Department of Health and Human Services

# OFFICE OF INSPECTOR GENERAL

# ENTERAL NUTRITION THERAPY: MEDICAL NECESSITY


JUNE GIBBS BROWN
Inspector General

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# OFFICE OF INSPECTOR GENERAL

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# EXECUTIVE SUMMARY

## PURPOSE

The purpose of this study was to determine whether Medicare Part B enteral nutrition therapy claims in 1995 met Medicare guidelines for medical necessity.

## BACKGROUND

Enteral nutrition therapy, commonly called tube feeding, is a means of providing nourishment to patients who cannot swallow because of severe or permanent medical problems. Patients are fed nutritional formulas through a tube which is threaded through the nose, or a surgical opening, and leads directly to the stomach or intestine. The three methods of delivering enteral nutrition are syringe, gravity, and pump.

In 1995, the Medicare program and its beneficiaries paid $660 million for enteral nutrition products. This cost covered formulas as well as equipment and supplies, with the equipment and supplies representing more than half the total. The pump delivery method cost approximately $281 million compared to $29 million and $18 millon for the gravity and syringe methods respectively.

In this study, we obtained medical data from physicians, nursing homes, home health agencies, and suppliers for a national sample of beneficiaries whose 1995 enteral nutrition claims were paid by Medicare's durable medical equipment regional carriers (DMERCs). We had physicians review the medical data and determine whether beneficiaries met medical necessity guidelines.

## FINDINGS

***Most beneficiaries met medical necessity guidelines for enteral nutrition in 1995.***

Eighty percent of beneficiaries met Medicare criteria for enteral nutrition; 3 percent did not; and 17 percent had insufficient or conflicting documentation. We estimate that Medicare allowed about $12.2 million (in formula, equipment, and supplies) for the 3 percent of beneficiaries who did not meet guidelines for enteral nutrition.

***There are vulnerabilities, however, with regard to the use of special enteral formulas and the pump delivery method.***

- Special Enteral Formulas

  Twenty-four percent of beneficiaries used special formulas. Of that subgroup, 10 percent did not meet medical necessity guidelines for special formulas; 77 percent did; and 13 percent had conflicting information. We estimate

questionable Medicare allowances for beneficiaries who did not meet special formula criteria to be about $2.9 million.

- Pump Delivery Method

  Seventy-six percent of beneficiaries use the pump delivery method of enteral nutrition. Of that subgroup, 9 percent did not meet Medicare criteria for the pump delivery method; 85 percent did; and 6 percent had conflicting information. The questionable allowance estimate for beneficiaries who did not meet Medicare guidelines for pump delivery method is about $7.5 million.

  Of the beneficiaries who met pump criteria, 37 percent did so based solely on Medicare's slow administration rate criterion which our medical reviewers believe is vulnerable to abuse. The beneficiaries who met that criterion did not have medical conditions warranting a slow administration rate. Had these beneficiaries not met pump criteria, Medicare would have reimbursed for the less expensive gravity delivery method, and saved about $28 million. Our medical reviewers also believe Medicare's aspiration criterion for the pump delivery method is vulnerable to abuse. Beneficiary medical charts generally did not demonstrate that aspiration occurred during tube feeding, which is a condition that makes the pump delivery method necessary.

## RECOMMENDATIONS

We recognize that it would not be manageable or cost effective for DMERCs to conduct a medical review for every claim. However, we believe the vulnerabilities we found with special enteral formulas and the pump delivery method require attention. We have two recommendations. The first has to do with Part B claims review, and the second has to do with changing the structure of payment for beneficiaries in nursing homes.

We recommend that DMERCs consider selecting claims for special formulas, pump equipment, and/or pump supply kits when they determine target areas for focused medical reviews. This recommendation has the added advantage of addressing claims for all beneficiaries regardless of place of service.

We recommend that when enteral nutrition is provided in nursing homes, the Medicare program should cover enteral formulas, equipment, and supplies under the nursing home daily rate rather than under Part B. Of beneficiaries with Part B enteral nutrition claims, more than two-thirds reside in homes. We believe if enteral nutrition therapy products are bundled into the nursing home daily rate, nursing homes will be motivated to select the most economical and appropriate formulas and delivery methods for beneficiaries.

## COMMENTS

A draft of this report was reviewed by the Health Care Financing Administration (HCFA) and the Assistant Secretary for Planning and Evaluation. Both concurred with our recommendations. In addition, HCFA provided information about several initiatives they are pursuing to address problems raised in this report. The full text of HCFA's comments are in Appendix C.

