DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date JUL 27 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Nationwide Audit of Six Ulcer Treatment Drugs Reimbursed Under the Medicaid Prescription Drug Program (A-06-92-00003)

To Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached are two copies of our final report entitled, "Nationwide Audit of Six Ulcer Treatment Drugs Reimbursed Under the Medicaid Prescription Drug Program." The objective of our audit was to estimate the potential cost savings available nationwide to the Medicaid program by limiting the reimbursement of ulcer treatment drugs to the manufacturers' recommended dosages.

We randomly selected 200 Medicaid recipients who received ulcer treatment drugs from each of 8 randomly selected States (1,600 recipients in total). We compared the dosages received by the recipients to the manufacturers' recommended dosages and computed a potential cost savings of $116,133 for those recipients for Calendar Year 1990. Extrapolating these sample results to all Medicaid recipients taking one of the ulcer treatment drugs, we estimate that national savings could be as much as $112 million annually. Accordingly, we recommended that the Health Care Financing Administration (HCFA) encourage States to establish procedures that prospectively limit payment for the six ulcer treatment drugs to the dosages recommended by the manufacturers.

The Acting HCFA Administrator responded to our draft report in a memorandum dated March 3, 1993. The HCFA disagreed with our recommendation and took exception to our methodology, including our sample size, criteria, conclusions, savings estimate, and the example used in the report.

We believe that our methodology was appropriate: (1) our sample size was adequate and in accordance with Office of Inspector General's policies and (2) our criteria, conclusions, and savings estimate were appropriate, reasonable, and supportable. Subsequent to receiving HCFA's comments, we met with the Director of the Division of Payment Systems and his staff to discuss their response. In that meeting, they agreed to provide the other States with copies of our report for each State's use.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 966-7104. Copies of this report are being sent to other interested Department officials.

To facilitate identification, please refer to Common Identification Number A-06-92-00003 in all correspondence relating to this report.

Attachments

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

NATIONWIDE AUDIT OF SIX ULCER TREATMENT DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM

JULY 1993 A-06-92-00003

SUMMARY

The Health Care Financing Administration (HCFA) has the opportunity to reduce Medicaid prescription drug expenditures by about $112 million annually. This can be accomplished by establishing procedures to limit reimbursement for six ulcer treatment drugs to the dosages recommended by the manufacturers.

The objective of our audit was to estimate the potential cost savings available nationwide to the Medicaid program by limiting the reimbursements for ulcer treatment drugs to the manufacturers' recommended dosages. We randomly selected 200 ulcer treatment drug patients from each of 8 States that were also chosen randomly. The eight States were Illinois, Indiana, Minnesota, Nebraska, North Dakota, Pennsylvania, Virginia, and Wisconsin. We reviewed reimbursement records for the resulting 1,600 Medicaid recipients who received ulcer treatment therapy through at least 1 of 6 ulcer treatment drugs.

The ulcer treatment drugs include Tagamet, Zantac, Pepcid, and Axid, which belong to a class of drugs known as histamine H_2-receptor antagonists (or H_2 antagonists). These drugs are prescribed for the treatment of gastric and duodenal ulcers. Unlike earlier drugs which tried to neutralize excess stomach acid, these drugs reduce the actual flow of acid. Carafate and Prilosec (formerly Losec) are not H_2 antagonists, but they are related ulcer treatment drugs and are prescribed in a similar manner.

The manufacturers of the six ulcer treatment drug products recommend an active treatment period of up to 8 weeks. The manufacturers recommend significant dosage reductions--at least 50 percent reductions--after the active treatment period. The reduced dosage treatment period is known as maintenance therapy. There are circumstances in which the active treatment dosages must be continued beyond the 8-week period. Because these circumstances are unusual, we did not attempt to quantify the rate of incidence or the dollar effect of the medically-necessary extended therapy.

Of the 1,600 Medicaid recipients that we reviewed, 606 or 38 percent of the recipients received dosages in excess of the manufacturers' recommendations. By comparing the amounts reimbursed in the 8 States on behalf of these 606 recipients to the amounts that would have been reimbursed had the dosages been consistent with manufacturers' recommendations, we computed a potential savings of $116,133 for Calendar Year (CY) 1990 for the

606 recipients. Extrapolating these sample results to all Medicaid recipients taking one of these drugs, we estimate that national savings would be about $112 million annually.

