

AUG 14 1992

Memorandum

Date

From

Bryan B. Mitchell
Principal Deputy Inspector General

Subject

Audit of Six Ulcer Treatment Drugs Reimbursed Under the Virginia Medicaid Prescription Drug Program (A-06-92-00009)

To

William Toby
Acting Administrator
Health Care Financing Administration

This is to alert you to the issuance on August 17, 1992, of our final report. A copy is attached.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requires State Medicaid agencies to operate drug use review programs on an ongoing basis. These programs are intended to assess actual patient drug use against predetermined standards. One of the standards recognized by OBRA '90 is the manufacturers' recommended dosages.

The manufacturers of six ulcer treatment drugs provide recommendations for the prescribing of their drug products in the treatment of gastric and duodenal ulcers. The Virginia Department of Medical Assistance Services (State agency), however, did not have any restrictions pertaining to the manufacturers' recommended dosages for ulcer treatment drugs. Accordingly, our review showed that about \$2.10 million (Federal share \$1.05 million) in cost savings could have been realized for Calendar Year 1990 had the State agency limited payment for these drugs to the amount needed to pay for the manufacturers' recommended dosages.

We recommended that the State agency establish procedures to limit the payment for these ulcer treatment drugs to the manufacturers' recommended dosages. We believe that the Health Care Financing Administration (HCFA) should take an active role in encouraging the State agency to implement our recommendation.

In a letter dated May 13, 1992, the Director of the Virginia Department of Medical Assistance Services agreed that ulcer treatment drugs were over-prescribed and over-utilized. The Director advised that the State agency was considering the development of an on-line point of sale capability that could restrict inappropriate prescribing.

Page 2 - William Toby

Because ulcer treatment drugs are among the most commonly prescribed Medicaid drugs, we are performing this review at eight randomly selected States to quantify the potential cost savings available nationwide to the Medicaid program by limiting the reimbursements for these drugs to the manufacturers' dosage. When we have completed our reviews of the remaining States, we will be issuing a consolidated report to HCFA on this subject.

For further information, contact:

Donald L. Dille
Regional Inspector General
for Audit Services, Region VI
(214) 767-8414

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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



AUGUST 1992 A-06-92-00009



Office of Audit Services
110L Commerce, Room 4E1A
Dallas, TX 75242

AUG 17 1992

Our Reference: Common Identification No. A-06-92-00009

Mr. Bruce U. Kozlowski, Director
Dept. of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

Dear Mr. Kozlowski:

This report provides you with the results of our audit of six ulcer treatment drugs reimbursed under the Medicaid prescription drug program of the Virginia Department of Medical Assistance Services (State agency). The objective of our audit was to determine the extent that ulcer treatment drugs were paid for by the Medicaid program in dosages that exceeded the manufacturers' recommended dosages.

The State agency has an opportunity to implement procedures to limit payments for the six ulcer drugs to the manufacturers' recommended dosages. We found that the recommended dosages were exceeded in 67 of the 200 sampled cases. We estimate that establishing restrictions based on manufacturers' recommendations could result in savings of about \$2,097,982 (Federal share \$1,048,991).

We believe that the implementation of such a restriction program can be cost effective in Virginia. For example, the State of Texas has already set up a prospective drug use review (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 the State agency establish prospective DUR procedures to limit payment for the six ulcer treatment drugs to the amounts paid for manufacturers' recommended dosages.

The Director of the Virginia Department of Medical Assistance Services responded to our draft report in a letter dated May 13, 1992. The Director agreed that ulcer treatment drugs were over-prescribed and over-utilized and advised that the State agency is currently developing a prospective and retrospective DUR program. The full text of the Director's comments are included as Appendix C to this report.

BACKGROUND

Medicaid is a federally-aided, State operated, and administered program that provides medical benefits to low income persons who are aged, blind, 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 the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS).

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

Tagamet, Zantac, Pepcid, and Axid belong to a classification of drugs known as histamine H₂-receptor antagonists (or H₂ 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 H₂ antagonists, but they are related ulcer treatment drugs and are prescribed in a similar manner.

Pharmaceutical publications such as **Facts and Comparisons** and **Physician's 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 that these drugs be prescribed in full dosages during an active treatment period of 4 to 8 weeks to promote healing of the ulcer. After the active treatment period, 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 recurrence. There was no manufacturer recommended maintenance therapy for Prilosec. These resources did not clearly define the 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 pathologic gastrointestinal hypersecretory conditions or "Zollinger-Ellison syndrome." Treatment of this rare disease with H₂ 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 their popularity and price. 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 these drugs at active dosage levels costs from \$60 to \$120.

SCOPE

The objective of our audit, which was conducted in accordance with generally accepted government auditing standards, was to determine the extent that ulcer treatment drugs were paid for by the Medicaid program in dosages that exceeded the manufacturers' recommended dosages. Achieving our audit objective did not require that we review the entire internal control structure of the State agency. 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, Physician's 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.

