Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Omission Of Drugs From The Federal Upper Limit List in 2001

Inspector General

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OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

OBJECTIVE

This inspection: (1) determined whether drugs that met the criteria established by Federal laws and regulations were included on the Federal Upper Limit list in 2001, and (2) calculated the potential savings that could have resulted in 2001 if additional drugs that met the established criteria had been included on the Federal Upper Limit list.

BACKGROUND

In 1987, 42 CFR § 447.332 authorized the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration) to establish Federal Upper Limits in order to limit the amount that Medicaid could reimburse for multiple-source drugs. A multiple-source drug is defined as "a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name." According to the State Medicaid Manual, these reimbursement limits, commonly known as Federal Upper Limits, were established to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs.

The regulation required CMS to establish a Federal Upper Limit amount for a drug product (i.e., each specific dosage form and dosage amount of a drug) when: (1) all versions of a drug product had been classified as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) at least three suppliers of the drug product are listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally. The Omnibus Budget Reconciliation Act of 1990, however, changed this criteria by requiring a Federal Upper Limit when three or more versions of a drug product have been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other versions. The Federal Upper Limit amount for a drug is set at 150 percent of the published price for the least costly therapeutically-equivalent product plus a reasonable dispensing fee. CMS publishes the list of drug products for which Federal Upper Limits have been established in the *State Medicaid Manual* and on its website at www.cms.gov/medicaid/drugs/drug10.asp.

We obtained a list of the top 200 multiple-source drugs based on retail sales for the year 2001, and determined if the drugs were on CMS's November 2001 Federal Upper Limit list. For each of the drugs not on the Federal Upper Limit list, we determined if any forms or strengths met the criteria for inclusion on the list. We then calculated a Federal Upper Limit amount for any drug products that met the criteria by multiplying the lowest

price published in the *Red Book for Windows* by 150 percent. We determined each State's average payment for these drug products by obtaining payment and utilization data from CMS. For drug products whose Federal Upper Limit amount would have been less than a State's average payment amount, we calculated potential Medicaid savings by multiplying the price difference by Medicaid utilization. We then aggregated the individual savings for each State to determine the overall potential savings to Medicaid.

FINDING

Ninety drug products met the established criteria but were not included on the Federal Upper Limit list in 2001.

If CMS had included 55 of these drug products on the Federal Upper Limit list, the Medicaid program could have saved $123 million in 2001. This represents 30 percent of the $411 million Medicaid reimbursed for these 55 products that year. Four drug products alone accounted for 71 percent of the $123 million in potential Medicaid savings. The Medicaid program could have saved $88 million in 2001 by placing these 4 products (albuterol aerosol, ipratropium bromide solution, enalapril maleate 20 mg tablets, and clozapine 100 mg tablets) on the Federal Upper Limit list.

The remaining 35 of the 90 drug products met the criteria for inclusion on the Federal Upper Limit list but did not have any associated savings. However, States would pay the Federal Upper Limit amount only if it were less than the estimated acquisition cost or State maximum allowed cost. Therefore, States would not have made higher payments if these products had been included on the Federal Upper Limit list.

After the start of this inspection but prior to the release of the final report, CMS added 9 of the 90 products to the Federal Upper Limit list. Seven of these drug products (albuterol aerosol, ipratropium bromide solution, aspirin/butalbital/caffeine tablets, and 4 strengths of enalapril maleate tablets) accounted for a significant portion ($94 million) of the savings we calculated for 2001.

RECOMMENDATION

Federal Upper Limits were created to help Medicaid save money by taking advantage of lower prices for multiple-source drugs available in the marketplace. Although the Federal Upper Limit list already includes over 400 drug products, there are more that could be added. At a time when Medicaid prescription drug costs are increasing, efforts should be made to include on the Federal Upper Limit list all drugs that meet the requirements. This could result in millions of dollars in savings to both State Medicaid programs and the Federal Government.

We recommend that CMS take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the Federal Upper Limit list.