# TABLE OF CONTENTS

# INTRODUCTION

## PURPOSE

The purpose of this study was to determine whether Medicare Part B enteral nutrition therapy claims in 1995 met Medicare guidelines for medical necessity.

## BACKGROUND

### *Enteral nutrition therapy*

Enteral nutrition therapy, commonly called tube feeding, is a means of providing nourishment to patients who cannot swallow because of a severe or permanent medical problem. The patient receives a nutritional formula through a tube which is threaded through the nose, or a surgical opening, and leads directly to the stomach or intestine.

Nutritional formulas vary in terms of ingredients. Each has a Health Care Financing Administration (HCFA) procedure code for reimbursement purposes. The most commonly used formulas are those coded B4150. They are composed of semi-synthetic intact proteins and are appropriate for the majority of patients. When special formulas (other than B4150 and B4152) are claimed, such as those for persons with allergies or blood glucose fluctuations, billers must have documentation of medical need for those formulas. For example, there is a special formula for patients with diabetes, and its procedure code is XX033. If documentation of medical necessity for special formula is not supplied and the code billed is for a more expensive formula than the commonly used B4150 formulas, Medicare will reimburse the special formula claim at the less expensive B4150 formula rate.

There are three methods of delivering formula to the digestive tract and each requires different supplies. The methods are syringe, gravity, and pump. The pump method is the most expensive and Medicare requires documentation that this method is medically necessary. If documentation is not supplied, Medicare will not pay for the pump equipment and will reduce the pump supplies reimbursement to the less expensive gravity supplies level.

In clinical practice, the three delivery methods fall into two categories of feeding schedules: intermittent and continuous. The implementation of a continuous feeding schedule requires the use of a pump to deliver formula at a constant rate over 24 hours. The pump method of delivery may be necessary when beneficiaries experience complications with the syringe or gravity method. For the person administering the enteral nutrition, the pump method is easier and more convenient.

Enteral nutrition is administered by trained persons, e.g., nursing staff if the patient is in a nursing home. When the patient lives at home, enteral nutrition is likely to be administered by a family member or staff from a home health services agency.

*Regional Medicare carriers*

Since Medicare covers enteral nutrition therapy under the prosthetic device benefit, claims are processed by a durable medical equipment regional carrier (DMERC). There are four DMERCs. Prior to the start-up of DMERCs in Fiscal Year 1994, parenteral and enteral nutrition claims were processed by two specialty carriers, and durable medical equipment claims were processed by more than 30 other carriers. The DMERCs were created by Federal regulation in 1993 to process claims for durable medical equipment, prosthetics, orthotics, and supplies, including parenteral and enteral nutrition. The purpose of regionalization was to (1) streamline claims processing for these types of claims, (2) reduce costs, (3) strengthen control over abusive supplier practices, and (4) bring more uniform coverage to beneficiaries across the country. Suppliers of enteral products are reimbursed by the DMERC which services the region where the patient lives.

With approval from HCFA, DMERCs establish medical policy and guidelines for the review of claims. Claims for enteral nutrition therapy must meet certain criteria in order to be considered medically necessary. Criteria include (1) severity or permanence of a condition which inhibits normal swallowing function, and (2) inability to take in, other than by tube feeding, the number of calories needed to maintain weight and strength commensurate with overall health status. Claims for special formulas (codes other than B4150 and B4152) must have documentation of medical need.

Claims for the pump delivery method must also have documentation of medical need. Medicare's medical necessity criteria for the pump include the following: (1) reflux or aspiration; (2) dumping syndrome (nausea/vomiting); (3) severe diarrhea; (4) circulatory overload; (5) blood glucose fluctuations (diabetes); and (6) formula administration rate of less than 100 cc per hour.

With initial enteral nutrition claims, the biller must send the DMERC a completed form known as a Certificate of Medical Necessity (CMN). A physician must complete the clinical portion of the CMN and sign it to attest that there is medical need for the enteral nutrition therapy.

If the DMERC receives enteral nutrition claims for a beneficiary (1) whose claims were deemed medically necessary by the pre-DMERC carrier and (2) whose enteral nutrition is still prescribed by a physician, Medicare considers those claims grandfathered and the DMERC will reimburse them. Grandfather provisions vary slightly at each DMERC, but all accept the previous carrier's determination that the beneficiary had medical need for enteral nutrition.