The State agency's computerized Medicaid prescription drug payment records contained 31,858 unduplicated Medicaid recipients who had prescriptions for Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec during Calendar Year (CY) 1990. Of these, we randomly selected a sample of 200 recipients. Our review was performed during January through March 1992.

Our review did not include an evaluation of the medical necessity of dosages for ulcer treatment drugs received by the 200 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 increases due to inflation and program growth since 1990.

RESULTS OF AUDIT

The State agency has an opportunity to implement procedures to limit payments for the six ulcer drugs to the manufacturers' recommended dosages. 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 67 of the 200 sampled cases. We

estimate that establishing restrictions based on manufacturers' recommendations could result in savings of about \$2,097,982 (Federal share \$1,048,991).

The State of Virginia did not have restrictions in place to limit payment for the six ulcer treatment drugs to the manufacturers' recommended dosages. We believe that the implementation of a restriction program that limits reimbursement for ulcer treatment drugs to the manufacturers' recommendations can be cost effective in Virginia. For example, 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. In response to an Office of Inspector General (OIG) audit, the State of Arkansas agreed that ulcer treatment drugs were over-prescribed and over-utilized and implemented a cost containment program for ulcer treatment drugs. Therefore, we are recommending that the State agency implement procedures to limit payment for the six ulcer treatment drugs to the amounts paid for manufacturers' recommended dosages.

VIRGINIA'S CURRENT PROCEDURES

A State agency official advised us that there were no restrictions in place to limit reimbursements for these drugs to the manufacturers' recommended dosages. We believe that Virginia should implement a restriction program to 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 period for claims that are not supported by physicians' statements of medical necessity.

RESULTS OF REVIEW OF A SAMPLE OF MEDICAID RECIPIENTS TO DETERMINE POTENTIAL COST SAVINGS

The State agency's computerized Medicaid prescription drug payment file contained 31,858 unduplicated Medicaid recipients who had prescriptions for Tagamet, Zantac, Pepcid, Axid, Carafate, or Prilosec during CY 1990. Of these, we randomly selected a sample of 200 recipients and found that dosages in 64 instances were not reduced when the period of expected active treatment ended and the maintenance therapy began. In addition, there were three instances where the active treatment period dosages exceeded the manufacturers' recommended dosages. In summary, 67 of the 200 Medicaid recipients in the sample, received dosages that exceeded the manufacturers' recommended dosages. The remaining 133 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 200 sampled recipients for the drugs was \$68,315. The applicable potential cost savings for the 200 recipients was \$13,171 or about 19 percent of the Medicaid paid amount. Using this data, the estimated annual savings would have been \$2,097,982 (Federal share \$1,048,991) if Virginia had limited dosages to manufacturers' recommendations. (See **Appendices** 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. Then 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 recipients.

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

<u>DRUG</u>	<u>ACTIVE CONDITIONS</u>	<u>MAINTENANCE THERAPY</u>	<u>REDUCTION IN DOSAGE</u>
Tagamet	1200 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 because, for certain illnesses, the manufacturers recommended shorter active treatment periods. For example, the manufacturer of Tagamet states in its prescribing information bulletin (TG:L83) regarding treatment of active duodenal ulcers, "...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."

The State agency's 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 judgmentally determined the number of days supply that the prescription provided.

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 completing the active treatment period. 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.

With regard to the maintenance treatment period, we did not set any limitations on the number of days, because there were no clearly defined manufacturers' recommendations regarding the termination of maintenance therapy.

ULCER TREATMENT DRUG LIMITATION PROGRAMS IN TWO STATES

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 estimated 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.

We performed a similar audit of ulcer treatment drugs within the Arkansas Medicaid program for CY 1989. Our audit showed the potential for cost savings of about \$1.27 million (Federal share

\$940,594) by limiting reimbursement to the manufacturers' recommended dosages. The Arkansas audit was limited to Tagamet, Zantac, and Pepcid.

The Administrator of the Arkansas Pharmacy Program agreed with the findings of our audit and indicated that the ulcer treatment drugs were over-prescribed and over-utilized. The Administrator advised that the State was implementing a cost containment program for ulcer treatment drugs and that the State planned to have a prospective review program by January 1993.

RECOMMENDATIONS

We recommend that the State agency implement procedures to limit the payment for all ulcer treatment drugs to the manufacturers' recommended dosages.

AUDITEE COMMENTS

The Director of the Virginia Department of Medical Assistance Services responded to our draft report in a letter dated May 13, 1992. The Director agreed that ulcer treatment drugs were over-prescribed and over-utilized. The Director stated that the State agency was considering the development of on-line point of sale capability to facilitate effective and efficient administration of DUR and selective restriction of inappropriate prescribing.

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The HHS action official will contact you to resolve the issues in this audit report. Any additional comments or information that you believe may have a bearing on the resolution of this audit may be presented at that time.

In accordance with the principles of the Freedom of Information Act (Public Law 90-23), OIG, Office of Audit Services (OAS) reports issued to the Department's grantees and contractors are made available, if requested, to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR Part 5.)

