Date: JAN 2 1992

From: Richard P. Kusserow, Inspector General

Subject: Need for Utilization Controls for Ulcer Treatment Drugs Reimbursed Under the Arkansas Medicaid Outpatient Prescription Drug Program (A-06-91-00001)

To: Gail R. Wilensky, Ph.D.
Administrator
Health Care Financing Administration

This is to alert you to the issuance on January 2, 1992, of our final report. A copy is attached.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requires State Medicaid agencies to provide prospective drug utilization review (DUR) programs by January 1, 1993. Such programs are intended to assess actual patient drug use against predetermined standards. One of these standards is manufacturers' recommended dosages. The assessment should monitor, among other things, therapeutic appropriateness, over-utilization, and incorrect drug dosage or duration of drug treatment. The OBRA '90, Section 1927, provides for Federal financial participation (FFP) of 75 percent through Calendar Year (CY) 1993 for amounts attributable to the statewide adoption of a DUR program meeting the OBRA '90 requirements.

In Arkansas, Medicaid DUR procedures have been used to detect misuse and abuse of prescription drugs covered under the Medicaid Program. However, these procedures have generally been limited to after-the-fact analyses of drug therapy and are not as comprehensive as the OBRA '90 requirements. Our review showed that about $1.27 million (Federal share $940,594) in cost savings could have been realized for CY 1989 had the State agency established DUR procedures to limit payments for certain ulcer treatment drugs to amounts paid for the manufacturers' recommended dosages.

We recommended that the State agency implement a prospective DUR program to limit the payment for all ulcer treatment drugs to the manufacturers' recommended dosages.
In a letter dated November 20, 1991, the Administrator of Arkansas' Pharmacy Program agreed with our findings and recommendations. The Administrator stated that the category of ulcer treatment drugs is over-prescribed and over-utilized and advised us that they planned to implement a cost containment program for ulcer treatment drugs, effective December 1, 1991.

As a result of our findings in Arkansas, we are expanding our review to eight randomly selected States. Because ulcer treatment drugs are among the most commonly prescribed Medicaid drugs, we believe that a prospective DUR program for ulcer treatment drugs could result in significant savings to the Medicaid program.

This issue has received some interest from the Senate Committee on Aging and other congressional committees. We understand local pharmaceutical companies are also expressing concerns about the effects these containment programs would have on the sale of their drugs.

For further information, contact:
Donald Dille
Regional Inspector General
for Audit Services, Region VI
FTS 767-8414

Attachment
NEED FOR UTILIZATION CONTROLS FOR ULCER TREATMENT DRUGS REIMBURSED UNDER THE ARKANSAS MEDICAID OUTPATIENT PRESCRIPTION DRUG PROGRAM
The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services’ (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by three OIG operating components: the Office of Audit Services, the Office of Investigations, and the Office of Evaluation and Inspections. The OIG also informs the Secretary of HHS of program and management problems, and recommends courses to correct them.

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Our Reference: Common Identification Number A-06-91-00001

Dr. Terry Yamauchi
Director
Arkansas Department of Human Services
P.O. Box 1437
Little Rock, Arkansas  72203-1437

Dear Dr. Yamauchi:

Enclosed for your information and use are two copies of an HHS/OIG Office of Audit Services report titled, "Need for Utilization Controls for Ulcer Treatment Drugs Reimbursed Under the Arkansas Medicaid Outpatient Prescription Drug Program." Your attention is invited to the audit findings and recommendations contained in the report.

Final determinations as to actions to be taken on all matters reported will be made by the HHS official named below. We request that you respond to each of the recommendations in this report within 30 days from the date of this letter to the HHS official named, presenting any comments or additional information that you believe may have a bearing on his final determination.

In accordance with the principles of the Freedom of Information Act (PublicLaw 90-23), HHS/OIG Office of Audit Services 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 Section 5.71 of the Department's Public Information Regulation, dated August 1974, as revised.) To facilitate identification, please refer to the referenced common identification number in all correspondence relating to this report.