Agency Comments

CMS states that they do not agree with the Office of Inspector General's (OIG's) savings estimates. Specifically, CMS states that OIG used only the *Red Book* to identify suppliers and prices, and did not subsequently verify the information provided in the *Red Book* with suppliers. In addition, CMS states that three of the products that we identified as leading to the most savings were recently added to the Federal Upper Limit list. Therefore, CMS believes that our savings estimates should be reduced accordingly. CMS also believes that it is nearly impossible to say with certainty that a particular group of products has been incorrectly excluded from the Federal Upper Limit list at any one time since pricing and product information changes frequently. CMS believes that their efforts to add and remove drug products on the Federal Upper Limit list should be recognized by OIG. Finally, CMS states it does not believe that products that would not lead to savings should be included on the Federal Upper Limit list.

While CMS disagrees with our savings estimates, we are unable to determine if they concur with our recommendation that drugs which meet the criteria should be included on the Federal Upper Limit list, as well as what, if any, actions CMS plans to take in response to our report. OIG stands by the drugs identified as meeting the criteria, the subsequent savings estimates, and our recommendation.

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INTRODUCTION

OBJECTIVE

This inspection: (1) determined whether drugs that met the criteria established by Federal laws and regulations were included on the Federal Upper Limit list in 2001, and (2) calculated the potential savings that could have resulted in 2001 if additional drugs that met the established criteria had been included on the Federal Upper Limit list.

BACKGROUND

Medicaid Program

Medicaid is a jointly-funded, Federal-State health insurance program for certain low income and medically-needy people. Individual States establish eligibility requirements, benefit packages, and payment rates for their Medicaid program under broad Federal standards set by the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration). Federal regulations mandate that States provide basic services to beneficiaries in order to receive Federal matching funds. States may also receive Federal funding if they provide other optional services. One of the most commonly covered optional services that States provide is prescription drug coverage. All 50 States and the District of Columbia currently offer prescription drug coverage under the Medicaid program. In calendar year 2001, Medicaid payments for prescription drugs totaled almost $24 billion.

Medicaid Drug Reimbursement Methodology

Each Medicaid agency is required to submit a State plan to CMS describing its payment methodology for covered drugs. Federal regulations require that each State's reimbursement for a drug not exceed the lower of its estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drug. States have implemented dispensing fees that range from $2.00 to $5.60 per prescription.

CMS allows States flexibility in defining estimated acquisition cost. Most States base their calculation of estimated acquisition cost on a drug's average wholesale price discounted by a certain percentage. This discount ranged from 5 percent to 15 percent in the year 2001. A small number of States use wholesale acquisition costs rather than average wholesale prices when determining estimated acquisition cost. Average wholesale prices and wholesale acquisition costs are reported by companies, such as First DataBank and Medical Economics.

For certain drugs, States also use the Federal Upper Limit and State Maximum Allowable Cost programs in determining reimbursement amounts. CMS has established Federal Upper Limit amounts for over 400 drugs. In addition, more than half of the States have implemented a Maximum Allowable Cost program in order to reduce reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their Maximum Allowable Cost program, and the method by which the Maximum Allowable Cost for a drug is calculated.

In summary, States often use a variety of different pricing mechanisms when setting reimbursement amounts. In most cases, States reimburse for a drug at the lower of its estimated acquisition cost, the Federal Upper Limit amount, the Maximum Allowable Cost, or the provider's usual and customary charge.

Federal Upper Limit List

In 1987, 42 CFR § 447.332 authorized CMS to establish Federal Upper Limits in order to limit the amount that Medicaid could reimburse for multiple-source drugs. A multiple-source drug is defined as " . . . a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name." According to the State Medicaid Manual, these reimbursement limits, commonly known as Federal Upper Limits, were established to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs.

The regulation required CMS to establish a Federal Upper Limit amount for a drug product (i.e., each specific dosage form and dosage amount of a drug) when: (1) all versions of a drug product had been classified as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) at least three suppliers of the drug product are listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally. The Omnibus Budget Reconciliation Act of 1990, however, changed this criteria by requiring a Federal Upper Limit when three or more versions of a drug product have been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other versions. FDA identifies equivalent drug products in their publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. According to FDA, drugs that are therapeutically equivalent are designated as "A-rated."

The regulation sets the Federal Upper Limit amount at 150 percent of the published price for the least costly therapeutically-equivalent product that can be purchased in quantities of 100 tablets or capsules plus a reasonable dispensing fee. If the drug product is not available in quantities of 100 or if the drug product is a liquid, then the Federal Upper Limit amount should be based on a commonly listed size. States are required to meet the Federal Upper Limit requirements only in the aggregate. This means that a State can pay more than the Federal Upper Limit amount for certain products as long as it pays less than the Federal Upper Limit amount for other products.

