



JUN 5 1992

Memorandum

Date *RPK*
From Richard P. Kusserow
Inspector General

Subject Medicaid Drug Rebates: Inaccurate Reporting of Medicaid
Drug Data by Pharmacists (A-06-91-00056)

To William Toby
Acting Administrator
Health Care Financing Administration

The attached final management advisory report is to advise you of the results of our review on Medicaid drug data submitted by pharmacists to the State Medicaid agencies (States). Twenty-two of the 46 States (or about 48 percent) responding to an Office of Inspector General questionnaire assessing selected indicators of the States' performance in implementing the rebate program, were having problems with the accuracy of their drug utilization data. These States had no procedures to monitor the accuracy of either the drug product or the number of dosage units reported as dispensed by the pharmacists. For example, one State performed a special study of dosage unit reporting and found that actual drug disbursements of about \$73,000 would have amounted to about \$7.4 million had the disbursements been based on the dosage unit data reported as dispensed by the pharmacists.

The impact of inaccurate reporting of dosage units can significantly distort a manufacturer's rebate payment amount. We believe that manufacturers will dispute rebate billings if there are problems with the accuracy of the utilization data. This could result in significant delays in the receipt of rebate payments.

We recommended that the Health Care Financing Administration (HCFA) require the States to develop procedures to monitor the accuracy of reporting by pharmacies of drugs dispensed. Further, we recommended that HCFA instruct the States to test a sample of paid Medicaid prescriptions to determine the accuracy of the dosage units reported as dispensed. If the test results disclose significant errors, we recommended that HCFA require the States to design computer edits to detect and correct obvious errors in reporting the number of drug dosage units dispensed.

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Proposed interim regulations have been prepared by HCFA officials which we believe should adequately implement our first recommendation. To implement our second recommendation, we believe that HCFA needs to revise the interim regulations that define pharmacy coding to also include a requirement for accurately reporting dosage units.

Some States alerted pharmacists and State pharmacy associations to the importance of accurately reporting drug data on Medicaid claims. This is a good first step toward improving accuracy. We believe that HCFA should also contact the various national pharmacy associations and request their participation in alerting pharmacists to the importance of accurate reporting.

In its response to our report, HCFA agreed that the amount of rebates ultimately received by the States is dependent on capturing reliable utilization data. The HCFA also agreed that manufacturers are more likely to dispute rebates if Government utilization data are perceived to be inaccurate. However, HCFA did not believe that further corrective actions were necessary because of several initiatives and actions taken in the interim regulations.

Although HCFA's initiatives and interim regulations may have a positive impact on the program, we believe that HCFA needs to take additional corrective actions. Our current survey work indicates that serious problems continue to exist with pharmacy coding and rebate disputes. Therefore, we continue to believe that our recommendations should be implemented and we will continue to keep you advised of our ongoing work.

Please advise us, within 60 days, on actions taken or planned on our recommendations. 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 top Department officials.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

MEDICAID DRUG REBATES:
INACCURATE REPORTING OF- MEDICAID
DRUG DATA BY PHARMACISTS



**Richard P. Kusserow
INSPECTOR GENERAL**

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The impact of inaccurate reporting of dosage units can significantly distort a manufacturer's rebate payment amount. We believe that manufacturers will dispute rebate billings if there are problems with the accuracy of the utilization data. This could result in significant delays in the receipt of rebate payments.

We recommended that the Health Care Financing Administration (HCFA) require the States to develop procedures to monitor the accuracy of reporting by pharmacies of drugs dispensed. Further, we recommended that HCFA instruct the States to test a sample of paid Medicaid prescriptions to determine the accuracy of the dosage units reported as dispensed. If the test results disclose significant errors, we recommended that HCFA require the States to design computer edits to detect and correct obvious errors in reporting the number of drug dosage units dispensed.

