Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ADDITION OF QUALIFIED DRUGS TO THE MEDICAID FEDERAL UPPER LIMIT LIST

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ABSTRACT

The objectives of this study were to (1) determine the length of time it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit list once the drugs met the statutory and regulatory criteria, and (2) calculate the losses that may have resulted due to drugs not being added to the list in a timely manner. We found that CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner. Of the 252 first-time generic drugs approved between January 2001 and December 2003, 109 products met the statutory and regulatory criteria for inclusion; however, only 25 were actually added. For the 25 drugs that were added, CMS took an average of 36 weeks to place the products on the list once the drugs were qualified for inclusion. As of July 15, 2004, the 84 drugs that were not added had been qualified for an average of 55 weeks. Qualified drugs not being added to the list in a timely manner cost the Medicaid program an estimated $167 million between 2001 and 2003. We recommend that CMS establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

OBJECTIVE

The objectives of this study were to: (1) determine the length of time it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit list once the drugs met the statutory and regulatory criteria, and (2) calculate the losses that may have resulted due to drugs not being added to the list in a timely manner.

BACKGROUND

Statutory and regulatory criteria require CMS to include a drug on the Federal upper limit list if: (1) at least three versions of the drug are rated as therapeutically equivalent by the Food and Drug Administration, and (2) the drug has at least three suppliers listed in current editions of national compendia. However, according to CMS staff, the agency will only establish a Federal upper limit if it would lead to cost savings. Neither the regulation nor the statute set timeliness guidelines for adding qualified drugs to the Federal upper limit list.

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. The CMS publishes the list of drug products with Federal upper limits in the *State Medicaid Manual* and on its Web site.

In February 2004, the Office of Inspector General (OIG) issued a report entitled *Omission of Drugs from the Federal Upper Limit List in 2001* (OEI-03-02-00670). We found that 90 drug products were not included on the Federal upper limit list in 2001 despite meeting the criteria established by Federal laws and regulations. Medicaid could have saved $123 million in 2001 by adding 55 of the 90 drug products to the Federal upper limit list. In June 2004, the OIG received a letter from the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations requesting that we provide further analysis of CMS's oversight of the Federal upper limit list.

We developed a list of first-time generic drug products approved by the Food and Drug Administration between January 2001 and December 2003. We then determined if and when each of these drug products qualified for inclusion on the Federal upper limit list according to statutory and regulatory criteria. For each calendar quarter that a

qualified drug was not included on the Federal upper limit list, we calculated potential Medicaid losses by: (1) subtracting the potential Federal upper limit amount from the average Medicaid price, and (2) multiplying the price difference by Medicaid utilization. We then aggregated the losses for each quarter to determine the overall potential losses to Medicaid caused by qualified drugs not being added to the Federal upper limit list in a timely manner.

FINDINGS

The CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner. The CMS did not consistently add qualified drugs to the Federal upper limit list in a timely manner during the period under review. Of the 252 first-time generic drugs approved between 2001 and 2003, 109 products met the statutory and regulatory criteria for inclusion on the Federal upper limit list. While 25 of the 109 drugs had been added to the list by July 15, 2004, very few were included in a timely manner. As of that date, 84 of the 109 drugs we reviewed had not been added by CMS.

For the 25 drugs that were added, CMS took an average of 36 weeks to place the products on the Federal upper limit list once they met all requirements for inclusion. Only 3 of the 25 drugs were included on the list at the time they qualified. Three of the drugs were added more than 1 year after they first became eligible for inclusion.

Eighty-four drugs approved between 2001 and 2003 are currently qualified for the Federal upper limit list but have not been added by CMS. As of July 15, 2004, these 84 drugs had been qualified for an average of 55 weeks yet were still not included on the Federal upper limit list. Twenty-nine of these drugs had been qualified for at least 80 weeks (approximately 1 year and 7 months).

Medicaid lost an estimated $167 million between 2001 and 2003 because qualified drugs were not added to the Federal upper limit list in a timely manner. Failure to add qualified drugs in a timely manner cost the Medicaid program an estimated $167 million (both Federal and State shares) between 2001 and 2003. Eighty-five percent ($143 million) of the estimated losses were attributable to lags in adding just 8 drugs.

The product with the highest loss figure, Fluoxetine 20 mg capsules (brand name Prozac), illustrates the effect of not adding drugs to the Federal upper limit list in a timely manner. The two-quarter lag in

adding the 20 mg dosage size of Fluoxetine capsules cost Medicaid an estimated $57 million.

In the next several months, new generic versions of several other major brand name drugs may become qualified for the Federal upper limit list. For example, Gabapentin (brand-name Neurontin), Oxycodone Hydrochloride (brand-name Oxycontin), and Paroxetine Hydrochloride (brand-name Paxil) have recently come off patent and, therefore, now have available generic versions. These 3 drugs accounted for a total of $5.3 billion in retail sales in 2003. As was the case with Fluoxetine, not adding these three drugs in a timely matter could cause substantial losses to Medicaid.

RECOMMENDATION

The CMS should establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

We believe that all qualified drugs should be included on the Federal upper limit list in a timely manner. The findings of both this report and our February 2004 report show that lags in adding qualified drugs are costing the Medicaid program substantial amounts. However, we are aware of the difficulties CMS faces in managing the Federal upper limit list. As CMS noted in their comments to the previous report, "pharmaceutical pricing and product information changes almost daily." While we continue to believe that all qualified drugs should be added to the Federal upper limit list in a timely manner, another option would be for CMS to consider focusing its resources on high-volume brand name drugs that are coming off patent. As our findings show, a large portion of the estimated losses can be attributed to lags in adding a small number of major drugs. If CMS makes a concerted effort to keep track of FDA ratings, number of suppliers, and published prices for these high-volume products, significant lags in placing qualified drugs on the Federal upper limit list could be avoided, thereby saving Medicaid millions of dollars per year.

