cost, but Medicaid does not. If this cost is not addressed, it means that a pharmacy faces a 2% loss on the drug product cost of each and every prescription dispensed to a Medicaid recipient. The Advisory Committee believes that this cost should be fully accounted for by the Medicaid pharmacy payment. The cost may be accounted for as a 2% add on to the drug product cost, or it can be a fixed, calculated amount that is added to the dispensing fee that accounts for the otherwise complete COD. The Myers and Stauffer report estimated that the fixed amount as an add-on to the COD would be $0.835 per prescription. This estimate was derived using the actual average cost of goods (drug product cost) per prescription for pharmacies responding to the survey.

There was one additional factor which was not addressed by the Myers and Stauffer report and the Advisory Committee did not have data to document. If a third party, such as Medicaid has a lot of

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[58] National Community Pharmacists Association, *2005 NCPA-Pfizer Digest*, October 2005, pp.10.

[59] Data from Hoovers.com as reported in Table 17. Financials by Industry for Publicly Held Companies, National Association of Chain Drug Stores Foundation, *The Chain Pharmacy Industry Profile, 2006*, p.37.

[60] The Minnesota pharmacies responding to the COD survey included 151 independent pharmacies (36.7%) and 261 chain pharmacies (63.3%). A weighted average net operating margin was calculated for Minnesota using the 3.6% margin for independents and the 4.55% margin for chains and this yielded a weighted average of 4.2%.

[61] See Scully, Wall Street's View of Pharmaceutical Manufacturers, Centers for Medicare & Medicaid Services, January 10, 2003, p. 21.

complicated rules and provisions (i.e., preferred drugs, prior authorizations, step therapy, etc.), that third party may consume a disproportionate share of the pharmacists labor cost. If this disproportionate effort is required for a specific third party, then it would be appropriate to allocate a larger share of the pharmacist labor costs to that third party's COD. The Advisory Committee did not have specific data on the time and effort required for Minnesota Medicaid prescriptions, but felt that the issue deserved mention and consideration if information suggesting excessive effort becomes available.

The baseline Minnesota Medicaid COD was $9.59 for mid-2006. This baseline COD and the additional factors are discussed above are itemized and reported in Exhibit 5. Exhibit 5 then reports cost factor and the total COD for the baseline COD, the All Cost COD, and the Pharmacy Payment Reform Advisory Committee (PPRAC) recommended COD after inclusion of these related additional factors. The baseline COD remains at $9.59 per prescription for 2006 and $9.88 for 2007. The All Cost COD is $12.63 per prescription for 2006 and $13.01 per prescription for 2007. The PPRAC Recommended COD with a Minnesota Wholesale Drug Tax adjustment is $12.55 for 2006 and $12.92 for 2007 and the COD without a Minnesota Wholesale Drug Tax adjustment is $11.71 for 2006 and $12.06 for 2007. If the COD without the Minnesota Wholesale Drug Tax adjustment is adopted, then the FUL should be increased by 2% to account for the cost of this tax.

The baseline Minnesota Medicaid COD for pharmacies with greater than 10% Medicaid prescriptions was $10.00 for mid-2006. This baseline COD and the additional factors are discussed above are itemized and reported in Exhibit 6. Exhibit 6 then reports cost factors and the total COD for the baseline COD, the All Cost COD, and the Pharmacy Payment Reform Advisory Committee (PPRAC) recommended COD after inclusion of these related additional factors. The baseline COD remains at $10.00 per prescription for 2006 and $10.30 for 2007. The All Cost COD is $13.36 per prescription for 2006 and $13.76 per prescription for 2007. The PPRAC Recommended COD with a Minnesota Wholesale Drug Tax adjustment is $12.96 for 2006 and $13.34 for 2007 and the COD without a Minnesota Wholesale Drug Tax adjustment is $12.12 for 2006 and $12.48 for 2007. If the COD without the Minnesota Wholesale Drug Tax adjustment is adopted, then the FUL should be increased by 2% to account for the cost of this tax.

V. Summary and Recommendations

The Pharmacy Payment Reform Advisory Committee (PPRAC) was established by the Minnesota legislature to evaluate the Minnesota impact of implementing the federal Deficit Reduction Act of 2005. The charge to the Advisory Committee was "use the information from the cost of dispensing study and make recommendations to the commissioner on implementation of pharmacy reforms contained in the Deficit Reduction Act of 2005."[62] Then, "the commissioner shall report the findings of the study and the recommendations of the advisory committee to the legislature by February 1, 2007. The commissioner, in consultation with the advisory committee, shall make recommendations to the legislature."[63]

The Advisory Committee has reviewed the current payments for multiple source prescriptions under the Medicaid program. The Deficit Reduction Act of 2005 proposed rule and implementation issues were reviewed to understand how the payment for multiple source prescriptions with FULs are likely to change under these new rules. The factors related to determining reasonable payments to pharmacists were reviewed and actual Minnesota pharmacy cost of dispensing data was collected and analyzed. Based on the Advisory Committee's review and the data examined a summary of findings is presented below. Then, recommendations are made for reforms to the method and amount of pharmacy payment for multiple source prescriptions that will be needed to pay pharmacies based on actual drug product and operating cost.

A. Findings and Recommendations

The Minnesota legislature established the Pharmacy Payment Reform Advisory Committee to advise the Commissioner on "how to adequately adjust Medicaid reimbursement rates to pharmacies to cover the costs of dispensing and additional costs to pharmacies." The legislation identified several specific issues to be addressed. In this section, the findings related to each of those issues are summarized and recommendations are provided.

What will be the impact of Medicaid pharmacy reimbursement for multiple-source drugs when they have a federal upper reimbursement limit set at the level established by the federal government under the Deficit Reduction Act of 2005?