Sincerely,

DONALD L. DILLE
Regional Inspector General
for Audit Services

Enclosures
Direct reply to:
Associate Regional Administrator
Division of Medicaid
Health Care Financing Administration
Department of Health and Human Services
Region VI
1200 Main Tower, Room 2030
Dallas, Texas 75242
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SUMMARY

The Arkansas Medicaid Agency (State Agency) has the opportunity to reduce annual Medicaid prescription drug expenditures by about $1.27 million (Federal share $940,594), by establishing drug use review (DUR) procedures which would limit prescribed dosages for three ulcer treatment drugs to the manufacturers’ recommended dosages. Our savings estimate is based on calendar year 1989 ulcer treatment drug usage and the cost of these drugs under Arkansas’ Medicaid program.

The Omnibus Budget Reconciliation Act of 1990 (OBRA ‘90) established the Medicaid prescription drug rebate program. The Act requires state Medicaid agencies to operate DUR programs on an on-going basis. These programs are intended to assess actual patient drug use data against predetermined standards which are contained in me compendia listed in the Act. One of these standards is manufacturers’ recommended dosage. The assessment shall monitor, among other things, therapeutic appropriateness, over-utilization, and incorrect drug dosage or duration of drug treatment. State agencies are required to have the DUR programs in place by January 1, 1993. The Act authorizes a Federal reimbursement of 75 percent (rather than me normal 50 percent) of the costs incurred to establish DUR procedures during calendar years 1991 through 1993.

Tagamet, Zantac and Pepdd, commonly known as ulcer treatment drugs, are routinely prescribed for the treatment of gastrointestinal disorders such as duodenal or benign gastric ulcers. These drugs belong to a classification of drugs known as histamine Hz-receptor antagonists (or H2 antagonists). The use of these drugs has virtually eliminated the need for stomach ulcer surgery. Unlike earlier drugs which tried to neutralize excess stomach add, these drugs reduce the actual flow of add.

Drug treatment is divided into active and maintenance treatment periods. Full dosages during the active treatment period promote healing, while reduced dosages during the maintenance treatment period prevent recurrence. Although the manufacturers recommend that dosages be reduced by 50 to 67 percent after a 4 to 8 week active treatment period, we found that no reductions were made in 65 percent of the sampled cases.
Even though State Agency officials have been evaluating this area for potential savings, they have not implemented OUR procedures because of limited financial and personnel resources. We are recommending that the State Agency use the enhanced administrative cost sharing offered by OBRA '90 to implement a prospective DUR program for ulcer treatment drugs.

In a letter dated November 20, 1991, the Administrator of Arkansas' Pharmacy Program agreed with our findings and recommendations. The Administrator stated that the category of ulcer treatment drugs is over-prescribed and over-utilized. Additionally, the Administrator advised us that the State Agency will be implementing a cost containment program for ulcer treatment drugs effective December 1, 1991. The complete text of the Administrator's comments is included as Appendix C to this report.
INTRODUCTION

The Office of Inspector General (OIG), Office of Audit Services, reviewed a random sample of 200 Arkansas Medicaid prescription drug payment records for recipients who had prescriptions for Tagamet, Zantac of Pepid during calendar year 1989. The objective of our review was to determine whether the State agency had adequate DUR procedures to limit the prescribing of these three ulcer treatment drugs to dosages recommended by the manufacturers.

We found that the State agency has the opportunity to reduce annual Medicaid prescription drug expenditures by about $1.27 million (Federal share $940,594), by establishing DUR procedures to limit three ulcer treatment drugs to manufacturers’ recommended dosages.

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.

Medicaid DUR Requirements

The Omnibus Budget Reconciliation Act of 1990 (OBRA ‘90) established the Medicaid prescription drug rebate program. The Act requires states to operate DUR programs on an ongoing basis to assess data against predetermined standards which are consistent with the following:

- American Hospital Formulary Service Drug Information,
- United States Pharmacopeia-Drug Information,
- American Medical Association Drug Evaluations, and
- Peer-reviewed medical literature.
The DUR assessment shall monitor, among other things, therapeutic appropriateness, overutilization, and incorrect drug dosage or duration of drug treatment. States are required to have their DUR programs in place by January 1, 1993. The Act requires states to operate both prospective and retrospective DUR programs. The prospective system shall provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient, typically at the point-of-sale. This review shall include a screening for, among other things, incorrect drug dosage or duration of drug treatment.

