



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date . AUG 14 1995

From June Gibbs Brown
Inspector General *June G Brown*

Subject Medicare Part B Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment (A-06-92-00079)

To Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached are two copies of our report entitled, "Medicare Part B Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment." The objective of our audit was to evaluate the Health Care Financing Administration's (HCFA) policies regarding reimbursement for drugs used with durable medical equipment (DME). The HCFA generally reimbursed self-administered drugs through a procedure code called "medication supplies." Medicare Part B payments for such drugs (net of beneficiary coinsurance and deductible) totaled about \$57.4 million during Calendar Year (CY) 1992. The Medicare Part B payments totaled \$111.2 million for CY 1993 and \$153.7 million for CY 1994. The HCFA approved these payments based on its position that drugs are covered under Medicare Part B as long as they are necessary for the effective use of the DME. Based on applicable statutory provisions and on the advice of the Office of the General Counsel, we believe that HCFA's policy of paying for self-administered outpatient prescription drugs in conjunction with DME lacks clear legislative authority.

In addition, HCFA did not have specific pricing policies for the payment of drugs used with DME. Consequently, there was no assurance that in CY 1992 about \$43.9 million of the total payments of \$57.4 million for self-administered outpatient drugs were properly priced and paid. We believe it is essential for the Medicare carriers to be given the identity of the drug manufacturers. This would allow the carriers to determine whether the manufacturers have been approved to market the drugs and would provide them with the information, such as drug name, form, strength, package size, and quantity dispensed, necessary to properly price the drug.

Subsequent to the completion of our audit field work, HCFA began to implement improved pricing policies and procedures. We believe that implementation of these policies and procedures are very positive steps. We will monitor the implementation and impact of these policies and procedures as we continue our work in this area.

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We are recommending that HCFA (1) seek legislation to expressly authorize the coverage of drugs used with DME and (2) fully implement policies and procedures at the carriers to ensure that drugs are properly priced and paid.

In its response to our draft report, HCFA stated that it did not concur with our recommendation that it seek legislation expressly authorizing coverage of drugs used with DME. The HCFA's response also pointed out that pricing policies have been developed since our audit field work was completed. We have revised this report and its recommendations to recognize those policy changes. Additionally, HCFA's response discussed problems encountered in obtaining drug pricing data, and requested the Office of Inspector General's assistance in obtaining such data.

The full text of HCFA's comments are included as **Appendix D** and are addressed as appropriate in the body of the report.

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 Department officials. To facilitate identification, please refer to Common Identification Number A-06-92-00079 in all correspondence related to this report.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PART B REIMBURSEMENT
TO PROVIDERS FOR DRUGS USED IN
CONJUNCTION WITH DURABLE
MEDICAL EQUIPMENT**



JUNE GIBBS BROWN
Inspector General

APRIL 1995
A-06-92-00079

**Memorandum**

AUG 14 1995

Date

From

June Gibbs Brown
Inspector General*June Gibbs Brown*

Subject

Medicare Part B - Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment (A-06-92-00079)

To

Bruce C. Vladeck
Administrator
Health Care Financing Administration

This report provides you with the results of our review entitled, "Medicare Part B Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment." The objective of our audit was to evaluate the Health Care Financing Administration's (HCFA) policies regarding reimbursement for drugs used with durable medical equipment (DME). The Social Security Act (the Act) expressly provides coverage for self-administered outpatient drugs only in very specific instances, none of which include drugs used in conjunction with DME. Nonetheless, HCFA has approved payments for self-administered drugs based on its position that drugs are covered under Medicare Part B as long as they are necessary for the effective use of the DME. Based on applicable statutory provisions, we believe that HCFA's policy of paying for self-administered outpatient prescription drugs used in conjunction with DME lacks clear legislative authority. Medicare Part B payments for drug claims with procedure code A4610 - "medication supplies" totaled about \$57.4¹ million (net of beneficiary coinsurance and deductible) during Calendar Year (CY) 1992. Medicare Part B payments totaled \$111.2 million for CY 1993, and \$153.7 million for CY 1994.

