Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID PAYMENTS FOR LESS-THAN-EFFECTIVE DRUGS

JUNE GIBBS BROWN
Inspector General

AUGUST 1994
OEI-03-94-00090

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EXECUTIVE SUMMARY

PURPOSE

To determine whether the Health Care Financing Administration (HCFA) is accurately identifying less-than-effective (LTE) drugs and sharing this information with Medicaid State agencies on a timely basis. This is a follow-up to prior Office of Inspector General (OIG) reviews on the same subject.

BACKGROUND

Since 1962, the Federal Food, Drug and Cosmetic Act has required that drugs be both safe and effective for their labeled indications. The Food and Drug Administration (FDA) is responsible for identifying LTE drugs and ensuring their withdrawal from the market.

Prescription drugs are covered under the Medicaid program, which is administered by the HCFA. As of October 1, 1982, Medicaid reimbursement was prohibited for LTE drugs, as well as for drugs designated by FDA as "identical, related, or similar" (known as IRS drugs) to LTE drugs. States were responsible for identifying LTE/IRS drugs and removing them from their lists of approved drugs.

In a 1985 review, the OIG found that States were dispensing and charging Medicaid for LTE drugs. We recommended that HCFA work with FDA to provide the States with a complete list of LTE drugs to use in screening claims. A follow-up review in 1990 revealed that HCFA's internal controls to prevent Medicaid reimbursement for LTE drugs were inadequate. We also found that HCFA and FDA did not have a system to routinely identify and maintain a list of all LTE drugs.

On January 1, 1993, the responsibility for identifying LTE/IRS drugs shifted from the State agencies to HCFA. Since that time, HCFA has relied primarily on drug manufacturers to supply them with this information.

FINDINGS

The HCFA and FDA have taken significant steps to strengthen the system for identifying LTE and IRS drugs and conveying needed information to States.

Through an interagency agreement, HCFA and FDA currently engage in a regular exchange of LTE/IRS data. The HCFA provides up-to-date information to manufacturers and States through periodic Medicaid Drug Rebate Program Releases and Quarterly Pricing data.

Despite these efforts, HCFA's list of LTE/IRS drugs was not complete.

The HCFA's list, recently supplied to Medicaid State agencies, should have included an additional 243 drugs. We identified these drugs by comparing a private database company's list of LTE/IRS drugs with the current HCFA list. The FDA made the determination that the 243 drugs were LTE/IRS and should be included on HCFA's list. The omission occurred because HCFA primarily relies on the manufacturers to self-report drug product information.

Improvements are underway to correct the problems identified in our current review.

The HCFA is in the process of adding the drugs we identified to the list of LTE/IRS drugs, and has notified or is in the process of notifying all the affected drug manufacturers, advising them of the civil monetary penalty implications if they knowingly provide false information. The FDA is taking steps beyond what was required in the intra-agency agreement to identify LTE/IRS drugs and forward future LTE/IRS drug determinations to HCFA, including information on the accuracy of reporting by drug manufacturers.

The HCFA has also developed an edit check to monitor reimbursement for LTE/IRS drugs. At the time of our review the edit check was in place and HCFA was in the process of notifying all State Medicaid Directors of the edit check through a Medicaid Drug Rebate Program Release.

CONCLUSION

The HCFA, with help from the FDA, has significantly improved the system for identifying and disseminating information on LTE/IRS drugs. When the improvements underway are totally implemented, the system will:

- adequately ensure that LTE/IRS drugs are properly identified;
- provide State agencies with a complete up-to-date compendium of such drugs; and
- alert HCFA to any State which is purchasing these drugs.

We are pleased that HCFA and FDA have taken such prompt action to correct the problems identified in our review.

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INTRODUCTION

PURPOSE

To determine whether the Health Care Financing Administration is accurately identifying less-than-effective drugs and sharing this information with Medicaid State agencies on a timely basis. This is a follow-up to prior Office of Inspector General (OIG) reviews on the same subject.

BACKGROUND

Prior to 1962, there was no Federal requirement that drugs sold in the United States be effective. The Federal Food, Drug and Cosmetic Act required only that drugs be tested and proven safe prior to marketing. In 1962, Congress amended the Act to require that drugs not only be safe but also effective for their labeled indications.

Since 1962, the Food and Drug Administration (FDA) has been responsible for identifying ineffective drugs and removing them from the market. Less-than-effective, or LTE, drugs, are those that lack substantial evidence of effectiveness for all labeled indications and for which the Secretary has not determined there is a compelling justification for their medical need. When FDA identifies an LTE drug, it publishes a proposal to withdraw the drug in the Federal Register under a Notice of Opportunity for Hearing.