Proposed interim regulations have been prepared by HCFA officials which we believe should adequately implement our first recommendation. To implement our second recommendation, we believe that HCFA needs to revise the interim regulations to include accurate dosage units in its definition of pharmacy coding.

Some States alerted pharmacists and State pharmacy associations to the importance of accurately reporting drug data on Medicaid claims. This is a good first step toward improving accuracy. We believe that HCFA should also contact the various national pharmacy associations and request their participation in alerting pharmacists to the importance of accurate reporting.

The Acting Administrator of HCFA responded to our draft report in a memorandum dated March 18, 1992. In that memorandum, the Acting Administrator agreed that the amount of rebates ultimately received by the States is dependent on capturing reliable utilization data. He also agreed that manufacturers are more likely to dispute rebates if Government utilization data are perceived to be inaccurate. However, HCFA did not believe that further corrective actions were necessary because of the interim regulations that were prepared and other initiatives that were taken.

Although HCFA's initiatives and interim regulations may have a positive impact on the program, we believe that HCFA needs to take additional corrective actions. Our current survey work indicates that serious problems continue to exist with pharmacy coding and rebate disputes. Therefore, we continue to believe that our recommendations should be implemented. The complete text of the Acting Administrator's comments is included as an attachment to this report.

BACKGROUND

The Omnibus Budget
Reconciliation Act of 1990
(OBRA '90), among other

provisions, established the Medicaid prescription drug rebate program. Manufacturers are required to make quarterly rebates to each State based on the volume of drugs sold through the Medicaid program in the State. The success of the drug rebate program is dependent, in part, on the reasonable accuracy of the drug utilization data supplied by the States.

The two critical data elements to be supplied by the States for each drug product are the National Drug Code (NDC) for the drug dispensed and the total number of dosage units dispensed. The initial accuracy of these two data elements emanates from the pharmacist when the Medicaid drug claim is submitted (either electronically or in paper form) to the State for payment. The State maintains a data base of paid claims which is the source for the drug utilization data submitted to the manufacturers.

METHODOLOGY

Our objectives were (1) to determine the critical data elements to be reported by the States to the manufacturers for use in calculating drug rebate amounts and (2) to assess the general perception of the accuracy of this data.

We reviewed the Medicaid drug rebate provisions of OBRA '90, and the standard rebate agreement between HCFA and the drug manufacturers. We interviewed the Administrator, Pharmacy Programs, Arkansas Department of Human Services, and reviewed selected data from that program. In addition, we interviewed congressional staff involved in drafting the Medicaid drug rebate legislation.

During April 1991, we sent a questionnaire to the States to assess and evaluate problems being encountered in implementing the Medicaid drug rebate program. We also reviewed a copy of the questionnaire that HCFA sent to the States, dated April 4, 1991. We reviewed the responses to HCFA's questionnaires from the States in Regions III and VI.

Our work was performed from January through December 1991.

RESULTS OF REVIEW

Twenty-two of the 46 States responding to an OIG questionnaire, or about 48 percent, were having problems in reporting accurate drug utilization data for use by the pharmaceutical manufacturers in determining rebate payments. There were no procedures to monitor either the accuracy of the drug reported or the number of dosage units reported as dispensed by the pharmacists. The remaining 24 States had procedures to monitor both types of data.

We believe that inaccurate reporting of drug utilization data can have a substantial impact on the key data to be used to calculate the rebate amount. For example, one State performed a special study of dosage unit reporting and found that actual drug disbursements of about \$73,000 would have amounted to about \$7.4 million had the disbursements been based on the dosage unit data reported as dispensed by the pharmacists.

There is a widespread perception in many segments of the pharmaceutical community that the data reported by pharmacies is sometimes erroneous. We believe that the absence of monitoring activities in several States provides support for this concern. We recommended that HCFA require States to establish procedures to monitor the accuracy of the drug utilization data.

