

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**USAGE AND DOCUMENTATION OF  
HOME OXYGEN THERAPY**



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Inspector General**

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# EXECUTIVE SUMMARY

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## PURPOSE

To determine if supplier documentation accurately reflects beneficiaries' medical need and reported use of home oxygen therapy.

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## BACKGROUND

Medicare covers home oxygen therapy for beneficiaries diagnosed with significant hypoxemia (a deficiency in the amount of oxygen in the blood). Home oxygen therapy accounts for the largest share of Medicare payments for durable medical equipment. Medicare allowances for oxygen equipment totaled over \$2 billion in 1997.

Suppliers of home oxygen equipment submit claims to the Durable Medical Equipment Regional Carriers for processing and payment. According to Medicare guidelines, oxygen suppliers must submit Certificates of Medical Necessity with oxygen claims, and keep original CMNs in their records. Home oxygen CMNs must contain sufficient medical information, including diagnoses and results of laboratory tests, to establish that beneficiaries meet Medicare coverage requirements.

For this inspection, we collected data from Medicare beneficiaries with paid claims for oxygen equipment in 1996 and the durable medical equipment suppliers who provided this equipment.

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## FINDINGS

**Nearly one-quarter of oxygen Certificates of Medical Necessity were inaccurate or incomplete.**

**While almost all beneficiaries used their stationary oxygen equipment, 13 percent of beneficiaries reported never using their portable systems.**

**Suppliers reported providing services, but were unable to fully document all of these services.**

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## RECOMMENDATIONS

**To address the vulnerabilities identified in this report, we recommend that the Health Care Financing Administration:**

**Ensure that system edits in place at the DMERCs are able to identify incomplete CMNs, and delay payments for oxygen equipment claims until complete CMNs are submitted. The HCFA should also conduct periodic checks to ensure that original CMNs signed by beneficiaries' physicians and kept on file by oxygen suppliers confirm the electronic versions of CMNs that suppliers submit to Medicare carriers.**

**Target oxygen equipment claims for focused medical review.** We realize that it would not be manageable or cost effective to perform extensive reviews on all oxygen equipment claims. However, we believe that our findings raise issues that can only be addressed through individual case review.

**Work to quickly establish specific service standards for home oxygen equipment suppliers as mandated by the Balanced Budget Act of 1997.** As part of these standards, we believe that suppliers should be required to maintain adequate documentation to verify the provision of equipment and patient services.

**Continue to alert physicians to the critical role they play in determining beneficiaries' medical need for and utilization of medical equipment paid for by Medicare.** In a January 1999 Fraud Alert concerning physician certification of the need for medical supplies and services, our office emphasized that, by signing CMNs, physicians are attesting that information on the entire CMN is true, accurate, and complete to the best of their knowledge.

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## AGENCY COMMENTS

We received comments on our draft report from HCFA. The full text of these comments can be found in Appendix C. A summary and our response follows.

### HCFA Comments

The HCFA concurred with all of our recommendations. They reported that current policy calls for DMERC systems to edit required fields on electronic CMNs for completeness. The HCFA also stated that the file copy CMNs the OIG reviewed are used primarily for suppliers' own records, and therefore may be abbreviated and may not include all the information the suppliers submit electronically. Nevertheless, HCFA agreed they should make it clear to suppliers that file copy CMNs signed by physicians should contain all the information suppliers' submit electronically.

Based on the information presented in our report, HCFA commented that portable oxygen systems might prove to be a fruitful target for focused medical review. The HCFA also indicated that they are planning to develop a regulation that will set service standards for home oxygen equipment suppliers.

The HCFA also provided two technical comments. With respect to our finding that Medicare paid \$263 million in 1996 for oxygen equipment covered by inaccurate or incomplete CMNs, HCFA stated this figure does not necessarily represent payments made for medically unnecessary or unreasonable services. The agency also believed it is important to clarify why laboratory reports did not confirm test results detailed on the CMNs, and to distinguish between test results recorded on CMNs that could not be supported by suppliers' records and test results recorded on CMNs that differed from suppliers' records.

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## OIG RESPONSE

We appreciate HCFA's positive response to our recommendations, and we concur with their proposed actions. We appreciate the fact that HCFA agreed to make it clear to suppliers that CMNs kept on file should contain all the information submitted electronically. While some suppliers may have retained only abbreviated versions of the CMN in their files, this practice is not in keeping with current policy. The *DMERC Supplier Manuals* require suppliers to keep the original CMN signed by the physician on file, along with any additional medical necessity information. This CMN must include all required information and be filled out completely and accurately. We believe, in most cases, the information from this file copy CMN is used to develop the final electronic version of the CMN that is submitted for claims processing. Therefore, in order to meet the requirements for coverage of oxygen therapy, file copies of the CMNs we reviewed should have been complete and accurate. As presented in this report, we did not always find this to be the case.

In response to HCFA's technical comments, we agree the \$263 million for oxygen equipment supported by inaccurate or incomplete CMNs does not presuppose a finding of medically unnecessary services. Rather, this estimate represents services where suppliers did not provide us with the complete documentary support required for Medicare reimbursement. With regard to HCFA's comments about laboratory test results, we have revised the relevant heading in the report. Our finding only relates to suppliers who provided laboratory test results for our review. When we report non-confirming test results, this refers only to laboratory tests where information from the actual lab report differed from information listed on the CMN.