The eight States we reviewed did not have restrictions to limit reimbursement for ulcer treatment drugs to the dosages recommended by manufacturers. A survey we conducted of all States, prior to our audit, showed that only nine States had limitation programs for ulcer treatment drugs. We believe that establishment of prospective limitation programs in the remaining 41 States (and the District of Columbia) would be very cost-effective. For example, the State of Texas has already set up a prospective system at a cost of about $180,000, and has estimated first year savings of $6 million for its ulcer treatment drugs. Therefore, we are recommending that HCFA encourage States to establish prospective limitation procedures that limit payment for the six ulcer treatment drugs to the dosages recommended by the manufacturers. Such limitation procedures should provide override mechanisms for special patient treatment deemed necessary by the physicians.

The Acting HCFA Administrator responded to our draft report in a memorandum dated March 3, 1993. In that memorandum, HCFA disagreed with our recommendation to encourage States to implement procedures for limiting utilization of ulcer treatment drugs to the manufacturers' recommended dosages. The HCFA took exception to our methodology, including our sample size, criteria, conclusions, savings estimate, and the example used in the report.

However, HCFA did not present any additional factual information which would require us to revise our findings and recommendations. We believe that our methodology was appropriate because (1) our sample size was adequate and in accordance with Office of Inspector General's (OIG) policies and (2) our criteria, conclusions, and savings estimate were appropriate, reasonable, and supportable. Subsequent to receiving HCFA's comments, we met with the Director of the Division of Payment Systems and his staff to discuss their response. In that meeting, they agreed to provide the other States with copies of our report for each State's use.

For more detail and our response to those comments see pages 9 through 12 of this report. Also, see Appendix C for a complete text of the Acting Administrator's comments.

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INTRODUCTION

The OIG reviewed a random sample of 1,600 Medicaid prescription drug payment records for recipients from 8 States who had prescriptions for Tagamet, Zantac, Pepcid, Axid, Carafate, and/or Prilosec during CY 1990. The eight randomly chosen States were Illinois, Indiana, Minnesota, Nebraska, North Dakota, Pennsylvania, Virginia, and Wisconsin. The objective of our audit was to estimate the potential cost savings available nationwide through limiting the reimbursements for ulcer treatment drugs to the manufacturers' recommended dosages.

We found that HCFA has an opportunity to reduce Medicaid prescription drug expenditures by about $112 million annually. This can be achieved by encouraging States to establish procedures to limit ulcer treatment drugs to manufacturers' recommended dosages. We believe that these estimates are conservative, since they are based on CY 1990 data and are not adjusted for inflation.

BACKGROUND

Medicaid is a federally aided, State operated and administered program that provides medical benefits to low-income persons who are aged, blind, or disabled or members of families with dependent children where one parent is absent, incapacitated, or unemployed. The program, authorized by title XIX of the Social Security Act, requires States to provide certain medical services and permits them to provide other services, such as outpatient prescription drugs, on an optional basis. Federal oversight is the responsibility of HCFA, an Operating Division of the Department of Health and Human Services.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requires State Medicaid agencies to operate drug use review (DUR) programs on an ongoing basis. These programs are intended to assess actual patient drug use against predetermined standards which are contained in the compendia listed in OBRA '90.

Drugs Reviewed and Manufacturers' Recommended Dosages

Tagamet, Zantac, Pepcid, and Axid belong to a classification of drugs known as histamine H_2-receptor antagonists (or H_2 antagonists). These drugs are prescribed for the treatment of gastric and duodenal ulcers and have reduced the need for stomach ulcer surgery. Unlike earlier drugs which tried to neutralize excess stomach acid, these drugs reduce the actual flow of acid. Carafate and Prilosec (formerly Losec) are not H_2 antagonists, but they are related ulcer treatment drugs and are prescribed in a similar manner.

Pharmaceutical publications such as **Facts and Comparisons** and **Physicians' Desk Reference**, as well as prescribing and product information (package inserts) published by the manufacturers, provide information concerning recommended dosages for these drugs. These resources show that the manufacturers recommend full dosage prescriptions during an active treatment period of 4 to 8 weeks to promote healing of the ulcer. After the active treatment, the manufacturers recommend that the dosages be reduced by 67 percent for Tagamet and 50 percent for Zantac, Pepcid, Axid, and Carafate as maintenance therapy to prevent reoccurrence. There was no manufacturers' recommendation regarding the length of the maintenance therapy period.