*Cost of enteral nutrition products*

In 1995, the Medicare program and its beneficiaries paid approximately $660 million for enteral nutrition therapy products (according to HCFA's Part B Extract and Summary System). This cost covered formulas as well as equipment and supplies, with the equipment and supplies representing more than half of the total cost. Below is a breakdown of the $660 million by formula, equipment, and supplies.

| Products | 1995 Medicare Part B Allowances |
|---|---|
| Formulas | $316,381,467 |
| IV Poles | 6,238,856 |
| Pump equipment | 44,887,197 |
| Pump supply kits | 236,641,625 |
| Gravity supply kits | 29,436,137 |
| Syringe supply kits | 17,769,943 |
| Other supplies | 6,101,893 |

*Recent Office of Inspector General studies on enteral nutrition*

Five recent Office of Inspector General studies addressed enteral nutrition therapy from other perspectives. They (1) compared enteral nutrition coverage policies of Medicare Part B and other payers, (2) compared reimbursement methodologies of Medicare Part B and other payers, (3) examined Part B payment levels for enteral nutrition therapy for beneficiaries in nursing homes, (4) examined Part B payments for enteral equipment and supplies for beneficiaries in nursing homes, and (5) assessed Part B payments for non-professional services which are covered under the Part A skilled nursing facility benefit. A list of study titles is in Appendix A.

Several studies showed that Medicare Part B's enteral nutrition therapy payments are higher than they should be. Recommendations focused on ways Medicare can save money, such as: (1) reducing reimbursement rates for specific products, (2) changing the reimbursement methodology in order to take advantage of market forces, (3) eliminating the enteral nutrition benefit from Part B when the beneficiary is in a nursing facility and folding enteral nutrition services into the nursing home daily rate rate. Together, the Inspector General's studies on enteral nutrition therapy provide comprehensive information for decision makers.

## SCOPE AND METHODOLOGY

We conducted this study from April 1996 through January 1997, beginning with a review of Medicare policies and guidelines for determining whether enteral nutrition

therapy claims are medically necessary. This study was part of Operation Restore Trust (ORT), the 2-year demonstration project of Federal and State Governments to identify, reduce, and prevent fraud, waste, and abuse in targeted areas. Targeted areas include nursing homes, hospices, home health agencies, and durable medical equipment companies.

*Sampling*

We selected a stratified random sample of 510 Medicare beneficiaries whose Part B claims were paid for enteral formula delivered in May 1995. The month was selected at random. Beneficiaries were selected from a HCFA 5 percent file of 1995 Medicare Part B enteral claims. Stratification was based on (1) whether beneficiaries lived in ORT or non-ORT States, and (2) whether beneficiaries had low, mid-range, or high monthly expenses for formula. (The ORT States are California, Florida, Illinois, New York, and Texas.) We did not select beneficiaries with formula expenses under $50 for the month. Allowances of less than $50 accounted for only 0.2 percent of total May 1995 allowances. Of beneficiaries selected for the sample, the highest formula allowance for May 1995 was $1,567.72. Below is a table describing each stratum.

| Strata | Criteria |
|---|---|
| 1 | ORT, Low monthly expenses ($50 to $224) |
| 2 | ORT, Mid-range monthly expenses ($225 to $399) |
| 3 | ORT, High monthly expenses (greater than $400) |
| 4 | Non-ORT, Low monthly expenses ($50 to $224) |
| 5 | Non-ORT, Mid-range monthly expenses ($225 to $399) |
| 6 | Non-ORT, High monthly expenses (greater than $400) |

*Data Collection*

Using the HCFA 5 percent file of 1995 Medicare Part B enteral claims, we identified all May 1995 enteral claims including formula, equipment, and supplies for the beneficiaries in our sample.

From the National Supplier Clearinghouse, we acquired the names and addresses of billers who were reimbursed for sample beneficiaries' claims. We wrote to the billers, and they provided us with physician-signed CMNs associated with the sample beneficiaries' formula claims. While we also asked billers for hard copies of the May 1995 claims for sample beneficiaries, most could not provide them since they bill electronically. Billers also gave us names and addresses of physicians and nursing facilities that provided care for sample beneficiaries during May 1995. The billers did not have names and addresses of home health agencies that provided care for beneficiaries, so we requested this information from beneficiaries' physicians.