Prescription drugs are an optional service under the Medicaid program, one which all States currently cover. Medicaid is administered by the Health Care Financing Administration (HCFA), which reimburses States for prescriptions drugs provided to Medicaid recipients. Manufacturers must report their prescription drugs to HCFA for reimbursement by Medicaid.

Medicaid reimbursement for LTE drugs has been prohibited since October 1, 1982 (Social Security Act, Section 1903 (i)(5) and Medicaid regulations 42 CFR 441.25). The prohibition includes all drugs for which hearing notices have been published in the Federal Register, whether before or after October 1, 1982, as well as drugs the FDA determines to be identical, related, or similar (known as IRS drugs) to an LTE drug.

From 1982 through 1992, States were responsible for identifying LTE/IRS drugs and removing them from their lists of approved drugs. Effective January 1, 1993, the responsibility for identifying these drugs shifted from the State agencies to HCFA. The HCFA relies primarily on drug manufacturers to provide them with the appropriate information. Once the manufacturers identify the drug as LTE/IRS, HCFA asks the FDA to verify this.

Related Work by the Office of Inspector General (OIG)

Two prior reviews in this area, done in 1985 and 1990, identified significant problems. In 1985, (ACN-03-60202, Enforcement of Regulations Prohibiting Medicaid Payments for Less-Than-Effective Drugs) we found that States were dispensing and charging Medicaid for LTE drugs. We recommended that HCFA work with FDA to provide the States with a complete list of LTE drugs to use in screening claims.

Our 1990 follow-up review (CIN-03-89-00220, Enforcement of Regulations Prohibiting Medicaid Payments for Less-Than-Effective Drugs) revealed that HCFA's internal controls to prevent Medicaid reimbursement for LTE/IRS drugs were still inadequate.

In view of the continuing problems identified in the prior reviews, we decided to determine if procedures and controls had been improved.

METHODOLOGY AND SCOPE

Between September 1993 and July 1994, we interviewed officials from HCFA, FDA, and a private company which provides a computerized drug database to over 40 State Medicaid programs. We reviewed HCFA and FDA policies, procedures, and related documents. We also compared HCFA's most current listing of LTE/IRS drugs with a listing of possible LTE/IRS drugs on the market as of November 23, 1993, provided by the private company. The FDA reviewed any discrepancies to determine if the drugs were properly identified.

We identified drugs by their National Drug Codes (NDCs). Throughout this report, we refer to the number of drugs which are LTE/IRS, as represented by NDC codes.

This report focuses on the current process for identifying these drugs and disseminating such information to the States. We did not attempt to quantify Federal reimbursement to State agencies for these drugs.

FINDINGS

THE HCFA AND FDA HAVE TAKEN SIGNIFICANT STEPS TO STRENGTHEN THE SYSTEM FOR IDENTIFYING LTE/IRS DRUGS AND CONVEYING NEEDED INFORMATION TO THE STATES.

The HCFA has assumed responsibility for identifying LTE/IRS drugs and disseminating information to the States. The system now in use is a significant improvement over the system employed in the OIG's previous review. Previously, each Medicaid State Agency made their own determination.

The HCFA has strengthened its system for identifying LTE/IRS drugs through an intra-agency agreement with the FDA.

Under terms of this agreement, FDA assists HCFA in determining if drugs are LTE or IRS. The specific provisions of the agreement are as follows:

1) The FDA sends HCFA a copy of any Notice of Opportunity for Hearing concerning an LTE drug, including a listing of all applicable IRS drugs within 5 days after publication in the Federal Register,

2) Every quarter, HCFA provides FDA with a list of all IRS drugs identified by the manufacturer which are not on FDA's most recent listing,

3) Every quarter, FDA provides HCFA with an updated list of LTE drugs,

4) The FDA informs HCFA of any significant actions taken on the drugs, and

5) The FDA provides HCFA with a listing of all drugs determined to be LTE/IRS drugs.

The HCFA conveys LTE/IRS drug information to manufacturers and State agencies through Medicaid Drug Rebate Program Releases and Quarterly Pricing Data.

The HCFA informs drug manufacturers and State agencies of their responsibilities and of impending changes regarding LTE/IRS drugs through Medicaid Drug Rebate Program Releases and Quarterly Pricing Data. From December 26, 1991 to June 29, 1994, HCFA had issued eleven notifications relating to such drugs.