There are circumstances in which the maintenance level dosages are inappropriate. For example, the drugs are used in the treatment of pathological hypersecretory conditions or "Zollinger-Ellison syndrome." According to available literature, treatment of this rare disease with H_2 antagonists continues for as long as clinically necessary with no active or maintenance treatment periods.

Limiting the prescribing of these drugs to the medically necessary dosages, recommended by the manufacturers, offers potential cost savings because of the popularity and price of the drugs. In recent years, Zantac and Tagamet have ranked as the top two drugs in terms of sales revenue among drugs sold worldwide and ranked in the top five in terms of sales revenue in the U.S. market. Using the average wholesale price, a 30-day supply of ulcer treatment drugs at active dosage levels costs from $60 to $120.

SCOPE OF AUDIT

We conducted our audit in accordance with generally accepted government auditing standards. The objective of our audit was to estimate the potential cost savings available nationwide to the Medicaid program by limiting the

reimbursements for ulcer treatment drugs to the manufacturers' recommended dosages. Specifically, we reviewed drug utilization data from eight States and determined the potential cost savings available for each State. The results from each State were used to project the cost savings available nationwide. Achieving our audit objective did not require that we review the entire internal control structure of the State agencies. Therefore, we reviewed only those controls relating to the utilization of the ulcer treatment drugs selected for review.

To accomplish our objective, we reviewed various drug compendia including, **Facts and Comparisons, Physicians' Desk Reference, American Hospital Formulary Service,** and **United States Pharmacopeial Drug Information** regarding manufacturers' recommended dosages and strengths for the drugs selected for review. We also examined product information (package inserts) for the drugs.

We excluded nine States from our universe because they operate limitation programs covering histamine H_2 antagonists and related drugs. We randomly selected an 8 State sample from the remaining 41 and the District of Columbia. The States selected were Illinois, Indiana, Nebraska, North Dakota, Minnesota, Pennsylvania, Virginia, and Wisconsin.

The State agencies' computerized Medicaid prescription drug payment records contained a total of 268,483 unduplicated Medicaid recipients who had prescriptions for Tagamet, Zantac, Pepcid, Axid, Carafate, and/or Prilosec during CY 1990. A breakdown of the number of recipients for each State is as follows:

NO. OF RECIPIENTS			
Illinois	**74,437**	**Minnesota**	**25,980**
Indiana	**30,171**	**Pennsylvania**	**70,083**
Nebraska	**6,587**	**Virginia**	**31,858**
North Dakota	**2,828**	**Wisconsin**	**26,539**

We randomly selected a sample of 200 recipients from each State for a total of 1,600 recipients. Our review was performed during October 1991 through April 1992. (See **Appendix A** for a description of sampling methodology.)

Our review did not include an evaluation of the medical necessity of dosages for ulcer treatment drugs received by the 1,600 sample Medicaid recipients. Therefore, our savings estimate did not consider those situations where manufacturers' recommended dosages for the drugs were exceeded due to medical necessity. Additionally, the savings estimate did not consider drug price or utilization increases due to inflation and program growth since 1990.

FINDINGS AND RECOMMENDATIONS

The HCFA needs to encourage States to establish procedures to limit payments for ulcer treatment drugs to the manufacturers' recommendations. Although the manufacturers recommended that dosages be reduced by 50 percent to 67 percent after a 4 to 8-week active treatment period, we found that the recommended dosages were exceeded in 606 of the 1,600 sampled cases. We estimate that establishing restrictions based on manufacturers' recommendations could result in savings of about $112 million annually.

The eight States we reviewed did not have restrictions in place to limit payment for the six ulcer treatment drugs to the manufacturers' recommended dosages. We believe that an effective method for limiting reimbursement for ulcer treatment drugs to the manufacturers' recommendations would be the establishment of prospective DUR programs by State agencies. Such programs should allow for variations from the manufacturers' recommended dosages when medically necessary. The State of Texas has already set up a prospective DUR system at a cost of about $180,000 and has estimated first year savings of $6 million for its ulcer treatment drugs. Therefore, we are recommending that HCFA encourage States to establish prospective DUR procedures that limit payment for the six ulcer treatment drugs to the amounts paid for manufacturers' recommended dosages.

