Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PAYMENTS FOR THERAPEUTIC SHOES

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E X E C U T I V E S U M M A R Y

PURPOSE

This report assesses the propriety of billings for therapeutic footwear provided to Medicare beneficiaries.

BACKGROUND

The Medicare Part B benefit covers therapeutic footwear for beneficiaries with diabetes and one or more of six qualifying conditions. According to documentation guidelines specified by Medicare, a doctor of medicine or a doctor of osteopathy who is treating the beneficiary's systemic diabetic condition under a comprehensive plan of care must certify the need for therapeutic footwear. This physician must also attest that the beneficiary suffers from one or more of the qualifying conditions.

A podiatrist or other physician must order or prescribe the necessary footwear. The footwear then must be fitted and furnished by a podiatrist or other qualified individual, such as a pedorthist, orthotist, or prosthetist.

If the certification statement completed by the physician who is treating the patient's systemic diabetic condition indicates that all Medicare requirements are met, the billing entity submits a claim form to the Durable Medical Equipment Regional Carrier (DMERC) for reimbursement, adding a ZX modifier to the appropriate procedure code. The ZX modifier certifies that all coverage requirements have been met, and pertinent documentation reflecting this is available in the supplier's files.

Eligible beneficiaries may receive either one pair of custom-molded shoes or one pair of depth shoes per year. According to DMERC policy, the beneficiary must have a foot deformity in order to be eligible for custom-molded shoes. In addition, beneficiaries receiving custom shoes are eligible to receive two pairs of custom-molded inserts per year. Beneficiaries receiving depth shoes are allowed three pairs of custom-molded inserts.

Suppliers of therapeutic footwear are reimbursed on a reasonable-charge basis. In 1996, maximum reasonable charge limits were $368 per pair for custom shoes, $123 per pair for depth shoes, and $62 per pair for inserts. Medicare allowances for these three products doubled from 1994 to 1996, rising from $7 million to $13.9 million.

FINDINGS

Documentation for 57 percent of therapeutic shoe claims was missing or inadequate.

We found that suppliers billed Medicare for providing therapeutic footwear to beneficiaries even though they did not have the required documentation to support medical necessity. In almost all of these cases, the suppliers had used a ZX modifier indicating that the proper documentation was on file. Problems included no orders and no physician certifications, improperly completed physician certifications, and physician certifications signed by podiatrists. We calculated that $7.7

million of the $13.9 million spent on therapeutic shoes and inserts in 1996 was improper due to inadequate documentation.

Medicare guidelines do not clearly define qualifications of non-physician entities who furnish therapeutic footwear.

The only requirement with respect to footwear expertise states, "The footwear must be fitted and furnished by a podiatrist or other **qualified** (emphasis added) individual **such as** (emphasis added) a pedorthist, orthotist or prosthetist." However, the guidelines do not specify standards, training, or minimum qualifications for non-physician entities. Suppliers do not have to submit any evidence of their expertise to Medicare.

Beneficiaries' responses indicate questionable eligibility.

A few beneficiaries self-reported that they did not have diabetes or other qualifying conditions. Almost half of the beneficiaries receiving custom-molded shoes denied having the requisite foot deformity.

Some beneficiaries report problems with the footwear.

Thirteen percent of beneficiaries reported seldom or never wearing the shoes. Most did not complain to the supplier; they simply stopped wearing the footwear.

There is potential for enormous growth in the shoe program.

The potential number of therapeutic footwear beneficiaries has barely been tapped, with less than 1 in 50 Medicare-aged diabetics receiving shoes in 1996. There are undoubtedly many diabetic beneficiaries who could benefit from therapeutic footwear, yet have not taken advantage of the benefit. At the same time, ambiguous guidelines and aggressive marketing practices may cause beneficiaries who do not need shoes to receive them. As a result, allowances for therapeutic footwear could rise to hundreds of millions of dollars per year.