CMS publishes the list of drug products for which Federal Upper Limits have been established in the *State Medicaid Manual*. The Federal Upper Limit list is also available on CMS's website at www.cms.gov/medicaid/drugs/drug10.asp. Any revisions to the Federal Upper Limit list are typically noted in Medicaid program memoranda and on the CMS website. CMS establishes an upper limit for specific forms and strengths for each multiple-source drug on the list. The Federal Upper Limit list also provides the source of the pricing information used to calculate the upper limit amount for each drug.

METHODOLOGY

Information from CMS

We met with CMS staff to obtain a better understanding of how CMS administers Federal Upper Limits. We discussed with CMS the procedures used to identify drugs that should be placed on the Federal Upper Limit list, as well as the methods used to calculate the Federal Upper Limit amount. CMS also provided documentation of these procedures.

Determining Whether Drugs Met Federal Upper Limit Criteria

Determining Drugs Not Currently on the Federal Upper Limit List. We obtained a list of the top 200 multiple-source drugs based on retail sales for the year 2001 from *Drug Topics* magazine. We compared the *Drug Topics* list to CMS's November 2001 Federal Upper Limit list. In making this comparison:

(1) If *Drug Topics* listed a specific form for a drug, then we determined if this specific form was on the Federal Upper Limit list.

(2) If *Drug Topics* did not list a specific form, then we determined if any form of the drug was on the Federal Upper Limit list.

For example, if *Drug Topics* magazine placed ibuprofen liquid on its list of top 200 multiple-source drugs, then the liquid form of ibuprofen would need to be specifically mentioned on the Federal Upper Limit list. However, had *Drug Topics* simply listed ibuprofen (with no specific form), then we determined if any forms of ibuprofen were part of the Federal Upper Limit list. If any form of the drug appeared on the Federal Upper Limit list, then we concluded that the drug was included. In total, we determined that 64 of the 200 multiple-source drugs from the *Drug Topics* list were not included on the Federal Upper Limit list as of November 2001.

Identifying All Versions of the 64 Drugs Not on the Federal Upper Limit List. Because CMS calculates an upper limit amount for every form and strength of a drug (i.e., each specific drug product) that meets the criteria set forth by Federal laws and regulations, we needed to identify all the forms and strengths for each of the 64 multiple-source drugs not on the Federal Upper Limit list. We used the October 2001 edition of the *Red Book for Windows* (published by Medical Economics) to gather this information.

According to the *Red Book*, these 64 multiple-source drugs were associated with 200 different drug products in various forms and strengths.

We then compiled a list of all the national drug codes (NDCs) associated with each of the 200 drug products. Each individual drug product manufactured or distributed in the United States has a unique NDC. NDC identifies the manufacturer of the drug product, the product dosage form, and the package size. For each NDC, the *Red Book* provides published prices (usually average wholesale prices and wholesale acquisition costs), supplier information, and FDA therapeutic equivalency data. The *Red Book* also lists whether the individual drug product is a brand or generic version.

Determining if the 200 Drug Products Met Federal Upper Limit Criteria. We used the *Red Book* to determine whether each of the 200 drug products met the established criteria for inclusion on the Federal Upper Limit list. We first determined whether each of the drug products had at least three versions deemed therapeutically-equivalent (A-rated) by FDA. For any drug products that met this criteria, we verified that there were at least three suppliers listed in the *Red Book*. In all, 90 of the 200 drug products met the criteria for inclusion on the Federal Upper Limit list. These 90 drug products comprised different forms and strengths of 42 drugs from *Drug Topics'* list of the top 200 multiple-source drugs. Table 1 below illustrates the steps taken to reach this number.