CURRENT PROCEDURES

State officials from all eight States informed us that they did not have any restrictions in place to limit reimbursements for these drugs to the manufacturers' recommended dosages. Some of the sampled States informed us that they operated retrospective DUR programs and had achieved some cost savings related to ulcer treatment drugs.

A prospective DUR program could prevent the submission of claims for inappropriate dosages by identifying dosages that exceed manufacturers' recommendations before the prescription is filled. Retrospective DUR programs operate in an after-the-fact manner by identifying inappropriate dosages **after** payment of the claim. A retrospective DUR is useful to prevent future payments for inappropriate dosages, but is not designed to correct payments already made for inappropriate dosages in all cases.

We believe that HCFA should encourage the States to establish prospective DUR programs that limit payments for ulcer treatment drugs to the manufacturers' recommended dosages. The limitation should not be imposed in cases where continued active treatment is necessary based on physicians' authorizations of medical necessity. Payments should be denied, however, for active treatment dosages that extend beyond the active treatment for claims that are not supported by physicians' statements of medical necessity.

RESULTS OF REVIEW OF A SAMPLE OF MEDICAID RECIPIENTS

The State agencies' computerized Medicaid prescription drug payment files contained a total of 268,483 unduplicated Medicaid recipients who had prescriptions for Tagamet, Zantac, Pepcid, Axid, Carafate, and/or Prilosec during CY 1990. We randomly selected a sample of 200 recipients from each State and found that dosages in 575 instances were not reduced to maintenance dosage levels when the period of expected active treatment ended and the maintenance therapy began. In addition, there were 65 instances where the active treatment period dosages exceeded the manufacturers' recommended dosages. The dosages in 31 of these 65 instances were reduced and the remaining 34 were not reduced when the maintenance therapy began. In summary, 606 of the 1,600 Medicaid recipients in the sample received dosages that exceeded the manufacturers' recommended dosages. The remaining 994 recipients in the sample received dosages equal to or lower than the manufacturers' recommended dosages. (See **Appendix A** for a description of our sampling methods.)

The total amount paid by Medicaid on behalf of the 1,600 sampled recipients for the drugs was $529,273. The applicable potential cost savings for the 1,600 recipients was $116,133 or about 22 percent of the Medicaid paid amount. Using this data, we estimate that national annual savings would have been about $112 million if all States in our universe had limited dosages to manufacturers' recommendations. (See **Appendix B** for computation of our sample results.)

In calculating the potential cost savings, we determined the difference between the number of tablets paid for and the number of tablets recommended by the manufacturers for each prescription. We multiplied this difference (number of tablets) by the drug price per tablet paid by Medicaid for the prescription. This calculation was made for both active and maintenance treatment periods. The results were combined into one potential cost savings amount for the sampled recipient.

The manufacturers' recommended daily dosages, which we used in our calculations, are shown as follows:

MANUFACTURERS' RECOMMENDED DAILY DOSAGES			
DRUG	ACTIVE CONDITIONS	MAINTENANCE THERAPY	REDUCTION IN DOSAGE
Tagamet	1,200 mg	400 mg	67%
Zantac	300 mg	150 mg	50%
Pepcid	40 mg	20 mg	50%
Axid	300 mg	150 mg	50%
Carafate	4 g	2 g	50%
Prilosec	20 mg	None	100%

Since these drugs are packaged in several different strengths, we determined the total number of tablets needed to equate to the recommended dosage levels. For example, if a physician prescribed Tagamet in 400 mg tablets, the number of tablets per day allowed in our calculations would be three (1200 mg divided by 400 mg) for active treatment or one (400 mg divided by 400 mg) for maintenance therapy.