We wrote to beneficiaries' physicians, nursing homes, and home health agencies to ask (1) if they provided care to the beneficiary; (2) clinical questions about the beneficiary's condition; and (3) questions about the formula given and methods of

administration and delivery. We also requested that these providers send us documentation of medical need for enteral formula and equipment. Documentation included but was not limited to reports of x-rays, lab results, discharge summaries, progress notes, and operative reports.

*Medical Review and Data Analysis*

With the documents we received from each type of respondent, we compiled a medical chart for each sample beneficiary. A team of physicians from Federal Occupational Health, a division of the Public Health Service, reviewed charts for 387 of the 510 sample beneficiaries to determine whether the claims for enteral nutrition therapy met Medicare's medical necessity guidelines. Medical reviews could not be done for 123 of the 510 sampled beneficiaries for the following reasons: either billers could not be located, billers could not be contacted because they were under investigation by another agency, beneficiaries' medical providers could not be identified, or beneficiaries were in the pretest sample.

The medical reviewers examined four areas for which Medicare has medical necessity guidelines: (1) enteral nutrition, (2) caloric intake, (3) special formulas, and (4) pump delivery method. For each area, the reviewers determined whether the beneficiary met Medicare guidelines, did not meet Medicare guidelines, or a determination could not be made due to insufficient or conflicting information. For each area, we quantified the medical review results. We then estimated Medicare allowances for beneficiaries who did not meet medical necessity guidelines for enteral nutrition, special formula, and pump delivery method. We also quantified the place of service for all 510 sample beneficiaries and the subgroups who did not meet medical necessity guidelines for special formula, and pump delivery method.

We sent the DMERCs lists of beneficiaries whose claims did not meet medical necessity guidelines and asked them to identify the grandfathered ones. We recognize that DMERCs are not responsible for medical necessity determinations on grandfathered claims. Those claims were deemed medically necessary by previous carriers. Since our medical review was based on the medical necessity guidelines used by the DMERCs, the findings in this report are presented for the total number of beneficiaries and a subtotal which excludes grandfathered beneficiaries.

We used the Survey Data Analysis (SUDAAN) software package to compute percentage, allowance, and confidence interval estimates presented in the Findings section and Appendix B. Appendix B also contains explanations of how we arrived at allowance estimates. Estimates are weighted based on sample selection probabilities in each stratum.

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

# FINDINGS

## MOST BENEFICIARIES MET MEDICAL NECESSITY GUIDELINES FOR ENTERAL NUTRITION IN 1995

Seventy-seven percent of beneficiaries with 1995 enteral claims met Medicare's medical necessity criteria. When we factored grandfathering provisions into our analysis, the percentage of beneficiaries who met the criteria rose from 77 to 80 percent. As we mentioned in the Background section, Medicare does not hold DMERCs accountable for medical necessity determinations for grandfathered claims.

Four percent of beneficiaries did not meet medical necessity criteria for enteral nutrition. Excluding grandfathered beneficiaries, only 3 percent did not meet the criteria. We estimate that Medicare allowed $17.6 million for medically unnecessary enteral nutrition therapy in 1995, or $12.2 million when grandfathered beneficiaries are excluded.

The remaining 19 percent of beneficiaries--and 17 percent of non-grandfathered beneficiaries--were ones for whom the medical review determination was "insufficient or conflicting documentation." Our medical reviewers explained that most of these medical charts had insufficient rather than conflicting data. Beneficiaries' physicians, nursing homes, or home health agencies did not send the supporting documents we requested, or the documents they sent were incomplete.

### *Conflicting data about prescribed calories*

Our medical reviewers frequently saw that beneficiaries' caloric needs written on CMNs differed from caloric information provided by nursing homes and/or physicians. However, in most cases the discrepancy in calories still fell within the Medicare guidelines. The medical reviewers took a conservative approach to these medical charts. Instead of determining that due to conflicting documentation a determination could not be made, they determined that Medicare's caloric guidelines were met. The results for nongrandfathered beneficiaries were that 91 percent of beneficiaries met the caloric guideline; 3 percent did not; and 6 percent could not be determined. We would add that a possible explanation for caloric discrepancies is that billers did not submit new CMNs, as required, when beneficiaries' caloric prescriptions changed.

## MEDICAL NEED FOR SPECIAL FORMULAS WAS NOT ALWAYS DOCUMENTED

Of the beneficiaries who used special formulas, 23 percent did not have documented medical need for them. Estimated questionable Medicare allowances for these undocumented special formulas totalled about $8 million. When we excluded grandfathered beneficiaries, 10 percent did not have the required documentation, and the questionable allowance estimate dropped to $2.9 million.