Table 1: Number of Drugs and Drug Products in Each Stage of Methodology

Methodology Step	Number of Drugs	Number of Drug Products
Drug Topics' Top 200 Multiple-Source Drugs	200	Not determined
Drugs on *Drug Topics'* List Not on the Federal Upper Limit List	64	200
Drugs Not on Federal Upper Limit list that Met Federal Upper Limit Criteria	42	90

Calculating Federal Upper Limit Amounts

To calculate a Federal Upper Limit amount for the 90 drug products that met the criteria for inclusion, we used pricing information and therapeutic equivalency data from the *Red Book*. Federal regulations set the upper limit amount at 150 percent of the least costly therapeutically-equivalent product that can be purchased in package sizes of 100 (with certain exceptions). Therefore, we determined which of the A-rated versions available in a package size of 100 had the lowest price listed in the *Red Book*. If a product was not available in a package size of 100, we determined the lowest price for the most common package size listed in the *Red Book*. We then multiplied this price by 150 percent to determine the Federal Upper Limit amount for the drug product. This potential Federal Upper Limit amount would apply to all NDCs

associated with the drug product. We did not verify that the prices published in the *Red Book* were actually available in the marketplace.

Calculating Medicaid Payments

To determine the amount Medicaid reimbursed for the 90 drug products that met the Federal Upper Limit criteria, we downloaded 50 Medicaid payment and utilization files for calendar year 2001 from CMS's website. We did not include Arizona because its drug payment and utilization file was not available. Each file contained variables representing total State payments, number of units reimbursed, and number of prescriptions written for every NDC listed on a paid claim in 2001. We removed NDCs associated with brand versions of the drug product from the file. We excluded brand versions because many State Medicaid agencies require a generic version of the drug product to be dispensed.

The total State payment amount listed in the files included both the payments for the drug product and the dispensing fees paid to the pharmacy. To determine a State's payments for the drug product only, we:

(1) Aggregated total State payments, number of units reimbursed, and number of prescriptions written for all generic NDCs associated with the product

(2) Calculated the total amount the State paid in dispensing fees for the drug product by multiplying the State's dispensing fee by the number of prescriptions written for the product

(3) Subtracted this amount from the total State payments for the drug product

We then calculated the average State payment by dividing the State's payments for the drug product (without the dispensing fee) by the number of units reimbursed. One of the 90 drug products did not have payment data listed in the State files, and was therefore, not included in subsequent calculations.

Calculating Potential Savings

We calculated the difference between the average State payment and the potential Federal Upper Limit amount. If the potential Federal Upper Limit amount for a drug product was less than the average State payment, we multiplied the price difference by the number of units reimbursed in order to determine each State's potential savings for the product. For each of the drug products with potential savings, we added the savings among all States. Finally, we aggregated the savings for all drug products to determine the overall potential savings to the Medicaid program.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDING

Ninety drug products met the established criteria but were not included on the Federal Upper Limit list in 2001

Each of the 90 drug products had at least 3 versions rated therapeutically equivalent by FDA, and were available from 3 or more suppliers. These 90 drug products accounted for $667 million in Medicaid reimbursement in 2001. Prior to the release of this report, CMS added 9 of the 90 products to the Federal Upper Limit list.

Adding 55 of the 90 drug products to the Federal Upper Limit list could have saved Medicaid $123 million in 2001

Medicaid could have saved $123 million in 2001 by adding 55 drug products to the Federal Upper Limit list. This represents 30 percent of the $411 million Medicaid reimbursed for the 55 products that year. Each of these drug products had at least three versions rated therapeutically equivalent by FDA and were available from three or more suppliers. These 55 products represented various forms and strengths of 25 drugs from *Drug Topics* magazine's list of top 200 multiple-source drugs by retail sales in 2001.

Four drug products accounted for 71 percent of the $123 million in potential Medicaid savings in 2001. The Medicaid program could have saved $88 million in 2001 by placing these four products (albuterol aerosol, ipratropium bromide solution, enalapril maleate 20 mg tablets, and clozapine 100 mg tablets) on the Federal Upper Limit list. Albuterol aerosol accounted for 42 percent of overall savings. The State of New York alone could have realized $9.2 million in savings had albuterol aerosol been included on the list in 2001. The total savings attributed to the four products are shown in Table 2 on the following page. A complete list of the 55 drug products and their savings is presented in Appendix A. We did not verify that the prices published in the *Red Book* were available in the marketplace.