Findings:
Implementation of the Deficit Reduction Act of 2005 (DRA) will follow rules published by CMS.[64] The DRA re-defines how the federal upper limits (FULs) for multiple source drugs will be established. The new FUL procedures rely upon the average manufacturer price (AMP) reported to CMS by drug manufacturers as part of the Medicaid Drug Rebate program. Revisions were made to the factors taken into account when a drug manufacturer calculates the AMP for its drug products. The DRA linked AMP to a new function—establishing the FUL for multiple source drugs. AMP now serves two distinct purposes in the Medicaid program: (1) setting the basis for drug manufacturer rebates and (2) establishing the FUL payment amount for pharmacies.

The AMP, as newly defined, is not the same as the average price paid by a retail community pharmacy. First, the AMP does not include the operating cost of the wholesaler. Second, the AMP includes

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[62] See Laws of Minnesota 2006, Chapter 282, Article 16, Section 15.
[63] See Laws of Minnesota 2006, Chapter 282, Article 16, Section 15.
[64] A proposed rule for implementation of the Deficit Reduction Act of 2005 was released in December 2006. At the time of this report, the rule had not been finalized. Consequently, this analysis and related recommendations are based on the proposed rule. The Pharmacy Payment Reform Advisory Committee reserves the right to assess any changes in the final rule, when it is published, and to revise its findings and recommendations.

discounts and rebates provided to PBMs and mail order pharmacy, but not available to retail community pharmacies. CMS even noted in the proposed rule: "retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for some manufacturer price concessions." Also, the AMP includes other reductions to price that are received by parties other than retail community pharmacies.

A recent GAO analysis found that 43 of 77 top multiple source drugs in Medicaid had an AMP-based FULs that was below the lowest acquisition cost available to retail pharmacies. The AMP-based FUL for these drugs averaged 15% to 65% below the average pharmacy acquisition cost. These findings indicate that pharmacies are likely to loose money on more than one-half of the generic prescriptions subject to the new AMP-based FULs.

Ironically, the proposed definition of "retail class of trade" will again result in an AMP that is not a price generally and currently available to the majority of the pharmacies providing prescriptions to Medicaid recipients. The new AMP will be substantially below the price paid by most retail community pharmacies. When the Office of the Inspector General reviewed the DRA legislation, it recommended 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.*"

The Deficit Reduction Act (DRA) provision setting the Medicaid FULs based on the drug manufacturer reported AMP is an effort to connect the payment amount for multiple source drugs to an actual price. The AMP is a reasonable starting point for estimating the acquisition cost for multiple source drug products, but it must be adjusted for the factors by which AMP is known to differ from the price that community pharmacies *actually pay* for the drug product. At the same time that Medicaid payment policy is implemented to assure 'actual' cost payment for the drug product, it is essential that the payment for the cost of dispensing and related additional costs also be adjusted to assure that 'actual' costs and expenses are paid for all components of the prescription payment.

Recommendations:

- Adjustment should be made to the pharmacy payment for multiple source prescriptions at the same time as the new FULs are implemented, so that both the drug product cost and the dispensing fee will be based on actual costs.
- Since the AMP amounts will not be known until the new FUL provisions are implemented, the actual change in payment for multiple source prescriptions under Minnesota Medicaid due to this new method for setting FULs should be evaluated after the program has begun.

What revenues are required to adequately adjust reimbursement to cover the cost to pharmacies for dispensing Medicaid prescription drugs?

Findings:

In Minnesota, the Medicaid fee-for-service system covered nearly 5.8 million prescriptions and spent $440 million in 2005. Due to the introduction of the Medicare Part D program and the shift of dual eligibles from Medicaid to Medicare, the number of fee-for-service Medicaid prescriptions in Minnesota for 2006 is estimated to have fallen by 45% to about 3.6 million prescriptions. This 2006 decline in Medicaid prescriptions amounts to about 2.1 million fewer prescriptions and about $200 million less in expenditures.

The majority of the growth in Medicaid drug program expenditures over the past decade has come from growth in the average prescription price with utilization growth accounting for a lesser share of the increase in expenditures. The majority of the prescription price growth has come from increases in drug product cost while dispensing fees have held steady, or even gone down in constant dollars, over the same

time period. States have routinely set the dispensing fees for pharmacies, but have allowed the drug manufacturer prices to grow relatively unfettered. Obviously setting lower dispensing fees and reduced pharmacy payment amounts has not been an effective means for moderating the growth rate in manufacturer drug product prices or Medicaid drug program expenditures.

Implementation of the new FULs has been estimated by CMS to produce overall national savings of $800 million in 2007 and will increase to about $2 billion annually by 2011 with a total savings of $8.04 billion over 5 years. Conservatively, the estimated savings to Minnesota Medicaid from the change in the FUL calculation is expected be in the range $84 million to over $160 million during the 5-year period 2007 to 2011. This savings would come from decreases in the Medicaid payments to pharmacies for multiple source prescriptions with FULs.

Implementation of the Deficit Reduction Act of 2005 permits state flexibility and at the same time creates some degree of uncertainty about the impact of the new payment rules for prescription drugs on access by Medicaid beneficiaries and payments to pharmacy providers. Since the savings to the Medicaid program would largely be realized through lower payments to pharmacies, the Minnesota savings in Medicaid drug expenditures from the reduction of FUL payments to pharmacies could be used to provide revenue for adjusting the pharmacy payments to avoid under-payment and loss of Minnesota pharmacies. The estimated savings to Minnesota Medicaid are expected to exceed the amount needed to adequately reimburse pharmacies for actual dispensing costs of Medicaid prescriptions.