Page 8 - Bruce U. Kozlowski

To facilitate identification, please refer to the above common identification number in all correspondence relating to this report.

Sincerely,

A handwritten signature in cursive script that reads "Donald L. Dille".

DONALD L. DILLE
Regional Inspector General
for Audit Services

SAMPLE DESCRIPTION

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

Sample Information: Total expenditures for the Virginia Medicaid outpatient prescription drug program were almost \$88 million during the period January 1, 1990 through December 31, 1990.

Population: The sampling population was 31,858 unduplicated Medicaid recipients who received Tagamet, Zantac, Pepcid, Axid, Carafate, and Prilosec during the 12-month period ending December 31, 1990.

Sample Design: Simple random sampling was used to select the sample items.

Sample Size: A sample of 200 Medicaid recipients who received Tagamet, Zantac, Pepcid, Axid, Carafate, and Prilosec was taken.

Source of Random Numbers: The OAS Statistical Sampling Software was used to determine the random numbers for drawing the sample.

Characteristics to be Measured: From our examination of the Virginia 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 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 200 sampled recipients for the 6 drugs was \$68,315. The potential cost savings for the 200 recipients was \$13,171 or about 19 percent of the Medicaid paid amount. Using this data and a 90 percent confidence level, the lower limit for our savings estimate was \$1,610,428, the upper limit was \$2,585,535, and the mid-point estimate was \$2,097,982.

SAMPLE RESULTS	
Sample Population (Unduplicated Medicaid recipients receiving Tagamet, Zantac, Pepcid, Axid, Carafate, and Prilosec during CY 1990)	31,858
Standard Sample Size	200
Number of Sample Recipients Receiving Dosages in Excess of the Manufacturers' Recommended Dosages	67
Value of Sample	\$68,315
Total Value of Dosages in Excess of Manufacturers' Recommendations	\$13,171
Total Adjusted Value of Sample	\$55,145
At the 90 Percent Confidence Level:	
Upper Limit	\$2,585,535
Lower Limit	\$1,610,428
Estimated Total Annual Savings	\$2,097,982
Federal Share	\$1,048,991



COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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May 13, 1992

Mr. Donald L. Dille
Regional Inspector General for Audit Services
Office of Inspector General
Department of Health and Human Services
1100 Commerce
Room 4E1A
Dallas, Texas 75242

Dear Mr. Dille:

As requested in your letter of March 13, 1992, we are responding with written comments addressing the Office of Inspector General's draft report on six ulcer treatment drugs reimbursed under the pharmacy program.

We agree that ulcer treatment drugs are over-prescribed and over-utilized in the Medicaid recipient population. A primary reason for this activity is that extended use causes very little problem for most patients due to low incidence of side effects from this class of drugs, as well as their effectiveness in avoiding complicated surgical procedures. Inappropriate utilization is also attributed to concurrent prescribing of G.I. irritating medications such as non-steroidal anti-inflammatory agents.

According to the OIG survey, dosages of the six ulcer treatment drugs were exceeded in 34 percent of the cases subjected to analysis. Applying these calculations to state utilization data from second quarter FY 92 and estimating that at least 10 percent of these cases would request medical necessity exceptions, the administrative controls required for monitoring this activity would warrant computer enhancements and program conversions to upgrade present capabilities.

Mr. Donald L. Dille
May 13, 1992
Page 2

Thus, in order to control this activity in the Medicaid population, several aggressive administrative steps are necessary. These steps include prescriber, pharmacist and recipient awareness of the problems with appropriate educational notifications and cooperation from these groups. We believe that discontinuance of coverage for either or both classes of drugs is inappropriate and would not comply with current OBRA 90 mandates.

In accordance with OBRA 90, curtailment of expenditures for rebated drugs can be subject to an acceptable restriction under prior authorization. This restriction is subject to 24-hour response time and would necessitate on-line capability or a system similar to what the Texas Medicaid program has initiated. We do not believe that a PC-based voice response system is adequate for an efficient prospective DUR program. Thus, our recommendation and proposed premise is that both prospective DUR and prior authorization be integrated into on-line point of sale capability to facilitate effective and efficient administration of DUR and selective restriction of inappropriate prescribing patterns.

Recent estimates of a pro-DUR on-line system incorporated into a point of sale have ranged from \$446,812 to \$922,500 to implement. There would be an additional expense if a prior authorization component was added to this system.

We apologize for the delay in our response and wish to emphasize that Virginia DMAS is currently developing a prospective DUR, retrospective DUR, and nursing home DUR program. We also have initiated preliminary steps to implement a preauthorization program for high cost drugs. In view of projected completion of these programs, the issues discussed in the OIG report will be addressed and measures taken to better control the reimbursement of ulcer treatment drugs.

Thank you for the opportunity to make comments and express our views related to these issues. Please contact us at (804) 786-3820 if you desire additional information or have any further questions.

Sincerely,



Bruce D. Kozlowski

BUK/dlt