In addition, HCFA does not have specific pricing policies for the payment of drugs used with DME. Consequently, there was no assurance that about \$43.9 million of these self-administered outpatient drugs were properly priced and paid during CY 1992. We believe it is essential for the Medicare carriers to be given the identity of the drug manufacturers. This would allow the carriers to determine whether the manufacturers have been approved to market the drugs and would provide them with the information, such as drug name, form, strength, package size, and quantity dispensed, necessary to properly price the drug.

Subsequent to the completion of our audit field work, HCFA began to implement improved pricing policies and procedures. We believe that implementation of these policies and procedures are very positive steps. We will monitor the implementation and impact of these policies and procedures as we continue our work in this area.

¹ The \$57.4 million is the extrapolation of our sample results to the payment universe. The total Medicare payment for procedure code A4610 is \$57.5 million.

We are recommending that HCFA (1) seek legislation to expressly authorize the coverage of drugs used with DME and (2) fully implement policies and procedures at the carriers to ensure that drugs are properly priced and paid.

The HCFA Administrator responded to our draft report in a memorandum dated February 5, 1995. The HCFA did not concur with our recommendation that it seek legislation expressly authorizing coverage of drugs used with DME. In response to our recommendation to develop policies and procedures to ensure proper pricing of the drugs, HCFA pointed out that pricing policies have been developed since our audit field work was completed. Additionally, HCFA's response discussed problems encountered in obtaining drug pricing data, and requested the Office of Inspector General's (OIG) assistance in obtaining such data. In that regard, OIG has several comprehensive pricing studies either underway or planned, and we will provide the results of these studies to HCFA when available.

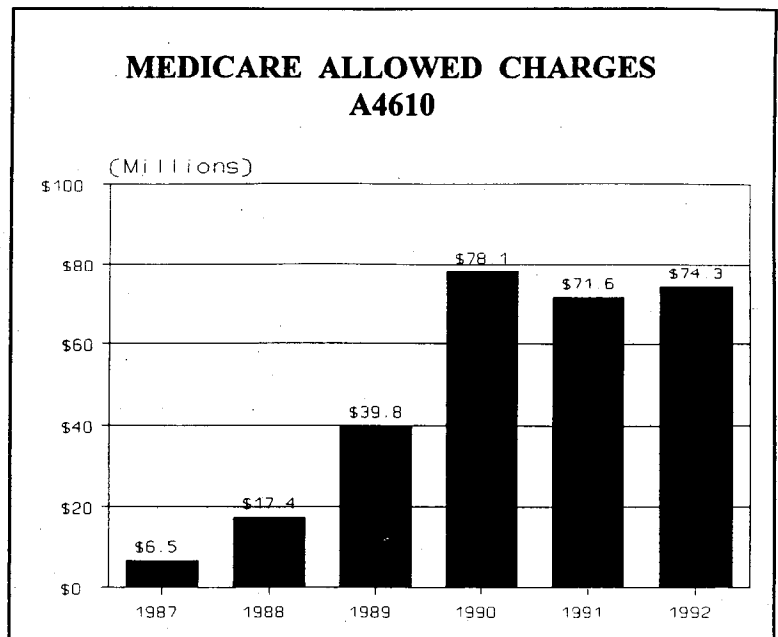
The full text of HCFA's comments are included as **Appendix D** and are addressed as appropriate in the body of the report.

BACKGROUND

Title XVIII of the Act provides for coverage of physician, outpatient hospital, DME, and a number of other medical services and supplies under the Medicare Part B (voluntary supplementary medical insurance) program. Claims for payment under Part B are submitted to carriers (usually large insurance companies) and the carriers pay the claims on behalf of Medicare, using Medicare reimbursement principles. The HCFA administers title XVIII of the Act (Medicare).

Medicare Part B coverage and payment extends to those items encompassed in the statutory definition of DME, those items determined to be medical supplies within the statutory meaning of home health services, and to certain outpatient prescription drugs specified by statute. Drugs are often used with DME for inhalation therapy. The types of DME which require prescription drugs are: nebulizers, infusion pumps, and intermittent positive pressure breathing machines. The physician prepares and signs a certificate of medical necessity stating that the beneficiary needs an item of DME. In addition, the physician gives the beneficiary a prescription for the drug. The beneficiary takes the certificate of medical necessity to a DME supplier (medical equipment company or a pharmacy which supplies DME) to either rent or buy the item of DME. The beneficiary then takes the drug prescription to a pharmacy or a medical equipment company that has a pharmacy to have the prescription drug dispensed. The medical equipment company and/or pharmacy then bills the Medicare carrier for the drug(s) dispensed and the item of DME.