Agency Comments

The CMS concurred with intent of our recommendation and stated that it had taken steps to support this objective. However, CMS did not concur with the OIG's methodology and the subsequent savings estimates.

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INTRODUCTION

OBJECTIVE

The objectives of this study were to: (1) determine the length of time it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit list once the drugs met the statutory and regulatory criteria, and (2) calculate the losses that may have resulted due to drugs not being added to the list in a timely manner.

BACKGROUND

Medicaid Program

Medicaid is a jointly funded, Federal and State health insurance program for certain low income and medically needy people. Individual States establish eligibility requirements, benefits packages, and payment rates for their Medicaid programs under broad Federal standards administered by CMS. 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 as well. 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 (CY) 2003, CMS estimates that Medicaid payments for prescription drugs totaled over $31 billion.[1]

Medicaid Drug Reimbursement Methodology

Each State is required to submit a Medicaid State plan to CMS describing its payment methodology for covered drugs. Federal regulations require, with certain exceptions, 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 $1.89 to $11.46 per prescription.

The CMS allows States flexibility to define estimated acquisition cost. Most States base their calculation of estimated acquisition cost on a drug's average wholesale price (AWP) discounted by a certain percentage. In CY 2003, this discount ranged from 5 percent to

[1] This amount includes both the Federal and State shares of payments. It does not include rebates collected under the Medicaid Drug Rebate program.

50 percent of AWP, sometimes depending on whether the drug was brand name or generic or on the type of pharmacy from which the drug was purchased. A small number of States use wholesale acquisition costs plus a percentage markup rather than or in addition to discounted AWPs when determining estimated acquisition cost.

For certain drugs, States also use the Federal upper limit and/or State maximum allowable cost programs in determining reimbursement amounts. The CMS has established Federal upper limit amounts for over 400 drugs. In addition, numerous States have implemented a maximum allowable cost program to limit 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 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 State maximum allowable cost, or the provider's usual and customary charge, plus a reasonable dispensing fee.

Federal Upper Limit List

Pursuant to 42 CFR § 447.332, CMS is to establish Federal upper limits in order to reduce the amount that Medicaid reimburses for multiple-source drugs. According to CMS, Federal upper limits were put in place to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs. Federal regulation (42 CFR § 447.301) defines a multiple-source drug 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." In other words, a multiple-source drug is a drug that has more than one brand or generic version.

Originally, under 42 CFR § 447.332, CMS was to establish a Federal upper limit amount for a drug when: (1) all versions of a drug had been rated as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) at least three suppliers of the drug were 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 changed the criteria originally established by the regulation by requiring a Federal upper limit when three or more versions of a drug had been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other

versions. The FDA identifies equivalent drugs in its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. According to FDA, drugs that are therapeutically equivalent are designated as "A-rated." Neither the regulation nor the statute set timeliness guidelines for adding qualified drugs to the Federal upper limit list.

Federal regulation (42 CFR § 447.332) 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 is not typically available in quantities of 100 or if the drug is a liquid, the Federal upper limit amount is based on a commonly listed size.

The CMS applies an additional standard in determining which drugs should be included on the Federal upper limit list. According to CMS staff, only drugs that could potentially lead to savings should be subject to Federal upper limits. Therefore, if a drug does not have a published price that when multiplied by 150 percent is lower than the AWP (upon which reimbursement is typically based), CMS does not include the product on the Federal upper limit list.[2]

In summary, statutory and regulatory criteria require that CMS include a drug on the Federal upper limit list if: (1) at least three versions of the drug are rated as therapeutically equivalent by FDA, and (2) the drug has at least three suppliers listed in national compendia. The CMS uses an additional standard that requires that the Federal upper limit amount would potentially lead to cost savings.

The CMS publishes a list of drugs for which Federal upper limits are established in the *State Medicaid Manual* and on its Web site.[3] Any revisions to the Federal upper limit list are typically noted in Medicaid program memoranda and on the CMS Web site. The 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.

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[2] In our previous report, we disagreed with CMS about the usage of this additional standard. States reimburse for a drug at the lower of its estimated acquisition cost, the Federal upper limit amount, the State maximum allowable cost, or the provider's usual and customary charge. Therefore, States would only pay the Federal upper limit amount for a drug if it were the lowest of these options.

[3] Federal upper limit information is located at www.cms.gov/medicaid/drugs/drug10.asp.

Related Work by the Office of Inspector General

In February 2004, the Office of Inspector General (OIG) issued a report entitled *Omission of Drugs from the Federal Upper Limit List in 2001* (OEI-03-02-00670). The OIG found that 90 drug products were not included on the Federal upper limit list in 2001 despite meeting the criteria established by Federal laws and regulations. Medicaid could have saved $123 million in 2001 by adding 55 of the 90 drug products to the Federal upper limit list. The remaining 35 drug products met the criteria for inclusion on the Federal upper limit list, but did not have any associated savings. The OIG recommended 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.

Inspection Requested by Congressional Subcommittee

On June 29, 2004, the OIG received a letter from the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. The letter expressed concern with the amount of time CMS takes to add new generic products to the Federal upper limit list, and requested that the OIG provide an analysis of the issue. Among other things, we were asked to determine the amount of time it takes for qualified drugs to be included on the Federal upper limit list, and the subsequent cost to the program of drugs not being added in a timely manner.

METHODOLOGY

Determining Generic Drugs Approved From 2001 to 2003

We developed a list of all first-time generic drugs approved by FDA between January 2001 and December 2003. According to FDA, a first-time generic is a drug that has never been approved as a generic before and is, therefore, a new generic to the marketplace. After deducting certain over-the-counter and physician-administered products, we created a list of 252 first-time generic drugs approved between 2001 and 2003.