The retrospective portion of the program requires states to use their mechanized drug claims processing systems to periodically examine the claims data for patterns of inappropriate or medically unnecessary care associated with specific drugs or groups of drugs.

To assist states, OBRA '90 provides for 75 percent Federal financial participation (rather than the normal 50 percent) for expenditures incurred during calendar years 1991 through 1993 to establish DUR programs.

Drugs Reviewed and Recommended Manufacturers’ Dosages

Tagamet, Zantac and Pepcid, commonly known as ulcer treatment drugs, are routinely prescribed for the treatment of gastrointestinal disorders such as duodenal or benign gastric ulcers. These drugs belong to a classification of drugs known as histamine Hz-receptor antagonists (or H2 antagonists). The use of these drugs has virtually eliminated the need for stomach ulcer surgery.

Unlike earlier drugs which tried to neutralize excess stomach acid, these drugs reduce the actual flow of add.

We determined the manufacturers’ recommended dosages by reviewing the compendia listed in OBRA '90, other publications such as Facts and Comparisons and Physician’s Desk Reference, and prescribing and product information (package inserts) published by the manufacturers and available at pharmacies. These resources showed that the manufacturers recommend that these three drugs be prescribed in full dosage amounts during an active treatment period of 4 to 8 weeks to promote healing. After the active treatment period, the manufacturers recommend that the dosages be reduced by 50 percent for Zantac and Pepcid and by 67 percent for Tagamet as maintenance therapy to prevent recurrence. However, these resources did not clearly define the manufacturers’ recommendations regarding the period of maintenance therapy.
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 of "Zollinger-Ellison syndrome." Treatment of this fare disease with $H_2$ antagonists continues for as long as clinically necessary with no active of 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 in the U.S. domestic market and ranked in the top five in the number of prescriptions written. A 30-day supply of these drugs costs from $60 to $75.

Arkansas Medicaid Drug Program

The Arkansas Medicaid prescription drug program is operated by the Division of Medical Services of the Arkansas Department of Human Services (State Agency). Each Medicaid recipient is entitled to receive up to six covered prescriptions per month. Each prescription may be filled for a maximum of one month’s supply. (Prescriptions resulting from Child Health Services screening and referral are unrestricted.) However, a 33 day supply may be allowed to cover circumstances such as the first day of the month falling on a weekend.

For the year ended December 31, 1989, the Arkansas Medicaid prescription drug program expenditures amounted to about $48 million. Of this amount, about $5 million, or 10 percent, of the program’s expenditures were for Tagamet, Zantac and Pepcid.

SCOPE OF AUDIT

The objective of our audit, which was conducted in accordance with generally accepted government auditing standards, was to determine whether the State Agency had DUR procedures to limit the prescribing of ulcer treatment drugs to the dosages recommended by the manufacturers. Achieving our audit objectives 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 three ulcer treatment drugs selected for review.

To accomplish our objectives, we reviewed the provisions of OBRA ‘90 pertaining to Medicaid drugs, and pertinent Federal drug regulations, policies and procedures. We reviewed the compendia listed in OBRA ‘90, as well as Facts and Comparisons and Physician’s Desk Reference regarding manufacturers’ recommended dosages and strengths for the three drugs
selected for review. Further, we reviewed various drug statistical data, and other information such as clinical studies on ulcer treatment drugs. We also contacted HCFA personnel, interviewed State agency officials responsible for administering the prescription drug program and other medical professionals involved with prescribing and dispensing prescription drugs.

The State agency's computerized Medicaid prescription drug payment records contained 14,837 unduplicated Medicaid recipients who had prescriptions for either Tagamet, Zantac, or Pepcid during calendar year 1989. Of these, we randomly selected a sample of 200 recipients. We obtained patient medical profiles from the State agency for our sample and calculated the variances between the amount paid by Medicaid and the amounts that would have been paid had the manufacturers' recommended dosages been prescribed. Our review was performed during the period October 1990 through February 1991.