RECOMMENDATIONS

We believe that Medicare coverage as well as documentation requirements should be revised. The lack of specific guidelines and the existence of ambiguous requirements have unnecessarily contributed to the growth of Medicare expenditures for therapeutic footwear. Therefore, we believe it is vital for the Health Care Financing Administration (HCFA) to remedy the questionable practices and irregularities uncovered in our inspection. We recommend that HCFA, in concert with the DMERCs and concerned national organizations, devise a strategy to 1) make coverage requirements more explicit and specific, 2) eliminate the documentation problems we encountered, and 3) develop a plan to ensure that the therapeutic footwear benefit contains quality assurance safeguards.

AGENCY COMMENTS

The HCFA concurred with our recommendations. However, they indicated that implementation would be difficult owing to a lack of financial resources. In order to secure adequate funding to

oversee benefits such as therapeutic footwear, HCFA has been working with Congress to explore various options. In response, HCFA proposed using an educational approach with suppliers, emphasizing coverage requirements and the importance of proper documentation. With respect to our recommendation regarding quality assurance safeguards, HCFA said it was unclear whether assuring appropriate documentation would meet the goal of instituting quality assurance safeguards. The HCFA also provided technical comments concerning two coverage aspects of the therapeutic footwear benefit, "poor circulation" and foot deformity. Further, they also provided technical comments about our future cost projections.

We concur with HCFA's proposal to undertake an educational initiative for diabetic footwear. Still, we believe further efforts, such as those suggested in our recommendations, are needed to curb the questionable practices and irregularities detailed in our report. With regard to our recommendation on quality assurance, we would like to clarify that documentation is a separate and distinct issue. We continue to believe that HCFA should work with the DMERCs and interested national organizations to develop a plan to ensure that the therapeutic footwear benefit contains quality assurance safeguards.

I N T R O D U C T I O N

PURPOSE

This report assesses the propriety of billings for therapeutic footwear provided to Medicare beneficiaries.

BACKGROUND

Title XVIII of the Social Security Act prescribes coverage requirements under Part B of the Medicare program. Part B covers services and items including durable medical equipment (DME). Although therapeutic footwear products for diabetics are not considered DME, they are covered under Medicare Part B, and claims for reimbursement are processed by the DME regional carriers (DMERCs). The four DMERCs process all Medicare claims for prosthetics, orthotics, medical supplies, and other DME. They are under contract with the Health Care Financing Administration (HCFA), the agency which administers the Medicare program.

An estimated 16 million people in the United States have diabetes, although half may not know they have the illness. Every year, about 625,000 new cases are diagnosed. Foot problems cause 20 percent of diabetic hospitalizations. Diabetics undergo approximately 54,000 lower limb amputations each year.

Medicare Coverage of Therapeutic Footwear

According to Medicare Carriers Manual section 2134, Medicare covers therapeutic footwear for vulnerable beneficiaries who meet certain requirements. Medicare coverage for therapeutic footwear became effective May 1, 1993. To meet the eligibility requirements, beneficiaries must be receiving treatment for diabetes. They must also have one or more of the following conditions:

1. Peripheral neuropathy with evidence of callus formation.
2. A history of pre-ulcerative calluses.
3. A history of previous foot ulceration.
4. Foot deformity.
5. Previous amputation of a foot or part of a foot.
6. Poor circulation.

According to HCFA's documentation guidelines, a doctor of medicine or a doctor of osteopathy who is treating the beneficiary's systemic diabetic condition under a comprehensive plan of care must certify the need for therapeutic footwear. This physician must also certify that the beneficiary suffers from one or more of the six qualifying conditions cited above. (A certification form recommended by the DMERCs is presented in Appendix A.)

A podiatrist or other physician must order or prescribe the necessary footwear. The footwear must be fitted and furnished by a podiatrist or other qualified individual, such as a pedorthist, orthotist, or prosthetist. The certifying physician may not supply the footwear unless he or she is the only qualified individual operating in the geographical area serving the beneficiary's address.

An order for the footwear which has been signed and dated by the prescribing physician must be kept on file by the footwear supplier. If the prescribing physician is the supplier, a separate order is not required, but the footwear provided must be clearly noted in the beneficiary's record.