Until 1993, HCFA generally reimbursed for these self-administered drugs through procedure code A4610 "medication supplies." Medicare allowed charges (including beneficiary coinsurance and deductible) for procedure code A4610 totaled about \$74.3 million in CY 1992. In CY 1993, HCFA revised its coding system and created 20 codes for these drugs (J7610 - J7799). Medicare allowed charges (including beneficiary coinsurance and deductible) for these codes totaled \$140.2 million and \$195.0 million in CY 1993 and CY 1994, respectively.



SCOPE OF AUDIT

We conducted our audit in accordance with generally accepted government auditing standards. The objective of our audit was to evaluate HCFA's policies regarding Medicare reimbursement for drugs used with DME. Achieving our audit objectives did not require that we review the internal control structures of HCFA or the Medicare carriers.

In order to evaluate the procedures for payments of self-administered outpatient drugs included under procedure code A4610, we selected a random sample of claims from HCFA's CY 1992 beneficiary file. The sample included 5,263 payments that were coded A4610. From those 5,263 sample payments, we selected a random sub-sample of 200 claims which were processed by 40 Medicare carriers. Our methodology included reviewing each paid claim with all supporting documentation to determine whether a self-administered outpatient drug used with DME was billed and paid.

In addition, to accomplish our objective, we reviewed applicable portions of the Act and the Medicare Carriers Manual (MCM); we interviewed Region VI HCFA officials; we spoke with officials from carriers, as necessary, concerning the claims; and we reviewed the sample of 200 paid claims. We also used the sample of 200 paid claims to evaluate the adequacy of documentation provided by the providers to the Medicare carriers for pricing the drugs.

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Our audit did not include an evaluation of the medical necessity of the drugs. For purposes of this review, we considered an item purchased to be a drug if the item purchased had a National Drug Code (NDC), and if a prescription was necessary for third party reimbursement. We did not independently verify any information we obtained from third party sources. Our field work was performed during July through November of 1993 by our Little Rock, Arkansas office working through the HCFA regional office in Dallas, Texas, and various Medicare contractors.

FINDINGS AND RECOMMENDATIONS

Based on our review of the applicable statutory provisions and based on the advice of the Office of the General Counsel (OGC), we believe that HCFA's policy of paying for self-administered outpatient prescription drugs used in conjunction with DME lacks clear legislative authority. Medicare Part B program expenditures included about \$57.4 million in CY 1992 for self-administered outpatient prescription drugs used in conjunction with DME. The reported expenditures grew to \$111.2 million for CY 1993, and to \$153.7 million for CY 1994. The payments have been made because of HCFA's position that drugs are covered under Medicare Part B as long as they are necessary for the effective use of the DME, regardless of the method of administration.

Additionally, there was no assurance that, in CY 1992, about \$43.9 million of the total drug payments of \$57.4 million were properly priced and paid because HCFA did not require carriers to obtain detailed pricing information. The MCM did not require specific information necessary for pricing drug claims.

Statutory and Regulatory Policy

Section 1832(a) of the Act authorizes Medicare Part B payments for "medical and other health services," as defined in various provisions throughout title XVIII of the Act. Payments for covered DME are addressed primarily in sections 1834(a) and 1861(s)(6). The term "medical and other health services" includes prescription drugs furnished on an outpatient basis only in the following limited and specific instances:

- prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant (section 1861(s)(2)(J));
- a covered osteoporosis drug and its administration, (section 1861(s)(2)(0));
- erythropoietin for dialysis patients (section 1861(s)(2)(P));
- pneumococcal vaccine and its administration (section 1861(s)(10)(A));
- hepatitis B vaccine and its administration (section 1861(s)(10)(B));
- oral anti-cancer drugs (section 1861(t)(2)(A));
- oxygen used with oxygen equipment (section 1834(a)(5)); and
- parenteral and enteral nutrients (included in the revised Omnibus Reconciliation Act of 1993 (OBRA '93) at section 13541).