OIG QUESTIONNAIRE RESULTS

During April 1991, the OIG sent a questionnaire to each of the 50 States and to the District of Columbia. Twenty-two of the 46 responding States, or about 48 percent, indicated problems in reporting accurate drug utilization data for use by the pharmaceutical manufacturers in determining rebate payments.

Thirteen of the 22 States had no procedures to monitor the accuracy of the drug or the dosage units reported as dispensed.

STATES WITH NO MONITORING PROCEDURES

- | | | |
|-------------|-------------------|-------------------|
| 1. Alaska | 6. Nevada | 10. South Dakota |
| 2. Colorado | 7. New Hampshire | 11. Virginia |
| 3. Hawaii | 8. Rhode Island | 12. West Virginia |
| 4. Kentucky | 9. South Carolina | 13. Wyoming |
| 5. Missouri | | |

In 8 of the 22 States, there were no procedures to monitor the accuracy of the drug reported as dispensed although the accuracy of the dosage units reported was being monitored.

STATES MONITORING DOSAGE UNITS REPORTED;;
BUT NOT MONITORING DRUG REPORTED AS DISPENSED

- | | | |
|--------------------|------------------|---------------|
| 1. Connecticut: | 4. Iowa | 7. New Mexico |
| 2. Dist. of Colum. | 5. Maryland. | 8. Oregon |
| 3. Georgia: . . | 6. Massachusetts | |

In 1 of the 22 States (Arkansas) there were no procedures to monitor the dosage units reported although the accuracy of the drug reported as dispensed was monitored.

The remaining 24 responding States monitored both the drug reported and the dosage units reported by the pharmacists.

STATES MONITORING BOTH DRUG REPORTED
AND DOSAGE UNITS REPORTED AS DISPENSED

- | | |
|-------------------|--------------------|
| 1. Alabama.. | 13. Montana, . . . |
| 2. California | 14. Nebraska |
| 3. Delaware | 15. New York |
| 4. Florida | 16. North Carolina |
| 5. Idaho | 17. North Dakota |
| 6. Illinois.. | 18. Oklahoma |
| 7. Indiana | 19. Pennsylvania |
| 8. Kansas | 20. Tennessee. . . |
| 9. Louisiana | 21. Texas. |
| 10. Maine | 22. Utah |
| 11. Minnesota | 23. Vermont |
| 12. Mississippi.. | 24. Washington. |

However, 4 of these 24 States responded that they expected some problems with the accuracy of the utilization data even though they had monitoring efforts. These States were Florida, Idaho, Indiana, and Tennessee.

While some States had no procedures to monitor the accuracy of the dosage units reported, seven States reported that they used computerized edits to check all claims.

STATES USING COMPUTER EDITS TO MONITOR
ACCURACY.. OF ALL DOSAGE- UNITS REPORTED

- | | |
|-----------------|---------------|
| 1. Connecticut: | 5.. Oklahoma |
| 2. Illinois. | 6. Tennessee |
| 3. Maryland | 7. Washington |
| 4. New York. | |

ONE STATE'S TEST OF DOSAGE UNITS REPORTING

One State's test of the accuracy of reporting the dosage units for a recent quarter showed that actual disbursements for 2,430 claims was about \$73,000, but would have been valued at about \$7.4 million (100 times greater) if a computerized edit had not caught the errors.

According to a State official, this computerized test was designed to: (1) multiply the reported dosage units by the unit price contained in the State's pricing file, (2) compare this computed amount to the pharmacists' billed amount, and (3) list any transactions where this computed amount exceeded the billed amount by five or more times. The test resulted in 2,430 inaccurate claims involving a wide variety of drugs and numerous different pharmacists.

The State had not determined the extent of errors for those cases where the computed amounts were two, three, or four times greater than the billed amounts. Using the results of the test as evidence of the need for action, the State persuaded the State pharmacists' association to notify its members about the importance of accurately reporting the drug and the dosage units actually dispensed.