Recommendations:

- The adjustment to pharmacy dispensing fees can be funded out of the savings from the lower FUL amounts and the substantially increased number of drug product subject to FULS which both reduce the payments to pharmacies.

Are Medicaid dispensing fees adequate to reimburse pharmacy providers for the costs of dispensing prescriptions under the Medicaid program?

Findings:
The current prescription payment for the Minnesota Medicaid program is a dispensing fee of $3.65 combined with estimated acquisition cost of the drug product, or the pharmacy's usual and customary price if it is lower. The current Medicaid dispensing fee falls substantially below the pharmacy's actual cost of dispensing. However, the current FULs provide the pharmacy with a margin on the drug product cost to balance out the inadequate dispensing fee.

When the new FULs are implemented they will be based on the AMP, which is expected to be substaintially below the current FULs and at, or below the pharmacy's actual purchase price for the drug product. Since the current dispensing fee falls well below actual costs, pharmacies would lose money on every multiple source prescription. The pharmacy dispensing fee needs to be increased to cover the actual costs of a pharmacy at the same time that Medicaid moves the drug product cost to the actual cost (AMP-based) FULs.

The Pharmacy Payment Reform Advisory Committee worked in conjunction with personnel from the Medicaid program in the Department of Human Services to solicit and contract with an independent outside organization to conduct "a study to measure the average cost of filling a Medicaid prescription in the State of Minnesota." That study was performed by Myers and Stauffer LC—a public accounting firm with experience in conducting such studies for state Medicaid programs. The State of Minnesota had 1,065 eligible pharmacies that received the survey and 515 pharmacies provided usable responses. This resulted in a net response rate of 48.4%. The final report of that study was provided to the Advisory Committee on December 29, 2006.

The cost of dispensing (COD) method used for the study did not include certain additional costs to the pharmacy including: (1) accounts receivable carrying costs, (2) inventory carrying costs, (3) the owner's total labor cost, (4) allocation of costs based on OTC drug products dispensed to Medicaid recipients, (5) advertising and marketing costs, (6) contributions, (7) uncollected Medicaid copays, (8) bad debts, (9) net profit after taxes (return on invested capital), and (10) the Minnesota Wholesale Drug Tax. These are real costs incurred by the pharmacy, but not accounted for in the baseline COD reported by the study.

Certain actual additional costs should be added to the baseline COD per prescription including: (1) uncollected Medicaid copays ($0.20), (2) pharmacy return on investment ($1.92), and (3) Minnesota Wholesale Drug tax ($0.835).

The Minnesota Wholesale Drug Tax is a 2% charge added on to the wholesale cost of all prescription drug purchases in Minnesota. This is a very real cost to the pharmacy and nearly all private third party programs pay this tax as an add-on to the prescription claims cost, but Medicaid does not. This actual cost could be addressed either by paying the new FUL plus 2% additional cost or by adding a cost factor of $0.835 per prescription. If this cost is not addressed, it means that Minnesota pharmacies face a 2% loss on the drug product cost for each and every prescription dispensed to a Medicaid recipient.

When the Medicaid prescription payments shift to the new actual cost-based FULs, Minnesota Medicaid should also shift to a dispensing fee based on actual costs (i.e., baseline COD plus additional costs). The FULs will change in price each month based on manufacturer drug price changes and the dispensing fee should be adjusted for inflation each year using the conservative CPI-All Items for Urban Consumers.

The baseline COD found in the study was $9.59 per prescription for 2006 and $9.88 for 2007. When all known additional costs were added to the COD the 'All Cost COD' was $12.94 per prescription for 2006 and $13.33 per prescription for 2007. The PPRAC recommends adding certain additional costs (see Exhibit 5) and the Minnesota Wholesale Drug tax to the COD yielding a COD of $12.55 per prescription for 2006 and $12.92 for 2007. If the Minnesota Wholesale Drug tax is not included in the COD as recommended by PPRAC, then Medicaid could pay 2% plus the FUL plus the PPRAC COD of $11.71 in 2006 and $12.06 in 2007.

The baseline COD for Minnesota pharmacies reported above was a Medicaid weighted average across all pharmacies in the study. The COD ranged from a low of $4.09 per prescription to a high of over $150.00 per prescription (the latter COD is probably from a new pharmacy that has not yet reached an efficient volume). The majority of Minnesota pharmacies (76%) had a baseline COD between $7.00 and $18.00 for 2006. The average baseline COD for pharmacies filling Minnesota Medicaid prescriptions in 2006 was $9.59. Pharmacies with more than 10% Medicaid prescriptions had an average COD of $10.00.

All of the COD numbers reported above were actual costs for the midpoint of 2006 (June 30). The COD data should be updated every year, either by a new COD study or by using the same method as that used by Myers and Stauffer for standardizing the fiscal years across Minnesota pharmacies. The COD values

reported for future years were adjusted for inflation going forward using the CPI-All Items for urban consumers assuming an estimated rate of 3% per year.

The baseline COD for Minnesota will be $10.17 in 2008, $10.48 in 2009, and $10.79 in 2010. The baseline COD for a pharmacy with greater than 10% Medicaid prescriptions will be $10.30 in 2007 and will grow to $11.26 by 2010.

Recommendations:

- The Medicaid dispensing fee for multiple source prescriptions with FULs should be changed when the new FULs are implemented by Minnesota Medicaid.
- The 2007 Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be set at $12.92 per prescription to cover actual costs including the Minnesota Wholesale Drug Tax.
- Alternatively, the 2007 Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be set at $12.06 per prescription, if the FULs are increased by 2% to account for the Minnesota Wholesale Drug tax.
- The Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be adjusted each year in the future either by a cost of dispensing study or an inflation adjustment based on the CPI-All Items for urban consumers.