# TABLE OF CONTENTS

	<b>PAGE</b>
<b>EXECUTIVE SUMMARY</b> .....	1
<b>INTRODUCTION</b> .....	5
<b>FINDINGS</b> .....	10
Inaccurate and Incomplete Certificates of Medical Necessity .....	10
Use of Oxygen Equipment .....	11
Lack of Service Documentation .....	13
<b>RECOMMENDATIONS</b> .....	15
<b>APPENDICES</b>	
A: Estimates and Confidence Intervals .....	17
B: Certificate of Medical Necessity for Home Oxygen (Form HCFA-484) .....	23
C: Comments on the Draft Report .....	24

# INTRODUCTION

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## PURPOSE

To determine if supplier documentation accurately reflects beneficiaries' medical need and reported use of home oxygen therapy.

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## BACKGROUND

### Medicare Payment Policies and Expenditures

Home oxygen therapy accounts for the largest share of Medicare payments for durable medical equipment (DME). Medicare payments for oxygen equipment more than doubled between 1992 and 1996, increasing from about \$900 million in 1992 to about \$1.9 billion in 1996. Medicare allowances for oxygen equipment totaled over \$2 billion in 1997.

Medicare reimburses suppliers for home oxygen equipment based on monthly fee schedule allowances which vary by State. These monthly fee schedule allowances cover the oxygen equipment, oxygen contents including all refills, equipment set-up and maintenance, and patient training. During the period of our review, monthly fee schedule allowances were about \$300 for stationary oxygen equipment rentals, and about \$50 for portable oxygen equipment rentals. The 1997 Balanced Budget Act legislated oxygen fee schedule reductions totaling 30 percent, with a 25 percent cut effective January 1, 1998 and a further 5 percent cut effective January 1, 1999.

### Medicare Coverage of Home Oxygen Therapy

Section 1861 (S)6 of the Social Security Act authorizes Medicare coverage of home oxygen therapy. Medicare covers home oxygen therapy for beneficiaries diagnosed with significant hypoxemia (a deficiency in the amount of oxygen in the blood). This condition is usually associated with severe respiratory problems. Medicare beneficiaries may qualify for home oxygen therapy if 1) their ability to breathe is severely impaired, 2) laboratory tests demonstrate medical need for oxygen therapy, 3) the attending physician prescribes oxygen therapy, and 4) alternative treatment modalities have been tried or considered and deemed clinically ineffective.

Oxygen delivery systems fall into two categories: stationary systems and portable systems. Beneficiaries may qualify for rental of stationary and/or portable oxygen systems. Stationary oxygen equipment includes oxygen concentrators, liquid systems, and gas systems. Oxygen concentrators are electrically powered machines which generate higher

concentrations of oxygen from room air. Gas and liquid oxygen systems administer oxygen directly from tanks or cylinders. Portable oxygen equipment includes small liquid cylinders and small gas tanks. These systems allow patients to perform activities away from their stationary units, including activities outside the home.

## Medical Documentation

Initial oxygen claims sent to the DMERCs must include a Certificate of Medical Necessity (CMN) for home oxygen therapy. Most suppliers submit claims and CMNs electronically. The CMN must contain sufficient medical information, including diagnoses and results of laboratory tests, to establish that the beneficiary meets coverage requirements. The CMN must be completed, signed, and dated by the ordering physician. According to Medicare guidelines, oxygen suppliers must submit appropriate CMNs with oxygen claims, and keep original CMNs in their records. The DMERCs revised the original home oxygen CMN (Form HCFA-484) and required suppliers to submit the revised version (Form HCFA-484.2) with claims after April 1, 1998. A copy of Form HCFA-484 is provided in Appendix B.

Medicare requires documentation of hypoxemia, as demonstrated by the results of either an arterial blood gas test (PaO<sub>2</sub> or PO<sub>2</sub>) or an oxygen saturation test (O<sub>2</sub>Sat). These tests measure the amount of oxygen in a patient's blood. Arterial blood gas tests provide a more precise and reliable measurement. Medicare guidelines stipulate that arterial blood gas test results are preferred for documenting medical necessity.

For coverage purposes, Medicare classifies beneficiaries into one of three groups depending on the results of arterial blood gas or oxygen saturation tests.

Group I. Medicare covers home oxygen therapy if a patient's arterial blood gas test result is at or below 55 mm Hg or their oxygen saturation test result is at or below 88 percent, at rest. Coverage is also available if the patient has higher blood gas levels at rest, but meets required levels during exercise or sleep. Physicians must re-certify beneficiaries in this group after 12 months of therapy, and suppliers must submit re-certification CMNs with oxygen claims for the 13<sup>th</sup> month of therapy.

Group II. Coverage is available if a patient's arterial blood gas test result is between 56 and 59 mm Hg or their oxygen saturation test result equals 89 percent, and there is evidence of 1) dependent edema suggesting congestive heart failure, 2) pulmonary hypertension or cor pulmonale, or 3) erythrocythemia with a hematocrit greater than 56 percent. Physicians must re-certify beneficiaries in this group if their oxygen therapy will continue beyond three months. Suppliers must submit re-certification CMNs containing new arterial blood gas or oxygen saturation test results with claims for the fourth month of therapy.