Determining if Approved Drugs Meet Federal Upper Limit Criteria

The CMS is required to include on the Federal upper limit list all prescription drugs that have three versions rated therapeutically equivalent by FDA and three suppliers listed in national compendia. For each of the 252 first-time generic drugs approved between 2001 and 2003, we determined if three therapeutically equivalent versions were listed by FDA, and, if so, the date that the third therapeutically equivalent version was approved. To determine if these drugs also met

the three-supplier criterion, we obtained data from the *Red Book™ for Windows®* CD-ROM (a national compendium). For each of the drugs with three A-rated versions, we determined the first subsequent quarter (i.e., the first quarter after a third A-rated version was approved) that three suppliers were listed in the *Red Book*. In total, 109 of the first-time generics approved in 2001, 2002, or 2003 met both criteria for inclusion on the Federal upper limit list. For the remainder of this report, the phrase "reviewed drugs" will refer to these 109 products.

Determining if Drugs were on the Federal Upper Limit List

We obtained the most recent Federal upper limit list from the CMS Web site. We also obtained from the Web site all changes to the list between November 22, 2000, and July 15, 2004, and the date that the Federal upper limit prices for a drug were to go into effect. We determined if any of the 109 reviewed drugs were on the Federal upper limit list, and, if so, the date they were added. For any drugs that were included on the list, we determined the amount of time between when they became qualified for the Federal upper limit list and the date they were actually added.[4]

Estimating Potential Losses

For each quarter that a drug was qualified for but not included on the Federal upper limit list, we compared the potential Federal upper limit amount (150 percent of the lowest published price) to the average Medicaid reimbursement amount for the drug that quarter.[5] If the result was a positive number (i.e., the Federal upper limit amount was less than the average Medicaid amount), we multiplied it by the total number of units reimbursed by Medicaid that quarter. The product of this multiplication shows the estimated losses Medicaid had that quarter due to the drug(s) not being included on the Federal upper limit list. We aggregated the quarterly totals to determine the total estimated losses to the program between 2001 and 2003.

A more complete discussion of our methodology is presented in Appendix C.

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[4] For the purposes of this report, the term "qualified" refers to the date that a drug met the statutory and regulatory criteria for inclusion on the Federal upper limit list.

[5] Because the Federal upper limit amount is calculated by multiplying the lowest published price for a drug by 150 percent, there are instances when this amount would be higher than the reimbursement amount based on discounted AWP. In order to limit the time required to do this analysis, we only calculated estimated losses for drugs that may have actually led to losses (e.g., had at least one published price that when multiplied by 150 percent was below AWP).

The CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner

The CMS did not consistently add qualified drugs to the Federal upper limit list in a timely manner during the period under review. Of the 252 first-time generic drugs approved between 2001 and 2003, 109 met the statutory and regulatory criteria for inclusion on the list. While 25 of the 109 drugs had been added to the Federal upper limit list by July 15, 2004, very few of the 25 were included in a timely manner. As of that date, an additional 84 of the 109 reviewed drugs had not been added by CMS. A list of the 109 drugs is presented in Appendix A.

The 25 drugs that were included on the Federal upper limit list had been qualified for an average of 36 weeks before being added by CMS. For the 25 drugs that were added, CMS took an average of 36 weeks to place the products on the Federal upper limit list once the drugs met the statutory and regulatory criteria for inclusion. Only 3 of the 25 drugs were included on the list at the time they first became qualified. Table 1 below presents a summary of the time CMS took to include the 25 drugs.

The longest period between when a drug initially qualified and when it was actually added to the Federal upper limit list was for two versions of Metformin Hydrochloride, a drug used to treat Type II diabetes. The third A-rated versions of Metformin Hydrochloride were approved in January of 2002, and the 500 mg and 850 mg dosage sizes had three suppliers as of April 1, 2002. However, CMS did not add the drugs until March 18, 2004, or 102 weeks after the drugs first became qualified.

Table 1: Amount of Time Between When a Drug Qualified and When a Drug Was Added

Number of Weeks Qualified	Number of Drugs
0 weeks	3
20 weeks	2
23 weeks	5
35 weeks	8
36 weeks	1
48 weeks	3
More than 52 weeks	3
Average 36 Weeks	**25 Drugs**

Sources: FDA Web site, *Red Book*, Federal upper limit list

In addition to the statutory and regulatory criteria, CMS applies an additional standard requiring that a Federal upper limit amount would potentially lead to cost savings before a drug is included on the list. Using CMS's additional standard, these 25 drugs were still not added to the Federal upper limit list in a timely manner. On average, the 25 drugs were included on the Federal upper limit list 32 weeks after they may have first led to cost savings (i.e., met CMS's additional standard).

Eighty-four drugs that were not added to the Federal Upper Limit list had been qualified for an average of 55 weeks.

Eighty-four of the 109 drugs we reviewed had not been added by CMS as of July 15, 2004. At that date, these 84 drugs had been qualified for an average of 55 weeks. Twenty-nine of these drugs had been qualified for at least 80 weeks (approximately 1 year and 7 months). A summary of these 84 drugs is presented in Table 2 below.

Table 2: Drugs Not Included on the Federal Upper Limit List as of 7/15/2004

Number of Weeks Qualified	Number of Drugs
15 weeks or less	16
28 weeks	14
41 weeks	11
54 weeks	9
67 weeks	5
80 weeks	15
93 weeks	5
More than 104 weeks	9
Average 55 Weeks	**84 Drugs**

Sources: FDA website, *Red Book*, Federal upper limit list

Twenty-three of these eighty-four met CMS's additional cost-savings standard as well. Each of these 23 drugs had sufficiently low published prices that may have led to savings, yet were still not included on the Federal upper limit list by CMS.

Medicaid lost an estimated $167 million between 2001 and 2003 because qualified drugs were not added to the Federal upper limit list in a timely manner

Between 2001 and 2003, only 27 of the 109 reviewed drugs were associated with potential losses caused by products not being added to the Federal upper limit list when they first qualified.[6] However, the failure to add these 27 drugs in a timely manner cost the Medicaid program (both Federal and State shares) an estimated $167 million over the 3-year period. A majority of the losses were attributable to just eight drugs. These 8 drugs, listed in Table 3 below, were each associated with more than $5 million in estimated losses, accounting for 85 percent ($143 million) of the total. A complete list of the drugs and their potential losses is provided in Appendix B.