INACCURATE REPORTING OF DRUG DATA

State agencies and segments of the pharmaceutical community agree that, historically, drug data has been incorrectly reported by pharmacists. A general perception of inaccurate reporting of drug data by pharmacists is shared by generic manufacturers, brand name manufacturers, congressional staff members, as well as, members of the academic community.

Prior to the rebate provisions neither the NDC being reported, nor the number of dosage units reported, made any difference in the reimbursement level to the pharmacists. Therefore,

pharmacists commingled the NDC codes as a matter of convenience in reporting data to State agencies. Although these data elements are not important in determining pharmacists' reimbursements, they are critical in determining the rebate amounts to be paid by manufacturers.

The way some pharmacists use their computer software can result in an incorrect NDC for the drug dispensed being reported to the State. Under Medicaid, multiple-source drugs have upper payment limits set by HCFA and the pharmacist receives the same amount for dispensing any drug in a particular drug group. The computer software used by some pharmacists will list the various drugs in a multiple-source drug group so that the pharmacist may choose the drug dispensed. The next time the pharmacist accesses the program to dispense a drug from this same drug group, the software will display the last drug chosen. As a matter of convenience, the pharmacist may select the drug shown on the computer screen even when a different drug was actually dispensed, to reduce data entry time.

Although this practice may not effect the payment to the pharmacist, on the States' records it overstates the quantity for the drug reported as dispensed and understates the quantity for the drug actually dispensed.¹ These distortions will result in the States making erroneous claims for rebate payments. Testing or monitoring the accuracy of the reported sales requires on-site inspection of the pharmacist's records. For the most part, prepayment computer edits will not identify inaccurate reporting of the drug dispensed.

There are instances where an error could be made when reporting the number of dosage units dispensed although the pharmacist may report the correct billing amount on the claim form (i.e., usual and customary charge). Typical examples of errors are reporting the dispensing of 33 tablets as 3,333 tablets, or the dispensing of 30 tablets as 3,000 tablets. In our opinion, this type of error would not usually result in an overpayment to the pharmacists because

¹A small overpayment could result if a State Medicaid Plan contains a provision to pay the lower of the HCFA upper limit amount or the pharmacist's usual and customary charge. The overpayment would occur when the usual and customary charge was the lower amount. The amount of the overpayment would be the difference between the upper limit amount and the usual and customary charge.

the billing amount will be used to determine the payment.' However, these errors could result in the manufacturers making improper rebate payments. These errors can be reduced through prepayment computer edits used to identify and correct obvious errors in reporting the dosage units dispensed. As previously mentioned, seven States already use such edits.

HCFA'S QUESTIONNAIRE RESULTS

The HCFA sent a brief questionnaire to the States, dated April 4, 1991, and specifically asked what efforts had been taken, or were planned to be taken, to alert and remind pharmacists of the importance of accurately reporting drug data. As a result of the questionnaire, we noted several States had sent alert bulletins to pharmacists. Some States arranged for State pharmacy associations to alert pharmacists. These actions are good first steps toward assuring accurate reporting of drug data. However, we believe that more needs to be done such as requesting national pharmacy groups to notify their members regarding the importance of accurately reporting the drug utilization data.

CONCLUSIONS AND RECOMMENDATIONS

There is a wide-spread perception that key data

reported by pharmacists is inaccurate because these inaccuracies do not effect the level of reimbursement to pharmacists. Potentially, 22 States may have problems with the accuracy of their drug utilization data. Accurate reporting of the drug and dosage units dispensed is essential in establishing the correct rebate amounts to be paid by the pharmaceutical manufacturers.

We recommended that HCFA:

- 0 require States to develop procedures to monitor the accuracy of reporting by pharmacies of drugs dispensed, if such procedures do not already exist at the State:

²A small overpayment could result when the pharmacist's usual and customary charge (billing amount) was less than the State's payment amount (the upper limit amount for multiple-source drugs and the estimated acquisition cost plus dispensing fee for single-source drugs). The amount of the overpayment would be the difference between the State's payment amount and the pharmacist's billing amount.