Group III. According to the Medicare Coverage Issues Manual Section 60-4, carriers must apply a “rebuttable presumption” of non-coverage for a patient with an arterial blood gas test result at or above 60 mm Hg, or an oxygen saturation test result at or above 90 percent. Physicians must submit additional evidence to carrier medical reviewers to justify the medical need for oxygen therapy in order for Medicare to reimburse claims in this group. According to the Coverage Issues Manual, “HCFA expects few claims to be approved for coverage in this category.”

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## METHODOLOGY

### Sampling

We selected a stratified random sample of Medicare beneficiaries with paid claims for stationary and/or portable oxygen equipment. Beneficiaries were selected from a database containing 5 percent of home oxygen therapy claims paid by Medicare in 1996. The 5 percent file was created from the 1996 HCFA Common Working File, which was 89 percent complete at the time of sample selection.

We designed a sample with three strata using two stratification criteria - total allowance and number of months of billings per beneficiary. Stratum 1 contains all beneficiaries in the 5 percent file whose total allowances for oxygen equipment were greater than \$4500. Stratum 2 contains beneficiaries with 4 or more months of billings in 1996. Stratum 3 contains beneficiaries with 3 or fewer months of billings in 1996. We selected a total of 801 beneficiaries. After removing deceased beneficiaries identified through the Medicare Beneficiary Enrollment Database, our working sample contained 529 beneficiaries. A description of each stratum is presented in Table 1.

**Table 1. Beneficiary Sample Specifications**

Strata	Criteria	Population	Selected Sample	Working Sample
1	Total allowances per beneficiary > \$4500	107	107	<b>86</b>
2	Beneficiaries with ≥ 4 months of billings	24689	408	<b>304</b>
3	Beneficiaries with ≤ 3 months of billings	8499	286	<b>139</b>
Total		33295	801	<b>529</b>

## Data Collection and Analysis

We collected data from Medicare beneficiaries and their suppliers from August 1997 to April 1998. The Survey Data Analysis (SUDAAN) software package was used to compute point estimates and corresponding 95 percent confidence intervals. We used sample beneficiaries' claims for oxygen equipment to compute allowance totals. (Point estimates and confidence intervals for all statistics presented in the Findings of this report are provided in Appendix A.)

It is important to note that the sampling unit for this inspection was the Medicare beneficiary; therefore, we cannot generalize supplier-specific data to the population of home oxygen suppliers. This information is only representative of the group of suppliers who provided oxygen to sample beneficiaries.

**Beneficiary data.** We designed a telephone survey instrument to collect data from sample beneficiaries. Survey items focused on the types of oxygen equipment used, frequency and duration of daily oxygen use, portable system use, and frequency of supplier service visits. We completed telephone interviews with 303 of the 529 beneficiaries in our sample, a 57 percent response rate. Of non-respondents, 10 percent were beneficiaries for whom we could not find phone numbers, 18 percent could not be reached by phone after multiple attempts, 13 percent refused to participate, and 2 percent were beneficiaries for whom we had incomplete surveys. Based on beneficiary responses, we determined whether and to what extent beneficiaries were using their stationary and portable oxygen systems, and whether and how often beneficiaries received portable oxygen refills and equipment service visits from suppliers.

**Supplier and CMN Data.** We developed a self-administered survey instrument for all suppliers who billed Medicare for sample beneficiaries' oxygen therapy claims in 1996. We mailed 605 survey instruments to these suppliers. Many of the questions on the supplier survey mirrored those on the beneficiary survey, including questions about oxygen equipment and supplier services provided to sample beneficiaries. We requested that suppliers provide copies of sample beneficiaries' oxygen CMNS, as well as lab reports showing arterial blood gas and/or oxygen saturation test results. Of the 605 surveys mailed, 91 percent (n=550) were completed and returned.

Based on supplier survey responses, we determined the types of stationary and portable equipment provided to beneficiaries, and the number of portable oxygen refills and equipment service visits provided to beneficiaries. In almost all cases, suppliers submitted file copy CMNS rather than printouts of electronic transmission CMNS. After reviewing all CMNS submitted with each supplier survey, we identified the earliest dated CMN covering oxygen therapy provided in 1996. Herein, this CMN will be referred to as the review CMN. All review CMNS were original forms (HCFA-484) in effect prior to DMERC revision. We used the review CMN to complete a series of questions regarding

document completeness, test results and dates, equipment prescription and justification, and re-certification.

After receiving completed supplier survey instruments, we selected a small sub-sample of 26 suppliers for a follow-up documentation review. All of these suppliers indicated that they had provided portable oxygen refills and/or oxygen equipment service visits between January 1, 1996 and December 31, 1997. In a mail request, we asked these suppliers to submit documentation to support their portable refill activity and/or equipment service visits. Twenty-three of the 26 suppliers provided the requested materials. One supplier submitted only a partial response, which we excluded from our review. Finally, two suppliers did not respond to the mail request despite multiple attempts to secure requested documentation.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# FINDINGS

## **Nearly one-quarter of oxygen Certificates of Medical Necessity were inaccurate or incomplete**

Twenty-three percent of the oxygen CMNS we reviewed had one or more of the following problems: incompleteness, non-confirming lab reports, and lack of justification for portable oxygen where portable claims were paid. Based on claims for oxygen services covered by these CMNS, we estimate that Medicare paid \$263 million in 1996 for oxygen equipment covered by inaccurate or incomplete CMNS.