Is reimbursement sufficient to enlist an adequate number of participating pharmacy providers so that pharmacy services are as available for Medicaid recipients under the program as for the state's general population?

Findings:
Prescription payments based on actual drug product cost and actual cost of dispensing and related additional costs can serve as a reasonable basis for pharmacy payment, if the actual costs are accurately measured and continue to be updated over time. The prescription price is a combination of a drug product and the related professional services of the pharmacist that accompany the product when it is provided to the patient. The essential components of a prescription price are: (1) the drug acquisition cost, (2) the cost of dispensing and related additional costs, and (3) a reasonable return on investment (ROI).

To assure that an adequate number of Minnesota pharmacies participate in the Medicaid program, the Medicaid payment for prescriptions must be sufficient to attract pharmacies into participation. However, according to the CMS impact analysis of the proposed rule to change the method for setting FULs, the lower payment rates will affect at least one-third of the pharmacies. This means that the new FULs would cut reimbursement so much that 350 or more Minnesota pharmacies would be significantly impacted.

Certainly the loss of 350 Minnesota pharmacies would be disruptive to access for many Medicaid recipients. The 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 Minnesota Medicaid program and the replacement of these critical access pharmacies, once lost, is not easily reversible. The estimated savings to Minnesota Medicaid from the change in the FUL calculation is $84 million to $160 million over the 5-year period 2007 to 2011. These reductions in Minnesota, if evenly spread across all pharmacies in the state, would mean a loss of revenue of more than $7,500 in 2007, $12,500 in 2008, and would grow to more than $20,800 in 2011. In reality, however, these losses will not be spread evenly across Minnesota pharmacies, but will disproportionately affect those pharmacies serving the largest number of Minnesota Medicaid recipients.

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 may 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.

The baseline COD for Minnesota will be $9.88 in 2007 and the COD recommended by PPRAC with the Minnesota Wholesale Drug Tax adjustment will be $12.92 in 2007 or without the Minnesota Wholesale Drug Tax adjustment will be $12.06. For Minnesota pharmacies with greater than 10% Medicaid prescriptions, those most likely to be hurt by this change in FULs, the baseline COD for Minnesota will be $10.30 in 2007 and the COD recommended by PPRAC with the Minnesota Wholesale Drug Tax adjustment will be $13.34 in 2007 or without the Minnesota Wholesale Drug Tax adjustment will be $12.48.

Recommendations:

- The Medicaid payment should be set to cover both the actual drug product costs as well as the actual cost of dispensing plus related additional costs.
- To prevent substantial harm or loss of pharmacies with greater than 10% Medicaid prescriptions, the 2007 Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be set at $13.34 per prescription to cover actual costs including the Minnesota Wholesale Drug Tax.
- Alternatively, to prevent substantial harm or loss of pharmacies with greater than 10% Medicaid prescriptions, the 2007 Minnesota Medicaid dispensing fee for multiple source prescriptions with FULs should be set at $12.48 per prescription, if the FULs are increased by 2% to account for the Minnesota Wholesale Drug tax.
- The impact on pharmacies with a higher than proportionate share (greater than 10%) of Medicaid prescriptions and those pharmacies in rural or low income areas should be monitored to avoid loss of the pharmacies most critical to Medicaid recipients.

Does the new payment system create disincentives for pharmacists to dispense generic drugs?

Findings:
Pharmacies in Minnesota will be paid substantially less for multiple source (generic) prescriptions under the new FUL payment system. The average Minnesota Medicaid price for a prescription without a FUL (mostly brand name drugs) in 2005 was $116.41, while the average price for prescriptions with FULs (generics) was $16.78 in 2005. The greatest savings to Medicaid comes from prescribing and dispensing of generics, not from underpaying pharmacies for multiple source (generic) prescriptions.

At present there are about 500 drug product groups with an established FUL. Under the proposed new rule, the number of drug product groups with FULs could grow to 3,000 or more. Minnesota also has State MACs or FULs for 734 drug product groups, although this still represents less than one-fourth of the total drug product groups expected to have FULs under the proposed rule.

The new FULs are expected to create a reduction in generic payments that will be about 35% less in 2007, 51% less in 2008 and would reach 67% less in 2009 to 2011. These drug product payment reductions without adjustment to the dispensing fee would result in generic payments to Minnesota pharmacies that are below the actual cost of dispensing and related additional costs without even accounting for the actual drug product cost. In other words, without adjustment to the dispensing fee, pharmacies would be paid below cost for many generic prescriptions in Medicaid. One executive with the National Community Pharmacists Association, said "The new limits on Medicaid reimbursement will be way below what

drugstores typically pay for those drugs." He went on to say that "The proposed rules would have the perverse effect of discouraging the use of generics."

Recommendations:

- The Medicaid payments for multiple source prescriptions should be monitored to make sure that payment is sufficient to cover the actual pharmacy costs for dispensing these generic prescriptions. This assessment of actual costs should include the cost of dispensing and related additional costs as well as the actual purchase prices that are generally and currently available to retail community pharmacies for multiple source drug products.

B. Summary

The pharmaceutical market is in the midst of substantial and dynamic change. The implementation of the Deficit Reduction Act of 2005 (DRA) includes provisions that will establish the federal upper limits (FULs) for multiple source drugs based on the average manufacturer price (AMP). With proper adjustments the AMP provides a reasonable estimate of the actual acquisition cost to the retail community pharmacies that serve the Medicaid drug recipients. About 90% of the savings expected from implementation of the DRA is expected to come from lower payments to pharmacies.