Generally, therapeutic footwear for diabetics is supplied and billed to the Medicare program by podiatrists or non-physician entities which specialize in footcare supplies and products. If the certification statement completed by the physician who is treating the patient's systemic diabetic condition indicates that all Medicare requirements are met, the billing entity submits a claim form to the DMERC for reimbursement, adding a ZX modifier to the appropriate procedure code. The ZX modifier certifies that all coverage requirements have been met, and pertinent documentation reflecting this is available in the supplier's files. The documentation itself does not have to be submitted with the claim form. To emphasize the importance of the ZX modifier as well as the integrity of Medicare billings, HCFA has stated, "If a supplier uses a ZX modifier despite the applicable requirements not being met, the supplier is submitting fraudulent claims to the Medicare program."

Coverage Limitations

Eligible beneficiaries may receive one pair of custom-molded shoes or one pair of depth shoes per calendar year. Beneficiaries receiving custom-molded shoes may receive two pairs of inserts (in addition to the inserts provided with the shoes) per year. Beneficiaries receiving depth shoes are eligible for up to three additional pairs of inserts each year.

The HCFA defines a custom-molded shoe (procedure code A5501) as one that 1) is constructed over a model of the patient's foot, 2) is made from leather or other suitable material of equal quality, 3) has removable inserts that can be altered or replaced if necessary, and 4) has some form of shoe closure. According to instructions contained in policies issued by the DMERCs, a beneficiary must have a foot deformity to qualify for custom-molded shoes.[1]

A depth shoe (procedure code A5500), according to HCFA guidelines, 1) has a full-length heel-to-toe filler which, when removed, provides a minimum of 3/16" of additional depth used to accommodate custom-molded or customized inserts, 2) is made from leather or other suitable material of equal quality, 3) has some form of shoe closure, and 4) is available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoe.

Inserts (procedure code A5502) are defined as total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot, and are made of suitable materials with respect to the individual patient's needs.

Medicare Allowances for Therapeutic Footwear

Suppliers of therapeutic footwear are reimbursed on a reasonable-charge basis rather than a fee

[1] "A custom-molded shoe (A5501) is covered when the patient has a foot deformity which cannot be accommodated by a depth shoe." (Region A DMERC Supplier Manual 20.1-3, Region B DMERC Supplier Manual XVII-166, Region C DMERC Supplier Manual 18.33, and Region D DMERC Supplier Manual IX-120.)

schedule. Medicare limits payment to 80 percent of the reasonable charge. In 1996, maximum reasonable charge limits were $368 per pair of custom-molded shoes, $123 per pair of depth shoes, and $62 per pair of inserts. These amounts include reimbursement for any expenses incurred for the fitting of the footwear.

Medicare allowances for depth shoes, custom-molded shoes, and inserts doubled from 1994 to 1996, going from $7 million to $13.9 million. In these 3 years, allowances for depth shoes more than doubled, rising from $2.1 million to about $5 million. Allowances for custom-molded shoes increased 50 percent from $3 million to $4.5 million. Allowances for inserts almost tripled, rising from $1.8 million to $4.4 million.

METHODOLOGY

We examined sections of the Medicare Carriers Manual and DMERC Supplier Manuals regarding the provision of therapeutic shoes and inserts for diabetics. Additionally, we reviewed data on diabetes in order to gain insight into the nature and prevalence of the disease and its impact on the foot. We also contacted several relevant national organizations to obtain information about diabetes and therapeutic foot care.

We obtained 1996 Medicare allowances for therapeutic footwear from the Part B Extract Summary System (BESS). In 1996, 97 percent of the total allowances were for procedure codes A5500, A5501, and A5502. Therefore, we focused the inspection on these three codes.

We selected our sample of beneficiaries and suppliers by using all of the 1996 claims for A5500 and A5501 from a 1 percent DME claims file developed from HCFA's National Claims History File. The random sample consisted of 474 claims (one claim per beneficiary) submitted by 333 suppliers. Fifteen percent of suppliers were podiatrists. The remaining 85 percent were non-physician entities such as pedorthists, shoe stores, and DME companies.