Table 3: Largest Losses Associated with Qualified Drugs

Drug	Number of Quarters Delay[7]	Estimated Losses
Fluoxetine HCL 20 mg capsule	2	$56,697,780
Buspirone HCL 15 mg tablet	2	$23,261,047
Metformin HCl 1 gm tablet	7	$16,011,279
Famotidine 20 mg tablet	1	$11,487,628
Buspirone HCL 10 mg tablet	2	$10,536,672
Tramadol HCl 50 mg tablet	2	$9,632,958
Metformin HCl 850 mg tablet	7	$8,893,822
Fluoxetine HCl 10 mg capsule	2	$6,404,089

Sources: FDA Web site, *Red Book*, Federal upper limit list, CMS State Medicaid Data

The product with the highest estimated loss figure, Fluoxetine Hydrochloride 20 mg capsules (brand name Prozac), illustrates the potential effect of not adding drugs to the Federal upper limit list in a timely manner. As Table 3 shows, the two-quarter lag in adding the

[6] Because Medicaid payment data were unavailable for 2004, we could only calculate potential losses for the period between 2001 and 2003. Thirty-three of the reviewed drugs did not meet the statutory and regulatory criteria until 2004, and were therefore not included in any savings estimates. In addition, failure to add some drugs with sufficiently low published prices in a timely manner did not actually lead to any losses.

[7] Medicaid expenditure data were only available by quarter. Therefore, for the purposes of calculating potential losses, if a drug was added to the Federal upper limit list at any point during a quarter, we considered it included for the entire quarter.

20 mg dosage size of Fluoxetine Hydrochloride capsules cost Medicaid an estimated $57 million.[8] The first generic version of Fluoxetine Hydrochloride 20 mg capsules was approved in August 2001. According to FDA, the product had three therapeutically equivalent versions as of January 2002. The April 2002 *Red Book* listed more than three suppliers for the drug. Based on the lowest published price, a Federal upper limit for Fluoxetine Hydrochloride 20 mg capsules should have been set at $0.60 (150 percent of $0.40) by April 1, 2002. However, CMS did not place Fluoxetine Hydrochloride 20 mg capsules on the Federal upper limit list until December 1, 2002 (at $0.60 per capsule). During this period, four other versions of Fluoxetine Hydrochloride also qualified for the Federal upper limit list. In total, not adding these four versions when they first qualified cost Medicaid an additional $15 million.

In the next several months, new generic versions of several other major brand name drugs may become qualified for the Federal upper limit list. For example, Gabapentin (brand-name Neurontin), Oxycodone Hydrochloride (brand-name Oxycontin), and Paroxetine Hydrochloride (brand-name Paxil) have recently come off patent. These three drugs accounted for a total of $5.3 billion in retail sales in 2003. As was the case with Fluoxetine, not adding these three drugs to the Federal upper limit list in a timely matter could cause substantial losses to Medicaid.

[8] The estimated $57 million in losses only includes the period between April 1 and September 30, 2002. It does not include the partial quarter between October 1 and December 1, 2002. Nor does it account for the fact the drug may have been qualified for inclusion as early as January 29, 2002.

RECOMMENDATION

The CMS should establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

We believe that all qualified drugs should be included on the Federal upper limit list in a timely manner. The findings of both this report and our February 2004 report show that lags in adding qualified drugs are costing the Medicaid program substantial amounts. However, we are aware of the difficulties CMS faces in managing the Federal upper limit list. As CMS noted in their comments to the previous report, "pharmaceutical pricing and product information changes almost daily." While we continue to believe that all qualified drugs should be added to the Federal upper limit list in a timely manner, another option would be for CMS to consider focusing its resources on high-volume brand name drugs that are coming off patent. As our findings show, a large portion of the estimated losses can be attributed to lags in adding a small number of major drugs. If CMS makes a concerted effort to keep track of FDA ratings, number of suppliers, and published prices for these high-volume products, significant lags in placing qualified drugs on the Federal upper limit list could be avoided, thereby saving Medicaid millions of dollars per year.

Agency Comments

The CMS concurred with intent of our recommendation and stated that it had taken steps to support this objective. However, CMS did not concur with the OIG's methodology and subsequent savings estimates.

Specifically, CMS stated that the OIG incorrectly describes the therapeutic equivalency criterion used to determine if drugs should be placed on the Federal upper limit list. According to CMS, for a drug to meet the criterion, the FDA must "list two therapeutically equivalent formulations of the drug when all formulations of that drug product are 'A' rated. Where there are also 'B' rated drugs included with the 'A' drugs, there must be at least three 'A' drugs listed as therapeutically and pharmaceutically equivalent." The CMS believes this criterion is more rigorous.

The CMS then lists additional actions they take above those performed by the OIG, including (1) consulting additional compendia beyond the *Red Book*, and (2) verifying that the drug is actually available in the market by contacting manufacturers and suppliers.

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

OIG Response

In their comments, CMS stated that they have taken steps to address our recommendation. However, CMS did not provide any details on these steps. Therefore, we cannot determine if CMS's efforts will alleviate the problems identified in this report.

In response to CMS's comments concerning therapeutic equivalency requirements, we point out that the Omnibus Budget Reconciliation Act of 1990 explicitly states, "[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 understand that before this statute was enacted, regulations may have allowed for a Federal upper limit to be established if only two versions of a drug were available and both were therapeutically equivalent. However, as we read the statutory provisions, a product must have three A-rated versions to be included on the Federal upper limit list.

In any case, CMS's interpretation would potentially allow for more instances where a product would be placed on the Federal upper limit list. The OIG's interpretation requires three versions of a drug to be A-rated while CMS takes the position that two may be sufficient. If the OIG followed CMS's interpretation, it is possible that we would have identified additional drugs that should have been added.