A recent study of the Minnesota pharmacy costs of dispensing (COD) has been conducted and found that the current dispensing fees under Medicaid ($3.65 per prescription) are substantially below the actual cost of dispensing ($9.88) in 2007. Also, there are additional costs to the pharmacy related to dispensing prescriptions that are not included in this COD. With these additional costs the appropriate dispensing fee based on actual cost in Minnesota should be $12.92 per prescription.

The recent implementation of the Medicare Part D prescription drug program is estimated to have reduced Minnesota Medicaid drug expenditures by 45% in 2006. This reduction in Medicaid amounts to about $200 million less in spending and 2.1 million fewer prescriptions. Implementation of the DRA AMP-based FULs is expected to produce savings of $84 to $160 million over the next five years for the Minnesota Medicaid program. These savings come almost entirely from reductions in the drug product cost allowance (FULs) to Minnesota pharmacies. While the movement of the drug product cost payment to an actual cost basis is reasonable payment policy, this shift in policy should also be balanced with a movement to an actual dispensing cost fee. The CMS analysis of the regulatory impact from the DRA implementation without a shift in dispensing fees concludes that about one-third of all pharmacies (350 pharmacies in Minnesota) would be significantly affected. CMS goes on to note that the pharmacies most likely to be affected would be those in rural or low income areas and those serving a high share of Medicaid recipients.

This drastic reduction in Minnesota pharmacies serving the Medicaid population can be avoided by adjusting the dispensing fees to reflect actual costs at the same time as the drug product allowance (FULs) for multiple source prescriptions is adjusted based on actual costs. Because the pharmaceutical market is so dynamic and various players in the market may shift their pricing patterns and market behaviors in light of the new Medicaid payment scheme, the actual costs and the impact of the DRA on pharmacies serving Minnesota Medicaid recipients should be monitored over time to assure adequate access to pharmaceutical services.

Exhibit 1
U.S. and Minnesota Medicaid Drug Expenditures
Estimated DRA Savings from AMP-Based FULs: 2003 to 2011

	Year	Medicaid Rx Expend.[A] ($ expenditures)	Ann. % Chg ($ expend)	DRA FUL Savings[C] ($ savings)	DRA Savings as % Rx Exp.
U.S. Mediciad Drug Expenditures					
U.S.	2003	$ 34,779,164,768			
U.S.	2004	$ 39,147,405,017	12.6%		
U.S.	2005	$ 39,798,447,825	1.7%		
U.S.	2006	*$ 22,098,156,441*	*-44.5%*		
U.S.	2007	*$ 24,307,972,085*	*10.0%*	$ 795,000,000	3.3%
U.S.	2008	*$ 26,738,769,293*	*10.0%*	$ 1,285,000,000	4.8%
U.S.	2009	*$ 29,412,646,222*	*10.0%*	$ 1,840,000,000	6.3%
U.S.	2010	*$ 32,353,910,845*	*10.0%*	$ 1,980,000,000	6.1%
U.S.	2011	*$ 35,589,301,929*	*10.0%*	$ 2,140,000,000	6.0%
	2007-11	$ 148,402,600,374		$ 8,040,000,000	5.4%
Minn. as % of U.S Medicaid Rx Expenditures			*2003-05*		*1.05%*
Minnestoa Mediciad Drug Expenditures					
Minnesota	2003	$ 355,471,421			
Minnesota	2004	$ 393,831,529	10.8%		
Minnesota	2005	$ 440,160,729	11.8%		
Minnesota	2006[B]	$ 244,400,000	-44.5%		
Minnesota	2007	*$ 268,840,000*	*10.0%*	$ 8,347,500	3.1%
Minnesota	2008	*$ 295,724,000*	*10.0%*	$ 13,492,500	4.6%
Minnesota	2009	*$ 325,296,400*	*10.0%*	$ 19,320,000	5.9%
Minnesota	2010	*$ 357,826,040*	*10.0%*	$ 20,790,000	5.8%
Minnesota	2011	*$ 393,608,644*	*10.0%*	$ 22,470,000	5.7%
	2007-11	$ 1,641,295,084		$ 84,420,000	5.1%
FUL Rx Payments as % of Minnesota Rx Payments			*2005*		*8.86%*
Minnestoa Mediciad Drug Expenditures for Prescriptions With FULs					
Minnesota	2003	$ 31,500,541			
Minnesota	2004	$ 34,899,869	10.8%		
Minnesota	2005	$ 39,005,389	11.8%		
Minnesota	2006[B]	$ 21,657,809	-44.5%		
Minnesota	2007	*$ 23,823,590*	*10.0%*	$ 8,347,500	35.0%
Minnesota	2008	*$ 26,205,949*	*10.0%*	$ 13,492,500	51.5%
Minnesota	2009	*$ 28,826,544*	*10.0%*	$ 19,320,000	67.0%
Minnesota	2010	*$ 31,709,198*	*10.0%*	$ 20,790,000	65.6%
Minnesota	2011	*$ 34,880,118*	*10.0%*	$ 22,470,000	64.4%
	2007-11	$ 145,445,400		$ 84,420,000	58.0%

[A] U.S. and Minnesota data for 2003 to 2005 were reported in *Pharmaceutical Benefits Under State Medical Assistance Programs, 2005/2006,* National Pharmaceutical Council, 2006. U.S. and Minnesota data for 2006 to 2011 are estimates.

[B] Survey of Average Cost of Filling a Medicaid Prescription in the State of Minnesota, Myers and Staffer, December 2006, p.9-10

[C] Medicaid Program; Prescription Drugs, 42 CFR Part 447, Proposed Rule, December 18, 2006, p. 96

[D] Minnesota Medicaid savings could be double these amounts shown, that is about $40 million per year and $160 million over the five year period.

