SEP 16 2002   Washington, D.C. 20201

TO: Thomas Scully
               Administrator
               Centers for Medicare & Medicaid Services

FROM: Janet Rehnquist
               Inspector General

SUBJECT: Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of
               Prescription Drug Products (A-06-02-00041)

As a follow-up to our previous work on Medicaid drug reimbursement, attached are two copies of the Department of Health and Human Services, Office of Inspector General's final report entitled, "Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products." This report provides extended analyses of information previously reported to you.[1] Our previous reports estimated the discounts below average wholesale price (AWP) commonly available to pharmacy purchasers of brand name drugs and generic drugs. The estimate for brand name drugs included both single source and multiple source innovator drugs. The estimate for generic drugs was for all non-innovator multiple source drugs, including those on the Centers for Medicare & Medicaid Services' (CMS) federal upper-limits (FUL) list as well as those drugs not on the FUL list.

The objectives of this report were to develop estimates of the discount below AWP available for single source drugs, all drugs without FULs, multiple source drugs without FULs, and multiple source drugs with FULs. We believe that these additional estimates will provide states with more information that will be useful in evaluating their drug reimbursement methodologies. Our current analyses were based on the data obtained from the previous reviews. We found that:

- *For single source innovator drugs:* pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.

- *For all drugs without FULs:* pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.

- *For multiple source drugs without FULs:* pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of multiple source drugs without FULs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.

- *For multiple source drugs with FULs:* pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

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[1] "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001 and "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002.

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The above analyses show that there is a wide range of discounts from AWP for pharmacy purchases depending on the category of drug that is being purchased. Based on the results of our additional analyses, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider using a four-tiered reimbursement methodology. This four-tiered system would consist of (1) **tier one** – a percentage discount off AWP for single source brand name drugs; (2) **tier two** – a percentage discount off AWP for innovator multiple source drugs without FULs; (3) **tier three** – a percentage discount off AWP for non-innovator multiple source drugs without FULs; and (4) **tier four** – the FUL price for those FUL multiple source drugs. The current method of reimbursing for brand name drugs and those non-FUL generic drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and generics that we found during our additional analyses.

Accordingly, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider adopting a four-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products. We also recommend that CMS share this report with the states.

In response to the recommendations in our draft report, CMS suggested that the OIG recommend a four-tiered reimbursement methodology, rather that the three-tiered system recommended in our draft report in order to differentiate branded generics (innovator multiple source drugs) and generics (non-innovator multiple source drugs). We agreed with the changes suggested by CMS and revised our final report to reflect CMS's comments.

We would appreciate your views and information on the status of any action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, at (410) 786-7104.

Your formal response to the report is summarized in the body of our final report, as well as attached as an Appendix. In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services, reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR part 5.) As such, within 10 business days after the final report is issued, it will be posted on the world wide web at http://oig.hhs.gov.

Please refer to Common Identification Number A-06-02-00041 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

MEDICAID PHARMACY – ADDITIONAL ANALYSES OF THE ACTUAL ACQUISITION COST OF PRESCRIPTION DRUG PRODUCTS

JANET REHNQUIST
INSPECTOR GENERAL

SEPTEMBER
A-06-02-00041

EXECUTIVE SUMMARY

The objective of this report is to provide extended analyses of Office of Inspector General (OIG) audit work related to actual acquisition costs by pharmacies for drugs reimbursed by the Medicaid program. This report enhances the discussion of the Medicaid drug reimbursement issues included in recently issued OIG reports to the Centers for Medicare & Medicaid Services (CMS) on the actual acquisition cost of Medicaid prescription drugs, and reports issued to individually reviewed states. The report for brand name drugs, entitled "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001, showed that pharmacies purchased such drugs at an estimated average discount of 21.8 percent below average wholesale price (AWP) during Calendar Year (CY) 1999 as compared to 18.3 percent from our review in CY 1994. This estimate for brand name drugs included both single source as well as multiple source brand name drugs.[1] The reports we issued to the states showed the results for the sample pharmacies in those states.

We also issued a report for generic drugs, entitled "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002, which showed that the actual generic drug acquisition cost was a national average of 65.9 percent below AWP. Our previous estimate, based on CY 1994 pricing data, showed a discount of 42.5 percent below AWP for generic drugs.

Subsequent to the issuance of our brand name drug report and the state reports, some states included in our review, as well as industry groups, expressed interest in additional information on the discount calculation. Specifically, there was considerable interest in obtaining the discount below AWP for just the single source innovator drugs included in our estimate for brand name drugs. Accordingly, we have provided the results for single source innovator drugs in this report. Because of the reimbursement methodologies used by most states, we also estimated the discount for all drugs (including single source and multiple source innovators as well as multiple source non-innovator drugs) that do not have federal upper limits (FUL).[2] Additionally, we calculated separate estimates for multiple source drugs (both innovators and non-innovators) with and without FULs. We believe that these estimates will provide states with information that will be useful in evaluating their present drug reimbursement methodologies.

Medicaid drug reimbursement to pharmacies for the ingredient cost of drugs is generally based on the estimated acquisition cost (EAC) unless an upper-limit amount has been established. Most states calculate EAC by using the AWP for a drug less a percentage discount. A pharmacy's usual and customary charge to the general public is also a limiting factor in reimbursement. Nationally, we estimated that the average discount was 10.3 percent below

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[1] A single source innovator drug is under patent protection and is produced by only one manufacturer. Upon expiration of the patent, an innovator drug can be produced by other manufacturers, resulting in the drug being categorized as an innovator multiple source drug.

[2] The FULs are developed by CMS for use by state Medicaid programs in reimbursing for drugs that have at least three generic equivalents available.

AWP for all brand name drugs and those generic drugs that are not on FUL drug list developed by CMS. Many states currently use a two-tiered reimbursement methodology to reimburse pharmacies for drugs: (1) a percentage discount off AWP for all brand name drugs and those non-FUL multiple source drugs and (2) an upper-limit price for those multiple source drugs identified as having FUL prices.

Our current analyses provide a more comprehensive breakdown of percentages for a variety of drug categories: single source innovator drugs; all drugs without FULs (single source innovator, multiple source innovator, and multiple source non-innovator); non-FUL multiple source drugs only; and multiple source drugs with FULs. Specifically, we found that:

- ***For single source innovator drugs:*** pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.

- ***For all drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.

- ***For multiple source drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of multiple source drugs without FULs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.

- ***For multiple source drugs with FULs:*** pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

The above analyses show that there is a wide range of discounts from AWP for pharmacy purchases depending on the category of drug that is being purchased. Based on the results of our additional analyses, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider using a four-tiered reimbursement methodology. This four-tiered system would consist of (1) **tier one** – a percentage discount off AWP for single source brand name drugs; (2) **tier two** – a percentage discount off AWP for innovator multiple source drugs without FULs; (3) **tier three** – a percentage discount off AWP for non-innovator multiple source drugs without FULs; and (4) **tier four** – the FUL price for those FUL multiple source drugs. The current method of reimbursing for brand name drugs and those non-FUL generic drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and generics that we found during our additional analyses.

Accordingly, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider adopting a four-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products. We also recommend that CMS share this report with the states.

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INTRODUCTION

BACKGROUND

Medicaid regulations limit the reimbursement of multiple source drugs to upper-limit amounts, if they meet certain criteria. Multiple source drugs include innovator as well as non-innovator drugs, with innovator meaning the brand name version of a drug and non-innovator indicating a generic version. The federal upper-limit (FUL) amounts are established by the Centers for Medicare & Medicaid Services (CMS) and can only be established when certain criteria are met. The criteria require that there be a certain number of drugs, depending on the therapeutic equivalency, published in the Food and Drug Administration's <u>Approved Drug Products with Therapeutic Equivalence Evaluations</u> and at least three suppliers of the drug. All other drugs, including single source drugs and multiple source drugs without FULs, are reimbursed at the estimated acquisition cost (EAC) of the drug plus a dispensing fee. State agencies are responsible for determining the EAC. Reimbursement is also limited by the pharmacist's usual and customary charge to the general public.

The EAC for most states is calculated by using the average wholesale price (AWP) for a drug less a percentage discount. The AWP is the price assigned to the drug by its manufacturer and is compiled by commercial organizations - **Red Book**, **First DataBank**, and **Medi-Span** - for use by the pharmaceutical community.

In 1997, the Office of Inspector General (OIG) issued separate reports on the actual acquisition cost of brand name and generic drugs. The 1997 reports were based on Calendar Year (CY) 1994 data and included comparisons of 18,973 invoice prices for brand name products and 9,075 invoice prices for generic products. The reports showed average discounts of 18.3 percent below AWP and 42.5 percent below AWP, respectively. The brand name discount estimate included single source as well as innovator multiple source drugs. The methodology utilized in these reviews was collaboratively developed with assistance from the sampled state agencies and CMS.

The OIG also issued reports to CMS on the actual acquisition cost of Medicaid prescription drugs based on CY 1999 data. The report for brand name drugs entitled, "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001, showed that pharmacies purchased such drugs at an estimated average discount of 21.8 percent below AWP during CY 1999. This estimate for brand name drugs again included both single source as well as multiple source brand name drugs and the review used the same methodology developed for the 1997 reviews. The report for generic drugs entitled, Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002, showed a discount of 65.9 percent below AWP.

The cost of the Medicaid drug program has increased significantly in recent years. Drug expenditures in CY 1994 totaled about $9.4 billion. In CY 1999, drug expenditures increased to about $17.9 billion.