An additional 35 drug products met the criteria for inclusion on the Federal Upper Limit list but did not have any associated savings. These 35 drug products represented various forms and strengths of 23 drugs from *Drug Topics* magazine's list of top multiple-source drugs by retail sales. For 34 of these 35 drug products, no State had an average payment amount for the product that was less than the potential Federal Upper Limit amount. Medicaid did not make any payments for 1 of the 35 drug products. Therefore, this product did not have any potential savings. States reimburse for a drug at the lower of its estimated acquisition cost, the Federal Upper Limit amount, the Maximum Allowable Cost, or the provider's usual and customary charge. States would only pay the Federal Upper Limit amount for a drug product if it were the lowest of these options. Therefore, States would not have made higher payments if these 35 products had been included on the Federal Upper Limit list.

Table 2: Drug Products With The Highest Potential Federal Upper Limit Savings

Drug Product	Total Medicaid Reimbursement	Potential Federal Upper Limit Amount	Potential Savings
Albuterol Aerosol, 0.09 mg/inh[1]	$87,481,266	$0.39	$52,299,768
Ipratropium Bromide, 0.02% solution[2]	$65,156,902	$0.34	$19,945,230
Enalapril Maleate, 20 mg tablet[2]	$21,332,860	$0.72	$7,918,226
Clozapine, 100 mg tablet	$83,652,722	$2.48	$7,742,010
Total	$257,623,750		$87,905,234

Source: OIG analysis of 2001 Medicaid drug utilization and payment data and October 2001 *Red Book* pricing data

After the start of this inspection but prior to the release of the final report, CMS added 9 of the 90 products to the Federal Upper Limit list. Seven of these drug products (albuterol aerosol, ipratropium bromide solution, aspirin/butalbital/caffeine tablets, and four strengths of enalapril maleate tablets) accounted for a significant portion ($94 million) of the savings we calculated for 2001. Albuterol aerosol was added to the Federal Upper Limit list on March 11, 2003, ipratropium bromide and enalapril maleate were added on August 24, 2003, and aspirin/butalbital/caffeine was added on November 2, 2003. According to our analysis, adding the other two products (buspirone hydrochloride and oxaprozin) would not have led to any savings that year.

[1]Albuterol aerosol was added to the Federal Upper Limit list on March 11, 2003.

[2]Ipratropium bromide solution and enalapril maleate tablets were added to the Federal Upper Limit list on August 24, 2003.

RECOMMENDATION

Federal Upper Limits were created to help Medicaid save money by taking advantage of lower prices for multiple-source drugs available in the marketplace. Although the Federal Upper Limit list already includes over 400 drug products, there are more that could be added to the list. At a time when Medicaid prescription drug costs are increasing, efforts should be made to include on the Federal Upper Limit list all drugs that meet the requirements. This could result in millions of dollars in savings to both State Medicaid programs and the Federal Government.

We recommend that CMS take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the Federal Upper Limit list.

Agency Comments

CMS states that they do not agree with the the Office of Inspector General's (OIG's) savings estimates. Specifically, CMS states that OIG used only the *Red Book* to identify suppliers and prices, and did not subsequently verify the information provided in the *Red Book* with suppliers. In addition, CMS states that three of the products that we identified as leading to the most savings were recently added to the Federal Upper Limit list. Therefore, CMS believes that our savings estimates should be reduced accordingly. CMS also believes that it is nearly impossible to say with certainty that a particular group of products has been incorrectly excluded from the Federal Upper Limit list at any one time since pricing and product information changes frequently. CMS believes that their efforts to add and remove drug products on the Federal Upper Limit list should be recognized by OIG. Finally, CMS states it does not believe that products that would not lead to savings should be included on the Federal Upper Limit list.

CMS also includes a technical comment stating that four sections of this report do not describe all the potential situations in which Federal Upper Limits may be established. CMS suggests that we revise these sections of the report.

The full text of CMS's comments is presented in Appendix B.

OIG Response

In the report, we recommended that all products that meet the criteria set forth in the statute and regulation be included on the Federal Upper Limit list. The regulatory criteria only require that three suppliers who offer therapeutically-equivalent products be listed in current editions of national pricing compendia, and that the Federal Upper Limit amount be set at 150 percent of the lowest published price. We strictly followed these criteria in identifying the 90 drug products that had not been included in 2001 and in calculating their potential Federal Upper Limit amounts.