Exhibit 2
Minnesota Medicaid Drug Expenditures for Drug Products
With and Without FULs: 2005

	Year	Drug Payments ($ expenditures)	Prescriptions (# of Rxs)	Avg Rx Cost ($/Rx)	NDCs with FUL (# of NDCs)
MN Non-FUL Rxs	2005	$ 401,155,340	3,446,143	$ 116.41	9,825
MN FUL Rxs	2005	$ 39,005,389	2,324,150	$ 16.78	5,917
MN All Rxs	*2005*	*$ 440,160,729*	*5,770,293*	*$ 76.28*	*15,742*
MN Non-FUL Rxs	2005	91.1%	59.7%	152.6%	62.4%
MN FUL Rxs	2005	8.9%	40.3%	22.0%	37.6%
MN All Rxs	*2005*	*100.0%*	*100.0%*	*100.0%*	*100.0%*

Source: Survey of Average Cost of Filling a Medicaid Prescription in the State of Minnesota, Myers and Staffer, December 2006, p.10

Exhibit 3
Medicaid Cost of Dispensing for Minnesota Pharmacies
By Various Pharmacy Characteristics: 2006[A,B]

Pharmacy Type

	Independent Pharmacies	Chain Pharmacies	Hospital Pharmacies	Long Term Care Pharmacies	All Non-Spec. Pharmacies
Pharmacies in Analysis[C]	151	261	85	5	502
Mean (unweighted average)	$ 9.27	$ 12.29	$ 11.72	$ 8.43	$ 11.25
Mean (weighted average) [D]	$ 8.46	$ 9.97	$ 10.37	$ 9.86	$ 9.59
Median (unweighted)	$ 8.54	$ 10.01	$ 10.64	$ 6.41	$ 9.61
Median (weighted) [D]	$ 7.93	$ 9.50	$ 9.41	$ 6.78	$ 9.22

Annual Rx Volume

	Total	0 to 9,999 Rxs per Year	10,000 to 29,999 Rxs per Year	30,000 to 49,999 Rxs per Year	50,000 to 74,999 Rxs per Year	75,000 & Higher Rxs per Year
Pharmacies in Analysis[C]	502	21	94	144	127	116
Mean (unweighted average)		$ 32.96	$ 13.96	$ 10.39	$ 9.25	$ 8.36
Mean (weighted average) [D]		$ 29.33	$ 13.14	$ 10.10	$ 9.22	$ 9.03
Median (unweighted)		$ 34.20	$ 12.63	$ 10.11	$ 9.26	$ 8.07
Median (weighted) [D]		$ 33.13	$ 11.74	$ 10.03	$ 9.32	$ 9.19

Annual Medicaid Rx Volume

	Total	0 to 999 Rxs per Year	1,000 to 1,499 Rxs per Year	1,500 to 2,499 Rxs per Year	2,500 to 4,999 Rxs per Year	5,000 & Higher Rxs per Year
Pharmacies in Analysis[C]	502	139	78	96	113	76
Mean (unweighted average)		$ 15.63	$ 10.24	$ 9.87	$ 9.22	$ 9.02
Mean (weighted average) [D]		$ 13.18	$ 10.23	$ 9.89	$ 9.26	$ 9.32
Median (unweighted)		$ 10.99	$ 9.24	$ 9.48	$ 8.80	$ 9.04
Median (weighted) [D]		$ 10.84	$ 9.23	$ 9.47	$ 8.84	$ 9.16

Annual Medicaid Utilization Ratio [E]

	Total	0.0% to 1.99% of All Rxs	2.0% to 4.99% of All Rxs	5.0% to 9.99% of All Rxs	10.0% to 14.99% of All Rxs	15.0% and Higher of All Rxs
Pharmacies in Analysis[C]	502	131	206	107	30	28
Mean (unweighted average)		$ 11.51	$ 11.88	$ 9.62	$ 11.10	$ 11.75
Mean (weighted average) [D]		$ 9.33	$ 9.89	$ 8.42	$ 10.00	$ 10.56
Median (unweighted)		$ 9.55	$ 9.82	$ 8.99	$ 10.57	$ 10.00
Median (weighted) [D]		$ 8.90	$ 9.24	$ 7.97	$ 10.13	$ 9.99

[A] Cost of dispensing estimated and adjusted to June 30, 2006 (the midpoint of the fiscal year ending December 31, 2006).

[B] Excludes any allowance for the Minnesota Wholesale Drug Tax and certain other allowances.

[C] 502 Minnesota (non-specialty) pharmaices provided usable responses to the survey.

[D] The cost of dispensing average (and median) was weighted by the number of Medicaid prescriptions filled by each pharmacy.

[E] Medicaid utilization ratio is the number of Medicaid Rxs divided by the total number of Rxs in a pharmacy.

Source: Survey of Average Cost of Filling a Medicaid Prescription in the State of Minnesota, Myers and Staffer, December 2006, Exhibit 13.