- o require States to perform tests of the dosage units being reported, and if the test shows that pharmacists are inaccurately reporting dosage unit data, then require the States to establish computer edits, or other procedures, to detect and correct the obvious errors: and
- o contact the various national pharmacy associations and request their participation in alerting pharmacists to the importance of assuring that the correct drug and dosage units are reported on claim forms.

HCFA'S ACTIONS

The HCFA officials prepared interim regulations which would require State agencies to establish and implement an oversight and auditing plan to ensure proper pharmacy coding and reporting practices. These proposed interim regulations should adequately implement our first recommendation. If these regulations were reworded to define pharmacy coding to also include a requirement for accurately reporting dosage units (rather than just NDCs), then these regulations would adequately implement our second recommendation.

AUDITEE COMMENTS

The Acting Administrator of HCFA responded to our draft report in a memorandum dated March 18, 1992. In that memorandum, the Acting Administrator agreed that the amount of rebates ultimately received by the States is dependent on capturing reliable utilization data. The HCFA also agreed that manufacturers are more likely to dispute rebates if governmental utilization data are perceived to be inaccurate.

The HCFA did not dispute our findings. However, HCFA did not believe that it needed to take additional corrective action because the interim regulations and other HCFA initiatives had addressed our findings. The Acting Administrator responded that HCFA:

- o has fostered accuracy in pharmacy coding by discussing operational and policy issues with representatives from State agencies on a regular basis;
- o has already required State agencies to establish procedures for compliance with the legal provisions entitling manufacturers to audit State data:

- o believes it would be inappropriate and financially burdensome for the States if HCFA were to mandate specified testing. Also, States can best identify their own diverse problems and, therefore, should be allowed to voluntarily implement testing procedures:
and
- o should function in a consulting role only.

OIG RESPONSE

Although HCFA's interim regulations and other initiatives may have a positive impact on the program, we believe that HCFA needs to take additional corrective actions. Our current work, which follows-up on some of the findings in this memorandum, indicates that serious problems continue to exist with pharmacy coding and rebate disputes.

Preliminary results from our more recent field work has shown that the problems identified in this memorandum are continuing to hinder the program. The problems of inaccurate pharmacy data remain significant. More specifically, many of the drug manufacturers have disputed States' rebate claims and have based those disputes on inaccurate pharmacy data. While figures on the disputed amounts are not readily available, we are currently conducting a nationwide review to estimate the total amount in dispute after the first year of the rebate program. Our preliminary results indicate that the total nationwide dispute figure is significant.

We believe the problem of disputed rebates has grown to the point of jeopardizing the success of the rebate program. We also believe that it will take aggressive action, and not just a consulting role, on HCFA's part to ensure accurate reporting in the rebate program. Accordingly, we continue to believe that our recommendations are appropriate. We will continue to keep you advised on our ongoing work.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

MAR 18 1992

Date

J. Michael Hudson

From

Acting Administrator

subject

OIG Draft Report - "**Medicaid** Drug Rebates: Inaccurate Reporting of Medicaid Drug Data by Pharmacists" (A-0691-00056)

TO

Inspector General
Office of the Secretary

We have reviewed the subject draft report in which the Office of Inspector General (OIG) examined the extent to which pharmacists were reporting inaccurate Medicaid drug data to State Medicaid agencies. This report seeks to examine potential inaccuracies in the reported data, the reporting process, and the possible effects of this inaccurate information on the Medicaid drug rebate program.

The **report** found that **22** of the 46 States (or 48 percent) participating in the study may have problems with the accuracy of their drug utilization data. Such **inaccuracies**, depending on their magnitude, could significantly distort a manufacturer's rebate payment amount. In an effort to ensure accurate reporting of drug and dosage information, OIG recommends that States develop procedures to test coding accuracy and contact professional organizations to disseminate information on coding.