Medicare requires documentation of medical necessity for special formulas. For example, if the formula claimed is for diabetics the medical record should indicate that the beneficiary is being treated for diabetes. If medical necessity for a special formula is not documented Medicare will reimburse the special formula claim at a less expensive formula rate.

Of the 40 sample beneficiaries who did not have documented need for special formula, 28 were in skilled nursing facilities, 4 were in regular nursing facilities, and 8 were at home. Excluding grandfathered beneficiaries, 16 sample beneficiaries did not have documented need for special formula, 10 were in skilled nursing facilities, 3 were in regular nursing facilities, and 3 were at home. Of the total 510 sample beneficiaries, 311 were in skilled nursing facilities, 41 in regular nursing facilities, 2 in custodial care facilities, and 156 at home.

## SOME BENEFICIARIES DID NOT HAVE MEDICAL JUSTIFICATION FOR THE PUMP DELIVERY METHOD

Seventy-eight percent of sample beneficiaries used the pump method of delivering formula to the digestive tract. Of those using the pump method, 80 percent met medical necessity guidelines, 14 percent did not, and 6 percent could not be determined. When we excluded grandfathered beneficiaries from our analysis, 85 percent of beneficiaries using the pump method met the medical necessity guidelines, 9 percent did not, and 6 percent could not be determined.

We estimate that the Medicare program and its beneficiaries paid $11.5 million for medically unnecessary pump equipment and related supplies in 1995. If grandfathered beneficiaries are excluded, the estimated questionable amount is $7.5 million.

Of the 41 sample beneficiaries who did not meet the pump criteria, 23 were in skilled nursing facilities, 4 were in regular nursing facilities, 1 was in a custodial care facility, and 13 were at home. Excluding grandfathered beneficiaries, 23 sample beneficiaries did not meet the pump criteria, 11 were in skilled nursing facilities, 3 were in regular nursing facilities, 1 was in a custodial care facility, and 8 were at home.

## CERTAIN MEDICAL NECESSITY GUIDELINES FOR THE PUMP DELIVERY METHOD MAY BE VULNERABLE TO ABUSE

Our medical reviewers believe two medical necessity criteria for the pump delivery method may be vulnerable to abuse. One is the formula administration rate of less than 100 cc per hour, and the other is the aspiration or reflux criterion.

Thirty-seven percent of non-grandfathered beneficiaries who met medical necessity guidelines for the pump method of delivery did so based only on the administration rate criterion. But the medical reviewers found that these beneficiaries did not have documentation for conditions warranting a slow delivery rate. If these beneficiaries'

pump claims had been deemed medically unnecessary, Medicare and its beneficiaries would have saved an estimated $28 million in 1995.

If a rate of administration less than 100 cc per hour is written on the CMN, Medicare considers the pump medically necessary. The reason why the beneficiary needs such a slow administration rate need not be documented. Our medical reviewers question why Medicare considers a slow rate, alone, presumptive evidence of meeting guidelines for the pump delivery method. They expressed concern that the slow rate, and therefore the pump, may have been prescribed for the convenience of nursing home staff. Among our sample beneficiaries, 61 percent were in skilled nursing facilities and 7 percent were in regular nursing facilities. The remaining 31 percent lived at home.

The other criterion which may be vulnerable to abuse is the documentation of aspiration/reflux as the medical reason for requiring the pump delivery method. Our medical reviewers believe that billers may be misinterpreting this criterion. Aspiration during swallowing is a common reason for initiating tube feedings. Once a tube is inserted, it by-passes the dysfunctional area. Aspiration during tube feeding, on the other hand, is due to reflux. The presence of aspiration from swallowing does not mean there is a risk of aspiration from reflux. The reviewed medical charts generally did not demonstrate that aspiration was from reflux.

Since Medicare reimburses claims where aspiration alone is indicated, and where a slow administration rate alone is documented, our medical reviewers determined those claims medically necessary. But they believe Medicare should clarify the one criterion, specifying that aspiration must be due to reflux, and should strengthen the second criterion by requiring documentation of a condition that warrants a slow administration rate.

# RECOMMENDATIONS

We recognize that it would not be manageable or cost effective for DMERCs to conduct a medical review for every claim. However, we believe the vulnerabilities we found with special enteral formulas and the pump delivery method require attention. We have two recommendations. The first has to do with Part B claims review, and the second has to do with changing the structure of payment for beneficiaries in nursing homes.