Finally, we recognize that CMS takes additional steps in determining product availability, and understand their reasons for doing so. However, CMS has not explained why the additional steps account for the delays identified by the OIG.

APPENDIX ~ A

Complete List of 109 Reviewed Drugs

Drug	Unit	Strength	3 A-rated Date	3 Supplier Date	Federal Upper Limit Date
Acetaminophen; Butalbital; Caffeine; Codeine	Capsule; Oral	325MG;50MG;40MG;30MG	22-Aug-01	01-Oct-01	
Amcinonide	Cream; Topical	0.10%	31-May-02	1-Jul-02	
Ammonium Lactate	Cream; Topical	12%	10-Apr-03	1-Jul-03	
Amoxicillin	Suspension; Oral	400MG/5ML	4-Dec-02	1-Jan-03	
Amoxicillin	Suspension; Oral	200MG/5ML	4-Dec-02	1-Apr-03	
Amoxicillin; Clavulanate Potassium	Tablet; Oral	875MG;125MG	17-Sep-02	1-Oct-02	
Amoxicillin; Clavulanate Potassium	Tablet; Oral	500MG;125MG	30-Oct-02	1-Jan-03	
Amoxicillin; Clavulanate Potassium	Suspension; Oral	200MG/5ML;28.5MG/5ML	16-Dec-02	1-Jan-03	
Amoxicillin; Clavulanate Potassium	Suspension; Oral	400MG/5ML;57MG/5ML	16-Dec-02	1-Jan-03	
Amoxicillin; Clavulanate Potassium	Chewable Tablet; Oral	200MG;28.5MG	3-Dec-03	1-Jan-04	
Amoxicillin; Clavulanate Potassium	Chewable Tablet; Oral	400MG;57MG	3-Dec-03	1-Jan-04	
Betamethasone Diproprionate	Augmented Gel; Topical	0.05%	2-Dec-03	1-Jan-04	
Betamethasone Diproprionate	Augmented Cream; Topical	0.05%	9-Dec-03	1-Jan-04	
Betamethasone Diproprionate; Clotrimazole	Cream; Topical	0.05%	5-Jun-01	01-Jul-01	
Bupropion Hydrochloride	ER Tablet; Oral	150MG	22-Mar-04	1-Apr-04	
Buspirone Hydrochloride	Tablet; Oral	5MG	27-Feb-02	01-Apr-02	01-Dec-02
Buspirone Hydrochloride	Tablet; Oral	10MG	27-Feb-02	01-Apr-02	01-Dec-02
Buspirone Hydrochloride	Tablet; Oral	15MG	27-Feb-02	01-Apr-02	01-Dec-02
Buspirone Hydrochloride	Tablet; Oral	30MG	25-Mar-04	01-Apr-04	
Butorphanol Tartrate	Nasal Spray	1MG/SPRAY	12-Mar-02	01-Apr-02	
Cefaclor	ER Tablet; Oral	500MG	4-Sep-02	1-Oct-02	
Cefuroxime Axetil	Tablet; Oral	250MG	2-Oct-02	1-Jan-03	
Cefuroxime Axetil	Tablet; Oral	500MG	2-Oct-02	1-Jan-03	
Clindamycin Hydrochloride	Capsule; Oral	300MG	18-Mar-03	01-Apr-03	
Econazole Nitrate	Cream; Topical	1%	26-Nov-02	1-Jan-03	
Ethinyl Estradiol; Norethindrone Acetate	Tablet; Oral	0.03MG;1.5MG	18-Sep-03	1-Oct-03	
Ethinyl Estradiol; Norethindrone Acetate	Tablet; Oral	0.02MG;1MG	18-Sep-03	1-Jan-04	
Ethinyl Estradiol; Norgestimate	Tablet; Oral	0.035MG;0.25MG	9-Jan-04	1-Apr-04	
Ethinyl Estradiol; Norgestimate	Tablet; Oral	0.035MG,0.035MG,0.035MG ;0.18MG,0.215MG,0.025MG	26-Mar-04	1-Apr-04	
Famotidine	Tablet; Oral	20MG	16-Apr-01	01-Jul-01	20-Nov-01
Famotidine	Tablet; Oral	40MG	16-Apr-01	01-Jul-01	20-Nov-01
Flecainide Acetate	Tablet; Oral	100MG	28-Oct-02	01-Jan-03	
Flecainide Acetate	Tablet; Oral	150MG	28-Oct-02	01-Jan-03	
Flecainide Acetate	Tablet; Oral	50MG	28-Oct-02	01-Jan-03	
Fludrocortisone Acetate	Tablet; Oral	0.1MG	21-Jan-03	1-Apr-03	
Fluoxetine Hydrochloride	Capsule; Oral	10MG	29-Jan-02	01-Apr-02	01-Dec-02
Fluoxetine Hydrochloride	Capsule; Oral	20MG	29-Jan-02	01-Apr-02	01-Dec-02
Fluoxetine Hydrochloride	Capsule; Oral	40MG	29-Jan-02	01-Apr-02	01-Dec-02