We agree with OIG that the amount of rebates ultimately received by States is dependent on capturing reliable utilization data. Manufacturers are also more likely to dispute rebates if governmental utilization data are perceived to be inaccurate. Nevertheless, HCFA has technical disagreements with the recommendations in the **report**. Our specific comments are attached for your consideration.

Thank you for the opportunity to review and comment on this draft report. Please advise us whether you are in agreement with our position on the report's recommendations at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the OIG Draft Report: "Medicaid Drug Rebates:
Inaccurate Reporting of Medicaid Drug Rata by Pharmacists"
(A-06-91-00056)

Recommendation 1

That **HCFA** require States to develop procedures to monitor the accuracy of the drug reported as dispensed, if such procedures do not already exist for the State.

HCFA Resuonse

We disagree **technically** with this recommendation. **As** OIG acknowledges, HCFA has already prepared interim regulations which would implement this recommendation.

Recommendation 2 .

That **HCFA** require States to perform tests of the dosage units being reported, and if the tests show that pharmacists are inaccurately reporting dosage unit data, then require the States to establish computer edits, or other procedures, to detect and **correct** the obvious errors.

HCF A Resuonse

In the text of the report, OIG also recommends rewording the interim regulations to define pharmacy coding to also include accurate reporting dosage units in addition to National Drug Code (NDC) requirements for specification of the drug dispensed and the number of dosage units. OIG maintains this revision would implement this **second** recommendation.

Technically, we disagree with this recommendation and **OIG's** assertion about revision of the interim regulations since we believe that our interim regulations already ensure accurate pharmacy wding. We believe accurate pharmacy **coding**, as now **described** in these regulations, includes all data reported by pharmacists to State Medicaid agencies including the proper number of dosage units and the proper drug code.

HCFA also fosters accuracy in pharmacy coding by discussing operational and policy issues with representatives from State agencies on a regular basis. We intend to continue to **convene** meetings among the States, pharmacies, and manufacturers in order to discover more systematic approaches to the improvement of pharmacy coding. We believe that acting in a **consulting** role is the best method for facilitating accurate reporting in the rebate program.

Additionally, HCFA has already required State agencies to establish procedures for compliance with the legal provisions entitling manufacturers' to audit State data. We believe these requirements, along with implementation of the auditing, enforcement, and investigation requirements of the interim regulations as written, fulfill this recommendation.

From our experiences with frequent contacts with States prior to and since implementation of the rebate program, we believe that it would be inappropriate and **financially** burdensome for HCFA to deliver any mandate for specified testing. The comprehensive success the program has enjoyed so **far** could be diminished by such actions, particularly for States that have already faced operational **challenges** during implementation of existing regulations.

While some States have already revised their programs to meet **OIG's** intent, others could not yet efficiently implement the elaborate automated system edits that may be required by this recommendation. HCFA believes that each State can best identify its own diverse problems, and that States recognize the potential benefits of meeting the objectives of this recommendation. Since we anticipate that all States **will** seek to implement such specifications voluntarily as their capabilities permit, a Federal mandate does not seem warranted.

Recommendation 3

That HCFA contact the various national pharmacy associations and request their participation in alerting pharmacists to the importance of assuring that the correct drug and dosage units are reponed on claims **forms**.

HCFA Response

We have a technical disagreement with this recommendation. **HCFA** has already taken a number of actions on our own initiative which we believe satisfy the intent of this recommendation. We have contacted the major pharmacy groups, and have been successful in our attempts to have articles about the importance of accuracy in pharmacy reporting placed in their publications. HCFA staff maintains constant contact with States and manufacturers, and a continuing refrain in these conversations is the importance of accurate reporting. These types of actions have been in process since the inception of the drug rebate program. We will continue to relay **this** message.