OBJECTIVES, SCOPE, AND METHODOLOGY

Our review was performed in accordance with generally accepted government auditing standards. The objective of this report was to provide additional analyses of the data compiled for our earlier reviews.[3] Specifically, our objectives were to develop estimates of the discount below AWP for single source drugs, all drugs without FULs, multiple source drugs without FULs, and multiple source drugs with FULs for Medicaid pharmacy providers. Our objectives did not require that we identify or review any internal control systems. Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription for instances such as therapeutic intervention, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid-specific administrative costs, and general overhead.

To accomplish our current objectives, we used the data that was obtained for the two prior reports as a basis for this report. We used a multistage sampling procedure (a detailed description of our sample design is included as **APPENDIX 1** to this report). State Medicaid agencies were designated as the primary sample units and Medicaid pharmacy providers as the secondary sample units. We selected a stratified random sample of 8 states from a universe of 48 states and the District of Columbia. Arizona was excluded from the universe of states because its Medicaid drug program was a demonstration project using prepaid capitation financing. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. Of the 8 states, 2 states (Montana and Florida) were selected from a universe of 10 states and the District of Columbia that were included in our previous review. The other 6 states (Colorado, Indiana, Texas, Washington, West Virginia, and Wisconsin) were selected from the remaining 38 states.

We obtained a listing of all Medicaid pharmacy providers from each sample state. The state agencies were responsible for classifying each pharmacy as a chain, independent, or non-traditional (nursing home pharmacies, hospital pharmacies, home intravenous feeding (IV), etc.). For purposes of these reviews, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a 1999 listing of the metropolitan statistical areas and their components. We selected a stratified random sample of 40 pharmacies from each state with 8 pharmacies selected from each of 5 strata -- urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional. We sampled the non-traditional category separately so it could be excluded from our estimates. We excluded the non-traditional category because we believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and those discounts would inflate our estimates.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1999. Supply sources included wholesalers, chain

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[3] "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001 and "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002.

warehouse distribution centers, generic distributors, and manufacturers. Each pharmacy was initially assigned a month from January 1999 to December 1999 in order to provide a cross-section of this 12-month time period. However, we permitted some pharmacies to provide invoices from other months in 1999 if invoices were not available for the requested period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain AWP for the drug. We used the **2000 Red Book**, a nationally recognized reference for drug product and pricing information, to obtain NDCs or identify over-the-counter items. Two prominent wholesalers, as well as four chain stores, whose invoices contained the wholesaler item numbers rather than NDCs, provided us with a listing that converted their item numbers to NDCs.

To identify single source drugs, we used information available on a pricing file supplied by **First DataBank**. The state of Florida provided the **First DataBank** file. To identify the drugs with FULs, we obtained a listing of FUL drugs from CMS that was effective on September 1, 1998. We also obtained a listing from CMS of the subsequent changes to the September list. From these listings, we identified the generic code numbers for the drugs on the FUL listing and compared those generic code numbers to the drugs on the invoices.

We obtained the AWP that was in effect as of the invoice date for each NDC on the invoices from the **First DataBank** pricing file. If a drug from an invoice was not on the pricing file, we eliminated that drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP.

We also calculated a discount below AWP for each pharmacy based on the total invoice dollars on the pharmacy invoice(s). This discount was computed by summing all invoice prices for a pharmacy and comparing that total to the sum of all the AWPs for the pharmacy. The estimates calculated using these weighted pharmacy discounts are included in the detailed sample results reported in **APPENDIX 2**.

We used Office of Audit Services (OAS) statistical software to calculate all estimates, as well as to generate all random numbers. We obtained the total number of pharmacies in the universe from the National Council for Prescription Drug Programs. We did not independently verify any information obtained from third-party sources. Additionally, we did not attempt to identify any special discounts, rebates, or other types of special incentives not reflected on the invoices. The results of our additional analyses were developed by our Little Rock, Arkansas OAS field office from January to May 2002.

FINDINGS AND RECOMMENDATIONS

Based on our findings, we recommend that CMS encourage states to consider changing the Medicaid reimbursement methodology that is normally used to reimburse pharmacies for outpatient prescription drugs. States on average paid AWP minus 10.3 percent in 1999, which represented reimbursement for all brand name drugs and those generic drugs that are not on the

FUL drug list developed by CMS. Multiple source drugs that were included on the CMS FUL list[4] must meet set criteria and are reimbursed at the FUL price. Thus, Medicaid used a two-tiered reimbursement methodology to reimburse pharmacies for drugs: (1) a percentage discount off AWP for all brand name drugs and those non-FUL multiple source drugs and (2) an upper-limit price for those multiple source drugs identified as having FUL prices.

Based on the results of our additional analyses, if states continue to reimburse for drugs based on AWP, we recommend that CMS encourage states to consider using a four-tiered reimbursement methodology. This four-tiered system would consist of (1) **tier one** – a percentage discount off AWP for single source brand name drugs; (2) **tier two** – a percentage discount off AWP for innovator multiple source drugs without FULs; (3) **tier three** – a percentage discount off AWP for non-innovator multiple source drugs without FULs; and (4) **tier four** – the FUL price for those FUL multiple source drugs. The current method of reimbursing for brand name drugs and those non-FUL multiple source drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and multiple source drugs that we found during our additional analyses.

Our review of CY 1999 Medicaid drug reimbursements showed that for brand name drugs, pharmacy invoice prices were discounted an average of 21.8 percent below AWP. We included in this calculation all single source innovator drugs and multiple source innovator drugs. The percentage discounts off AWP for all generic drugs reimbursed in CY 1999 (including those generics on the FUL) was 65.9 percent.

Our additional analyses of this data, however, provide a more comprehensive breakdown of discount percentages for single source innovator drugs, all drugs without FULs (single source innovator and multiple source drugs), non-FUL multiple source drugs only, and multiple source drugs with FULs. Specifically, we found that:

- ***For single source innovator drugs:*** pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.

- ***For all drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.

- ***For multiple source drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of multiple source drugs without FULs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.

- ***For multiple source drugs with FULs:*** pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

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[4] Many states have established their own programs for limiting reimbursement for generic drugs. These programs are often referred to as state maximum allowable cost (MAC) programs. Reimbursement for generic drugs on these state MAC programs is limited to the MAC price for a given generic drug. When we refer to FUL generic drugs, we are also considering these to include those drugs covered by state MAC programs.

The above analyses show that there is a wide range of discounts depending upon the category of drug that is being purchased. The following provides the details of those findings.

SINGLE SOURCE INNOVATOR DRUGS

As part of our expanded analyses, we developed an estimate of the average discount below AWP for **tier–one** type drugs (single source innovator drugs) at which pharmacies were able to purchase these drugs. We estimated that pharmacies purchased single source innovator drugs at a discount of 17.2 percent below AWP.[5] The estimate was based on a comparison to AWP of 12,685 invoice prices with a standard error of 0.25 percent. Our previous estimate (included in report A-06-00-00023), which included innovator multiple source drugs, was 21.8 percent below AWP with a standard error of 0.35 percent.

As discussed above, the results presented in our original report on brand name drugs included both single source and multiple source innovator drugs. We presented our prior work as a combination because that was how CMS accounted for innovator multiple source drugs and that was how drug manufacturers paid rebates under the Medicaid rebate program. The rebate percentage is greater for brand name drugs than for generic drugs. However, there was considerable interest in having us break down single source innovator and multiple source innovator drugs into the two categories. While the estimate of the discount fell to 17.2 percent when multiple source innovator drugs were removed from our calculations, the discount remains considerably higher than the discount used by most states in their determination of EAC (which was an average of 10.3 percent). The following chart provides a distribution of the 12,685 invoice price discounts and shows that most single source innovator drugs are discounted between 15 and 20 percent.
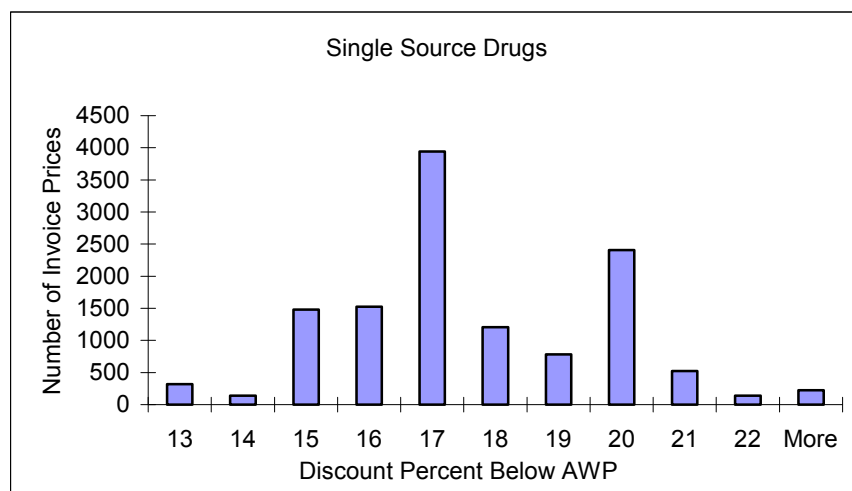
Single Source Drugs

ALL DRUGS WITHOUT FULS

In order to develop a discount estimate that could be compared to the single discount percentage (on average 10.3 percent nationally in CY 1999) that was used by states to reimburse pharmacies for prescription drugs, we included all drugs from the invoices in our review except those innovator multiple source and non-innovator multiple source drugs that were on the FUL listings. We calculated this total average discount estimate to be 27.2 percent below AWP compared to the 10.3 percent used on average by the states. The estimate was based on a comparison to AWP of 19,357 invoice prices with a standard error of 0.34 percent.