Our review was limited to the more commonly prescribed ulcer treatment drugs including Tagamet, Zantac and Pepcid. Our review did not include an evaluation of the medical necessity of dosages for ulcer treatment drugs received by 200 sample Medicaid recipients. Therefore, our savings estimate did not consider those situations where manufacturers' recommended dosages for the three drugs can be exceeded due to medical necessity. Additionally, the savings estimate did not consider increases due to inflation, program growth since 1989 and the fact that three less commonly prescribed ulcer treatment drugs are also subject to manufacturers' recommended maintenance dosages.
FINDINGS AND RECOMMENDATIONS

The State agency has the opportunity to establish DUR procedures to limit payments for certain ulcer treatment drugs to the manufacturers' recommended dosages. Although the manufacturers recommend that dosages be reduced by 50 to 67 percent after a 4 to 8 week active treatment period, we found that no reductions were made in 65 percent of the sampled cases. We estimate that establishing adequate DUR procedures based on manufacturers’ recommendations could result in savings of about $1.27 million (Federal share $940,594), which is a proposed reduction of 2 percent.

Even though State agency officials have been evaluating this area for potential savings, they have not implemented DUR procedures because of limited financial and personnel resources. However, OBRA ’90 authorizes state agencies to claim 75 percent (rather than the normal 50 percent) of costs incurred to establish DUR procedures during calendar years 1991 through 1993.

We believe that such a DUR program can be cost effective. For example, 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. Although Texas has a much larger program, we believe Arkansas will realize significant savings by establishing DUR procedures for the ulcer treatment drugs. Therefore, we are recommending that the State agency implement a prospective DUR program to limit the payment for ulcer treatment drugs to the amounts paid for manufacturers’ recommended dosages. The limitation should not be imposed in those cases where continued active treatment is necessary based on the 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.

ARKANSAS’ CURRENT DUR PROCEDURES

In Arkansas, Medicaid DUR procedures have been used to detect misuse and abuse of prescription drugs covered under the Medicaid program. However, these procedures have generally been limited to after-the-fact analyses of drug therapy and are not as comprehensive as the OBRA ’90 requirements.

In 1990, because of concerns over escalating ulcer treatment drug costs, the State agency contracted for an independent study of Medicaid recipients using H₂ antagonists drugs. The purpose of this study was to identify individual
Medicaid recipients who had received from 1 to 28 prescriptions during the 12 month period October 1988 through September 1989. Using the results of this study, the State agency identified 632 recipients that may have had potential overutilization. To determine whether overutilization had occurred, the State sent letters of inquiry, signed by a staff physician, to the prescribing physicians asking for a review of the appropriateness of drug therapy dosages for each recipient who had received more than 12 prescriptions during the 12 month period. From 283 physician responses received, the State agency determined that a cost savings of approximately $204,060 could have been realized had the H₂ antagonists prescriptions been disallowed after 12 prescriptions during the 12 month period.

Although the State agency’s study focused on the number of prescriptions received during the year, rather than reducing the dosages to the manufacturers’ recommended level for maintenance therapy, it shows that these officials were aware of the opportunity for cost savings through improved procedures to control overutilization of ulcer treatment drugs.

We believe that, while this study indicates that cost savings could be realized by limiting the number of prescriptions for ulcer treatment drugs, the use of prospective, rather than a retrospective utilization program would be more cost effective. In our opinion, the recipients would be better served by a program which would detect and prevent inappropriate prescribing before the fact. A prospective system could achieve costs savings by preventing drug overprescribing and ensuring that the drugs were medically necessary. At the same time, a prospective system could be designed to allow the physician flexibility in meeting recipients’ health care needs in special medically necessary cases through a mechanism to override the normal dosages.

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

Our review of a sample of Medicaid recipients’ prescription data showed that about $1.27 million (Federal share $940,594) in cost savings could have been realized for calendar year 1989 had the State agency established DUR procedures to limit payments for certain ulcer treatment drugs to amounts paid for the manufacturers’ recommended dosages.