Drug	Unit	Strength	3 A-rated Date	3 Supplier Date	Federal Upper Limit Date
Fluoxetine Hydrochloride	Solution, Oral	20MG/5ML	29-Jan-02	01-Apr-02	01-Dec-02
Fluoxetine Hydrochloride	Tablet; Oral	10MG	29-Jan-02	01-Apr-02	01-Dec-02
Fosinopril Sodium	Tablet; Oral	10MG	23-Apr-04	1-Jul-04	
Fosinopril Sodium	Tablet; Oral	20MG	23-Apr-04	1-Jul-04	
Fosinopril Sodium	Tablet; Oral	40MG	23-Apr-04	1-Jul-04	
Hydrocodone Bitartrate; Ibuprofen	Tablet; Oral	7.5MG;200MG	31-Dec-03	1-Jan-04	
Ipratropium Bromide	Nasal Spray	0.021MG/SPRAY	31-Mar-03	1-Jul-03	
Ipratropium Bromide	Nasal Spray	0.042MG/SPRAY	31-Mar-03	1-Jul-03	
Isotretinoin	Capsule; Oral	10MG	24-Dec-02	1-Jan-03	
Isotretinoin	Capsule; Oral	20MG	24-Dec-02	1-Jan-03	
Isotretinoin	Capsule; Oral	40MG	24-Dec-02	1-Jan-03	
Lidocaine; Prilocaine	Cream; Topical	2.5%;2.5%	27-Aug-03	1-Oct-03	
Lisinopril	Tablet; Oral	30MG	1-Jul-02	1-Oct-02	11-Mar-03
Lithium Carbonate	ER Tablet; Oral	300MG	21-Apr-03	1-Jul-03	
Lithium Carbonate	ER Tablet; Oral	450MG	21-Aug-03	1-Oct-03	
Lovastatin	Tablet; Oral	10MG	17-Dec-01	01-Jan-02	01-Dec-02
Lovastatin	Tablet; Oral	20MG	17-Dec-01	01-Jan-02	01-Dec-02
Lovastatin	Tablet; Oral	40MG	17-Dec-01	01-Jan-02	01-Dec-02
Mefloquine Hydrochloride	Tablet; Oral	250MG	29-Dec-03	1-Jan-04	
Megestrol Acetate	Suspension; Oral	40MG/ML	15-Feb-02	01-Apr-02	
Metformin Hydrochloride	Tablet; Oral	500MG	24-Jan-02	1-Apr-02	18-Mar-04
Metformin Hydrochloride	Tablet; Oral	850MG	24-Jan-02	1-Apr-02	18-Mar-04
Metformin Hydrochloride	Tablet; Oral	1GM	24-Jan-02	1-Apr-02	
Metolazone	Tablet; Oral	2.5MG	23-Dec-03	1-Jan-04	
Metolazone	Tablet; Oral	10MG	24-Dec-03	1-Apr-04	
Metolazone	Tablet; Oral	5MG	1-Mar-04	1-Apr-04	
Midodrine Hydrochloride	Tablet; Oral	5MG	11-Sep-03	1-Jan-04	
Mirtazapine	Tablet; Oral	15MG	19-Jun-03	1-Oct-03	
Mirtazapine	Tablet; Oral	30MG	19-Jun-03	1-Oct-03	
Mirtazapine	Tablet; Oral	45MG	19-Jun-03	1-Oct-03	
Mixed Salts (Amphetamine)	Tablet; Oral	2.5MG	14-Jun-02	1-Jul-02	
Mixed Salts (Amphetamine)	Tablet; Oral	1.25MG	19-Jun-02	1-Jul-02	
Mixed Salts (Amphetamine)	Tablet; Oral	5MG	14-Jun-02	1-Oct-02	
Mixed Salts (Amphetamine)	Tablet; Oral	7.5MG	14-Jun-02	1-Oct-02	
Mixed Salts (Amphetamine)	Tablet; Oral	1.875MG	9-Sep-03	1-Apr-04	
Mixed Salts (Amphetamine)	Tablet; Oral	3.125MG	9-Sep-03	1-Apr-04	
Mixed Salts (Amphetamine)	Tablet; Oral	3.75MG	9-Sep-03	1-Apr-04	
Mometasone Furoate	Ointment; Topical	0.10%	14-Nov-03	1-Jan-04	
Mupirocin	Ointment; Topical	2%	7-Nov-03	1-Jan-04	
Nizatidine	Capsule; Oral	150MG	5-Jul-02	1-Oct-02	11-Mar-03

Drug	Unit	Strength	3 A-rated Date	3 Supplier Date	Federal Upper Limit Date
Nizatidine	Capsule; Oral	300MG	5-Jul-02	1-Oct-02	11-Mar-03
Ofloxacin	Tablet; Oral	200MG	2-Sep-03	1-Oct-03	
Ofloxacin	Tablet; Oral	300MG	2-Sep-03	1-Oct-03	
Ofloxacin	Tablet; Oral	400MG	2-Sep-03	1-Oct-03	
Omeprazole	DR Capsule; Oral	20MG	1-Nov-02	1-Jan-03	
Omeprazole	DR Capsule; Oral	10MG	1-Nov-02	1-Oct-03	
Oxaprozin	Tablet; Oral	600MG	31-Jan-01	01-Apr-01	01-Dec-02
Paroxetine Hydrochloride	Tablet; Oral	10MG	8-Mar-04	1-Apr-04	
Paroxetine Hydrochloride	Tablet; Oral	20MG	8-Mar-04	1-Apr-04	
Paroxetine Hydrochloride	Tablet; Oral	30MG	8-Mar-04	1-Apr-04	
Paroxetine Hydrochloride	Tablet; Oral	40MG	8-Mar-04	1-Apr-04	
Pergolide Mesylate	Tablet; Oral	.05 MG	4-Sep-03	1-Jan-04	
Pergolide Mesylate	Tablet; Oral	.25MG	4-Sep-03	1-Jan-04	
Pergolide Mesylate	Tablet; Oral	1MG	4-Sep-03	1-Jan-04	
Prednisolone Sodium Phosphate	Solution; Oral	5MG/5ML	23-Dec-02	1-Jan-03	
Promethazine Hydrochloride	Suppository; Rectal	12.5MG	11-Apr-03	1-Jul-03	
Propafenone Hydrochloride	Tablet; Oral	300MG	7-Feb-02	01-Apr-02	
Rimantidine Hydrochloride	Tablet; Oral	100MG	30-Aug-02	01-Oct-02	
Sotatol Hydrochloride	Tablet; Oral	120MG	8-Apr-04	1-Jul-04	27-Jun-04
Sotatol Hydrochloride	Tablet; Oral	160MG	8-Apr-04	1-Jul-04	27-Jun-04
Sotatol Hydrochloride	Tablet; Oral	80MG	8-Apr-04	1-Jul-04	27-Jun-04
Tamoxifen Citrate	Tablet; Oral	10MG	20-Feb-03	1-Apr-03	
Tamoxifen Citrate	Tablet; Oral	20MG	20-Feb-03	1-Apr-03	
Tizanidine Hydrochloride	Tablet; Oral	2MG	3-Jul-02	1-Oct-02	11-Mar-03
Tizanidine Hydrochloride	Tablet; Oral	4MG	3-Jul-02	1-Oct-02	11-Mar-03
Torsemide	Tablet; Oral	100MG	27-May-03	1-Jul-03	
Torsemide	Tablet; Oral	10MG	27-May-03	1-Jul-03	
Torsemide	Tablet; Oral	20MG	27-May-03	1-Jul-03	
Torsemide	Tablet; Oral	5MG	27-May-03	1-Jul-03	
Tramadol Hydrochloride	Tablet; Oral	50MG	19-Jun-02	1-Jul-02	11-Mar-03
Trimethobenzamide Hydrochloride	Capsule; Oral	300MG	28-Aug-03	1-Oct-03	