The selection of the three codes represented $11.3 million in allowances out of a universe of $12.1 million in total therapeutic footwear allowances when the sample was selected. At the conclusion of the study, we obtained more complete figures for 1996 which revealed that the three selected codes had accounted for $13.9 million in allowances out of a total of $14.4 million.

Additionally, we obtained 1996 Part B claims histories for each beneficiary in the sample. The histories displayed the procedure code and date of service for each Part B service provided in 1996 along with the unique physician identification number (UPIN) for the physician rendering the service.

Beneficiary Information Requests

We contacted the beneficiaries by telephone and by mail. We first removed the beneficiaries known to be deceased from the pool of potential respondents, leaving us with 443. We then called the beneficiaries with known telephone numbers. We mailed questionnaires to those beneficiaries whom we could not contact by telephone.

Our beneficiary information requests covered several major areas, including, 1) confirmation of diabetes and qualifying conditions, 2) identification of the physician treating the diabetes, 3)

confirmation of the receipt of footwear, and 4) satisfaction with the products received. In all, 337 beneficiaries or close relatives completed the information requests (76 percent response rate).

Supplier Information Requests

In this report, we use the term "supplier" to refer to the entity which billed Medicare for the therapeutic shoes provided to the beneficiary. We mailed information requests to the 333 suppliers representing the 474 sample claims. Claims for deceased beneficiaries were not excluded from these requests.

The supplier data collection instruments contained requests for copies of documentation, including, 1) the shoe order or prescription, 2) the physician certification, 3) the supplier's credentials, and 4) a picture and/or description of the shoes provided. We also asked questions about the suppliers' marketing practices to determine how information about the benefit was reaching the beneficiaries. Suppliers returned completed requests for 462 of the 474 sampled claims (97.5 percent response rate). We also visited a number of suppliers and certifying physicians to confirm the accuracy of the information received.

Analysis

We analyzed the beneficiary responses concentrating on several key issues. We checked to see if the beneficiaries verified having diabetes and receiving special shoes. We also reviewed beneficiary responses to questions concerning their attending physicians, foot problems, typical footwear utilization patterns, and satisfaction with footwear.

We reviewed the supplier responses to confirm that each piece of requested documentation--particularly the physician certification--was enclosed. We examined the certifications to ensure that the forms were completed, signed, and dated by the physicians treating the beneficiaries' systemic diabetic conditions.

We checked footwear orders and physician certifications to ensure that beneficiaries had one or more of the six qualifying conditions to receive the footwear and that they were under a comprehensive plan of care for their diabetes. We determined that Medicare guidelines for therapeutic footwear were not met if orders or certifications were missing, if certifications were incomplete, or if certifications were completed by podiatrists.

We compared beneficiary and supplier responses to related questions to detect inconsistencies and aberrant practices. We sought to verify that the name of the physician treating the beneficiary's diabetic condition was the same physician completing the physician's certification form. We also checked the Part B billing histories to determine if the physician's UPIN number indicated that services were provided in 1996.

We used chi-square independence tests to determine if certain categorical variables influenced other categorical variables. The size of the chi-square test statistic indicates whether the difference between the observed and expected values is due merely to chance or reflects the influence of one variable over the other.

Chi-square statistics, percentage estimates and corresponding 95 percent confidence intervals for

beneficiary and supplier data were computed using standard statistical formulas for systematic random samples. For categorical variables, the sample size was calculated to produce estimates within 5 percent of the true value at the 95 percent confidence level. Point estimates and confidence intervals are provided in Appendix B.

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

F I N D I N G S

DOCUMENTATION FOR 57 PERCENT OF THERAPEUTIC SHOE CLAIMS WAS MISSING OR INADEQUATE.