### **Fourteen percent of CMNS were incomplete**

According to Medicare guidelines, home oxygen CMNS must contain specific information to establish a beneficiary's medical need for the benefit. If CMNS do not contain all of this information, Medicare payments should not be processed. However, 14 percent of CMNS had one or more required sections not completed. Incomplete sections included oxygen prescription date, length of need for oxygen therapy, name and address of provider performing qualifying tests, oxygen prescription, physician signature, and date signed by physician. About 48 percent of these incomplete CMNS were *initial* certifications for home oxygen therapy.

### **Some lab reports provided by suppliers did not confirm CMN test results**

Thirty percent of suppliers submitted actual lab reports corresponding to the arterial blood gas or oxygen saturation test results recorded on review CMNS. Of these suppliers who submitted actual lab reports, 27 percent submitted reports that did not confirm the test results recorded on CMNS. Many of these lab reports did not agree with the test condition reported on the review CMN. The test condition indicates the circumstances under which the arterial blood gas or oxygen saturation test was performed, such as "at rest," "while sleeping," "while exercising," or "on oxygen." Other lab reports did not match the test values or test dates reported on review CMNS.

The agreement of actual lab reports with test results recorded on CMNS varies by type of qualifying test. While 33 percent of CMNS with pulse oximetry test results had non-confirming lab reports, 20 percent of CMNS with arterial blood gas test results had non-confirming lab reports. For CMNS with both pulse oximetry and arterial blood gas test results, only 10 percent had corresponding lab reports that did not confirm CMN results.

## **Medicare paid for portable oxygen equipment not justified on CMNS**

Medicare reimbursed portable equipment claims for 23 percent of review CMNS that did not provide justification for portable oxygen equipment. In order for portable oxygen equipment to be covered during the period of our review, beneficiaries' physicians must have prescribed a portable system and included a narrative justification of why the patient needed portable equipment on the CMN.

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## **While almost all beneficiaries used their stationary oxygen equipment, 13 percent of beneficiaries reported never using their portable systems**

### **Overall, beneficiaries were using stationary oxygen equipment as part of a prescribed home oxygen therapy regimen**

Almost all beneficiaries used the stationary oxygen equipment paid for by Medicare, and most beneficiaries reported using these systems every day. Only 6 percent of beneficiaries reported that they did not use their stationary equipment every day (n=14). Twelve of the 14 beneficiaries used oxygen concentrators, one used a stationary liquid system, and one used a stationary gas system. All but one of these beneficiaries reported using the stationary equipment a few times per week.

### **Thirteen percent of beneficiaries never used their portable oxygen equipment**

Thirteen percent of beneficiaries indicated that they had never used the portable oxygen equipment paid for by Medicare. We estimate that Medicare paid about \$9.7 million in 1996 for portable oxygen equipment that beneficiaries never used.

Nearly one in five beneficiaries who did report using their portable oxygen equipment used the portable systems only two days per month or less. Nine percent of beneficiaries used their portable oxygen systems one day per month or less; another 10 percent of beneficiaries reported using their portable equipment one day every two weeks. Beneficiaries with gas portable systems used their portable equipment significantly less than beneficiaries with liquid portable systems, as shown in Table 2. Twenty-eight percent of beneficiaries with gas portable systems used the systems one day every two weeks or less, compared to only 8 percent of beneficiaries with liquid portable systems. Fifty-eight percent of beneficiaries with gas portable systems used the systems every day or a few days per week, while about 82 percent of beneficiaries with liquid portable systems used these systems every day or a few days per week.

**Table 2. Frequency of Beneficiaries' Portable Oxygen Use**

<b>How Often Portable System Was Used:</b>	<b>Overall</b>	<b>Portable Gas<sup>1</sup></b>	<b>Portable Liquid<sup>1</sup></b>
Every Day	21 %	22 %	29 %
Few days per week	36 %	36 %	53 %
One day per week	10 %	14 %	9 %
One day every 2 weeks	10 %	17 %	2 %
One day per month or less	9 %	11 %	6 %
Never used portable system	13 %	NA	NA

<sup>1</sup> Computations of use percentages by portable equipment type exclude beneficiaries who reported never using portable systems.

Information gathered from suppliers may provide further evidence of beneficiaries' infrequent usage of their portable systems. About 22 percent of sample suppliers who billed for portable oxygen equipment in 1996 did not provide any refills for these portable systems between January 1, 1996 and December 31, 1997. We estimate that Medicare paid about \$24 million in 1996 for portable equipment claims for which suppliers did not provide refills.

As shown in Table 3, almost all of the suppliers who did not provide refills were providing gas portable systems to beneficiaries. Twenty-nine percent of gas portable suppliers reported that they did not provide any refills between January 1, 1996 and December 31, 1997, while less than one percent of liquid portable suppliers did not provide any refills during the two-year period.