The HCFA has established a policy of reimbursing for drugs used in conjunction with DME. The HCFA policy is stated in section 2100.5 of the MCM. The basis for HCFA's DME drug reimbursement policy is the statutory provisions pertaining to coverage and reimbursement of DME. The HCFA believes that drugs are covered under Medicare Part B as long as the drugs are necessary for the effective use of the DME regardless of the method of administration.

The MCM section 2100.5 states:

Coverage of Supplies and Accessories -- Reimbursement may be made for supplies, e.g., oxygen ..., that are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment, ... e.g., tumor chemotherapy agents used with an infusion pump or heparin used with a home dialysis system. However, the coverage of such drugs or biologicals does not preclude the need for a determination that the drug or biological itself is reasonable and necessary for treatment of the illness or injury or to improve the functioning of a malformed body member.

Congressional intent to cover drugs used with DME under Part B of Medicare is not clear in our view. We believe that had the Congress intended to cover drugs used in conjunction with DME, it would have included drugs in the definition of "covered items" reimbursed as DME under section 1861(s)(6) of the Act. The HCFA's policy of paying for drugs administered by a beneficiary in conjunction with DME lacks clear legislative authority and may exceed the scope of Medicare benefits authorized by the statute. The OIG's position is based on the advice of OGC.

Results of Review of a Sample of Medicare Part B Drugs

The Part B Extract Summary System showed that, in CY 1992, \$57.5 million was expended for "medication supplies" prescribed by physicians to be used in conjunction with DME. This figure does not include beneficiary coinsurance and deductible amounts.

Our review of 200 claims disclosed that, in 198 instances, either the claims or the supporting documentation showed that self-administered outpatient drugs were used. Our sample results were used to project an estimate of the nationwide cost to the Medicare Part B program of self-administered outpatient drug coverage. We estimate that the coverage costs totaled about \$57.4 million in CY 1992. (See **Appendix A** for our sample description and **Appendix B** for the sample results.)

The payments have been made because of HCFA's position that drugs are covered under Medicare Part B as long as they are necessary for the effective use of the DME.

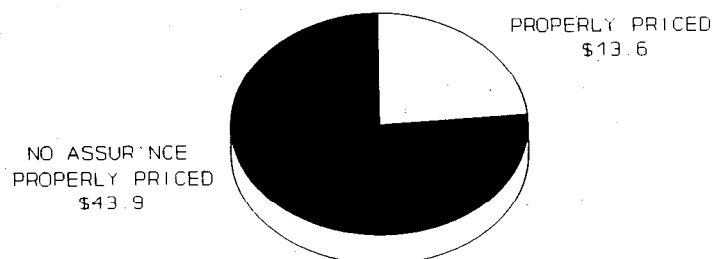
Pricing Policies for Drugs Used with DME

If HCFA intends to continue covering drugs used with DME, it should establish specific pricing policies for such drugs. With regard to the pricing policies for drugs, a regional HCFA official referred us to section 5202 of the MCM. However, this manual section provides pricing policies for injections of pharmaceuticals that occur in physicians' offices. The official acknowledged that HCFA has not made a distinction, for payment purposes, between drugs furnished incident to a physician's service and drugs administered through DME.

Further, the official referred us to 42 Code of Federal Regulations (CFR) 405.517 as Medicare policy on payment for drugs that are not paid on a cost or prospective payment basis for drugs furnished incident to a physician's service. This policy requires payments for drugs to be based on the lower of the estimated acquisition cost or the national wholesale price of the drug. According to the policy cited, the estimated acquisition cost is to be determined based on surveys of the actual invoice prices paid for the drug. For multiple-source (generic) drugs, payment is to be based on the lower of the estimated acquisition cost, or the wholesale price, defined as the median price for all sources of the generic form of the drug. However, the official advised us that HCFA has not yet enforced the payment methodology described in 42 CFR 405.517, but has left the pricing to the discretion of the Medicare carriers.