As the following chart shows, most of the invoice prices fall below the average estimate of 27.2 percent. Therefore, we would not recommend establishing a discount percentage as high as 27.2 percent for this category of drugs because of the concern that many pharmacies may not be able to purchase certain brand name drugs at these discounts. However, we are providing this information to show a comparison to the single discount percentage that is, on average, currently used by most states. The following chart shows the distribution of the discounts below AWP for the 19,357 invoice prices.

Single Source & Multiple Source Drugs Without Federal Upper Limits
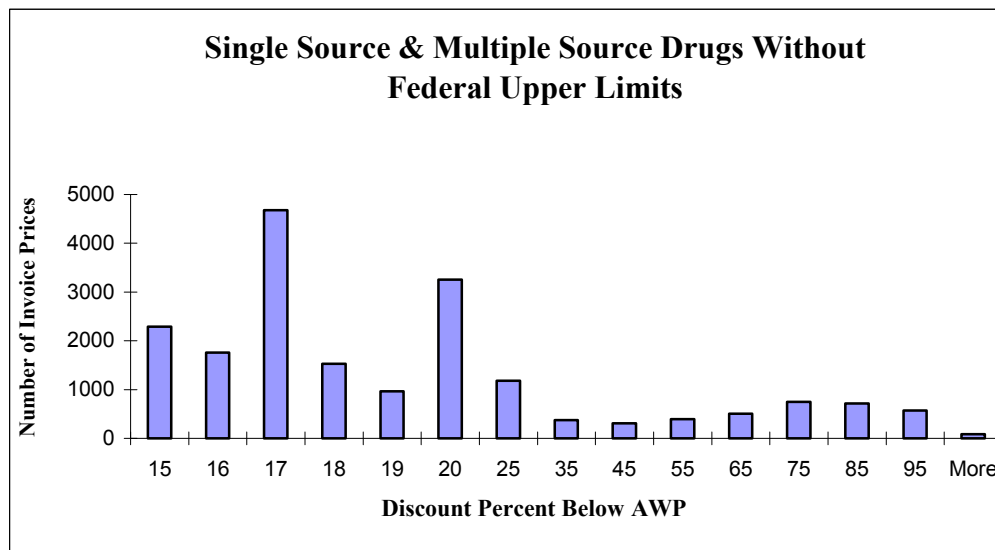
MULTIPLE SOURCE DRUGS WITHOUT FULS

As previously stated most states used the same single percentage discount (on average 10.3 percent) for single source, multiple source innovator, and multiple source non-innovator drugs that were not on the CMS FUL list. However, we estimated that pharmacies purchased multiple source drugs that did not have FULs at a discount of 44.2 percent below AWP. The estimate was based on a comparison of 6,672 invoice prices to AWP with a standard error of 0.61 percent.

This average discount estimate from our review is significantly greater than what states, on average, paid during the period reviewed. The following chart shows the distribution of the discounts for the 6,672 invoice prices.

Multiple Source Drugs Without Federal Upper Limits
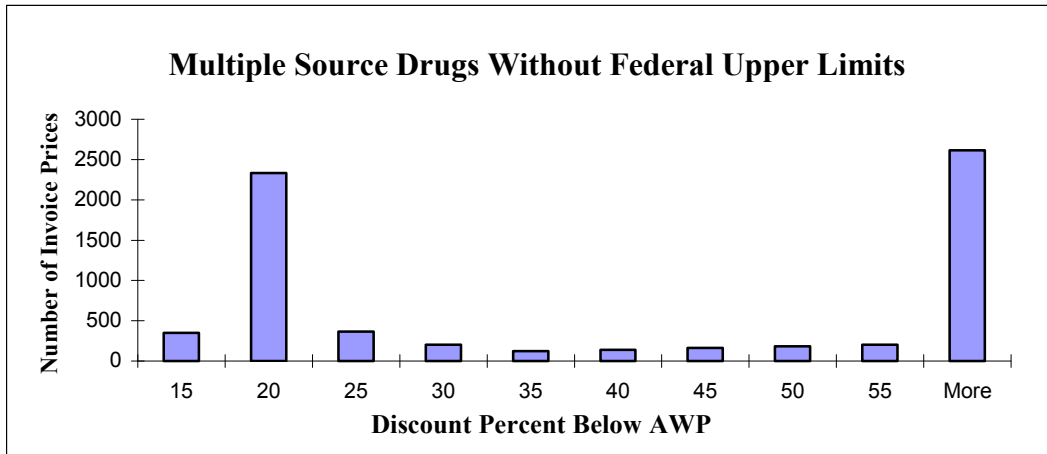
Discount for Innovator Multiple Source Drugs Without FULs

We believe the use of only one EAC, or one discount from AWP, for multiple source drugs without FULs is not the best method for reimbursing these drugs. If the results of our review (an average discount of 44.2 percent) were used as the EAC for multiple source drugs that are not on the CMS FUL list, some drugs would be reimbursed at a level far below a pharmacy's cost for those drugs. As the distribution chart above shows, there were a large number of invoice price discounts that fell in the 20 percent range. These drugs represented, for the most part, innovator multiple source drugs.

As a result, we calculated a separate estimate for the innovator multiple source drugs that are not on the CMS FUL list. We estimated that discount to be 24.4 percent below AWP. The estimate was based on 2,503 invoice prices with a standard error of 0.92 percent. The following chart provides a distribution of the invoice price discounts for innovator multiple source drugs that are not on the CMS FUL list.

Innovator Multiple Source Drugs Without Federal Upper Limits
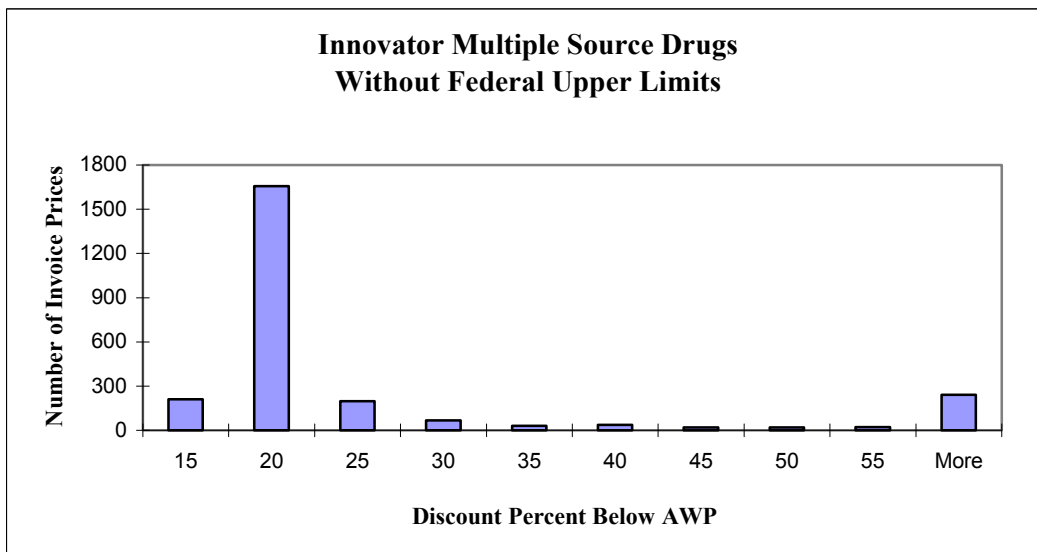
Discount for Non-Innovator Multiple Source Drugs Without FULs

As the chart above shows, most of the innovator multiple source drugs fell in the 20 percent discount range. The effect of removing the innovator multiple source drugs from our analyses of multiple source drugs without FULs resulted in increasing the estimated discount for non-innovator multiple source drugs without FULs to 54.2 percent. The estimate was based on 4,169 invoice prices with a standard error of 0.89 percent. The following chart provides a distribution of the invoice price discounts.

**Multiple Source Non-Innovator Drugs
Without Federal Upper Limts**

Number of Invoice Prices vs. Discount Percent Below AWP
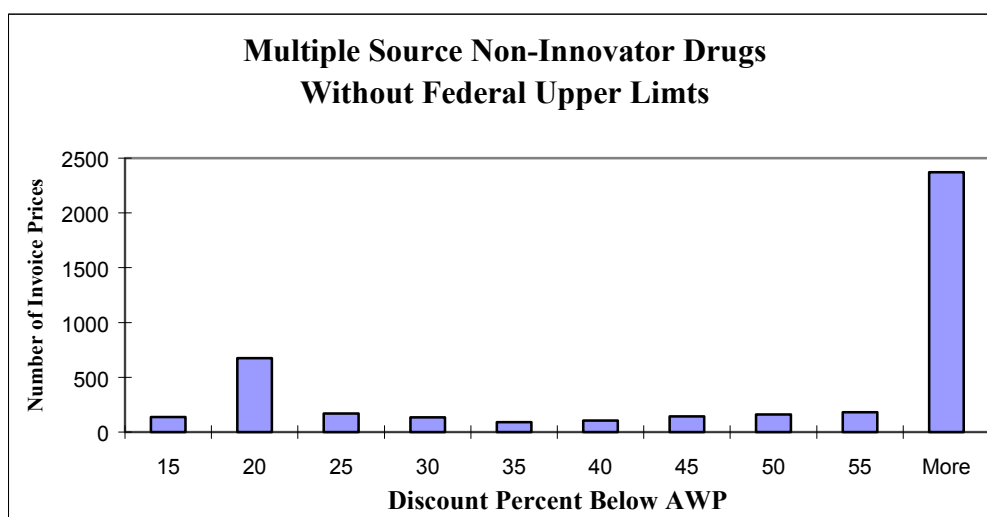
The discount below AWP for non-innovator multiple source drugs not on the CMS FUL list was significantly greater than the innovator multiple source drugs. This difference and the results of our review of the discounts available on innovator multiple source drugs without FULs would support the use of a separate EAC for those multiple source drugs that are not on the CMS FUL list. The establishment of such an EAC should take into consideration the wide range in the discounts for innovator multiple source and non-innovator multiple source drugs, 24.4 and 54.2 percent, respectively. We believe that the results from our review will be useful for states that are considering reimbursing for drugs using one EAC for innovator single source drugs and another EAC for multiple source drugs that are not on the CMS FUL list.