We recommend that DMERCs consider selecting claims for special formulas, pump equipment, and/or pump supply kits when they determine target areas for focused medical reviews. This recommendation has the added advantage of addressing claims for all beneficiaries regardless of place of service.

We recommend that when enteral nutrition is provided in nursing homes, the Medicare program should cover enteral formulas, equipment, and supplies under the nursing home daily rate rather than under Part B. Of beneficiaries with Part B enteral nutrition claims, more than two-thirds reside in homes. We believe if enteral nutrition therapy products are bundled into the nursing home daily rate, nursing homes will be motivated to select the most economical and appropriate formulas and delivery methods for beneficiaries.

## COMMENTS

A draft of this report was reviewed by the Health Care Financing Administration (HCFA) and the Assistant Secretary for Planning and Evaluation. Both concurred with our recommendations. In addition, HCFA provided information about several initiatives they are pursuing to address problems raised in this report. The full text of HCFA's comments are in Appendix C.

# APPENDIX A

## RECENT OFFICE OF INSPECTOR GENERAL STUDIES ON ENTERAL NUTRITION

| Issued | Title and Number |
|---|---|
| 1997 | *Enteral Nutrition Therapy: Medical Necessity*, OEI-03-94-00022. |
| 1997 | *Medicare Payments for Enteral Nutrition Therapy Equipment and Supplies in Nursing Homes,* OEI-06-92-00866. |
| 1996 | *Enteral Nutrient Payments in Nursing Homes,* OEI-06-92-00861. |
| 1996 | *Payments for Enteral Nutrition: Medicare and Other Payers*, OEI-03-94-00021. |
| 1995 | *Medicare Payments for Non-Professional Services in Skilled Nursing Facilities*, OEI-06-92-00864. |
| 1995 | *Coverage of Enteral Nutrition Therapy: Medicare and Other Payers*, OEI-03-94-00020. |

# APPENDIX B

ESTIMATES AND CONFIDENCE INTERVALS — PAGE

## ESTIMATES AND CONFIDENCE INTERVALS

We used the Survey Data Analysis (SUDAAN) software package to compute percentage, allowance and confidence interval estimates presented in the following tables. Estimates are weighted based on the stratified random sample design and are reported at the 95 percent confidence level. Tables presenting questionable allowance estimates are followed by narratives explaining our allowance estimation procedures.

Table 1.

**Distribution of Beneficiaries by Determination of Medical Necessity for Enteral Nutrition Therapy**

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Percent | 95% Confidence Interval | Weighted Percent | 95% Confidence Interval |
| Met Criteria | 77.49 | 73.00-81.98 | 79.91 | 75.40-84.42 |
| Did Not Meet Criteria | 3.92 | 1.84-6.00 | 3.18 | 1.22-5.14 |
| Insufficient/ Conflicting Documentation | 18.59 | 14.42-22.76 | 16.91 | 12.68-21.14 |

Table 2.

**Questionable Medicare Allowance Estimates for Enteral Nutrition Therapy**

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Total Estimate | 95% Confidence Interval | Weighted Total Estimate | 95% Confidence Interval |
| Questionable Medicare Allowances | $17,584,195 | $12,177,027-$22,991,363 | $12,166,757 | $7,732,654-$16,600,860 |

For beneficiaries who did not meet enteral medical necessity criteria, SUDAAN was used to estimate total Medicare allowances for unnecessary enteral therapy claims, including formula, equipment and supplies. The SUDAAN 5 percent May 1995 estimates were then generalized to 100 percent 1995 estimates. A second allowance estimate was developed after removing grandfathered beneficiaries from the analysis. The allowance estimate drops from $17.6 million to $12.2 million for medically unnecessary enteral therapy claims in 1995 after removing grandfathered beneficiaries.

Table 3.

## Distribution of Beneficiaries by Whether Caloric Criteria Were Met

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Percent | 95% Confidence Interval | Weighted Percent | 95% Confidence Interval |
| Met Caloric Criteria | 88.78 | 85.43-92.13 | 91.10 | 87.91-94.29 |
| Did Not Meet Caloric Criteria | 4.42 | 2.26-6.58 | 3.19 | 1.29-5.09 |
| Conflicting Information | 6.79 | 4.10-9.48 | 5.72 | 3.07-8.37 |

Table 4.