We used the same sample of 200 drug claims in order to evaluate the adequacy of the information necessary for pricing and payment. Using the claims, the supporting documentation and the **Drug Topics Red Book** pricing publication, we concluded that in CY 1992 there was no assurance that, about \$43.9 million of these self-administered outpatient drugs were properly priced and paid. (See **Appendix C** to the report for our sample results.)

SELF-ADMINISTERED OUTPATIENT DRUGS 1992 MEDICARE EXPENDITURES (In Millions)



In order for carriers to price and pay drug claims properly, we believe that as a minimum the carriers should be provided information on the drug name, manufacturer, form, strength, package size, and quantity. Such information was often not provided with the claims. In fact, some or all of the information was not provided for 146 of the 200 sampled claims. Only 3 of the 40 carriers submitted documentation to us that showed their bases for paying drug claims. These carriers paid the claims based on the name, form, strength, and quantity but without regard to the manufacturer, the package size, or whether the drugs were brand name or generic. We believe it is essential for carriers to be given the identity of the drug manufacturers in order for the carriers to determine whether the manufacturers have been approved to market the drugs.

Subsequent to the completion of our audit field work, HCFA began to implement improved pricing policies. Effective January 1, 1993, HCFA added 20 new HCFA Common Procedure Coding System (HCPCS) codes for inhalation therapy drugs. Also, new pricing policies which require reimbursement at the median generic price were sent to HCFA regions on March 15 and May 24, 1994. The new pricing instructions should be incorporated into the MCM in the near future. We believe that full implementation of these policies would raise the level of assurance that HCFA is paying an appropriate price for self-administered outpatient drugs.

CONCLUSIONS AND RECOMMENDATIONS

Medicare carriers reimbursed providers for self-administered outpatient drugs at a total program cost of \$57.4 million for CY 1992, \$111.2 million for CY 1993 and \$153.7 million for CY 1994. The HCFA's position is that drugs are covered under Medicare Part B as long as the drugs are necessary for the effective use of the DME. We do not believe that such reimbursement is supported by section 1861 of the Act. Based on advice from OGC, we conclude that HCFA's policy of paying for self-administered outpatient prescription drugs in conjunction with DME lacks clear legislative authority.

Additionally, specific pricing policies are needed for drugs used with DME if it is HCFA's intention to continue the coverage. There is no assurance that, in CY 1992, about \$43.9 million of these self-administered outpatient drugs were properly priced and paid because the claims did not include information on approved drug manufacturers. Subsequent to the completion of our audit field work, HCFA began to implement improved policies and procedures. We believe full implementation of these policies and procedures should eliminate most of the pricing problems identified in the audit.

If HCFA deems that the coverage is necessary, we recommend that HCFA (1) seek legislation to expressly authorize the coverage of drugs used with DME and (2) fully implement policies and procedures at the carriers to ensure that drugs are properly priced and paid. Such procedures should include requiring carriers to obtain either the 11-digit NDC code, or at a minimum, the name of the manufacturers that produce the drugs.

HCFA'S COMMENTS

The HCFA's comments are summarized below and the full text of its comments is included as **Appendix D**.

The HCFA believes that authority exists for coverage of drugs used with DME. The HCFA therefore did not concur with our recommendation to seek express legislative authority. The HCFA pointed to section 1834(a)(5) of the Act which discusses a payment methodology for oxygen equipment covered under the DME benefit. Additionally, HCFA pointed to section 13541 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) in which the Congress addressed the Medicare payment methodology for nutrients used to furnish parenteral therapy. The HCFA also pointed out that both oxygen and nutrients are classified as drugs by the Food and Drug Administration. With regard to our finding on the restrictions of self-administered outpatient drugs, HCFA points out that section 1861(s)(2)(J) of the Act provides for coverage of immunosuppressive drugs that are self-administered. Also, section 1861(s)(2)(C) provides for coverage of self-administrable drugs that are required for hospital diagnostic services furnished to outpatients.