Sources: FDA Web site, *Red Book*, Federal upper limit list

APPENDIX ~ B

Estimated Losses to Medicaid

Drug	Strength	Form	Quarters Delay	Potential Losses
Fluoxetine HCL	20 MG	Capsule	2	$56,697,780
Buspirone HCL	15 MG	Tablet	2	$23,261,047
Metformin HCl	1 GM	Tablet	7	$16,011,279
Famotidine	20 MG	Tablet	1	$11,487,628
Buspirone HCL	10 MG	Tablet	2	$10,536,672
Tramadol HCl	50 MG	Tablet	2	$9,632,958
Metformin HCl	850 MG	Tablet	7	$8,893,822
Fluoxetine HCL	10 MG	Capsule	2	$6,404,089
Metformin HCl	500 MG	Tablet	7	$4,922,364
Fluoxetine HCL	40 MG	Capsule	2	$4,015,053
Fluoxetine HCL	10 MG	Tablet	2	$3,276,601
Tamoxifen Citrate	10 MG	Tablet	3	$2,285,933
Oxaprozin	600 MG	Tablet	6	$2,184,381
Buspirone HCL	5 MG	Tablet	2	$2,163,399
Famotidine	40 MG	Tablet	1	$1,601,892
Fluoxetine HCL	20 MG/5 ML	Solution	2	$1,299,147
Mirtazapine	30 MG	Tablet	1	$572,887
Nizatidine	150 MG	Capsule	1	$448,501
Tamoxifen Citrate	20 MG	Tablet	3	$444,140
Mirtazapine	45 MG	Tablet	1	$413,550
Flecainide Acetate	50 MG	Tablet	3	$339,654
Mirtazapine	15 MG	Tablet	1	$254,751
Flecainide Acetate	100 MG	Tablet	3	$148,689
Flecainide Acetate	150 MG	Tablet	3	$115,875
Lisinopril	30 MG	Tablet	1	$32,077
Nizatidine	300 MG	Capsule	1	$20,014
Rimantidine HCL	100 MG	Tablet	1	$829
TOTAL				**$167,465,012**

Sources: FDA Web site, *Red Book*, Federal upper limit list

METHODOLOGY

Determining Generic Drugs Approved From 2001 to 2003

We developed a list of all first-time generic drugs approved by FDA between January 2001 and December 2003. According to FDA, a first-time generic is a drug that has never been approved as a generic before and is, therefore, a new generic to the marketplace. Prior to approval of a first-time generic, only brand versions were available for sale. Using information obtained from the FDA Web site, we determined that 331 first-time generic drugs were approved during this time period.[9]

To focus on prescription drugs that are typically available at pharmacies, we removed from the list 50 injectable drugs and 17 over-the-counter products. We also removed 12 drugs that had additional branded versions (i.e., non-generics) available before 2001, and therefore may have been eligible for inclusion on the Federal upper limit list prior to the review period. After these deductions, 252 drugs remained on our list of first-time generics approved between January 2001 and December 2003.

Determining if Approved Drugs Meet Federal Upper Limit Criteria

The CMS is required to include on the Federal upper limit list all prescription drugs that have three versions rated therapeutically equivalent by FDA and three suppliers listed in national compendia. On June 1, 2004, we downloaded a file containing therapeutic equivalence data from the FDA Web site. For each of the 252 first-time generic drugs approved between 2001 and 2003, we determined if three therapeutically equivalent versions were listed on the FDA file, and, if so, the date that the third therapeutically equivalent version was approved. Of the 252 drugs, 113 had at least 3 versions rated therapeutically equivalent by FDA.

To determine if these drugs also met the three-supplier criterion, we obtained data from the *Red Book™ for Windows®* CD-ROM, a national drug compendium published quarterly by Micromedex (hereinafter, referred to as *Red Book*). For each of the 113 drugs with three A-rated versions, we determined the first subsequent quarter (i.e., the first quarter after a third A-rated version was approved) that three suppliers were listed in *Red Book*. All but 4 drugs had the required number of suppliers listed in a subsequent quarter, leaving 109 of the first-time generics approved in 2001, 2002, or 2003 that met the criteria for inclusion on the Federal upper limit list.

[9] The 331 drugs represent various forms and dosage sizes of approved products. For example, a product with dosage sizes of 20 mg, 40 mg, and 80 mg counted as three drugs.

Determining if Drugs were on the Federal Upper Limit List

We obtained the current Federal upper limit list from the CMS Web site. We also obtained from the Web site all changes to the list between November 22, 2000, and July 15, 2004. We determined if any of the 109 reviewed drugs were on the Federal upper limit list, and, if so, the date they were added. For any drugs that were included on the list, we determined the amount of time between when they became qualified for the Federal upper limit list and the date they were actually added.

For example, Oxaprozin had its third A-rated version approved in January 2001. We checked subsequent quarters of *Red Book* and determined that the drug had three suppliers as of April 1, 2001. Oxaprozin was added to the Federal upper limit list on December 1, 2002. Therefore, the amount of time between when Oxaprozin first qualified for the Federal upper limit list and when it was actually added equaled 87 weeks.