## Distribution of Beneficiaries by Whether Special Enteral Nutrition Formula Was Used

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Percent | 95% Confidence Interval | Weighted Percent | 95% Confidence Interval |
| Beneficiaries Used Special Formula | 26.73 | 22.52-30.94 | 24.40 | 20.13-28.67 |
| Beneficiaries Did Not Use Special Formula | 73.27 | 69.06-77.48 | 75.60 | 71.33-79.87 |

Table 5.

**Distribution of Beneficiaries by Determination of Medical Necessity for Special Enteral Nutrition Formula**

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Percent | 95% Confidence Interval | Weighted Percent | 95% Confidence Interval |
| Need for Special Formula Documented | 66.38 | 57.72-75.04 | 76.89 | 68.48-85.30 |
| Need for Special Formula Not Documented | 22.96 | 15.41-30.51 | 10.25 | 4.78-15.72 |
| Conflicting Information | 10.66 | 4.64-16.68 | 12.86 | 5.73-19.99 |

Table 6.

**Questionable Medicare Allowance Estimates for Special Enteral Formula**

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Total Estimate | 95% Confidence Interval | Weighted Total Estimate | 95% Confidence Interval |
| Questionable Medicare Allowances | $7,984,260 | $5,518,183-$10,450,338 | $2,907,435 | $1,515,193-$4,299,678 |

For beneficiaries where medical necessity for special enteral formula was not documented, we used SUDAAN to estimate total Medicare allowances and services for undocumented special formula in 1995. Special formulas are those with HCFA procedure codes B4151, B4153-B4156, and XX030-XX077. Medicare reimburses at the B4150 level if medical necessity for special formula is not documented.

We multiplied undocumented special formula services by Medicare's per unit controlling allowable for code B4150. We then subtracted this quantity from Medicare allowances for undocumented special formula, and the difference is our estimate of questionable allowances.

When grandfathered beneficiaries were removed from the analysis, the allowance estimate drops from $8 million to about $2.9 million in questionable allowances for undocumented special enteral formula in 1995.

Table 7.

## Distribution of Beneficiaries by Whether Pump Delivery Method Was Used

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Percent | 95% Confidence Interval | Weighted Percent | 95% Confidence Interval |
| Beneficiaries Used Pump Method | 77.63 | 73.00-82.26 | 76.36 | 71.40-81.32 |
| Beneficiaries Did Not Use Pump Method | 22.37 | 17.74-27.00 | 23.64 | 18.68-28.60 |

Table 8.

## Distribution of Beneficiaries by Determination of Medical Necessity for Pump Delivery Method

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Percent | 95% Confidence Interval | Weighted Percent | 95% Confidence Interval |
| Met Pump Criteria | 80.29 | 75.33-85.25 | 84.76 | 80.00-89.52 |
| Did Not Meet Pump Criteria | 13.58 | 9.35-17.81 | 8.91 | 5.15-12.67 |
| Conflicting Information | 6.13 | 3.05-9.21 | 6.33 | 3.06-9.60 |

Table 9.

**Questionable Medicare Allowance Estimates for Pump Delivery Method**

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Total Estimate | 95% Confidence Interval | Weighted Total Estimate | 95% Confidence Interval |
| Questionable Medicare Allowances | $11,513,424 | $7,062,657-$15,964,191 | $7,535,529 | $3,794,730-$11,276,328 |

For beneficiaries where medical necessity for the pump delivery method was not documented, we used SUDAAN to estimate total Medicare allowances for undocumented pump equipment and supply kit claims. We computed total allowances and services for undocumented pump equipment and supply kits separately, because when Medicare denies pump delivery method claims, it pays for the substitute gravity delivery method.

We multiplied undocumented pump supply kit services by the difference between the cost of a pump supply kit and the cost of a substitute gravity supply kit to estimate questionable Medicare allowances for undocumented pump supply kits. Medicare paid an estimated $8.2 million for undocumented pump supply kits in 1995. Medicare allowances for undocumented pump equipment in 1995 totaled an estimated $3.3 million. By adding these two figures, we estimated that Medicare paid about $11.5 million for undocumented pump delivery method claims in 1995.

When we removed grandfathered beneficiaries from the analysis, the allowance estimate drops to $7.5 million for undocumented pump delivery method claims in 1995.

Table 10.

**Distribution of Beneficiaries Who Met Pump Criteria Based Solely on Administration Rate**

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Percent | 95% Confidence Interval | Weighted Percent | 95% Confidence Interval |
| Administration Rate Only Criteria Documented | 37.72 | 31.06-44.38 | 37.41 | 30.51-44.31 |
| Administration Rate NOT Only Criteria Documented | 62.28 | 55.62-68.94 | 62.59 | 55.69-69.49 |

Table 11.