We reviewed the manufacturers' recommended active treatment periods for various illnesses and concluded that a maximum of 8 weeks would be appropriate since, except for special circumstances, it represents the maximum active treatment period for the drugs. Therefore, in our calculations we used 62 days (the maximum number of days in a 2-month supply) as the applicable active treatment period. We believe that this period is reasonable although the manufacturers recommended shorter active treatment periods for certain illnesses. For example, the manufacturer of Tagamet states in its prescribing information bulletin (TG:L83) regarding treatment of active duodenal ulcer, "...while healing with Tagamet often occurs during the first week or two,

treatment should be continued for 4-6 weeks unless healing has been demonstrated by endoscopic examination."

Nebraska's, Virginia's, and Illinois' computerized Medicaid prescription drug payment records did not contain information indicating the number of days supply that a prescription represented. Because of this, we reviewed each prescription, including the fill date of the next prescription, and estimated the number of days supply that the prescription provided. We reviewed the days supply provided for each prescription for the States of Indiana and Wisconsin. When this amount appeared erroneous, we changed the days supply. Any change was based on such items as the quantity supplied and the fill date of the next prescription. For the three remaining States, we relied on the information provided concerning days supply.

We allowed one active treatment period for each different drug received by the Medicaid recipients. We started the count of days for determining the active treatment period on October 1, 1989, 3 months prior to the beginning of our review period. By doing so, we were able to determine whether a recipient receiving one of the drugs in the first month of our review period had already completed the active treatment. We restarted the count of days for determining an active treatment period if there was a break in treatment of 30 days or more before the active treatment period was completed. We recognize that in special circumstances the active treatment period could extend beyond 62 days. For purposes of this study, however, we did not consider such special cases.

We did not set any limitations on the number of days for the maintenance treatment period because there were no clearly defined manufacturers' recommendations regarding the termination of maintenance therapy.

EXAMPLE OF AN ULCER TREATMENT DRUG LIMITATION PROGRAM

The State of Texas has a program for ulcer treatment drugs which has produced significant savings consistent with good medical practice. Under the program, Medicaid recipients are limited to acute dosage levels of ulcer treatment drugs for up to 62 days. The dispensing pharmacist is able to determine whether a recipient has reached or exceeded the end of a 62-day active treatment period by calling a toll-free 800 number (using a touch-tone phone) directly linked to the profile data for each recipient. Texas State agency officials estimate that the personal computer-based voice response system, that cost approximately $180,000, saved the Medicaid program approximately $6 million during State Fiscal Year 1991.

The physicians are able to override the 62-day active treatment limit for higher dosage levels by writing the diagnosis on the face of a prescription. The pharmacist must submit a copy of the prescription to be reimbursed.

RECOMMENDATION

We recommend that HCFA encourage the States to implement restrictive procedures on a prospective basis that limit the payment for all ulcer treatment drugs to the manufacturers' recommended dosages. Such limitation procedures should provide override mechanisms for special patient treatment deemed necessary by the physicians.

HCFA'S COMMENTS

The Acting HCFA Administrator responded to our draft report in a memorandum dated March 3, 1993. In that memorandum, HCFA disagreed with our recommendation to encourage States to implement procedures for limiting utilization of ulcer treatment drugs to the manufacturers' recommended dosages. The HCFA questioned (1) the use of manufacturers' recommended dosages; (2) the sample size–that the savings calculation did not account for excessive dosages for legitimate medical reasons; (3) the reference to the use of the Texas State agency's procedures for ulcer treatment drugs; and (4) that States already require prior authorization for ulcer treatment drugs as part of their DUR programs. (See **Appendix C** for the complete text of HCFA's comments.)

OIG'S RESPONSE

The HCFA's comments did not acknowledge the main point of our report–that ulcer treatment drugs are overprescribed and overutilized and, therefore, offer the potential for significant cost savings. The HCFA response also did not acknowledge the positions of the States in this matter. We conducted the pilot audit in the State of Arkansas, and followed with audits in eight additional States. The following are paraphrased comments from the nine States' official responses to our individual State ulcer treatment drug audits:

- ***Arkansas*** - Agreed with the findings of our audit and indicated that the ulcer treatment drugs were overprescribed and overutilized. It plans to implement a cost containment program for ulcer treatment drugs.

- ***Virginia*** - Agreed with our recommendation of limiting ulcer treatment drugs to the manufacturers' recommended dosages.

- ***North Dakota*** - Agreed with our recommendation of limiting ulcer treatment drugs to the manufacturers' recommended dosages.