Estimating Potential Losses

For each quarter that a drug was qualified for but not included on the Federal upper limit list, we compared the potential Federal upper limit amount to the average Medicaid reimbursement amount for the drug that quarter. Because the Federal upper limit amount is calculated by multiplying the lowest published price for a drug by 150 percent, there are instances when this amount would be higher than the reimbursement amount based on discounted AWP. In order to limit the time required to do this analysis, we only calculated estimated losses for drugs that may have been associated with actual losses if not added in a timely manner (e.g., had at least one published price significantly below AWP).

Calculating Potential Federal Upper Limit Amounts

To calculate a potential Federal upper limit amount, we used pricing information 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, for every calendar quarter that a drug was not included on the Federal upper limit list, 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 drug was not typically 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 each quarter. We did not verify that the prices published in the *Red Book* were actually available in the marketplace.[10]

[10] According to staff, CMS often verifies that the lowest published price is actually available in the marketplace by contacting manufacturers and/or distributors.

Calculating Medicaid Reimbursement Amounts

To determine the amount Medicaid reimbursed for the drugs, we downloaded 50 Medicaid payment and utilization files for CY 2001 through CY 2003 from CMS's Web site. State reimbursement data was only available by quarter. We did not obtain data from the first 2 quarters of CY 2004 because the files were not yet available; therefore, potential losses could only be calculated through the end of CY 2003. We also did not include data from Arizona because its drug reimbursement and utilization files were not available. Each file contained variables representing total State reimbursement, number of units reimbursed, and number of prescriptions written for every drug by calendar quarter.

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

(1) calculated the total amount paid in dispensing fees for the drug by multiplying the State's dispensing fee by the number of prescriptions written for the drug in each State each quarter;

(2) subtracted total dispensing fees from the total reimbursement for the drug in each State each quarter; and

(3) aggregated reimbursement for the drug only, number of units reimbursed, and number of prescriptions written for the drug each quarter.

We then calculated the average Medicaid reimbursement amount per quarter for each of the drugs by dividing the total of all States' reimbursement for the product (without the dispensing fee) by the total number of units reimbursed.

Calculating Potential Losses

For each drug for which the untimely addition may have led to losses, we subtracted the potential Federal upper limit amount from the average Medicaid reimbursement amount. If the result was a positive number (i.e., the Federal upper limit amount was less than the average Medicaid amount), we multiplied it by the total number of units reimbursed that quarter. The product of this multiplication shows the estimated losses Medicaid had that quarter due to the drug(s) not being included on the Federal upper limit list. We aggregated the quarterly totals to determine the total estimated losses to the program between 2001 and 2003.

Our methodology assumes that each of the reviewed drugs became qualified for the Federal upper limit list on the first day of a calendar quarter. However, drugs could be added to the Federal upper limit list at any time. To allow for this when calculating losses, we considered a drug that was added at any point in the quarter to be included for the entire quarter, and therefore it was not accounted for in our estimates. For example, Oxaprozin first became qualified for the Federal upper limit list on April 1, 2001, but the

drug was not added to the Federal upper limit list until December 1, 2002. Therefore, we calculated potential losses for the last 3 quarters of 2001 and the first 3 quarters of 2002 (April 1, 2001, through September 30, 2002), but did not calculate losses for the period between October 1, 2002, and December 1, 2002 (the date Oxaprozin was added). Because of this, our estimates of program losses may be below the true amount. Furthermore, because State reimbursement data was not available for CY 2004, we were unable to calculate losses for any drugs approved between 2001 and 2003 that did not meet all criteria for inclusion until 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

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TO: Daniel R. Levinson
Acting Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *"Addition of Qualified Drugs to the Medicaid Federal Upper Limit List,"* (OEI-03-04-00320)

Thank you for the opportunity to review and comment on the subject draft report. The OIG report addresses the time frame that it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit (FUL) list after statutory and regulatory criteria were met. This report also addresses the potential losses to the Medicaid program due to the untimely addition of these drugs. Our response to the audit recommendation follows.

OIG Recommendation

The CMS should establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

CMS Response

While we concur with the intent of the recommendation made by the OIG and note that CMS has taken steps to support this objective, we cannot concur with the OIG methodology in performing this review and the subsequent savings estimates for the reasons that follow.

The OIG report incorrectly describes the therapeutic equivalency criteria used to establish drugs to be placed on the FUL list. Specifically, the report states that a FUL 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). The actual criteria are more rigorous. Instead, the FDA's Orange Book must list two therapeutically equivalent formulations of the drug when all formulations of that drug product are "A" rated. Where there are also "B" rated drugs included with the "A" drugs, there must be at least three "A" drugs listed as therapeutically and pharmaceutically equivalent.

Once a product has met the FDA criteria, CMS must also verify that the drug meets the necessary compendium criteria. OIG said that they obtained data from the *Red Book* compendium. CMS consults the three national drug-pricing compendia which includes *Red Book, First Data Bank* and *Medi-Span* to identify current market data. If there are three suppliers of the drug, the FUL system selects the lowest price (Average Wholesale Price,

Wholesale Acquisition Cost, or Direct Price) that can be purchased by pharmacists and multiplies it by 150 percent as required by 42 CFR 447.332, to arrive at the FUL price.

While this verification gives us the universe of drugs that may be included in the FULs, it does not determine our final list. Before a drug is placed on the FUL list, it is important to be certain that the products listed are actually available in the marketplace. New drugs may be in limited supply or unavailable nationwide. To meet this list, we then manually verify that the FUL drug continues to be available from manufacturers or suppliers to assure current market availability. Both of these steps must be completed before CMS can add a drug to the FUL list.

For these reasons, we can support neither the number of drugs the OIG estimates should have been added to the FUL nor the resultant savings.

ACKNOWLEDGMENTS

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

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Tricia Davis, *Director, Medicare and Medicaid Branch*