One such Program Release notified manufacturers that they are required to include LTE/IRS drugs in quarterly reports to HCFA, using HCFA's codes established for this purpose. The Medicaid Drug Rebate Program requires drug manufacturers to submit quarterly reports to HCFA on Medicaid utilization of their drugs.

In another Program Release, HCFA notified State agencies that they will receive a quarterly pricing file with updated LTE/IRS drug information. The HCFA further advised States that they will be held accountable for using HCFA's drug information to identify LTE/IRS drugs.

DESPITE THESE EFFORTS, HCFA'S LIST OF LTE/IRS DRUGS WAS NOT COMPLETE.

The list of drugs which HCFA supplied to States did not contain 243 LTE/IRS drugs currently on the market. This occurred because of HCFA's primary reliance on the manufacturers to self-report drug product information.

We identified these drugs by first comparing a private company's list of all possible LTE/IRS drugs to the HCFA list.[1] We then provided the results of this comparison to FDA for their review. The FDA verified that 243 drugs from the private list were LTE/IRS and needed to be added to HCFA's list of drugs.

Of the 243 drugs, 161 had not been reported to HCFA as being LTE/IRS. The remaining eighty-two were not reported to HCFA at all. The 243 drugs were manufactured or distributed by 70 firms. Of the 70 firms, 44 had not reported their products as LTE/IRS to HCFA. Seventeen firms had not reported their products to HCFA at all. Nine firms had products that were both reported incorrectly or not reported to HCFA at all.

IMPROVEMENTS ARE UNDERWAY TO CORRECT THE PROBLEMS IDENTIFIED IN OUR CURRENT REVIEW.

Both HCFA and FDA have moved quickly to correct the problems identified in our current review. These steps will improve the quality and completeness of the information given to the State agencies and improve HCFA's ability to identify claims involving LTE/IRS drugs.

The HCFA notified all manufacturers, in its June 29, 1994 Medicaid Drug Rebate Release, that over 200 drugs had been incorrectly identified as effective drugs. They informed the manufacturers that they were changing these drugs designation to LTE/IRS and were notifying each individual manufacturer or labeler. The HCFA urged the firms to ensure that the information reported to HCFA is complete and accurate and stressed that manufacturers are responsible for knowing the status of LTE/IRS drugs. Finally, HCFA pointed out that the OIG will initiate on-site audits of drug labelers and that the OIG has the authority to impose Civil Monetary Penalties for each item of false information that was knowingly provided to HCFA.

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[1] At the time of the comparison, HCFA's list contained 934 LTE/IRS drugs.

Additionally, the HCFA has notified 48 specific manufacturers or distributors about the products that the FDA determined were LTE/IRS. In the notification, HCFA also advised manufacturers of the civil monetary penalty implications if they knowingly provide false information to the FDA. At the time of our review, HCFA was also in the process of notifying the other manufacturers or distributors that did not report their drugs.

The FDA is taking steps beyond what was required in the interagency agreement to strengthen the identification of LTE/IRS drugs. First, the FDA will analyze, on a semi-annual basis, their list of unapproved drugs and forward information to HCFA on LTE/IRS drugs identified. The FDA has also received drug product information from a private company specializing in pharmaceutical database information. This private company has agreed to periodically forward any drugs suspected to be LTE/IRS to the FDA. The FDA will check this information as well as determine if manufacturers are reporting the correct codes to HCFA. Findings will be shared with HCFA.

The HCFA has also developed an edit check to monitor reimbursement for LTE/IRS drugs. This edit check will print out an exception list for reimbursed drugs that appear on HCFA's drug list. The exception list will be shared with the appropriate State Agencies that showed the utilization. The HCFA is in the process of notifying all State Medicaid Directors, through a Medicaid Drug Rebate Program Release, that this mechanism was effective for the State utilization data received on or after March 8, 1994. The notification also reminds the States that federal financial participation funds are not available when LTE/IRS drugs are purchased by State Medicaid agencies.

CONCLUSION

The HCFA, with help from the FDA, has significantly improved the system for identifying and disseminating information on LTE/IRS drugs. When the improvements underway are totally implemented, the system will

- adequately ensure that the LTE/IRS drugs are properly identified;
- provide State agencies with a complete up-to-date compendium of such drugs; and
- alert HCFA to any States which are purchasing these drugs.

We are pleased that HCFA and FDA have taken such prompt action to correct the problems identified in our review.

OFFICE OF INSPECTOR GENERAL

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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The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

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