- ***Pennsylvania*** - Report finding substantiates concerns that physicians are overprescribing ulcer treatment drugs without regard to the manufacturers' recommended dosages. The State agency is planning to recommend the establishment of a prospective DUR program for ulcer treatment drugs to the Agency's DUR board.

- ***Illinois*** - Believed that our report had merit and is planning to implement a prospective DUR program that will limit payment for all ulcer treatment drugs to the manufacturers' recommended dosages.

- ***Indiana*** - Report findings reflect what is commonly believed to be a nationwide incidence of misutilization of ulcer treatment drugs. It will give due consideration to the audit findings during future program enhancements. Thanked us for the "insightful audit."

- ***Minnesota*** - Just placed Prilosec on prior authorization when usage exceeds 8 weeks. It will take our recommendations under further advisement and review them with the Minnesota DUR Board.

- ***Nebraska*** - The audit information will better enable the State to make decisions on prospective DUR programs.

- ***Wisconsin*** - Stated it will continue to review our recommendations and will attempt to further evaluate our findings to determine whether the State can benefit. This may be in the form of enhanced DUR for ulcer treatment drugs or a prior authorization process.

Regarding HCFA's disagreement with our use of the manufacturers' recommended dosages, it should be noted that the dosages and usages are determined on the basis of manufacturer testing and Food and Drug

Administration's approval. Also, none of the States we audited expressed disagreement, and most agreed with using the manufacturers' recommendations as the evaluation criteria. Regarding the criticism of our sample size, it should be noted that we reviewed 1,600 randomly selected claims. That sample size is more than adequate for reaching conclusions reached in this report and is in accordance with OIG's sampling policies.

The HCFA contended that our savings estimate did not account for excessive dosages for legitimate medical reasons. Our objective was to estimate potential savings. We did not attempt to pinpoint the exact dollar savings because we did not believe it was necessary in order to present a convincing argument for recognizing manufacturers' recommended dosages.

The HCFA also objected to our reference to Texas as a model State for controlling the prescribing and cost of ulcer treatment drugs. The HCFA questioned Texas' procedure, stating that its shortcoming is that it is confrontational and undermines the physicians' willingness to cooperate in the DUR process. As pointed out on page 9 of this report, the Texas physicians are able to override Texas' 62-day active treatment for higher dosage levels. To override, the pharmacist submits a copy of the prescription to be reimbursed with the patient's diagnosis written on the face by the physician. Therefore, we disagree with HCFA's contention that the process is confrontational and undermining. Also, we did not report (nor intend to imply) that other States should use Texas as a model. Instead, we pointed out the Texas program as an example of how one State has controlled the costs of ulcer treatment drugs through recognizing the manufacturers' recommended dosages.

The HCFA further contended that our savings estimate figures are flawed because our calculations did not recognize States that already require prior authorization for ulcer treatment drugs. However, we initially contacted 49 States (Arizona was excluded) and the District of Columbia to discuss any existing ulcer treatment drug restriction programs which were in effect. As stated on page 3 of this report, we excluded nine States from our savings estimate because they already operated limitation programs for ulcer treatment drugs.

In summary, we continue to believe that our recommendation for HCFA to encourage the States to implement restrictive procedures for ulcer treatment drugs is appropriate.

Subsequent to receiving the response, we met with the Director of the Division of Payment Systems and his staff to discuss their comments. During that meeting, they agreed to send copies of our report to the other States for their use.

APPENDICES

SAMPLE DESCRIPTION

Sample Objective: Project potential cost savings for excess Medicaid drug utilization attributable to Medicaid recipients who received the ulcer treatment drugs Tagamet, Zantac, Pepcid, Axid, Carafate, and/or Prilosec for CY 1990.

Sample Information: Expenditures for the Medicaid outpatient prescription drug programs of the 42 States totaled about $3.6 billion during the period January 1, 1990 through December 31, 1990.

Population: The sampling population was all unduplicated Medicaid recipients who received Tagamet, Zantac, Pepcid, Axid, Carafate, and/or Prilosec during the 12-month period ending December 31, 1990.

Sample Design: A multistage sample was taken with the primary sample units (States) selected from a universe of 42 States with no restrictions limiting ulcer treatment drugs to manufacturers' recommended dosages. The sampling units were then selected from the sampling population for each primary sample unit. Simple random sampling was used to select both the primary sample units and the sampling items.