MULTIPLE SOURCE DRUGS WITH FULS

There are a large number of drugs reimbursed by states following the FULs established by CMS. We estimated that the invoice price for multiple source drugs with FULs was 72.1 percent below AWP. The estimate was based on a comparison of 5,575 invoice prices to AWP with a standard error of 0.95 percent.

The following chart shows the distribution of the discounts for the individual invoice prices.

Multiple Source With Federal Upper Limits

Number of Invoice Prices (y-axis: 0, 200, 400, 600, 800, 1000, 1200, 1400, 1600)

Discount Percent Below AWP (x-axis: 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, More)
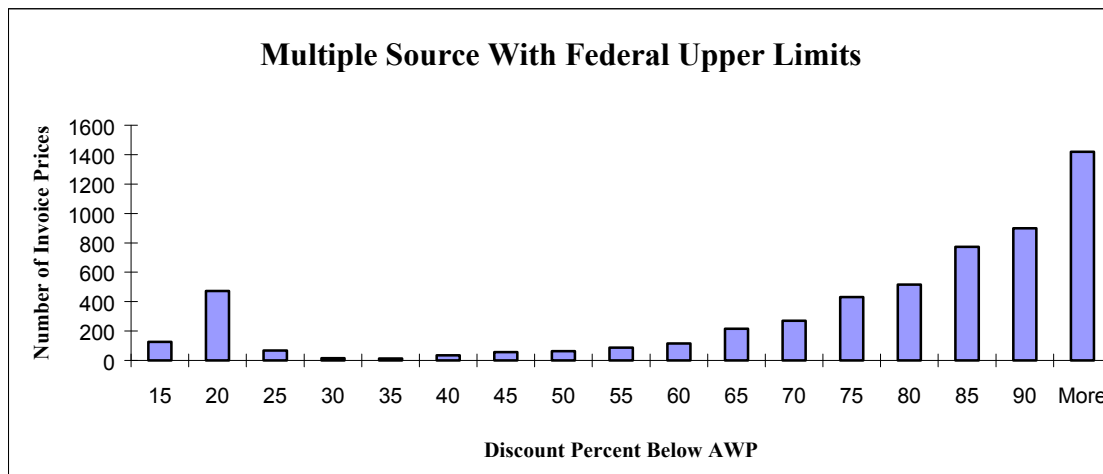
We did not evaluate the FUL prices established by CMS. However, as shown in the above chart, it appears drug manufacturers were providing deeper discounts on purchases of those drugs that were on the CMS FUL listings as compared to those multiple source drugs that were not listed. We are especially interested in the fact that about 1,400 of the 5,575 invoice prices were greater than 90 percent below AWP for those drugs. We will be further reviewing this area in consultation with CMS.

INDIVIDUAL STATE RESULTS

All of our work reported in this current report and our two prior reports involved eight sampled states. We issued individual reports detailing the results of our reviews on brand name and generic drugs to those states. As a result of the extended analyses included in this current report, we plan to share with these eight states their individual results based on this analyses. However, for CMS's use, we have included the results of the additional analyses for the individual states in **APPENDICES 3** through **10**.

CONCLUSIONS AND RECOMMENDATIONS

The results of our additional analyses included in this report provide further support for the recommendation contained in our earlier reports that CMS require the states to bring pharmacy drug reimbursement more in line with the actual acquisition cost of brand name and generic drugs. Our estimate of the discount below AWP for single source innovator drugs, 17.2 percent, was significantly greater than the discount used by most states for reimbursing drugs not on the FUL list (an average discount of 10.3 percent) even after removing multiple source innovator drugs from our calculations.

We also estimated that pharmacies purchased all drugs without FULs at a discount of 27.2 percent below AWP. When this 27.2 percent figure is compared to the national state average discount of 10.3 percent, it appears that states were paying substantially higher

reimbursement rates for drugs than necessary. However, we would not recommend the use of a single discount for drugs without FULs, such as the 27.2 percent value we determined. Rather than using one EAC for reimbursing drugs without FULs, states should consider using different EACs – one for single source drugs, one for innovator multiple source drugs without FULs, and another for non-innovator multiple source drugs without FULs.   If states used these three EACs for certain categories of drugs and reimbursed for FUL drugs using the FULs developed by CMS, they would have a four-tiered reimbursement system. One state already uses a three-tiered system and three states are currently considering similar reimbursement methodologies. (See **APPENDIX 11**.)

We believe that the three-tiered approach already being used by one state and the proposed changes to reimbursement by three other states represent a significant advancement in ensuring that Medicaid reimburses drugs more in line with the actual acquisition costs of drugs and provides support for all other states to consider using a four-tiered reimbursement methodology. Accordingly, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider adopting a four-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products. Such a four-tiered system would provide for separate discount percentages for (a) single source innovator drugs, (b) multiple source innovator drugs not on the FUL listing, (c) non-innovator multiple source drugs not on the FUL listing, and (d) all drugs on the FUL listing. We also recommend that CMS share this report with the states.

CMS'S COMMENTS

In response to the recommendations in our draft report, CMS agreed to share our report with the states. However, CMS suggested that the OIG recommend a four-tiered reimbursement methodology, rather than the three-tiered system recommended in our draft report in order to differentiate branded generics (innovator multiple source drugs) and generics (non-innovator multiple source drugs). In addition, CMS offered a technical comment regarding the criteria for the establishment of FUL prices. The full text of CMS's comments is included as **APPENDIX 12** to this report.

OIG'S RESPONSE

We agreed with the changes suggested by CMS and revised our final report to reflect CMS's comments.

OTHER MATTERS

The CMS recently developed a legislative proposal that was included as part of the President's fiscal year 2003 budget that proposes to change the basis for calculating Medicaid outpatient prescription drug rebates. This change would substitute AWP in place of the average manufacturer's price in the rebate formula. We previously issued a report[6] to CMS that recommended such a change and detailed several advantages of doing so. We support CMS's proposed change and agree with CMS that connecting the rebate amount to AWP could result in AWPs that more closely reflect the actual acquisition cost of a given drug. If this change is approved and implemented, states may, at some point, have to re-evaluate their reimbursement methodology to see if further changes are needed.

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[6] "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052).

<div align="center">**SAMPLE DESCRIPTION**[7]</div>

<u>Sample Objectives:</u>

Develop a nationwide estimate of the extent of the discount below AWP of actual invoice prices paid by Medicaid pharmacies for prescription drugs.

<u>Population:</u>

The primary sampling population was all states providing coverage of prescription drugs as an optional service under section 1905 (a) (12) of the Social Security Act (the Act). Section 1903 (a) of the Act provides for federal financial participation in state expenditures for prescription drugs.

<u>Sampling Frame:</u>

The primary sampling frame was a listing of all states and the District of Columbia, participating in the Medicaid prescription drug program except for Arizona and Tennessee. Arizona was excluded because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was also excluded because of a waiver received to implement a managed care program for Medicaid.

<u>Sample Design:</u>

A stratified multistage sample was designed with states as the primary sample units and Medicaid pharmacy providers within those states as the secondary sample units. A stratified random sample of states was selected for the primary sample and a stratified random sample of pharmacies was selected for the secondary sample. A sample of eight pharmacies was selected from each of five strata. The five strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). Each pharmacy was assigned a month from 1999 for which to provide invoices. All pharmacies were initially assigned a month from January 1999 to December 1999 in a method designed to provide a cross-section of the 12-month period. However, some pharmacies were permitted to submit invoices from other months in 1999, as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply

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[7] This sample was used for both of our original reports involving brand name and generic drugs (A-06-00-00023 and A-06-01-00053). The results of this sample then became the basis for the additional analyses we performed on drug reimbursement and reported in this current report.

was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Eight states were selected for review from our primary sampling frame. Eight pharmacies were selected from each stratum of our secondary sample frame. Therefore, a maximum of 40 pharmacies was selected from each state. Of the 8 states, 2 states were selected from the universe of 10 sampled states plus the District of Columbia in our previous review. The remaining 6 states were selected from the remaining universe of 38 states.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage of the discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that refused to provide the requested information. If a stratum had eight or fewer pharmacies, we reviewed all pharmacies in that stratum. Spares were substituted for pharmacies that were not providers during the review period and for misclassified pharmacies.   If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that supplier type during the assigned month.

Estimation Methodology:

We used OAS statistical software for stratified multistage variable sampling to project the percentage difference between actual invoice prices and AWP for each stratum, as well as an overall percent difference.

Other Evidence:

We obtained AWP from a pricing file received from the state of Florida.