**Table 3. Portable Refills Provided By Portable System Supplied**

<b>Whether Supplier Provided Portable Refills:</b>	<b>Overall</b>	<b>Gas Portable Only</b>	<b>Liquid Portable Only</b>	<b>Supplied Both Types</b>
Provided Refills	78 %	71 %	99 %	94 %
Did Not Provide Refills	22 %	29 %	1 %	6 %

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## **Suppliers reported providing services, but were unable to fully document all of these services**

### **Suppliers reported providing portable system refills and equipment service visits**

Suppliers who provided portable oxygen equipment refills were asked to report the number of refills they provided between January 1, 1996 and December 31, 1997. We confined our analysis of portable system refills to suppliers who provided oxygen to beneficiaries for the full two-year period of review. Suppliers who furnished gas portable systems reported providing a median of 23 refill tanks, or about one tank per month, to beneficiaries over this period. One of these suppliers reported providing 559 refill tanks to a beneficiary during this period; while, for seven cases, suppliers reported providing only one refill tank over the two-year period. Suppliers who furnished liquid oxygen systems reported refilling beneficiaries' stationary tanks, from which portable units were replenished, a median of 51 times over the two-year period. The reported number of liquid system refills ranged from a minimum of zero to a maximum of 210.

Suppliers were also asked to report how many times they sent an employee to subject beneficiaries' homes to make sure that oxygen equipment was operating properly for the period January 1, 1996 to December 31, 1997. Again, we confined our review of equipment service visits to suppliers who provided oxygen to beneficiaries for the full two-year period. Suppliers reported providing a median of 13 equipment service visits to beneficiaries during this period, or about one visit every other month. The number of equipment service visits provided varied greatly from a minimum of zero visits to a maximum of 209 visits between January 1, 1996 and December 31, 1997.

### **Some suppliers were unable to provide documentation to support their reported services**

We asked a small sub-sample of suppliers to submit documentation to support the refill activity they reported in our survey. These suppliers indicated when they completed the survey that they had documentation to support refill activity. The six sub-sample suppliers who provided liquid systems were able to fully document all refill activity. However, only 42 percent of the 12 sub-sample suppliers who provided gas portable systems were able to fully document refill activity. Of the 58 percent that could not fully document the number of portable gas refills they reported in our survey, three suppliers documented over half of reported refills, and 4 suppliers documented only 50 percent or less of the reported refills. Two of the four suppliers in the latter group did not provide any documentation supporting the number of reported refills.

When asked to submit documentation supporting oxygen equipment service visits, only about 35 percent of sub-sample suppliers (8 of 23) were able to fully document these visits. Of those that could not fully document service visits, 7 suppliers documented 80 percent or more of reported visits, 5 suppliers documented 54 to 68 percent of visits, and 3 suppliers documented 50 percent or less of reported equipment service visits.



# RECOMMENDATIONS

**To address the vulnerabilities identified in this report, we recommend that the Health Care Financing Administration:**

**Ensure that system edits in place at the DMERCs are able to identify incomplete CMNs, and delay payments for oxygen equipment claims until complete CMNs are submitted. The HCFA should also conduct periodic checks to ensure that original CMNs signed by beneficiaries' physicians and kept on file by oxygen suppliers confirm the electronic versions of CMNs that suppliers submit to Medicare carriers.**

**Target oxygen equipment claims for focused medical review.** We realize that it would not be manageable or cost effective to perform extensive reviews on all oxygen equipment claims. However, we believe that our findings raise issues that can only be addressed through individual case review.

**Work to quickly establish specific service standards for home oxygen equipment suppliers as mandated by the Balanced Budget Act of 1997.** As part of these standards, we believe that suppliers should be required to maintain adequate documentation to verify the provision of equipment and patient services.

**Continue to alert physicians to the critical role they play in determining beneficiaries' medical need for and utilization of medical equipment paid for by Medicare.** In a January 1999 Fraud Alert concerning physician certification of the need for medical supplies and services, our office emphasized that, by signing CMNs, physicians are attesting that information on the entire CMN is true, accurate, and complete to the best of their knowledge.

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make it clear to suppliers that file copy CMNs signed by physicians should contain all the information suppliers' submit electronically.

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## OIG RESPONSE

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**Estimates and Confidence Intervals**

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	<b>PAGE</b>
<b>TABLE 1.</b> Inaccurate or Incomplete CMNS .....	18
<b>TABLE 2.</b> Incomplete CMNS .....	18
<b>TABLE 3.</b> Actual Lab Reports and Test Results Recorded on CMNS .....	18
<b>TABLE 4.</b> Agreement of Actual Lab Reports With CMN Test Results By Type of Qualifying Test .....	19
<b>TABLE 5.</b> Source of Conflict Between Actual Lab Reports and Test Results Recorded on CMNS .....	19
<b>TABLE 6.</b> Medicare Paid for Portable Oxygen Equipment Not Justified on CMNS .....	19
<b>TABLE 7.</b> Distribution of Beneficiaries By Stationary Equipment Use .....	20
<b>TABLE 8.</b> Beneficiaries Who Never Used Portable Oxygen Equipment .....	20
<b>TABLE 9.</b> Distribution of Beneficiaries By Frequency of Portable Equipment Use .....	20
<b>TABLE 10.</b> Frequency of Portable Equipment Use: Gas Portable Equipment .....	21
<b>TABLE 11.</b> Frequency of Portable Equipment Use: Liquid Portable Equipment .....	21
<b>TABLE 12.</b> Portable Oxygen Equipment Refills .....	21
<b>TABLE 13.</b> Portable Equipment Refills and Equipment Service Visits Reported By Suppliers, 2-Year Period .....	22
<b>TABLE 14.</b> Supporting Documentation: Portable Equipment Refills .....	22
<b>TABLE 15.</b> Supporting Documentation: Equipment Service Visits .....	22

**Estimates and Confidence Intervals**

The tables below contain statistical estimates presented in the Findings section of this report. We used the Survey Data Analysis (SUDAAN) software package to compute percentages, means, medians, totals and confidence intervals. These estimates are weighted based on the stratified random sample design and are reported at the 95 percent confidence level.