With regard to our second recommendation, HCFA pointed out the addition of 20 new HCPCS codes for inhalation therapy drugs that were effective January 1, 1993. Also, HCFA noted that new pricing policies which require reimbursement at the median generic price were sent to the Regional Administrators on March 15, 1994, and May 24, 1994. The comments further pointed out that the new pricing instructions should be contained in the MCM in the near future. With regard to the use of NDCs, the comments stated that since the Medicare allowances for drugs are based on average wholesale price, identification of the manufacturer is not relevant.

Further, HCFA's comments discussed problems encountered in obtaining drug pricing data, and requested the OIG's assistance in obtaining such data.

Finally, HCFA's comments discussed several measures which it believes will help curtail Medicare costs.

OIG'S RESPONSE

The HCFA's comments regarding our first recommendation were not responsive to the key point raised in our report. That is, coverage of self-administered outpatient drugs used in conjunction with DME is not authorized by the Act. Instead, the comments were devoted to the sections of the Act, and OBRA '93, which provide for coverage of oxygen, nutrients for parenteral therapy, and self-administered immunosuppressive drugs. We acknowledge that the Medicare Part B program is authorized in section 1861 of the Act to provide coverage of outpatient self-administered immunosuppressive drugs. We also acknowledge that both oxygen (section 1834(a)(5)) and nutrients (section 13541 of OBRA '93) are covered by Medicare Part B. These drugs are not in question. However, there is no statutory provision for coverage of self-administered outpatient inhalation therapy drugs. The coverage of one very specific class of self-administered outpatient drugs should not and does not imply that any or all other classes of drugs should be covered especially given the fact that the Act is very specific as to what services are covered. Accordingly, we continue to believe that our recommendation is appropriate and valid.

With regard to our recommendation for pricing policy, we believe the policies that have been and are being implemented by HCFA are very positive steps. However, we believe that HCFA should consider the use of NDCs for its drug reimbursement policy. The HCPCS codes identify only the chemical compounds but do not identify the manufacturers, while the NDCs do. Therefore, through use of NDCs, the carriers would be able to identify products from approved manufacturers. At a minimum, the drug providers should be required to supply the names of the manufacturers that produced the drugs.

With regard to HCFA's request for OIG's assistance in obtaining pricing data, we have several comprehensive pricing studies either underway or planned, and we will provide the results of those studies to HCFA upon completion.

DESCRIPTION OF SAMPLE

Sample**Objectives:**

Project potential cost savings for Medicare Part B self-administered drugs used in conjunction with durable medical equipment such as nebulizers, infusion pumps and intermittent positive pressure breathing machines. Also, project dollar value of self-administered drugs which could not be priced.

Sample**Information:**

Expenditures for the Medicare Part B program for medication supplies used in conjunction with durable medical equipment during CY 1992.

Population:

The sampling population was all Medicare Part B program medication supplies payments greater than zero for CY 1992.

Sample Design:

A simple random number sample was used. A total of 5,344 payments from the one percent beneficiary file for CY 1992 was used. We excluded 81 instances where no payment was made from our universe. We obtained 200 paid Medicare claims and calculated the amount of self-administered outpatient drugs. That amount was extrapolated to the sample population and the entire Medicare Part B population.

We used these same 200 paid Medicare claims to determine if the billed drugs can be priced by using the **Drug Topics Red Book** pricing publication. Next, we calculated the amount of outpatient self-administered drugs which could not be priced. We extrapolated that amount to the one percent beneficiary sample population and to the entire Medicare Part B population.

Sample Size:

A sample of 200 paid Medicare Part B medication supplies claims was chosen.

Source of

Random Numbers: The Office of Audit Services' Statistical Sampling Software was used to determine the random numbers for drawing the sample.

Characteristics**to be Measured:**

The amounts paid by the Medicare Part B program for self-administered outpatient drugs.

Other Evidence:

We reviewed the claims and supporting documentation to determine the amount of drugs included. If the information was incomplete, we called the carrier and requested that information. We based our pricing decisions on the evidence found on the submitted claim and supporting documentation. We did not anticipate contacting the carrier regarding whether a drug can be priced or not.