Sample Size: Eight primary sample units (States) were selected. A sample of 200 Medicaid recipients who received Tagamet, Zantac, Pepcid, Axid, Carafate, and/or Prilosec was taken from each State.

Source of Random Numbers:	The OIG's Statistical Sampling Software was used to determine the random numbers for drawing the samples.
Characteristics to be Measured:	From our examination of each State's Medicaid payment history tapes, we calculated the per tablet price for each prescription received by the Medicaid recipients in our sample. When the dosages and/or duration of treatment exceeded the manufacturers' recommendations, we computed a dollar value for the excess drugs used. This value was used to determine the cost savings that would have been realized if there had been a control in place to limit payments for Tagamet, Zantac, Pepcid, Axid, Carafate, and/or Prilosec tablets to the manufacturers' recommended dosages and durations of treatment.
Other Evidence:	None.
Extrapolation:	The total amount paid by Medicaid on behalf of the 1,600 sampled recipients for the 6 drugs was $529,273. The potential cost savings for the 1,600 recipients was $116,133 or about 22 percent of the Medicaid paid amount. Using this data and a 90 percent confidence level, the lower limit for our savings estimate was $60,803,019, the upper limit was $163,154,330, and the mid-point estimate was $111,978,675.

SAMPLE RESULTS	
Sample Population	268,483
Standard Sample Size	1,600
Sample Recipients Receiving Dosages in Excess of Manufacturers' Recommended Dosages	606
Value of Sample	$529,273
Value of Dosages in Excess of Manufacturers' Recommendations	$116,133
At the 90% Confidence Level Upper Limit Lower Limit	 $163,154,330 $60,803,019
Estimated Annual Savings	$111,978,675

SAMPLE RESULTS BY INDIVIDUAL STATES				
	Illinois	Indiana	Minnesota	Nebraska
Sample Population	74,437	30,171	25,980	6,587
Standard Sample Size	200	200	200	200
Sample Recipients Receiving Dosages in Excess of Manufacturers' Recommended Dosages	75	83	82	75
Value of Sample	$67,903	$62,591	$70,280	$59,831
Value of Dosages in Excess of Manufacturers' Recommendations	$15,641	$14,029	$15,627	$11,988
At the 90% Confidence Level				
Upper Limit	$7,086,735	$2,595,654	$2,490,797	$480,850
Lower Limit	$4,555,859	$1,637,065	$1,569,035	$308,821
Estimated Annual Savings	$5,821,297	$2,116,360	$2,029,916	$394,836
Federal Share	$2,910,649	$1,346,640	$1,074,029	$242,903

SAMPLE RESULTS BY INDIVIDUAL STATES				
	North Dakota	Pennsylvania	Virginia	Wisconsin
Sample Population	2,828	70,083	31,858	26,539
Standard Sample Size	200	200	200	200
Sample Recipients Receiving Dosages in Excess of Manufacturers' Recommended Dosages	63	87	67	74
Value of Sample	$54,592	$72,468	$68,315	$73,293
Value of Dosages in Excess of Manufacturers' Recommendations	$10,539	$18,635	$13,171	$16,503
At the 90% Confidence Level				
Upper Limit	$183,913	$7,862,404	$2,585,535	$2,689,526
Lower Limit	$114,140	$5,197,500	$1,610,428	$1,690,279
Estimated Annual Savings	$149,026	$6,529,952	$2,097,982	$2,189,903
Federal Share	$101,546	$3,709,666	$1,048,991	$1,300,145

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Memorandum

Date MAR 3 1993

From William Toby, Jr.
Acting Administrator

Subject Office of Inspector General (OIG) Draft Audit Report: "Nationwide Audit of Six Ulcer Treatment Drugs Reimbursed Under The Medicaid Prescription Drug Program," A-06-92-00003

To Bryan B. Mitchell
Principal Deputy Inspector General

We reviewed the subject draft audit report concerning the results of OIG's review of six ulcer treatment drugs reimbursed under the Medicaid prescription drug program.