DETAILED SAMPLE RESULTS

SINGLE SOURCE DRUGS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	52	2,707	16.63	16.60
Rural-Independent	1,243	55	2,043	17.85	17.71
Urban-Chain	5,745	56	6,109	16.97	16.91
Urban-Independent	2,398	53	1,826	17.64	17.64
Non-Traditional	1,123	58	1,194	26.26	25.39
Overall (Exc. Non-Trad.)	10,394	216	12,685	17.19	17.15

ALL DRUGS <u>WITHOUT</u> FEDERAL UPPER LIMITS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	52	4,175	27.38	22.24
Rural-Independent	1,243	55	3,033	26.24	23.27
Urban-Chain	5,745	56	9,470	28.22	23.96
Urban-Independent	2,398	54	2,679	24.98	22.95
Non-Traditional	1,123	62	2,096	41.95	34.86
Overall (Exc. Non-Trad.)	10,394	217	19,357	27.16	23.48

* Weighted based on total dollars on each pharmacy's invoice(s).

DETAILED SAMPLE RESULTS

MULTIPLE SOURCE DRUGS <u>WITHOUT</u> FEDERAL UPPER LIMITS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	52	1,468	43.63	37.87
Rural-Independent	1,243	54	990	42.35	38.38
Urban-Chain	5,745	56	3,361	47.03	45.56
Urban-Independent	2,398	54	853	38.68	37.10
Non-Traditional	1,123	58	902	56.75	56.49
Overall (Exc. Non-Trad.)	10,394	216	6,672	44.23	42.03

MULTIPLE SOURCE DRUGS <u>WITH</u> FEDERAL UPPER LIMITS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	51	1,431	69.36	73.56
Rural-Independent	1,243	55	737	71.06	75.97
Urban-Chain	5,745	56	2,740	73.08	78.70
Urban-Independent	2,398	53	667	71.56	76.63
Non-Traditional	1,123	48	617	76.00	79.55
Overall (Exc. Non-Trad.)	10,394	215	5,575	72.13	77.41

* Weighted based on total dollars on each pharmacy's invoice(s).

SAMPLE RESULTS BY STATE
SINGLE SOURCE DRUGS

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	254	16.61	1.79	15.57	17.66
	Rural-Independent	73	6	189	17.38	0.94	16.78	17.99
	Urban-Chain	357	4	638	17.15	0.86	16.45	17.85
	Urban-Independent	128	6	218	16.85	0.64	16.43	17.27
	Non-Traditional	65	7	115	27.67	10.94	21.25	34.10
	Overall (Excl. Non-Trad.)	617	23	1,299	17.06	0.26	16.63	17.50
FLORIDA	Rural-Chain	137	7	195	15.83	2.56	14.28	17.38
	Rural-Independent	68	8	449	17.96	0.37	17.76	18.17
	Urban-Chain	2,052	8	986	17.81	0.34	17.62	18.01
	Urban-Independent	656	8	220	16.94	1.10	16.30	17.58
	Non-Traditional	363	8	84	29.75	14.56	21.38	38.12
	Overall (Excl. Non-Trad.)	2,913	31	1,850	17.53	0.13	17.31	17.74
INDIANA	Rural-Chain	187	7	414	17.13	2.18	15.80	18.46
	Rural-Independent	105	8	293	17.09	1.11	16.47	17.71
	Urban-Chain	608	7	949	17.60	1.61	16.60	18.60
	Urban-Independent	183	5	217	20.74	8.43	14.62	26.86
	Non-Traditional	178	8	159	26.13	9.17	20.91	31.34
	Overall (Excl. Non-Trad.)	1,083	27	1,873	18.00	0.73	16.80	19.20
MONTANA	Rural-Chain	57	6	255	15.65	1.70	14.57	16.73
	Rural-Independent	104	4	130	16.73	0.62	16.22	17.23
	Urban-Chain	37	8	753	16.34	0.98	15.84	16.84
	Urban-Independent	31	7	183	17.93	3.23	16.16	19.69
	Non-Traditional	47	8	179	26.23	7.67	22.16	30.29
	Overall (Excl. Non-Trad.)	229	25	1,321	16.56	0.26	16.12	16.99
TEXAS	Rural-Chain	225	7	236	16.21	1.68	15.19	17.24
	Rural-Independent	398	8	253	17.56	0.79	17.11	18.02
	Urban-Chain	1,682	8	514	15.96	3.82	13.75	18.18
	Urban-Independent	778	8	260	17.29	0.99	16.71	17.86
	Non-Traditional	214	7	158	23.86	12.98	15.92	31.79
	Overall (Excl. Non-Trad.)	3,083	31	1,263	16.52	0.74	15.30	17.74
WASHINGTON	Rural-Chain	81	6	232	16.65	1.12	15.93	17.37
	Rural-Independent	137	5	104	21.28	8.36	15.25	27.31
	Urban-Chain	512	6	359	15.97	0.91	15.36	16.58
	Urban-Independent	272	5	183	18.14	0.86	17.51	18.77
	Non-Traditional	123	6	92	24.62	5.52	21.00	28.23
	Overall (Excl. Non-Trad.)	1,002	22	878	17.34	0.55	16.44	18.24
WEST VIRGINIA	Rural-Chain	160	6	601	18.03	1.30	17.18	18.89
	Rural-Independent	119	8	292	17.45	0.48	17.18	17.72
	Urban-Chain	137	8	865	17.88	0.77	17.44	18.31
	Urban-Independent	62	7	307	17.77	0.89	17.25	18.29
	Non-Traditional	18	6	180	24.12	11.21	17.97	30.26
	Overall (Excl. Non-Trad.)	478	29	2,065	17.81	0.20	17.48	18.14
WISCONSIN	Rural-Chain	102	6	520	16.22	2.41	14.64	17.79
	Rural-Independent	239	8	333	17.54	0.59	17.20	17.87
	Urban-Chain	360	7	1,045	16.33	2.16	15.00	17.66
	Urban-Independent	288	7	238	18.13	1.32	17.32	18.94
	Non-Traditional	115	8	227	26.15	8.46	21.41	30.89
	Overall (Excl. Non-Trad.)	989	28	2,136	17.13	0.34	16.57	17.70

| ST | Category | Universe Of Pharm. | Sample Pharm. | Drug Prices Reviewed | Percent Below AWP | | 90% Confidence Level | |
| | | | | | Sample | | | |
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	254	16.10	1.51	15.22	16.98
	Rural-Independent	73	6	189	17.28	1.23	16.49	18.07
	Urban-Chain	357	4	638	17.05	0.95	16.28	17.82
	Urban-Independent	128	6	218	16.75	0.72	16.28	17.22
	Non-Traditional	65	7	115	25.90	9.79	20.15	31.65
	Overall (Excl. Non-Trad.)	617	23	1,299	16.92	0.29	16.45	17.40
FLORIDA	Rural-Chain	137	7	195	15.63	2.62	14.04	17.22
	Rural-Independent	68	8	449	17.79	0.45	17.54	18.03
	Urban-Chain	2,052	8	986	17.79	0.34	17.59	17.98
	Urban-Independent	656	8	220	17.00	1.14	16.34	17.66
	Non-Traditional	363	8	84	27.69	14.44	19.38	35.99
	Overall (Excl. Non-Trad.)	2,913	31	1,850	17.51	0.13	17.29	17.72
INDIANA	Rural-Chain	187	7	414	17.29	2.25	15.91	18.66
	Rural-Independent	105	8	293	16.95	1.09	16.34	17.56
	Urban-Chain	608	7	949	17.57	1.66	16.54	18.60
	Urban-Independent	183	5	217	21.10	9.57	14.16	28.04
	Non-Traditional	178	8	159	26.93	9.91	21.29	32.56
	Overall (Excl. Non-Trad.)	1,083	27	1,873	18.06	0.81	16.73	19.39
MONTANA	Rural-Chain	57	6	255	15.83	2.11	14.50	17.17
	Rural-Independent	104	4	130	17.05	0.70	16.48	17.62
	Urban-Chain	37	8	753	16.40	1.07	15.85	16.95
	Urban-Independent	31	7	183	18.19	3.82	16.10	20.27
	Non-Traditional	47	8	179	24.71	8.00	20.47	28.95
	Overall (Excl. Non-Trad.)	229	25	1,321	16.80	0.31	16.28	17.31
TEXAS	Rural-Chain	225	7	236	16.21	1.76	15.14	17.29
	Rural-Independent	398	8	253	17.13	0.72	16.71	17.54
	Urban-Chain	1,682	8	514	15.98	3.53	13.93	18.02
	Urban-Independent	778	8	260	17.20	1.08	16.58	17.82
	Non-Traditional	214	7	158	22.70	12.03	15.34	30.06
	Overall (Excl. Non-Trad.)	3,083	31	1,263	16.45	0.69	15.32	17.58
WASHINGTON	Rural-Chain	81	6	232	16.63	0.85	16.09	17.18
	Rural-Independent	137	5	104	21.32	8.34	15.29	27.35
	Urban-Chain	512	6	359	15.62	0.50	15.29	15.95
	Urban-Independent	272	5	183	18.34	1.15	17.50	19.18
	Non-Traditional	123	6	92	22.95	5.43	19.39	26.51
	Overall (Excl. Non-Trad.)	1,002	22	878	17.22	0.53	16.35	18.09
WEST VIRGINIA	Rural-Chain	160	6	601	17.95	1.16	17.18	18.72
	Rural-Independent	119	8	292	17.31	0.55	17.00	17.62
	Urban-Chain	137	8	865	17.78	0.73	17.37	18.18
	Urban-Independent	62	7	307	17.81	0.95	17.26	18.37
	Non-Traditional	18	6	180	23.55	11.49	17.25	29.85
	Overall (Excl. Non-Trad.)	478	29	2,065	17.72	0.18	17.42	18.02
WISCONSIN	Rural-Chain	102	6	520	16.15	2.35	14.62	17.68
	Rural-Independent	239	8	333	17.58	0.51	17.28	17.87
	Urban-Chain	360	7	1,045	16.24	1.87	15.09	17.40
	Urban-Independent	288	7	238	17.86	1.17	17.14	18.57
	Non-Traditional	115	8	227	26.81	11.36	20.44	33.19
	Overall (Excl. Non-Trad.)	989	28	2,136	17.03	0.30	16.53	17.53