**Table 1.**  
**Inaccurate or Incomplete CMNs**

	<b>Point Estimate</b>	<b>95% Confidence Interval</b>
Percent of Incomplete or Inaccurate CMNs	22.85%	18.96% - 27.01%
Total Medicare Allowances in 1996 for Oxygen Equipment Covered by Incomplete or Inaccurate CMNs	\$262,625,991	\$205,904,911 - \$319,347,071

**Table 2.**  
**Incomplete CMNs**

	<b>Percent</b>	<b>95% Confidence Interval</b>
Incomplete CMNs	13.56%	10.17% - 16.95%
Incomplete Initial CMNs	48.37%	34.89% - 61.85%

**Table 3.**  
**Actual Lab Reports and Test Results Recorded on CMNs**

	<b>Percent</b>	<b>95% Confidence Interval</b>
Suppliers Submitted Actual Lab Reports	29.83%	25.34% - 34.32%
Actual Lab Reports Did Not Confirm Test Results Recorded on Review CMNs	26.62%	18.72% - 34.52%

**Table 4.**

**Agreement of Actual Lab Reports With  
CMN Test Results  
By Type of Qualifying Test\***

Type of Test Recorded on CMN	Percent of CMNs With Non-Confirming Lab Reports	95% Confidence Interval
Oxygen Saturation Test Only	33.43%	22.61% - 44.25%
Arterial Blood Gas Test Only	19.65%	5.46% - 33.84%
Both Test Types	10.41%	0% - 24.62%

\* Difference between percentages is significant at the 94% confidence level (p=0.0522).

**Table 5.**

**Source of Conflict Between Actual Lab Reports  
and Test Results Recorded on CMNs**

	Number of Cases
Test Condition	25
Test Values	12
Test Date	9
Test Type	3
Provider Performing Qualifying Test	1

**Table 6.**

**Medicare Paid for Portable Oxygen Equipment  
Not Justified on CMNs**

	Percent	95% Confidence Interval
Review CMNs Without Portable Justification: Portable Claims Paid	23.42% (n=24)	14.11% - 32.73%

**Table 7.**  
**Distribution of Beneficiaries By Stationary Equipment Use**

	<b>Percent</b>	<b>95% Confidence Interval</b>
Used Stationary Oxygen Equipment	98.83%	97.61% - 100%
Used Stationary Oxygen Equipment Every Day	94.44%	91.36% - 97.52%
Did Not Use Stationary Oxygen Equipment Every Day	5.56%	2.48% - 8.64%

**Table 8.**  
**Beneficiaries Who Never Used Portable Oxygen Equipment**

	<b>Point Estimate</b>	<b>95% Confidence Interval</b>
Percent of Beneficiaries Who Never Used Portable Equipment Reimbursed by Medicare	13.46% (n=30)	8.64% - 18.2.8%
Total Medicare Allowances in 1996 For Portable Equipment Beneficiaries Never Used	\$9,734,960	\$5,182,570 - \$14,287,350

**Table 9.**  
**Distribution of Beneficiaries By Frequency of Portable Equipment Use**

	<b>Percent</b>	<b>95% Confidence Interval</b>
Every Day	21.25%	15.25% - 27.25%
Few Days Per Week	36.36%	29.28% - 43.44%
One Day Per Week	10.44%	6.17% - 14.71%
One Day Every 2 Weeks	9.86%	5.43% - 14.29%
One Day Per Month or Less	8.63%	4.55% - 12.71%

**Table 10.**

**Frequency of Portable Equipment Use:  
Gas Portable Equipment**

	<b>Percent</b>	<b>95% Confidence Interval</b>
Every Day	22.41%	13.93% - 30.86%
Few Days Per Week	35.72%	26.02% - 45.42%
One Day Per Week	14.27%	7.56% - 20.95%
One Day Every 2 Weeks	16.68%	9.08% - 24.28%
One Day Per Month or Less	10.92%	4.80% - 17.04%

**Table 11.**

**Frequency of Portable Equipment Use:  
Liquid Portable Equipment**

	<b>Percent</b>	<b>95% Confidence Interval</b>
Every Day	29.31%	17.31% - 41.31%
Few Days Per Week	53.43%	40.12% - 66.74%
One Day Per Week	9.16%	1.83% - 16.49%
One Day Every 2 Weeks	2.02%	0% - 5.94%
One Day Per Month or Less	6.09%	0% - 12.73%

**Table 12.**

**Portable Oxygen Equipment Refills**

	<b>Point Estimate</b>	<b>95% Confidence Interval</b>
Total Medicare Allowances in 1996 for Portable Equipment for which Suppliers Did Not Provide Refills	\$23,782,718	\$17,051,620 - \$30,513,816

**Table 13.**

**Portable Equipment Refills and Equipment Service Visits  
Reported by Suppliers, 2-Year Period**

Type of Service	Median	IQR*	Minimum	Maximum
Gas Portable System Refills	23.20	59.22	1	559
Liquid Portable System Refills	51.24	62.03	0	210
Equipment Service Visits	12.65	15.28	0	209

\* The interquartile range (IQR) is the difference between the 25<sup>th</sup> and 75<sup>th</sup> percentiles in a distribution. It is a measure of spread that discounts extreme cases, and is therefore insensitive to outliers.