OIG recommends that the Health Care Financing Administration (HCFA) encourage States to establish prospective limitation procedures that limit payment for the six ulcer treatment drugs to the dosages recommended by the manufacturers. Such limitation procedures should provide override mechanisms for special patient treatment deemed necessary by the physicians.

HCFA nonconcurs with the recommendation. We believe OIG's survey and methodology have limitations, and we question the criteria used by OIG to determine if the ulcer treatment drugs reimbursed by Medicaid were medically necessary.

Thank you for the opportunity to review and comment on this draft audit report. Our specific comments are attached for your consideration. Please advise us if you agree with our position on the report's recommendation at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the Office of Inspector General (OIG) Draft Audit Report:
"Nationwide Audit of Six Ulcer Treatment Drugs Reimbursed
Under the Medicaid Prescription Drug Program,"
A-06-92-00003

OIG Recommendation

Recommend that HCFA encourage the States to implement prospective restrictive procedures that limit the payment for all ulcer treatment drugs to the manufacturers' recommended dosages. Such limitation procedures should provide override mechanisms for special patient treatment deemed necessary by the physicians.

HCFA Response

HCFA does not concur with the recommendation. We believe the methodology used in the audit is seriously flawed and substantially undermines the credibility of the conclusions reached. We question the validity of such a small sample size and the use of the standard dosages criteria recommended by drug manufacturers to determine the potential savings to be realized by limiting Medicaid reimbursement for the six ulcer treatment drugs.

The OIG report extrapolates savings based on the identification of 606 of 1,600 sampled cases where dosages for six anti-ulcer drugs were not reduced to maintenance levels after 62 days of treatment. Further, the report indicates that no attempt was made to evaluate whether there were legitimate medical reasons, or medical necessity, for the instances where the dosage duration parameters were exceeded.

The criteria used by OIG to determine the medical necessity of the ulcer treatment drugs are not the only medical necessity criteria that have been developed for the use of these drugs. One set of ulcer treatment drug criteria, developed by the University of Maryland and the Philadelphia College of Pharmacy and Science under a cooperative agreement with HCFA, suggests that in treating gastroesophageal reflux disease (GERD), the maximum daily dosages should not exceed 1,600 milligrams (mg) for cimetidine, 300 mg for ranitidine, and 300 mg for nizatidine, for periods greater than 62 days but less than or equal to 93 days. Instances of adherence to these GERD criteria, however, would clearly exceed the dosage duration criteria used in the OIG report.

In the report, OIG assumes that exceeding the dosage duration criteria in the manufacturers' recommendations is not legitimate. While we have no doubt that some dosage and duration criteria for ulcer treatment drugs are exceeded without medical justification, we do not believe OIG should have assumed that this was true for 38 percent of the sample reviewed.

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The OIG draft report used Texas as a model program for ulcer treatment drugs which has produced significant savings consistent with good medical practice. In Texas, claims which exceed the manufacturers' dosage duration criteria are denied. A toll-free telephone number is provided for pharmacists to access the Medicaid data to determine whether the dosage duration criteria have been met or exceeded. Upon submission of appropriate medical justification for exceeding the dosage/duration requirement, the claim would be paid.

We have some questions about the Texas approach. The great virtue of drug utilization review (DUR) is that it relies on education, rather than punitive action, to convince physicians to change their prescribing practices. The shortcoming of Texas' current practice is that it denies claims that exceed manufacturers' dosage/duration criteria without first discussing the matter with the prescribing physician. This approach establishes at the outset a confrontational situation that has the potential to undermine physician willingness to cooperate with the DUR process.

It is our understanding, however, that Texas will soon establish an on-line electronic drug claims processing system and will include its ulcer treatment drug dosage and duration criteria in its prospective DUR. Under this arrangement, when a pharmacist receives an alert that the dosage/duration criterion for an ulcer treatment drug has been exceeded, he or she can suspend the claim to obtain additional information, or can override the claim if adequate information is available to medically justify exceeding the criterion. Such an approach will largely eliminate our present concerns about how Texas applies criteria with regard to ulcer treatment drugs.

We are concerned about OIG's calculation of possible savings. We believe that OIG should attempt to evaluate whether there were legitimate medical reasons for exceeding the dosage duration parameters. Also, some of these drugs may already require prior authorization in some States which would affect the amount of possible savings that could be achieved.