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	370	22.50	4.25	20.02	24.98
	Rural-Independent	73	6	284	23.00	3.87	20.51	25.49
	Urban-Chain	357	4	1,040	29.60	2.64	27.44	31.76
	Urban-Independent	128	7	322	25.01	3.20	23.08	26.95
	Non-Traditional	65	8	190	42.90	19.53	32.27	53.53
	Overall (Excl. Non-Trad.)	617	24	2,016	27.19	0.83	25.82	28.55
FLORIDA	Rural-Chain	137	7	334	32.03	12.60	24.40	39.66
	Rural-Independent	68	8	600	23.41	3.30	21.61	25.22
	Urban-Chain	2,052	8	1,574	29.71	5.64	26.44	32.98
	Urban-Independent	656	8	317	24.36	2.74	22.78	25.94
	Non-Traditional	363	8	159	43.52	14.49	35.19	51.86
	Overall (Excl. Non-Trad.)	2,913	31	2,825	28.47	1.43	26.11	30.83
INDIANA	Rural-Chain	187	7	639	31.40	9.83	25.41	37.39
	Rural-Independent	105	8	455	24.51	3.72	22.43	26.59
	Urban-Chain	608	7	1,451	26.83	2.51	25.28	28.38
	Urban-Independent	183	5	340	28.54	9.04	21.98	35.10
	Non-Traditional	178	8	293	41.24	13.87	33.36	49.12
	Overall (Excl. Non-Trad.)	1,083	27	2,885	27.68	1.07	25.92	29.44
MONTANA	Rural-Chain	57	6	417	27.70	3.75	25.32	30.08
	Rural-Independent	104	4	186	24.58	3.15	22.03	27.12
	Urban-Chain	37	8	1,139	24.93	2.32	23.73	26.12
	Urban-Independent	31	7	270	26.41	5.67	23.31	29.51
	Non-Traditional	47	8	316	41.54	17.41	32.31	50.76
	Overall (Excl. Non-Trad.)	229	25	2,012	25.66	0.84	24.28	27.04
TEXAS	Rural-Chain	225	7	352	23.47	4.80	20.53	26.41
	Rural-Independent	398	8	398	26.08	2.81	24.46	27.69
	Urban-Chain	1,682	8	810	27.98	4.15	25.57	30.38
	Urban-Independent	778	8	397	26.08	5.18	23.08	29.07
	Non-Traditional	214	7	251	42.27	12.57	34.58	49.96
	Overall (Excl. Non-Trad.)	3,083	31	1,957	26.92	0.94	25.38	28.47
WASHINGTON	Rural-Chain	81	6	322	23.15	1.65	22.08	24.22
	Rural-Independent	137	5	153	30.72	10.96	22.81	38.63
	Urban-Chain	512	6	526	24.52	2.40	22.91	26.12
	Urban-Independent	272	5	240	22.76	2.30	21.08	24.44
	Non-Traditional	123	7	219	42.29	13.20	34.31	50.26
	Overall (Excl. Non-Trad.)	1,002	22	1,241	24.78	0.87	23.34	26.21
WEST VIRGINIA	Rural-Chain	160	6	951	29.22	3.11	27.17	31.27
	Rural-Independent	119	8	446	27.23	3.50	25.26	29.19
	Urban-Chain	137	8	1,333	28.94	2.64	27.45	30.43
	Urban-Independent	62	7	462	23.03	3.37	21.06	25.00
	Non-Traditional	18	8	279	32.21	11.05	27.42	37.00
	Overall (Excl. Non-Trad.)	478	29	3,192	27.84	0.59	26.86	28.82
WISCONSIN	Rural-Chain	102	6	790	25.00	6.98	20.46	29.54
	Rural-Independent	239	8	511	26.85	5.81	23.53	30.17
	Urban-Chain	360	7	1,597	26.59	2.62	24.97	28.20
	Urban-Independent	288	7	331	23.61	2.76	21.92	25.31
	Non-Traditional	115	8	389	40.45	8.70	35.57	45.33
	Overall (Excl. Non-Trad.)	989	28	3,229	25.62	0.73	24.42	26.83

SAMPLE RESULTS BY STATE
ALL DRUGS WITHOUT FULS – WEIGHTED BY INVOICE DOLLARS   APPENDIX 6

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	370	18.50	2.24	17.19	19.81
	Rural-Independent	73	6	284	20.65	3.64	18.31	22.99
	Urban-Chain	357	4	1,040	26.28	3.36	23.53	29.02
	Urban-Independent	128	7	322	21.76	2.89	20.01	23.51
	Non-Traditional	65	8	190	37.84	22.21	25.74	49.93
	Overall (Excl. Non-Trad.)	617	24	2,016	23.93	1.01	22.27	25.59
FLORIDA	Rural-Chain	137	7	334	24.84	7.37	20.38	29.31
	Rural-Independent	68	8	600	20.18	2.08	19.04	21.31
	Urban-Chain	2,052	8	1,574	26.29	4.72	23.55	29.03
	Urban-Independent	656	8	317	22.41	4.29	19.93	24.89
	Non-Traditional	363	8	159	35.58	16.96	25.82	45.33
	Overall (Excl. Non-Trad.)	2,913	31	2,825	25.20	1.23	23.18	27.23
INDIANA	Rural-Chain	187	7	639	25.51	9.01	20.02	31.01
	Rural-Independent	105	8	455	21.30	3.30	19.46	23.14
	Urban-Chain	608	7	1,451	23.06	3.07	21.16	24.96
	Urban-Independent	183	5	340	25.08	10.48	17.47	32.69
	Non-Traditional	178	8	293	35.20	13.10	27.76	42.64
	Overall (Excl. Non-Trad.)	1,083	27	2,885	23.65	1.17	21.72	25.58
MONTANA	Rural-Chain	57	6	417	20.73	1.57	19.74	21.73
	Rural-Independent	104	4	186	22.35	3.62	19.43	25.27
	Urban-Chain	37	8	1,139	21.34	1.91	20.36	22.32
	Urban-Independent	31	7	270	23.16	4.76	20.55	25.76
	Non-Traditional	47	8	316	34.95	18.09	25.37	44.53
	Overall (Excl. Non-Trad.)	229	25	2,012	21.89	0.85	20.49	23.30
TEXAS	Rural-Chain	225	7	352	19.37	2.04	18.12	20.62
	Rural-Independent	398	8	398	21.78	1.74	20.78	22.77
	Urban-Chain	1,682	8	810	21.79	2.56	20.30	23.28
	Urban-Independent	778	8	397	24.40	5.85	21.01	27.79
	Non-Traditional	214	7	251	32.23	9.19	26.61	37.85
	Overall (Excl. Non-Trad.)	3,083	31	1,957	22.27	0.72	21.08	23.46
WASHINGTON	Rural-Chain	81	6	322	18.97	1.12	18.24	19.69
	Rural-Independent	137	5	153	25.18	8.59	18.98	31.38
	Urban-Chain	512	6	526	20.35	1.98	19.03	21.67
	Urban-Independent	272	5	240	20.68	1.64	19.49	21.87
	Non-Traditional	123	7	219	36.89	15.83	27.33	46.44
	Overall (Excl. Non-Trad.)	1,002	22	1,241	20.99	0.69	19.86	22.12
WEST VIRGINIA	Rural-Chain	160	6	951	24.10	2.77	22.27	25.93
	Rural-Independent	119	8	446	23.88	4.89	21.13	26.62
	Urban-Chain	137	8	1,333	25.88	5.58	22.73	29.02
	Urban-Independent	62	7	462	20.71	2.29	19.38	22.05
	Non-Traditional	18	8	279	25.05	10.55	20.48	29.62
	Overall (Excl. Non-Trad.)	478	29	3,192	24.11	0.79	22.81	25.41
WISCONSIN	Rural-Chain	102	6	790	21.57	5.06	18.27	24.86
	Rural-Independent	239	8	511	27.44	12.09	20.53	34.35
	Urban-Chain	360	7	1,597	23.77	2.39	22.30	25.25
	Urban-Independent	288	7	331	22.07	2.56	20.50	23.64
	Non-Traditional	115	8	389	35.69	12.92	28.44	42.94
	Overall (Excl. Non-Trad.)	989	28	3,229	23.93	1.12	22.09	25.78