Exhibit 4
Medicaid Cost of Dispensing for Minnesota Pharmacies
By Pharmacy Type and Location: 2006[A,B]

Pharmacy Type

	Non-Specialty Pharmacies[C]	Specialty Pharmacies[D]	All Pharmacies[E]
Pharmacies in Analysis	502	13	515
Mean (unweighted average)	$ 11.25	$ 59.18	$ 12.46
Mean (weighted average)[F]	$ 9.59	$ 47.47	$ 11.34
Median (unweighted)	$ 9.61	$ 50.05	$ 9.68
Median (weighted)[F]	$ 9.22	$ 47.71	$ 9.29

Geographic Location

	Urban[G] Pharmacies	Rural[G] Pharmacies	All Pharmacies
Pharmacies in Analysis[C]	322	180	502
Mean (unweighted average)	$ 12.20	$ 9.54	$ 11.25
Mean (weighted average)[F]	$ 9.87	$ 8.99	$ 9.59
Median (unweighted)	$ 10.01	$ 9.01	$ 9.61
Median (weighted)[F]	$ 9.22	$ 8.86	$ 9.22

[A] Cost of dispensing estimated and adjusted to June 30, 2006 (the midpoint of the fiscal year ending December 31, 2006).

[B] Excludes any allowance for the Minnesota Wholesale Drug Tax and certain other allowances.

[C] 502 Minnesota (non-specialty) pharmaices provided usable responses to the survey.

[D] 13 specialty pharmacies were excluded since the majority of their prescriptions were for intravenous, infusion or other specialty products.

[E] 515 Minnesota pharmaices (specialty and non-specialty) provided usable responses to the survey.

[F] The cost of dispensing average (and median) was weighted by the number of Medicaid prescriptions filled by each pharmacy.

[G] Pharmacies in a county that is part, or all, in a metropolitan statistical area (MSA) were classified as urban and all others as rural.

Source: Survey of Average Cost of Filling a Medicaid Prescription in the State of Minnesota, Myers and Staffer, December 2006, Exhibit 13

Exhibit 5
Medicaid Reasonable Payment to Minnesota Pharmacies
Cost of Dispensing[A,B] and Additional Costs: 2006 & 2007

	Minn. COD Baseline Myers & Staufffer COD/Rx	Mn PPRAC Recommended COD without MN Whse Tax COD/Rx	Mn PPRAC Recommended COD with MN Whse Tax COD/Rx	Minnesota All Costs COD COD/Rx
Pharmacies in Analysis[C]	502	502	502	502
Base COD Mean (Medicaid weighted)[D]	$ 9.590	$ 9.590	$ 9.590	$ 9.590
Additional Costs				
Accounts Receivable	$ -	$ -	$ -	NA
Inventory Carrying Costs	$ -	$ -	$ -	NA
Owner's Extra Labor Cost[E]	$ -	$ -	$ -	$ 0.001
COD allocation for Medicaid OTCs	$ -	$ -	$ -	NA
Advertising & Marketing Expenses	$ -	$ -	$ -	$ 0.261
Charity Care & Contributions	$ -	$ -	$ -	$ 0.043
Bad Debt	$ -	$ -	$ -	$ 0.092
Uncollected Medicaid Copays	$ -	$ 0.200	$ 0.200	$ 0.200
Reasonable Net Profit After Tax	$ -	$ 1.920	$ 1.920	$ 1.920
Minn. Wholesale Drug Tax	$ -	$ -	$ 0.835	$ 0.835
Total COD mid-2006	$ 9.59	$ 11.71	$ 12.55	$ 12.94
Inflation Adjustment Factor	*3.0%*	*3.0%*	*3.0%*	*3.0%*
Total COD mid-2007 (infl. adjusted)	$ 9.88	$ 12.06	$ 12.92	$ 13.33

[A] Cost of dispensing estimated and adjusted to June 30, 2006 (the midpoint of the fiscal year ending December 31, 2006).

[B] Excludes any allowance for the Minnesota Wholesale Drug Tax and certain other allowances.

[C] 502 Minnesota (non-specialty) pharmaices provided usable responses to the survey.

[D] The cost of dispensing average was weighted by the number of Medicaid prescriptions filled by each pharmacy.

[E] Ownwers work more hours per week, but the COD study capped owners salary base on staff pharmacist salaries.

NA Information not available.

Source: Survey of Average Cost of Filling a Medicaid Prescription in the State of Minnesota, Myers and Staffer, December 2006, Exhibit 13.

Exhibit 6
Medicaid Reasonable Payment to Minnesota Pharmacies
With Greater than 10% Medicaid Prescriptions
Cost of Dispensing[A,B] and Additional Costs: 2006 & 2007

	Minn. COD Baseline Myers & Staufffer COD/Rx	Mn PPRAC Recommended COD without MN Whse Tax COD/Rx	Mn PPRAC Recommended COD with MN Whse Tax COD/Rx	Minnesota All Costs COD COD/Rx
Pharmacies in Analysis[C]	58	58	58	58
Base COD Mean (Medicaid weighted)[D]	$ 10.000	$ 10.000	$ 10.000	$ 10.000
Additional Costs				
Accounts Receivable	$ -	$ -	$ -	NA
Inventory Carrying Costs	$ -	$ -	$ -	NA
Owner's Extra Labor Cost[E]	$ -	$ -	$ -	$ 0.010
COD allocation for Medicaid OTCs	$ -	$ -	$ -	NA
Advertising & Marketing Expenses	$ -	$ -	$ -	$ 0.261
Charity Care & Contributions	$ -	$ -	$ -	$ 0.043
Bad Debt	$ -	$ -	$ -	$ 0.092
Uncollected Medicaid Copays	$ -	$ 0.200	$ 0.200	$ 0.200
Reasonable Net Profit After Tax	$ -	$ 1.920	$ 1.920	$ 1.920
Minn. Wholesale Drug Tax	$ -	$ -	$ 0.835	$ 0.835
Total COD mid-2006	$ 10.00	$ 12.12	$ 12.96	$ 13.36
Inflation Adjustment Factor	*3.0%*	*3.0%*	*3.0%*	*3.0%*
Total COD mid-2007 (infl. adjusted)	$ 10.30	$ 12.48	$ 13.34	$ 13.76

[A] Cost of dispensing estimated and adjusted to June 30, 2006 (the midpoint of the fiscal year ending December 31, 2006).