CMS believes that drugs that meet the criteria but have no associated savings should not be included on the Federal Upper Limit list. However, the Omnibus Budget Reconciliation Act of 1990 states that "[CMS] shall establish a Federal upper reimbursement limit..." Furthermore, States reimburse for a drug at the lower of its estimated acquisition cost, the Federal Upper Limit amount, the Maximum Allowable Cost, or the provider's usual and customary charge. Therefore, States would only pay the Federal Upper Limit amount for a drug product if it were the lowest of these options, and including a drug on the list would not lead to higher payments.

In response to CMS's technical comment concerning therapeutic equivalency requirements, we point out that the statute explicitly requires the establishment of a Federal Upper Limit when there are at least three therapeutically equivalent products that have been A-rated by FDA. The statute states that "[CMS] shall establish a Federal Upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such..." We believe that this statement is clear in its intent that CMS must set a Federal Upper Limit in situations in which three products have been A-rated by FDA and the other criteria are met. CMS's comments indicate that the agency takes the position that it also has the discretion to set Federal Upper Limits under certain additional circumstances. For the purposes of this report, OIG applied a conservative interpretation of the Federal Upper Limit criteria, but would expect additional savings to result from a broader application of the criteria.

In conclusion, OIG believes that the savings estimates for 2001 presented in this report are correct for the time period we reviewed. OIG also reaffirms its recommendation that CMS should include all products that meet the criteria on the Federal Upper Limit list.

APPENDIX A

Drug Products With Federal Upper Limit Savings

The table below lists the 55 drug products that, if included on the Federal Upper Limit list, could have led to $123 million in Medicaid savings in 2001. Unless otherwise noted, drug information is based on package sizes of 100.

Drug Product	Total Medicaid Reimbursement	Potential Federal Upper Limit	Potential Savings
APAP/Butabital/Caffeine			
325 mg-50 mg-40 mg, Capsule	$89,384.49	$0.36	$324
325 mg-50 mg-40 mg, Tablet	$3,909,337.28	$0.07	$2,660,418
500 mg-50 mg-40 mg, Capsule	$721,437.87	$0.69	$31,031
500 mg-50 mg-40 mg, Tablet	$2,506,195.89	$0.54	$706,407
Albuterol			
.09 mg/inh, Aerosol, 17 gm[1]	$87,481,265.89	$0.39	$52,299,768
2 mg/5 ml, Syrup, 480 ml	$3,242,419.13	$0.02	$1,111,100
Aspirin/Butalbital/Caffeine			
325 mg-50 mg-40 mg, Capsule	$411,383.11	$0.57	$138
325 mg-50 mg-40 mg, Tablet[2]	$536,594.21	$0.06	$363,022
Aspirin/Butalbital/Caffeine/Codeine			
325 mg-50 mg-40 mg-30 mg, Capsule	$2,188,509.43	$0.84	$179,712
Bupropion HCL			
100 mg, Tablet	$5,106,598.56	$0.80	$173,685
75 mg, Tablet	$4,759,489.74	$0.65	$1,656
Clotrimazole			
1%, Cream, 15 gm	$9,064,256.21	$0.23	$3,501,129
1%, Solution, 30 ml	$605,040.37	$0.61	$148
Clozapine			
100 mg, Tablet	$83,652,722.25	$2.48	$7,742,010
25 mg, Tablet	$7,907,922.22	$0.98	$578,799
Cromolyn Sodium			
10 mg/ml, Solution, 2ml	$6,187,808.53	$0.19	$1,338,246
Desmopressin Acetate			
4 mcg/ml, Solution, 10 ml	$512,170.58	$10.02	$199,539
Diflorasone Diacetate			
.05%, Cream, 30 gm	$842,858.89	$1.50	$262
.05%, Ointment, 30 gm	$1,016,670.39	$1.54	$315
Dipyridamole			
25 mg, Tablet	$366,648.16	$0.10	$152,414
50 mg, Tablet	$1,015,602.14	$0.13	$491,145
75 mg, Tablet	$339,020.00	$0.14	$6,575
Enalapril Maleate			
2.5 mg, Tablet[3]	$4,782,059.14	$0.41	$1,544,162
5 mg, Tablet[3]	$16,945,321.12	$0.51	$5,648,266
10 mg, Tablet[3]	$20,365,750.25	$0.54	$6,767,074
20 mg, Tablet[3]	$21,332,859.73	$0.72	$7,918,226
Erythromycin			
250 mg, Enteric Coated Tablet	$295,673.48	$0.22	$13,881
Fluvoxamine Maleate			
25 mg, Tablet	$1,643,208.29	$2.20	$114
50 mg, Tablet	$10,737,096.08	$2.47	$2,370
Glyburide Micronized			
1.5 mg, Tablet	$129,870.76	$0.25	$4,953
3 mg, Tablet	$1,479,788.03	$0.32	$6,346