SAMPLE RESULTS BY STATE
MULTIPLE SOURCE DRUGS WITHOUT FULS   APPENDIX 7

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP Sample Mean	Standard Deviation	90% Confidence Level Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	116	35.73	14.26	27.41	44.05
	Rural-Independent	73	5	95	38.28	7.68	32.83	43.73
	Urban-Chain	357	4	402	49.33	4.81	45.39	53.26
	Urban-Independent	128	7	104	42.41	14.17	33.85	50.98
	Non-Traditional	65	7	75	60.61	14.93	51.85	69.38
	Overall (Excl. Non-Trad.)	617	23	717	45.28	1.86	42.22	48.35
FLORIDA	Rural-Chain	137	7	139	45.84	15.01	36.76	54.93
	Rural-Independent	68	8	151	38.89	11.13	32.81	44.97
	Urban-Chain	2,052	8	588	50.46	10.25	44.52	56.41
	Urban-Independent	656	8	97	39.78	9.19	34.46	45.09
	Non-Traditional	363	6	75	57.25	19.78	44.08	70.42
	Overall (Excl. Non-Trad.)	2,913	31	975	47.57	2.66	43.19	51.95
INDIANA	Rural-Chain	187	7	225	50.01	9.33	44.32	55.71
	Rural-Independent	105	8	162	35.60	6.91	31.74	39.46
	Urban-Chain	608	7	502	45.76	5.62	42.28	49.23
	Urban-Independent	183	5	123	42.18	7.79	36.53	47.83
	Non-Traditional	178	7	134	53.60	13.60	45.32	61.88
	Overall (Excl. Non-Trad.)	1,083	27	1,012	44.90	1.47	42.49	47.32
MONTANA	Rural-Chain	57	6	162	43.58	8.20	38.37	48.79
	Rural-Independent	104	4	56	41.40	7.72	35.17	47.63
	Urban-Chain	37	8	386	42.24	5.59	39.36	45.12
	Urban-Independent	31	7	87	44.30	9.42	39.15	49.45
	Non-Traditional	47	8	137	54.03	18.99	43.97	64.08
	Overall (Excl. Non-Trad.)	229	25	691	42.47	1.96	39.25	45.69
TEXAS	Rural-Chain	225	7	116	38.67	10.91	31.99	45.35
	Rural-Independent	398	8	145	40.76	4.82	37.99	43.54
	Urban-Chain	1,682	8	296	44.04	7.78	39.52	48.55
	Urban-Independent	778	8	137	38.13	6.67	34.27	41.98
	Non-Traditional	214	7	93	57.76	16.75	47.51	68.00
	Overall (Excl. Non-Trad.)	3,083	31	694	41.73	1.65	39.01	44.45
WASHINGTON	Rural-Chain	81	6	90	41.58	5.06	38.31	44.85
	Rural-Independent	137	5	49	50.02	19.38	36.02	64.02
	Urban-Chain	512	6	167	42.50	7.04	37.80	47.20
	Urban-Independent	272	5	57	34.76	2.82	32.71	36.81
	Non-Traditional	123	7	127	55.00	9.93	49.01	60.99
	Overall (Excl. Non-Trad.)	1,002	22	363	41.35	1.90	38.22	44.49
WEST VIRGINIA	Rural-Chain	160	6	350	48.25	7.04	43.61	52.89
	Rural-Independent	119	8	154	45.55	7.65	41.25	49.85
	Urban-Chain	137	8	468	45.66	4.50	43.12	48.20
	Urban-Independent	62	7	155	33.24	8.66	28.17	38.31
	Non-Traditional	18	8	99	43.15	15.09	36.61	49.69
	Overall (Excl. Non-Trad.)	478	29	1,127	44.89	1.29	42.76	47.01
WISCONSIN	Rural-Chain	102	6	270	38.65	11.49	31.16	46.14
	Rural-Independent	239	8	178	44.75	7.79	40.29	49.21
	Urban-Chain	360	7	552	47.31	5.61	43.86	50.77
	Urban-Independent	288	7	93	37.86	7.40	33.31	42.40
	Non-Traditional	115	8	162	61.34	13.76	53.62	69.06
	Overall (Excl. Non-Trad.)	989	28	1,093	43.05	1.37	40.79	45.30

SAMPLE RESULTS BY STATE   APPENDIX 8
MULTIPLE SOURCE DRUGS WITHOUT FULS – WEIGHTED BY INVOICE DOLLARS

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	116	30.97	15.18	22.11	39.83
	Rural-Independent	73	5	95	34.46	10.41	27.07	41.85
	Urban-Chain	357	4	402	49.40	9.99	41.23	57.57
	Urban-Independent	128	7	104	36.01	11.90	28.82	43.21
	Non-Traditional	65	7	75	56.30	22.87	42.87	69.73
	Overall (Excl. Non-Trad.)	617	23	717	43.09	3.10	37.99	48.20
FLORIDA	Rural-Chain	137	7	139	43.79	20.89	31.13	56.44
	Rural-Independent	68	8	151	32.76	9.01	27.84	37.69
	Urban-Chain	2,052	8	588	50.34	14.31	42.03	58.64
	Urban-Independent	656	8	97	38.54	15.67	29.48	47.59
	Non-Traditional	363	6	75	57.57	23.09	42.19	72.94
	Overall (Excl. Non-Trad.)	2,913	31	975	46.96	3.78	40.74	53.19
INDIANA	Rural-Chain	187	7	225	42.54	13.74	34.16	50.92
	Rural-Independent	105	8	162	31.34	8.29	26.70	35.97
	Urban-Chain	608	7	502	42.46	8.00	37.51	47.40
	Urban-Independent	183	5	123	39.52	11.11	31.46	47.58
	Non-Traditional	178	7	134	55.50	15.29	46.18	64.82
	Overall (Excl. Non-Trad.)	1,083	27	1,012	40.90	2.09	37.45	44.34
MONTANA	Rural-Chain	57	6	162	33.63	6.90	29.25	38.01
	Rural-Independent	104	4	56	41.13	14.13	29.73	52.52
	Urban-Chain	37	8	386	38.10	7.86	34.05	42.15
	Urban-Independent	31	7	87	40.34	14.34	32.50	48.19
	Non-Traditional	47	8	137	52.05	23.88	39.40	64.70
	Overall (Excl. Non-Trad.)	229	25	691	38.67	3.30	33.23	44.10
TEXAS	Rural-Chain	225	7	116	33.37	7.80	28.60	38.15
	Rural-Independent	398	8	145	35.54	5.70	32.26	38.82
	Urban-Chain	1,682	8	296	40.38	10.06	34.54	46.21
	Urban-Independent	778	8	137	37.96	12.84	30.53	45.39
	Non-Traditional	214	7	93	57.63	20.62	45.02	70.24
	Overall (Excl. Non-Trad.)	3,083	31	694	38.63	2.27	34.89	42.37
WASHINGTON	Rural-Chain	81	6	90	32.67	7.86	27.59	37.75
	Rural-Independent	137	5	49	46.08	19.72	31.84	60.32
	Urban-Chain	512	6	167	41.47	9.19	35.33	47.60
	Urban-Independent	272	5	57	30.32	2.72	28.34	32.30
	Non-Traditional	123	7	127	55.29	12.57	47.70	62.87
	Overall (Excl. Non-Trad.)	1,002	22	363	38.36	2.28	34.61	42.11
WEST VIRGINIA	Rural-Chain	160	6	350	40.98	7.94	35.76	46.21
	Rural-Independent	119	8	154	41.84	9.65	36.42	47.26
	Urban-Chain	137	8	468	41.61	4.08	39.31	43.92
	Urban-Independent	62	7	155	30.51	6.95	26.44	34.58
	Non-Traditional	18	8	99	41.54	18.65	33.45	49.62
	Overall (Excl. Non-Trad.)	478	29	1,127	40.02	1.44	37.65	42.38
WISCONSIN	Rural-Chain	102	6	270	36.47	13.25	27.84	45.10
	Rural-Independent	239	8	178	41.70	19.92	30.31	53.09
	Urban-Chain	360	7	552	50.07	5.88	46.45	53.69
	Urban-Independent	288	7	93	37.61	12.74	29.79	45.44
	Non-Traditional	115	8	162	58.79	19.00	48.13	69.45
	Overall (Excl. Non-Trad.)	989	28	1,093	43.02	2.38	39.11	46.93