The State agency’s computerized Medicaid prescription drug payment records contained 14,837 unduplicated Medicaid recipients who had prescriptions for either Tagamet, Zantac, Or Pepcid during calendar year 1989. Of these, we randomly selected a sample of 200 recipients and found that dosages were not always reduced when the period of active treatment ended and the maintenance
therapy period began. In addition, there were 13Q instances (65 percent) where
the active treatment period dosages exceeded the manufacturers’ recommended
dosages. In summary, 130 of the 200 Medicaid recipients in the sample, received dosages in excess of the manufacturers’ recommended dosages. The
remaining 70 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 three drugs was $59,040. The applicable potential cost savings for the 200 recipients was $17,076 or about 29 percent of the Medicaid paid amount. Using
this data and a 90 percent confidence level, the point estimate for annual
savings was about $1.27 million (Federal share $940,594). (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. Then, we multiplied this difference (number of tablets) by the
average drug price (per tablet) paid by Medicaid during 1989. This calculation
was made for both the 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:

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<tr>
<th>DRUG</th>
<th>ACTIVE CONDITIONS</th>
<th>MAINTENANCE THERAPY</th>
<th>REDUCTION IN DOSAGE</th>
</tr>
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<tbody>
<tr>
<td>Tagamet</td>
<td>1200 mg</td>
<td>400 mg</td>
<td>67%</td>
</tr>
<tr>
<td>Zantac</td>
<td>300 mg</td>
<td>150 mg</td>
<td>50%</td>
</tr>
<tr>
<td>Pepcid</td>
<td>40 mg</td>
<td>20 mg</td>
<td>50%</td>
</tr>
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</table>

Since each drug is 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 eight weeks would be appropriate since, except for special circumstances, it represents the maximum active treatment period for the three drugs. Therefore, in our calculations we used 56 days 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:L80) 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:

In determining whether a recipient had completed the active treatment period, we restarted the count of days if the recipient was switched from one H$_2$ antagonists drug to another, or if there was a break in treatment of more than 30 days. We started the count of days for determining the active treatment period on January 1, 1989, the beginning of our review period, without regard to whether a recipient was receiving one of the drugs prior to that time. We allowed one active treatment period per recipient in our calculations. We recognize that in special circumstances the active treatment period could extend beyond 56 days. For purposes of this study, however, we did not identify 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.

THE STATE OF TEXAS' PROGRAM

Texas has a DUR program for ulcer treatment drugs which has produced significant savings consistent with good medical practice. On September 1, 1990, the State of Texas implemented an H$_2$ antagonists related drug limitation program as part of its continuing utilization review and cost containment efforts. Under the program, Medicaid recipients are limited to acute dosage levels of Axid, Pepcid, Tagamet, Zantac, Carafate and Priosec (formerly Losec) for up to 62 days, or two consecutive 31-day months per calendar year. Claims submitted by pharmacists for maintenance dosage levels are honored, after the recipient has exceeded the allowable 62 day period of acute dosage only if the appropriate physician override procedure has been followed.
The physician override mechanism allows continuation of higher than maintenance dosage levels when the prescribing physician determines that these doses are necessary. The prescribing physician must write the diagnosis on the face of the prescription in order to constitute a valid Override. A special form with a copy of the prescription showing the override in the physician's handwriting must be submitted for the claim to be honored.

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. Prompted by a recorded message, the pharmacist enters his provider identification number and then the client's Medicaid recipient identification number. The computer linked System then gives a response as to whether the recipient can continue at active treatment dosage levels.

Texas State agency officials estimate that the personal computer based voice response system that cost approximately $180,000 will save the Medicaid program approximately $6 million during State fiscal year 1991. We believe a similar system should be considered in Arkansas. This same level of savings will not be possible in Arkansas since Texas' program is much larger and since Texas' drug limitation program includes three more drugs—Axid, Carafate and Priosec. In this regard, we believe that Arkansas Officials should consider including these three additional drugs when implementing a limitation program for ulcer treatment drugs.
RECOMMENDATIONS

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

STATE AGENCY COMMENTS

In a letter dated November 20, 1991, the Administrator of Arkansas' Pharmacy Program expressed agreement with our findings and recommendations, stating that the category of ulcer treatment drugs is both over-prescribed and over-utilized. The Administrator stated that the State Agency will be implementing a cost containment program for ulcer treatment drugs effective December 1, 1991. The complete text of the Administrator's comments is included as Appendix C to this report.
APPENDIXES
### Sample Description

**Sample Objective:** Project potential cost savings for excess Medicaid drug utilization attributable to Arkansas’ Medicaid recipients who received the ulcer treatment drugs Tagamet, Zantac, or Pepcid for calendar year 1989.