**Table 14.**

**Supporting Documentation: Portable Equipment Refills**

Degree To Which Reported Services Were Documented	Gas Portable Refills	Liquid Portable Refills
Fully Documented Services	5	6
Documented over 50 Percent of Services	3	0
Documented 50 Percent or Less of Services	4	0
<b>Total</b>	<b>12</b>	<b>6</b>

**Table 15.**

**Supporting Documentation: Equipment Service Visits**

Degree To Which Reported Services Were Documented	Equipment Service Visits
Fully Documented Services	8
Documented 80-96 Percent of Services	7
Documented 54-68 Percent of Services	5
Documented 25-50 Percent of Services	3
<b>Total</b>	<b>23</b>



**Form HCFA-484**

Department of Health and Human Services  
Health Care Financing Administration

Form Approved  
OMB No. 0938-0534

**ATTENDING PHYSICIAN'S CERTIFICATION OF MEDICAL NECESSITY FOR  
HOME OXYGEN THERAPY** (Legible handwritten entries acceptable)

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HCFA, P.O. Box 26684, Baltimore, MD 21297; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Patient's Name, Address, and HIC No. \_\_\_\_\_ Supplier's Name, Address, and Identification No. \_\_\_\_\_

Certification:  Initial  Revised  Renewed

**INFORMATION BELOW TO BE ENTERED ONLY BY PHYSICIAN OR PHYSICIAN'S EMPLOYEE**

1. Pertinent Diagnoses, ICD-9-CM Codes, and Findings - CHECK ALL THAT APPLY:

<input type="checkbox"/> Emphysema (492.8)	<input type="checkbox"/> Chronic Obstructive Bronchitis (491.2)
<input type="checkbox"/> COPD (496)	<input type="checkbox"/> Chronic Obstructive Asthma (493.20)
<input type="checkbox"/> Cor Pulmonale (416.9)	<input type="checkbox"/> Congestive Heart Failure (428.0)
<input type="checkbox"/> Interstitial Disease (515)	<input type="checkbox"/> Secondary Polycythemia (289.0)
<input type="checkbox"/> Other _____	<input type="checkbox"/> Hematocrit 57% or more Yes <input type="checkbox"/> No <input type="checkbox"/>

Specify Code

2.A. I last examined this patient for this condition on: \_\_\_\_\_  
Month / Day / Year

2.B. Home oxygen prescribed: \_\_\_\_\_  
Month / Day / Year

2.C. Estimated length of need:  
 1-3 months  4-12 months  Lifetime

3.A. Results of Most Recent Arterial Blood Gas and/or Oxygen Saturation Tests (Patient Breathing Room Air)

	PO2	O2 Saturation	Date
(1) At Rest .....			
(2) Walking .....			
(2) Sleeping .....			
(3) Exercising .....			
(4) Other: .....			

3.C. Physician/Provider Performing Test(s) (Printed/Typed Name and Address): \_\_\_\_\_

3.B. If performed under conditions other than room air, explain: \_\_\_\_\_

**NOTE:** If PO2 Level exceeds 59 mm Hg or the arterial blood saturation exceeds 89% at rest on room air, the claim will be disallowed without compelling medical evidence. Check block  if you have attached a separate statement on your letterhead of additional documentation.

4. Oxygen Flow Rate: \_\_\_\_\_ Liters per minute  Continuous (24 hrs/day)  
 Noncontinuous (Enter hrs/day): \_\_\_\_\_ Walking \_\_\_\_\_ Sleeping \_\_\_\_\_ Exercise Program \_\_\_\_\_ Other (specify) \_\_\_\_\_

5. Oxygen Equipment Prescribed if you have prescribed a particular form of delivery, check applicable block(s). Otherwise leave blank.

<p><b>A. Supply System</b></p> <p>(1) Stationary Source <input type="checkbox"/> Concentrator <input type="checkbox"/> Liquid Oxygen <input type="checkbox"/> Compressed Gas <input type="checkbox"/> Other _____</p> <p>(2) Portable or Ambulatory Source <input type="checkbox"/> Liquid Oxygen <input type="checkbox"/> Compressed Gas <input type="checkbox"/> Other _____</p>	<p><b>B. Delivery System</b></p> <p><input type="checkbox"/> (1) Nasal Cannula <input type="checkbox"/> (2) O2 Conserving Device <input type="checkbox"/> Pulse O2 System <input type="checkbox"/> Reservoir System <input type="checkbox"/> Other _____</p> <p><input type="checkbox"/> (3) Transtracheal Catheter <input type="checkbox"/> (4) Other _____</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

6. If you have prescribed a portable or ambulatory system, describe activities/exercise that patient regularly pursues which require this system in the home and which cannot be met by a stationary system (e.g., amount and frequency of ambulation). \_\_\_\_\_

**CERTIFICATION**

THE PATIENT HAS APPROPRIATELY TRIED OTHER TREATMENT MEASURES WITHOUT SUCCESS. OXYGEN THERAPY AND OXYGEN EQUIPMENT AS PRESCRIBED IS MEDICALLY INDICATED AND IS REASONABLE AND NECESSARY FOR THE TREATMENT OF THIS PATIENT. THIS FORM AND ANY STATEMENT ON MY LETTERHEAD ATTACHED HERETO HAS BEEN COMPLETED BY ME, OR BY MY EMPLOYEE AND REVIEWED BY ME. THE FOREGOING INFORMATION IS TRUE, ACCURATE, AND COMPLETE, AND I UNDERSTAND THAT ANY FALSIFICATION, OMISSION, OR CONCEALMENT OF MATERIAL FACT MAY SUBJECT ME TO CIVIL OR CRIMINAL LIABILITY.