APPENDIX A

Drug Product	Total Medicaid Reimbursement	Potential Federal Upper Limit	Potential Savings
HC/Neo Sulf/Polymyx			
1%-0.35%-10000 U/mL, Solution-Otic, 10 ml	$4,010,585.08	$1.53	$1,061,891
1%-0.35%-10000 U/mL, Suspension-Otic, 10 ml	$6,794,382.04	$1.53	$1,806,367
Indomethacin			
25 mg, Capsule	$234,076.01	$0.05	$23,200
50 mg, Capsule	$214,407.05	$0.08	$2,334
75 mg, Extended Release Capsule	$1,152,338.18	$0.69	$316,656
Ipratropium Bromide			
0.02%, Solution, 2.5 ml[3]	$65,156,902.28	$0.34	$19,945,230
Methadone HCL			
10 mg/mL, Solution, 946 ml	$70,613.56	$0.10	$19,778
40 mg, Tablet	$301,985.47	$0.37	$64
Methylphenidate HCl			
20 mg, Extended Release Tablet	$7,440,180.34	$1.06	$141
Morphine Sulfate			
15 mg, Extended Release Tablet	$1,691,463.24	$0.80	$5,161
Phentermine HCl			
30 mg, Capsule	$136,369.61	$0.18	$104,872
37.5 mg, Capsule	$1,993.44	$0.58	$947
37.5 mg, Tablet	$199,607.09	$0.30	$149,489
Sotalol HCL			
80 mg, Tablet	$6,536,421.53	$0.39	$4,947,453
120 mg, Tablet	$1,063,691.05	$0.54	$785,364
160 mg, Tablet	$559,271.45	$0.67	$406,557
240 mg, Tablet	$97,550.50	$0.94	$72,637
Timolol Maleate			
0.25%, Gel Forming Solution, 5 ml	$268,795.65	$4.62	$1
0.5%, Gel Forming Solution, 5ml	$5,062,860.34	$5.50	$242
Warfarin			
2.5 mg, Tablet	$3,601,587.06	$0.58	$1,391
3 mg, Tablet	$2,213,985.36	$0.58	$4,462
4 mg, Tablet	$2,144,529.40	$0.59	$1,741
6 mg, Tablet	$735,396.70	$0.84	$89
7.5 mg, Tablet	$1,071,049.80	$0.86	$87
TOTAL	**$410,935,004.45**		**$123,099,389**

[1] Albuterol aerosol was added to the Federal Upper Limit list on March 11, 2003.

[2] Aspirin/Butalbital/Caffeine tablets were added to the Federal Upper Limit list on November 2, 2003.

[3] Ipratropium bromide solution and enalapril maleate tablets were added to the Federal Upper Limit list on August 24, 2003.

Centers for Medicare & Medicaid Services's Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 17 2003

TO: Dara Corrigan
Acting Principal Deputy Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: *Omission of Drugs from the Federal Upper Limit List* (OEI-03-02-00670)

Thank you for the opportunity to review and comment on the above-referenced draft report regarding the omission of drugs from the Federal Upper Limit list.

This OIG report investigates 200 possible additions to the Federal Upper Limit list and states that the Red Book was used to verify whether three suppliers were listed for each product. According to the report, 90 of the 200 drug products met the necessary criteria for Federal Upper Limit eligibility and would have saved the Medicaid program $123 million in 2001 if they had been added to the list.

Among the 90 drug products that met the necessary criteria for Federal Upper Limit eligibility, the report identifies four specific products that could have generated $88 million in savings in 2001 if they were included on the Federal Upper Limit list: Albuterol Aerosol, Ipratropium Bromide Solution, Enalapril Maleate 20mg, and Clozapine 100mg.