We found that suppliers billed Medicare for providing therapeutic footwear to beneficiaries even though they did not have the required documentation to support medical need for the products. Medicare policy requires that both an order/prescription and a physician's certification be kept on file by the supplier in order to establish medical need for the footwear. In all but five of the questioned claims, suppliers had appended a ZX modifier indicating that they had the required documentation on file. Problems with physician certifications predominated the documentation problems, although there were also claims without the required order/prescription.

We estimate that Medicare paid $6.2 million of the $11.3 million on which our sample was based

for claims that did not have the required documents to support medical need. Estimated allowances for claims without the required documentation total $7.7 million when applied to the $13.9 million allowed for the three codes in 1996. In all, approximately 57 percent of the claims from the responding suppliers lacked appropriate documentation to justify coverage. The documentation irregularities we found are detailed below. (Note: Adding the individual categories of documentation problems does not add up to the total because some claims had more than one problem.)

Physician certifications were the most common documentation problem.

Almost 50 percent of the physician certifications for therapeutic footwear were improper. In total, for 230 of the 462 respondent claims, either there were no certifications on file, the certifications were completed improperly or had information missing, or the certifications were completed by a podiatrist.

- Suppliers failed to submit physician certification statements for 18 percent of therapeutic footwear claims. After they received our requests, some suppliers obtained and submitted a physician certification statement signed in 1997 as support for the claim filed in 1996.

- Physicians completed certifications improperly or left out vital information for 26 percent of therapeutic footwear claims. The problems we found included, 1) no qualifying conditions indicated, 2) undated or outdated certifications, or 3) no foot deformities documented for beneficiaries for whom custom-molded shoes were prescribed.

- Podiatrists completed physician certifications for 10 percent of therapeutic footwear claims. Medicare requires that the physician certification must be completed by the physician who is managing the patient's diabetic illness. According to DMERC instructions, "The certifying physician cannot be a podiatrist."

Additionally, for 6 percent of therapeutic footwear claims, we questioned whether the certifying physician was the physician responsible for managing the patient's systemic diabetic condition. In these cases, the UPIN numbers of the certifying physicians never appeared in the beneficiaries' 1996 Part B billing histories, and the beneficiaries had provided the names of different physicians as their primary doctors. This raised doubts whether the "comprehensive plan of care" requirement had been met. We realize, however, that there could be valid reasons why a physician's services do not appear among UPIN listings.

The physician who manages a patient's systemic diabetic illness under a comprehensive plan of care is usually either an internist, general practitioner, or family medicine specialist. However, we found that for some claims, the certifying physician was an orthopedic surgeon or rehabilitation specialist. While contact with some of these specialists indicates many of them feel they should be able to certify the need for shoes, Medicare guidelines seem to prohibit them from doing so, as they are not the primary physician managing the diabetes.

We felt we had insufficient information to make a judgment in these cases. We will refer these cases to the DMERCs for their further review and disposition.

Some suppliers failed to obtain physician orders/prescriptions.

According to HCFA policy, the prescribing physician must complete an order or prescription which must be kept on file by the footwear supplier. If the prescribing physician is the supplier (such as a podiatrist), a separate order is not required. Podiatrists or other physicians supplied the footwear for 13 percent of the claims. For claims filed by non-physician suppliers, 16 percent did not have orders from the prescribing physicians. Approximately half of those with missing orders also had questionable certifications.

MEDICARE GUIDELINES DO NOT CLEARLY DEFINE QUALIFICATIONS FOR NON-PHYSICIAN ENTITIES WHO FURNISH THERAPEUTIC FOOTWEAR.

Medicare guidelines do not specify standards, training, or minimum qualifications for non-physician entities in the fitting and furnishing of therapeutic footwear. The only requirement with respect to footwear expertise states, "The footwear must be fitted and furnished by a podiatrist or other **qualified** (emphasis added) individual **such as** (emphasis added) a pedorthist, orthotist or prosthetist." It is unclear whether the original intent of this guideline was to require that a supplier be credentialed or be a pedorthist, prosthetist, or orthotist. Evidently, any individual with a Medicare provider number could purport to be a "qualified" shoe supplier and fit and provide therapeutic footwear. The individual does not have to submit any evidence of their expertise to HCFA. According to some clinicians, therapeutic shoes may actually harm patients if they are fitted by inexperienced suppliers. They suggest that shoes should only be fitted by practitioners trained to work with the diabetic foot.