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	97	62.46	13.29	54.70	70.21
	Rural-Independent	73	6	65	74.52	8.65	68.95	80.08
	Urban-Chain	357	4	296	74.70	4.34	71.15	78.25
	Urban-Independent	128	6	78	73.05	7.22	68.32	77.78
	Non-Traditional	65	6	57	72.55	13.43	63.96	81.14
	Overall (Excl. Non-Trad.)	617	23	536	73.17	1.51	70.68	75.65
FLORIDA	Rural-Chain	137	7	145	68.89	7.41	64.40	73.38
	Rural-Independent	68	8	91	67.14	12.91	60.09	74.19
	Urban-Chain	2,052	8	453	73.56	4.85	70.75	76.38
	Urban-Independent	656	8	70	68.91	5.96	65.47	72.36
	Non-Traditional	363	5	31	80.94	9.24	74.19	87.69
	Overall (Excl. Non-Trad.)	2,913	31	759	72.15	1.30	70.00	74.29
INDIANA	Rural-Chain	187	7	237	73.40	6.90	69.19	77.61
	Rural-Independent	105	8	77	58.88	7.00	54.96	62.79
	Urban-Chain	608	7	421	74.80	4.43	72.06	77.54
	Urban-Independent	183	5	95	76.74	5.36	72.85	80.63
	Non-Traditional	178	5	75	72.42	5.30	68.58	76.26
	Overall (Excl. Non-Trad.)	1,083	27	830	73.34	1.13	71.48	75.20
MONTANA	Rural-Chain	57	6	126	56.48	24.80	40.73	72.23
	Rural-Independent	104	4	50	75.80	6.25	70.76	80.84
	Urban-Chain	37	8	338	72.24	5.21	69.56	74.92
	Urban-Independent	31	7	64	81.80	3.40	79.94	83.66
	Non-Traditional	47	7	91	70.77	16.36	61.39	80.16
	Overall (Excl. Non-Trad.)	229	25	578	71.23	2.78	66.66	75.80
TEXAS	Rural-Chain	225	6	138	66.08	7.34	61.22	70.95
	Rural-Independent	398	8	114	65.68	10.87	59.42	71.93
	Urban-Chain	1,682	8	223	70.34	6.59	66.52	74.16
	Urban-Independent	778	8	112	72.19	10.17	66.30	78.07
	Non-Traditional	214	4	57	74.53	12.95	63.97	85.08
	Overall (Excl. Non-Trad.)	3,083	30	587	69.89	1.65	67.18	72.60
WASHINGTON	Rural-Chain	81	6	125	74.48	8.07	69.27	79.70
	Rural-Independent	137	5	52	76.08	5.59	72.04	80.12
	Urban-Chain	512	6	127	73.70	4.93	70.41	76.99
	Urban-Independent	272	5	45	73.30	15.25	62.18	84.42
	Non-Traditional	123	7	87	79.79	2.91	78.03	81.54
	Overall (Excl. Non-Trad.)	1,002	22	349	73.98	2.14	70.46	77.50
WEST VIRGINIA	Rural-Chain	160	6	319	75.50	6.37	71.30	79.70
	Rural-Independent	119	8	108	78.10	3.47	76.15	80.05
	Urban-Chain	137	8	488	77.04	7.73	72.68	81.40
	Urban-Independent	62	7	128	52.70	26.00	37.48	67.92
	Non-Traditional	18	7	101	67.17	18.28	58.29	76.05
	Overall (Excl. Non-Trad.)	478	29	1,043	73.63	1.68	70.86	76.40
WISCONSIN	Rural-Chain	102	6	244	67.85	13.50	59.06	76.64
	Rural-Independent	239	8	180	76.90	5.81	73.58	80.22
	Urban-Chain	360	7	394	76.20	1.98	74.98	77.42
	Urban-Independent	288	7	75	73.61	8.16	68.61	78.62
	Non-Traditional	115	7	118	76.21	5.13	73.12	79.31
	Overall (Excl. Non-Trad.)	989	28	893	74.76	1.18	72.81	76.70

MULTIPLE SOURCE DRUGS WITH FULS – WEIGHTED BY INVOICE DOLLARS

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	97	65.70	17.46	55.51	75.89
	Rural-Independent	73	6	65	73.07	21.19	59.44	86.70
	Urban-Chain	357	4	296	74.22	5.24	69.94	78.51
	Urban-Independent	128	6	78	81.82	5.34	78.31	85.32
	Non-Traditional	65	6	57	77.08	15.88	66.92	87.24
	Overall (Excl. Non-Trad.)	617	23	536	74.85	1.94	71.65	78.04
FLORIDA	Rural-Chain	137	7	145	72.87	9.67	67.01	78.73
	Rural-Independent	68	8	91	67.26	18.52	57.15	77.38
	Urban-Chain	2,052	8	453	80.24	6.70	76.35	84.13
	Urban-Independent	656	8	70	71.39	9.64	65.82	76.96
	Non-Traditional	363	5	31	86.36	7.18	81.12	91.60
	Overall (Excl. Non-Trad.)	2,913	31	759	77.60	1.85	74.56	80.63
INDIANA	Rural-Chain	187	7	237	73.79	7.13	69.44	78.14
	Rural-Independent	105	8	77	60.13	13.86	52.38	67.87
	Urban-Chain	608	7	421	78.56	6.40	74.60	82.51
	Urban-Independent	183	5	95	82.26	7.24	77.01	87.51
	Non-Traditional	178	5	75	73.24	9.83	66.11	80.37
	Overall (Excl. Non-Trad.)	1,083	27	830	76.57	1.59	73.96	79.19
MONTANA	Rural-Chain	57	6	126	59.42	24.51	43.85	74.99
	Rural-Independent	104	4	50	85.65	4.00	82.42	88.88
	Urban-Chain	37	8	338	77.84	6.88	74.30	81.38
	Urban-Independent	31	7	64	84.63	5.04	81.87	87.39
	Non-Traditional	47	7	91	73.81	22.79	60.74	86.89
	Overall (Excl. Non-Trad.)	229	25	578	77.72	2.55	73.52	81.92
TEXAS	Rural-Chain	225	6	138	72.18	16.14	61.49	82.88
	Rural-Independent	398	8	114	70.70	8.12	66.02	75.38
	Urban-Chain	1,682	8	223	78.66	3.21	76.80	80.53
	Urban-Independent	778	8	112	75.30	14.03	67.18	83.42
	Non-Traditional	214	4	57	78.18	11.89	68.49	87.86
	Overall (Excl. Non-Trad.)	3,083	30	587	76.31	1.51	73.82	78.80
WASHINGTON	Rural-Chain	81	6	125	81.03	8.87	75.30	86.77
	Rural-Independent	137	5	52	85.34	1.13	84.52	86.16
	Urban-Chain	512	6	127	75.07	10.03	68.37	81.76
	Urban-Independent	272	5	45	86.80	4.90	83.23	90.37
	Non-Traditional	123	7	87	81.80	4.10	79.32	84.28
	Overall (Excl. Non-Trad.)	1,002	22	349	80.14	2.18	76.55	83.73
WEST VIRGINIA	Rural-Chain	160	6	319	78.60	9.20	72.54	84.66
	Rural-Independent	119	8	108	83.00	5.24	80.05	85.95
	Urban-Chain	137	8	488	79.96	6.18	76.48	83.45
	Urban-Independent	62	7	128	56.13	27.70	39.91	72.35
	Non-Traditional	18	7	101	74.96	18.88	65.78	84.13
	Overall (Excl. Non-Trad.)	478	29	1,043	77.17	1.93	74.00	80.35
WISCONSIN	Rural-Chain	102	6	244	76.40	12.41	68.32	84.48
	Rural-Independent	239	8	180	81.85	6.57	78.10	85.60
	Urban-Chain	360	7	394	79.00	6.15	75.21	82.79
	Urban-Independent	288	7	75	81.09	9.69	75.13	87.04
	Non-Traditional	115	7	118	81.03	4.51	78.31	83.74
	Overall (Excl. Non-Trad.)	989	28	893	80.03	1.54	77.49	82.56

STATES USING A THREE-TIERED REIMBURSEMENT SYSTEM

One state already uses a three-tiered system and three other states are currently considering a change from their current reimbursement system to a three-tiered reimbursement methodology. The state with the three-tiered system reimburses single source drugs at AWP minus 10 percent and multiple source drugs at AWP minus 12 percent. One state proposed a reimbursement of 14 percent below AWP for single source drugs and a discount of 25 percent below AWP for multiple source drugs. A second state is considering a reimbursement of AWP minus 15 percent for single source drugs and AWP minus 50 percent for all other non-FUL drugs. A third state is considering AWP minus 14 percent and AWP minus 50 percent, respectively. We believe that the change to a three-tiered system already being used by one state and the proposed changes by three other states provide further support for all other states to consider a multi-tiered reimbursement system.
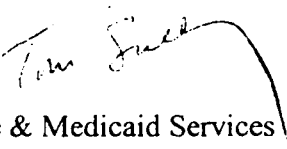
DEPARTMENT OF HEALTH & HUMAN SERVICES

DATE: AUG 20 2002

TO: Janet Rehnquist
Inspector General
Office of Inspector General

FROM: Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Pharmacy-Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products" (A-06-02-00041)

Thank you for the opportunity to review and comment on the above-referenced draft report regarding additional analyses of the actual acquisition cost of prescription drugs. The Centers for Medicare & Medicaid Services (CMS) appreciates the effort that went into this report.

OIG Recommendation
That CMS encourage states to consider adopting a three-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products.

CMS Response
The CMS suggests that OIG recommend a four-tier reimbursement methodology for the following reason. Tier two, of the suggested three-tier system, represents a 44.2 percent discount from the average wholesale price at which pharmacies purchase multiple source drugs without Federal upper limits (FULs). The term "multiple source drug" includes the branded generics (innovator multiple source drugs) and the generics (non-innovator multiple source drugs). This percentage indicates that the branded generics' discount would be the same as the discount for generic drugs. This conflicts with the findings on pages 7-8 of this report. Pages 7-8 identify the discount for innovator multiple source drugs without FULs as 24.4 percent and the discount for non-innovator multiple source drugs without FULs as 54.2 percent. Your recommendation for a three-tiered reimbursement system, with one tier including all non-FUL multiple source drugs, is not consistent with this finding.

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Therefore, we suggest that OIG recommend a four-tiered reimbursement methodology. The four-tiered system would consist of single source innovator drugs, innovator multiple source drugs without FULs, non-innovator multiple source drugs without FULs, and FUL drugs.

OIG Recommendation
That CMS share this report with the states.

CMS Response
We concur. We will share this report with the states.

Attachment

Page 3- Janet Rehnquist

Technical Comment

Page 1, Background- The criteria for the establishment of FUL prices are not completely accurate. We suggest that the report either delete the criteria for the establishment of the FUL amounts or include the following language:

"The criteria require that there be a certain number of drugs, depending on the therapeutic equivalency, published in the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations and at least three suppliers of the drug."