The Centers for Medicare and Medicaid Services (CMS) do not agree with the savings estimates. Since the Red Book data does not always reflect the most current availability of drugs, many of the items may not actually meet the three supplier criteria. In fact, the CMS often follows-up on the information in the compendia by calling the suppliers directly to verify availability. As a result, the report should indicate that each of the 90 items might not really be available from three sources despite the existence of the three suppliers in the Red Book. In addition, this report also mentions that the Red Book was used to calculate a Federal Upper Limit amount for the 90 drug products that met the criteria for inclusion. Again, the prices in Red Book often have to be verified; therefore, using these prices to calculate potential Federal Upper Limit prices could have resulted in an overstatement of savings for the Medicaid program.

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Of the four specific products identified by the OIG as potentially generating $88 million in savings in 2001, Albuterol Aerosol was added to the Federal Upper Limit list in February 2003 and Ipratropium Bromide and Enalapril Maleate were added in July 2003. Because these products are included on the Federal Upper Limit list, the amount that Medicaid could have saved should be reduced accordingly. Although the report suggests that products should be added to the Federal Upper Limit list even when a Federal Upper Limit amount exceeds the average Medicaid payment, we continue to believe that placing a Federal Upper Limit on an item that would clearly generate more cost savings by being reimbursed at the Maximum Allowable Cost or Estimated Acquisition Cost level would serve no purpose, and in fact would be detrimental to the program. According to the most recent Federal Upper Limit data that is current through June 2003, Clozapine 100mg tablets would not generate savings because the Federal Upper Limit amount for this product exceeds the Average Wholesale Prices (AWPs) for this item and would therefore exceed the typical Medicaid payment of a percentage discount off of AWP.

OIG Recommendation

The OIG recommends CMS take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the Federal Upper Limit list.

CMS Response

First, it is important to note that pharmaceutical pricing and product information changes almost daily. As a result, because the pharmaceutical marketplace is constantly evolving, it is nearly impossible to say with certainty that a particular group of products has been incorrectly excluded from the Federal Upper Limit list at any one time. The CMS makes every effort to ensure that all drugs meeting the Federal Upper Limit criteria are included on the Federal Upper Limit list. To address the frequent marketplace changes, regular updates to the list are issued to the states and are posted on the Federal Upper Limit website. In fact, since the publication of the last Federal Upper Limit list in 2001, 39 drug products have been added to the list through the release of such updates. At the same time, 64 products have been deleted because they no longer meet the necessary criteria. In addition, CMS continues to welcome information from manufacturers, states, and pharmacy industry representatives regarding drug products that may be eligible for Federal Upper Limit pricing but are not on the current list, as well as those products that may no longer meet the necessary criteria and should be removed from the list. When such information is received, CMS performs a thorough investigation to determine whether adjustments can be made to the Federal Upper Limit list. Because this report only captures one particular period of time and the overall Federal Upper Limit program represents an ongoing process, these continuous updates should be recognized in the OIG draft report findings.

Attachment

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Technical Comment

Four sections of this report incorrectly describe the therapeutic equivalency criteria used to establish Federal Upper Limit prices: the background portion of the Executive Summary, the fourth paragraph on page two, the second paragraph on page four, and the second paragraph of the Findings section on page six. Each of these four sections states that a Federal Upper Limit is established on a product if three or more versions of the product have been classified as therapeutically equivalent by the Food and Drug Administration (FDA). This description is correct in instances where several therapeutically equivalent versions of a product are listed along with a version of the same product that is not therapeutically equivalent. However, a Federal Upper Limit can also be established for a drug product where all of the versions of the drug listed by the FDA are therapeutically equivalent—in those cases, there can be as few as two versions of the product listed by the FDA as long as they are both therapeutically equivalent. To present a more accurate description of the Federal Upper Limit criteria related to therapeutic equivalency, we suggest that each of the above mentioned sections be revised to reflect instances where all versions of the product are therapeutically equivalent versus instances where there are products that are therapeutically equivalent and products that are not therapeutically equivalent mixed together.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

David Tawes, *Team Leader*
Tanaz Dutia, *Program Analyst*
Linda Frisch, *Program Specialist*