[B] Excludes any allowance for the Minnesota Wholesale Drug Tax and certain other allowances.

[C] 58 Minnesota pharmaices with more than 10% Medicaid prescriptions provided usable survey responses and represent about 120 pharmacies in Minnesota.

[D] The cost of dispensing average was weighted by the number of Medicaid prescriptions filled by each pharmacy.

[E] Ownwers work more hours per week, but the COD study capped owners salary base on staff pharmacist salaries.

NA Information not available.

Source: Survey of Average Cost of Filling a Medicaid Prescription in the State of Minnesota, Myers and Staffer, December 2006, Exhibit 13.

APPENDIX 1

LAWS OF MINNESOTA 2006
CHAPTER 282, ARTICLE 16, SECTION 15

and

CHAPTER 256B.0625, MINNESOTA STATUTES

Sec. 15. **PHARMACY PAYMENT REFORM ADVISORY COMMITTEE.**

Subdivision 1. **Definitions.** For purposes of this section, the following words, terms, and phrases have the following meanings:

(a) "Department" means the Department of Human Services.

(b) "Commissioner" means the commissioner of the Department of Human Services.

(c) "Cost of dispensing" includes, but is not limited to, operational and overhead costs; professional counseling as required under the Omnibus Budget Reconciliation Act of 1990, excluding medication management services under Minnesota Statutes, section 256B.0625, subdivision 13h; salaries; and other associated administrative costs. In addition, cost of dispensing includes expenses transferred by wholesale drug distributors to pharmacies as a result of the wholesale drug distributor tax under Minnesota Statutes, sections 295.52 to 295.582.

(d) "Additional costs" include, but are not limited to, costs relating to coordination of benefits, bad debt, uncollected co-pays, payment lag times, and high rate of rejected claims.

(e) "Advisory committee" means the Pharmacy Payment Reform Advisory Committee established by this section.

Subd. 2. **Advisory committee.** The Pharmacy Payment Reform Advisory Committee is established under the direction of the commissioner of human services. The commissioner, after receiving recommendations from the Minnesota Pharmacists Association, the Minnesota Retailers Association, the Minnesota Hospital Association, and the Minnesota Wholesale Druggists Association, shall convene a pharmacy payment reform advisory committee to advise the commissioner and make recommendations to the legislature on implementation of pharmacy reforms contained in title VI, chapter IV, of the Deficit Reduction Act of 2005. The committee shall be comprised of seven private sector representatives with management/operations experience, representing each of the following pharmacy practice settings: independent and chain pharmacy entities, one of whom must have expertise in pharmacoeconomics; managed care; hospital outpatient pharmacies; and wholesale drug distribution. The committee shall be staffed by an employee of the department who shall serve as an ex officio nonvoting member of the committee. The department's pharmacy program manager shall also serve as an ex officio, nonvoting member of the committee. The committee is governed by Minnesota Statutes, section 15.059, except that committee members do not receive compensation or reimbursement for expenses. The advisory committee members shall serve a two-year term and the advisory committee will expire on January 31, 2008. At least five of the committee members shall be registered pharmacists.

Subd. 3. **Cost of dispensing study.** The department shall conduct a prescription drug cost of dispensing study to determine the average cost of dispensing Medicaid prescriptions in Minnesota. The department shall contract with an independent third party to conduct a Medicaid prescription drug cost of dispensing study. The cost of dispensing

study shall be completed by an independent third party no later than January 1, 2007, and reported to the department and the advisory committee upon completion.

Subd. 4. **Content of study.** The study shall determine the cost of dispensing the average prescription and any additional costs that might be incurred for dispensing Medicaid prescriptions. The study shall include the current level of dispensing fees paid to providers for dispensing Medicaid prescription drugs and an estimate of revenues required to adequately adjust reimbursement to cover the cost to pharmacies for dispensing Medicaid prescription drugs.

Subd. 5. **Methodology of study and publishing requirement.** The independent third-party entity performing the cost of dispensing research shall submit to the advisory committee the entity's proposed research methodology and shall make the data available to allow other independent researchers to review the study results. The data shall be published in a manner that does not identify the source of the data.

Subd. 6. **Recommendations.** The advisory committee shall use the information from the cost of dispensing study and make recommendations to the commissioner on implementation of pharmacy reforms contained in title VI, chapter IV, of the Deficit Reduction Act of 2005. The commissioner shall report the findings of the study and the recommendations of the advisory committee to the legislature by February 1, 2007. The commissioner, in consultation with the advisory committee, shall make recommendations to the legislature on how to adequately adjust Medicaid reimbursement rates to pharmacies to cover the costs of dispensing and additional costs to pharmacies. Reports shall include the current level of dispensing fees paid to providers for dispensing Medicaid prescription drugs and an estimate of revenues required to adequately adjust reimbursement to cover the cost to pharmacies for dispensing Medicaid prescription drugs to ensure that:

(1) reimbursement is sufficient to enlist an adequate number of participating pharmacy providers so that pharmacy services are as available for Medicaid recipients under the program as for the state's general population;

(2) Medicaid dispensing fees are adequate to reimburse pharmacy providers for the costs of dispensing prescriptions under the Medicaid program;

(3) Medicaid pharmacy reimbursement for multiple-source drugs included on the federal upper reimbursement limit is set at the level established by the federal government under United States Code, title 42, section 1396r-8(e)(5); and

(4) the new payment system does not create disincentives for pharmacists to dispense generic drugs.

EFFECTIVE DATE.This section is effective the day following final enactment.