**Sample Information:** Total expenditures for the Arkansas Medicaid outpatient prescription drug program were about $48 million during the period January 1, 1989 through December 31, 1989. Expenditures for the ulcer treatment drugs Tagamet, Zantac, and Pepcid were about $5 million for 85,689 prescriptions.

**Population:** The sampling population was 14,837 unduplicated Medicaid recipients who received Zantac, Tagamet, and/or Pepcid during the 12 month period ending December 31, 1989.

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

**Sample Size:** A sample of 200 Medicaid recipients who received Tagamet, Zantac and/or Pepcid 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 Arkansas Medicaid drug payment history tapes, we calculated the average price paid for each Medicaid recipient receiving ulcer treatment drugs. 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 Zantac, Tagamet and Pepcid tablets to the manufacturers' recommended dosages and durations of treatment.

Other Evidence: We also obtained Medicaid drug recipient medical profiles from the State Agency for all of the 200 sample items. These profiles were reviewed for the purpose of determining the length of time a recipient had used the ulcer treatment drug, diagnosis, prescribing physician, and possible drug interactions.

Extrapolation: The total amount paid by Medicaid on behalf of the 200 sampled recipients for the three drugs was $59,040. The potential cost savings for the 200 recipients was $17,076 or about 29 percent of the Medicaid paid amount. Using this data and a 90 percent confidence level, the lower limit for our savings estimate was $1,039,354, the upper limit was $1,494,233 and the mid-point or point estimate was $1,266,793.
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<tr>
<th><strong>Sample Results</strong></th>
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<tr>
<td><strong>Sample Population</strong></td>
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<tr>
<td>(Unduplicated Medicaid recipients receiving Zantac, Tagamet and Pepcid during calendar year 1989)</td>
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<tr>
<td><strong>Standard Sample Size</strong></td>
</tr>
<tr>
<td><strong>Number of Sample Recipients Receiving Dosages in Excess of the Manufacturers' Recommended Dosages</strong></td>
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<tr>
<td><strong>Value of Sample</strong></td>
</tr>
<tr>
<td><strong>Total Value of Dosages in Excess of Manufacturers’ Recommendations</strong></td>
</tr>
<tr>
<td><strong>Total Adjusted Value of Sample</strong></td>
</tr>
<tr>
<td><strong>Estimated Total Annual Savings</strong></td>
</tr>
<tr>
<td>(Used point estimate at a confidence level of 90 percent)</td>
</tr>
<tr>
<td><strong>Federal Share</strong></td>
</tr>
</tbody>
</table>
Arkansas Department of Human Services
Division of Economic and Medical Services
P.O. Box 1437
Little Rock, Arkansas 72203-1437

Mr. Donald L. Dille
Regional Inspector General
Office of Inspector General
Office of Audit Services
1200 Commerce, Room 411A
Dallas, Texas 75242

Reference: cam Identification Number A-06-91-00001

November 20, 1991

Dear Mr. Dille:

I have been asked to respond to your letter dated October 18, 1991, concerning the result of your audit of the need for utilization of ulcer treatment drugs.

The audit report was complete and accurate. Arkansas is planning to implement a prospective DRG program by January 1992, as you recommend in your audit draft. In the interim, the Arkansas Medicaid Prescription Drug Program has made an effort to reduce costs in the anti-ulcer category of medication, effective December 1, 1991. I am attaching a copy of the official letter that outlines the details of cost containment for the anti-ulcer drugs. This change is expected to reduce expenditures by approximately 20%.

I agree that this category of drugs is over-prescribed and over-utilized. Considerable savings is possible by limiting the usage of these medications to the manufacturer's recommended dosage and treatment periods.

Thank you for sharing your audit findings with us. I expect you to find a similar opportunity for reducing costs in each state you include in your study.

I can offer any further assistance, please call.

Sincerely,

Thelma Underwood, P.D., R.B. Pharm.
- t o e , Pharmacy Program

"The Arkansas Department of Human Services is in compliance with Title VI and VII of the Civil Rights Act and is a participant in an equal opportunity service program."

APPENDIX C