Attending Physician's Signature: (A STAMPED SIGNATURE IS NOT ACCEPTABLE) \_\_\_\_\_ Date: \_\_\_\_\_

Physician's Name, Address, Telephone No., and Identification No.: \_\_\_\_\_

Form HCFA-484 (5-90) 4-11 R FPM 1940-261-13413R09

## **Comments on the Draft Report**

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In this appendix, we present in full the comments from the Health Care Financing Administration.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator  
Washington, D.C. 20201

**DATE:** JUN 30 1999

**TO:** June Gibbs Brown  
Inspector General

**FROM:** Nancy-Ann Min DeParle  
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Usage and Documentation of Home Oxygen Therapy," (OEI-03-96-00090)

We appreciate the opportunity to comment on the issues raised in the above-referenced report concerning beneficiary use and supplier documentation of home oxygen therapy. The report indicates that nearly one-quarter of oxygen Certificates of Medical Necessity (CMNs) were inaccurate or incomplete and estimates that Medicare paid \$263 million in 1996 for oxygen equipment covered by such CMNs. The report also found that 13 percent of beneficiaries surveyed reported never using their portable oxygen systems.

HCFA concurs with the OIG report recommendations. Our specific comments follow:

OIG Recommendation

HCFA should ensure that system edits in place at the Durable Medical Equipment Regional Carriers (DMERCs) are able to identify incomplete CMNs, and delay payments for oxygen equipment claims until complete CMNs are submitted. The HCFA should also conduct periodic checks to ensure that original CMNs signed by beneficiaries' physicians and kept on file by oxygen suppliers confirm the electronic versions of CMNs that suppliers submit to Medicare carriers.

HCFA Response

We concur. Payments for oxygen equipment claims should not be paid until complete CMNs are submitted. The DMERC system edits for completeness of all required fields in the electronic version of the CMN. This is our current policy, and we will endeavor to ensure that it is applied uniformly by all four DMERCs.

It is our understanding that the OIG reviewed hard copy CMNs from supplier files in this study. Since these hard copies are used by suppliers primarily for their own records, we believe many of them are abbreviated and do not include all the information the suppliers submit electronically. We would also point out that, during routine postpay audits, contractors verify the validity and accuracy of the CMNs to ensure that the items are medically necessary. Nevertheless, we agree that HCFA should make it clear to suppliers

Page 2 - June Gibbs Brown

that the hard copy CMNs signed by beneficiaries' physicians which they keep on file should contain all the information they submit electronically. We also agree that HCFA should conduct periodic checks to ensure that this is being done.

OIG Recommendation

HCFA should target oxygen equipment claims for focused medical review.

HCFA Response

We concur. As oxygen is such a large percentage of the total payments for DME, the DMERCs already target a large number of suppliers for focused review. The OIG study, however, suggests that--while almost all beneficiaries used their stationary oxygen equipment, 13 percent of beneficiaries reported never using their portable systems--the latter might prove to be an especially fruitful target of focused reviews of home oxygen.

OIG Recommendation

HCFA should work to quickly establish specific service standards for home oxygen equipment suppliers as mandated by the Balanced Budget Act of 1997.

HCFA Response

We concur. When we release the final regulation detailing the additional business standards for Durable Medical Equipment, Prosthetic Orthotic, Supplies (DMEPOS) suppliers, we will begin working on another regulation which will set service standards for home oxygen suppliers. (The Notice of Proposed Rulemaking for the business standards was published in the Federal Register on January 20, 1998.)

OIG Recommendation

HCFA should continue to alert physicians to the critical role they play in determining beneficiaries' medical need for and utilization of medical equipment paid for by Medicare.

HCFA Response

We concur. Education of physicians is an ongoing process. We plan to emphasize the physicians role as "gatekeeper," and require that all carriers publish DMEPOS related issues in their bulletins, which are geared directly to the physician community. Currently, some DMERCs do publish articles geared to educate physicians in carrier bulletins and we are working on expanding that process.

Technical Comments

We have the following comments on the report findings listed on page 5 of the report.

Page 3 - June Gibbs Brown

“Medicare paid \$263 million in 1996 for oxygen equipment covered by inaccurate or incomplete CMNs.”

This number does not necessarily represent payments made for services that were not medically necessary or reasonable.

“Twenty-seven percent of laboratory reports provided by suppliers did not confirm CMN test results.”

Thirty-three percent of CMNs had non-confirming pulse oximetry laboratory reports. Twenty percent of CMNs had non-confirming arterial blood gas laboratory reports. -- It is important to explain why these reports were non-confirming and make a distinction between test results identified on the CMN that could not be supported by the supplier's records and test results on the CMN that were different than what appeared in the supplier's records. The second circumstance indicates possible fraud while the first represents a possible documentation problem.