Extrapolation:

The amount paid by Medicare for our 200 sample items totaled \$23,467.73. Using the point estimate and the \$617,954 total A4610 procedure code reimbursements for our one percent sample, we calculated a ratio of the projected reimbursed amount for the sample from the 1 percent sample to the reimbursed amount for all CY 1992 A4610 Medicare Part B transactions on the 1 percent sample. We multiplied this ratio times the \$57,488,842 total A4610 procedure code reimbursements for the entire Medicare Part B universe to calculate the dollar value of total reimbursements for self-administered outpatient drugs. See **Appendix B**.

Next, we used another point estimate and the \$617,954 total A4610 procedure code reimbursements for our one percent sample to calculate a percentage of the dollar value of self-administered outpatient drugs which could not be priced. We then multiplied this calculated percentage times the \$57,488,842 total A4610 procedure code reimbursements for the entire Medicare Part B universe to calculate the dollar value of total reimbursement of self-administered outpatient drugs which could not be properly priced. See **Appendix C**.

NATIONWIDE ESTIMATE OF CY 1992
MEDICARE PART B PAYMENTS FOR
SELF-ADMINISTERED OUTPATIENT DRUGS

SAMPLE ONE RESULTS	
Sample Population	5,263
Sample Medicare Part B Claims With Procedure Code A4610 - Medication Supplies	200
Value of A4610 Procedure Code Sample	\$23,468
Value of Drugs Included in Procedure Code Sample	\$23,440
Point Estimate	\$616,819
At the 90% Confidence Level Lower Limit Upper Limit	\$565,497 \$668,141
Estimated CY 1992 Medicare Part B Payments for Self-Administered Drugs Under Procedure Code A4610	\$57,373,864

**NATIONWIDE ESTIMATE OF CY 1992 MEDICARE PART B PAYMENTS FOR
SELF-ADMINISTERED OUTPATIENT DRUGS IN WHICH THERE WAS NO
ASSURANCE THAT THE DRUGS WERE PROPERLY PRICED AND PAID**

SAMPLE TWO RESULTS	
Sample Population	5,263
Sample Medicare Part B Claims - Determination of Whether Drugs Could Be Priced or Not	200
Value of Drugs Which Were Self- Administered Drugs	\$23,440
Value of Drugs in Which There Was No Assurance That The Drugs Were Properly Priced	\$17,658
Point Estimate	\$471,814
At the 90% Confidence Level Lower Limit Upper Limit	\$414,424 \$529,204
CY 1992 Estimated Payments For Self- Administered Drugs In Which There Was No Assurance That The Drugs Were Properly Priced	\$43,892,731



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date . FEB 9 1995 .
From Bruce C. Vladeck *Bruce Vladeck*
Administrator
Subject Office of Inspector General (OIG) Draft Report: "Medicare Part B Reimbursement
to Providers for Drugs Used in Conjunction With Durable Medical Equipment"
(A-06-92-00079)
To June Gibbs Brown
Inspector General

We reviewed the above-referenced report in which OIG concludes that the Health Care Financing Administration's policy of paying for self-administered outpatient prescription drugs in conjunction with durable medical equipment "lacks clear legislative authority."

Our detailed comments on the report's findings and recommendations are attached for your consideration. Thank you for the opportunity to review and comment on this draft report. Please contact us if you would like to discuss our comments and response.

Attachment

Health Care Financing Administration's (HCFA) Comments
on Office of Inspector General (OIG) Draft Report:
Medicare Part B Reimbursement to Providers for Drugs Used
in Conjunction With Durable Medical Equipment"
(A-06-92-00079)

Recommendation

Seek legislation to expressly authorize coverage of drugs used in conjunction with durable medical equipment (DME).

HCFA Response

We do not concur with this recommendation. The report states that HCFA's policy of paying for drugs used in conjunction with DME "lacks clear legislative authority." We believe that HCFA does have adequate authority to cover drugs which are required for the functioning of DME.

Medicare has been covering drugs used with DME for over 20 years. Despite the open knowledge of this coverage, Congress has never questioned our authority to cover these drugs. Moreover, in 1989, Congress indicated concurrence with this policy by establishing at section 1834(a)(5) of the Social Security Act (the Act) a methodology for determining the payment amount for oxygen equipment covered under the DME benefit, and for the oxygen that is used with DME. Oxygen is classified as a drug by the Food and Drug Administration (FDA). In addition, in section 13541 of the Omnibus Budget Reconciliation Act of 1993, as well as in previous reconciliation bills, Congress addressed the methodology for determining Medicare payment amounts for nutrients covered under the prosthetic device benefit that are used to furnish parenteral therapy. These nutrients are classified as drugs by FDA.