**Questionable Medicare Allowance Estimates for Beneficiaries Who Met Pump Criteria Based Solely on Administration Rate**

| | All Beneficiaries | | Non-Grandfathered Beneficiaries | |
|---|---|---|---|---|
| | Weighted Total Estimate | 95% Confidence Interval | Weighted Total Estimate | 95% Confidence Interval |
| Questionable Medicare Allowances | $29,035,305 | $22,200,311-$35,870,298 | $28,000,773 | $21,194,606-$34,806,940 |

We used SUDAAN to estimate questionable Medicare allowances for the pump delivery method for beneficiaries where medical necessity for this method was documented based solely on the administration rate criterion. The procedure used to compute these estimates is explained under Table 9.

We estimated that Medicare and its beneficiaries could have saved about $29 million in 1995 if these beneficiaries' pump delivery method claims had been deemed medically unnecessary. When grandfathered beneficiaries are removed from the analysis, the estimate of potential Medicare savings drops to $28 million.

Table 12.

**Distribution of Beneficiaries by Place of Service on May 1995 Formula Claim**

| | Weighted Percent | 95% Confidence Interval |
|---|---|---|
| Skilled Nursing Facility | 61.02 | 56.47-65.57 |
| Nursing Facility | 7.03 | 4.70-9.36 |
| Custodial Care Facility | 0.57 | 0-1.33 |
| Home | 31.38 | 27.07-35.69 |

# APPENDIX C

COMMENTS FROM THE HEALTH CARE FINANCING ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

The Administrator
Washington, D.C. 20201

DATE: JUN - 7 1997

TO: June Gibbs Brown
Inspector General

FROM: Bruce C. Vladeck
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Enteral Nutrition Therapy: Medical Necessity," (OEI-03-94-00022)

We reviewed the above-referenced report concerning the vulnerabilities found with the use of special enteral formulas and pump delivery methods.

Our comments are attached for your consideration. Thank you for the opportunity to review and comment on this report.

Attachment

Health Care Financing Administration (HCFA) Comments on
Office of Inspector General (OIG) Draft Report entitled "Enteral Nutrition Therapy: Medical Necessity," (OEI-03-94-00022)

OIG Recommendation

DMERCs should consider selecting claims for special formulas, pump equipment, and/or pump supply kits when they determine target areas for focused medical reviews.

HCFA Response

We concur. HCFA is currently involved in several efforts to reduce and control enteral nutrition costs. HCFA convened a workgroup to focus on ways to reduce costs for the enteral nutrition therapy (ENT) benefit. The workgroup comprising HCFA Central Office and Dallas Regional Office staff is developing a pricing scheme to collapse enteral nutrient codes for category IV, a defined formula for special metabolic needs, and category V, which covers modular components like protein, carbohydrates, and fats. This will be accomplished by weighting the 1995 Medicare allowances paid under codes from within the respective categories and using the average of the product-specific allowances paid under codes from within each respective category. The workgroup is also exploring other actions such as consolidated billing, competitive bidding strategies, implementing a fee schedule for enteral nutrients, or bundling payments for ENT into the nursing facility per diem. Additionally, durable medical equipment regional carriers targeted their focused medical review process on the ENT benefit. Edits are in place to look at claims featuring payments for pump supply kits, pump equipment, and special formulas, specifically B4035, B4150, and B9002. The results of these edits from the period April-June 1996 to July-September 1996 identified a total savings of $8.4 million.

OIG Recommendation

When tube feedings are provided in nursing homes, the Medicare program should cover enteral formulas, equipment, and supplies under the nursing home daily rate rather than under Part B. Of beneficiaries with Part B enteral nutrition claims, more than two-thirds reside in homes. If tube feeding products are bundled into the nursing home daily rate, nursing homes will be motivated to select the most economical and appropriate formulas and delivery methods for beneficiaries.

HCFA Response

We concur. HCFA agrees enteral nutrition services supplied to skilled nursing facility patients should be covered and paid for on a per diem basis as routine services subject to the reasonable costs limit. While the statute does not contain this condition, the President's proposed fiscal year 1998 budget provides for a prospective payment system and consolidated billing of ancillary services, under which enteral nutrition services provided to patients during a Part A stay (whether provided under Part A or Part B) would be billed under Part A and included in the prospective per diem rate.