Note that the restriction at sections 1861(s)(2)(A) and (B) of the Act which limits Medicare coverage to drugs that are not self-administered only applies to the benefits described by those sections of the Act. The statute does not require application of a similar restriction to the other benefits described at section 1861(s) of the Act, unless the statute so states. For example, the statute at section 1861(s)(2)(J) of the Act does not limit coverage of immunosuppressive drugs to drugs that are not self-administered. Therefore, we cover immunosuppressive drugs that are self-administrable. Also, under section 1861(s)(2)(C), we cover drugs, including drugs that can be self-administered, that are required in the performance of hospital diagnostic services furnished to outpatients. We also note that while the Act excludes coverage of drugs as a "medical supply" in the definition of home health services, there is no similar exclusion at section 1861(n) of the Act which limits the parameters of the DME benefit.

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We also believe this policy is so well established and accepted by the Medicare program that legislation would be needed to change it.

Recommendation

Develop policies and procedures for the carriers to ensure that drugs are properly priced.

HCFA Response

Medicare's payment methodology for drugs, such as drugs used with DME, that are not paid on a cost or prospective payment basis is contained at 42 CFR 405.517. This section requires payment for a drug based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. For multiple-source drugs, payment is based on the lower of the estimated acquisition cost or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug. This regulation was published in the Federal Register on November 25, 1991, and has been in effect since January 1, 1992. Implementing instructions were sent to the Regional Administrators and the carriers on March 15, 1994, and May 24, 1994. We agree that these instructions should be contained in the Medicare Carriers Manual and will issue these instructions in the near future.

The report does not take into account the revised HCFA Common Procedure Coding System (HCPCS) for drugs. Effective January 1, 1993, 20 new codes (J7610 - J7799) describing the drugs used as inhalation therapy supplies in DME were added to HCPCS. These codes identify the specific drug name, strength, and size. Since the Medicare allowances for drugs are based on the average wholesale price, identification of the manufacturer is not relevant.

The DME regional carriers are in the process of further refining HCPCS to provide more codes to describe additional drugs that can be used in DME. The local carriers have begun using the 20 new J codes in lieu of A4610. As a result, claims submitted for A4610 have been significantly reduced.

Payment allowances based on estimated acquisition costs may significantly reduce Medicare expenditures for these drugs. We had intended to obtain data on estimated acquisition costs through use of a national survey. However, we have been unsuccessful in obtaining Office of Management and Budget clearance of a national survey form. In addition, the DME regional carriers are examining the feasibility of establishing payment allowances for drugs based on the estimated acquisition cost. We would welcome any assistance you may be able to provide in obtaining appropriate data.

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Concerning drugs used with DME for inhalation therapy, such as nebulizers and intermittent positive pressure breathing (IPPB) machine therapy, HCFA believes that the additional activities will help to curtail Medicare costs:

- o The DME regional carriers medical review (MR) policy on nebulizers is being circulated for comment. One of the primary objectives of this MR policy will be to ensure this therapy is only covered for those who have a medical need for such therapy.
- o The current policy on IPPB machine therapy is very broad. It provides for the coverage of IPPB machine therapy under Medicare's DME benefit when ordered by a physician for a patient whose ability to breathe is severely impaired. We published a proposed notice and are preparing specifications for a final notice that will limit Medicare coverage of IPPB machine therapy to very specific categories of patients. That is, to patients at risk of respiratory failure because of decreased respiratory function secondary to kyphoscoliosis or neuromuscular disorder, to patients with acute severe bronchospasm or exacerbated chronic obstructive pulmonary disease who fail to respond to other standard therapy, and to the management of atelectasis that has not improved with simple therapy (that is, incentive spirometry, postural drainage, or aerosol therapy).
- o The DME regional carriers are also revising their MR policy on infusion pumps which will help ensure appropriate Medicare coverage for this equipment and the supplies used with it to provide infusion therapy in the home.