In our requests to non-physician entities for information, we asked for evidence of expertise, such as credentials in pedorthics. Of the 273 non-physician suppliers who responded to our requests, 52 (19 percent) did not provide credentials. Furthermore, suppliers who did not provide credentials for a claim were significantly less likely to have the proper documentation on file. (See computation notes in Appendix B.)

BENEFICIARY RESPONSES INDICATE THAT SOME WERE NOT ELIGIBLE FOR THE FOOTWEAR PROVIDED.

A number of beneficiaries reported not having the conditions necessary to qualify for the footwear provided.

- Three percent of beneficiaries denied having diabetes.
- Twelve percent of beneficiaries denied having any of the six qualifying conditions.
- Forty-seven percent of beneficiaries who received custom-molded shoes denied having foot deformities or amputations, a required condition for Medicare's coverage of custom-molded shoes, according to DMERC instructions.

We will forward the claims involving these denials to the appropriate DMERCs for their review.

SOME BENEFICIARIES REPORT PROBLEMS WITH THE FOOTWEAR.

Most of the beneficiaries who reported receiving shoes said they were satisfied with the footwear. However, 20 percent of beneficiaries reported that they were dissatisfied. One beneficiary wrote, "Most of these people, once they get your money, they can care less about your satisfaction."

While most responding beneficiaries (including some who expressed dissatisfaction) reported that they wore the shoes often, 13 percent reported that they seldom or never wore the shoes. Reasons commonly given for seldom or never wearing the shoes included, 1) the shoes fit poorly, 2) the shoes hurt their feet, and 3) the shoes were "heavy" or "hot." (One beneficiary reported that the shoes caused an ulcer which led to an amputation.) Most of the beneficiaries who reported these problems did not complain to their shoe suppliers. They simply stopped wearing the footwear.

We calculated that Medicare allowed $1.1 million in 1996 for shoes which beneficiaries rarely or never wore. Clearly, the problem of ill-fitting or uncomfortable shoes has economic consequences as well as quality assurance issues. In our view, if Medicare is paying for a product, then the supplier should take appropriate steps to ensure that the product provided is suitable.

Finally, 4 percent of the beneficiaries with 1996 therapeutic footwear claims denied receiving shoes or inserts that year. These claims will also be forwarded to the DMERCs for review.

THERE IS POTENTIAL FOR ENORMOUS GROWTH IN THE SHOE PROGRAM.

While increasing allowances indicate that Medicare is paying more for therapeutic footwear each year, the potential number of eligible beneficiaries has barely been tapped. The potential for enormous growth in the therapeutic footwear benefit could produce both positive and negative consequences. Approximately 3.2 million Americans over the age of 65 have diabetes. If we assume that all these persons are Medicare-eligible, then less than one out of 50 received therapeutic footwear in 1996. There are undoubtedly numerous diabetic beneficiaries who need the shoes yet are not even aware the benefit exists. There have been numerous programs attempting to distribute information to these beneficiaries. When they begin to take advantage of the benefit, diabetic foot complications may decrease dramatically.

At the same time, ambiguous coverage guidelines and aggressive marketing practices may result in beneficiaries receiving shoes who may not actually have a need for the footwear. Not only would this result in increased allowances, but would also open the program up to the fraud and abuse that has plagued numerous areas of DME.

We believe that almost every diabetic beneficiary is technically eligible for, and may at some point become aware of, Medicare's therapeutic footwear benefit. To illustrate the potential cost for therapeutic footwear, we calculated cost estimates if between 20 and 90 percent of diabetic beneficiaries were to receive shoes and inserts. We calculated that if 20 percent of diabetic

beneficiaries received footwear, allowances could rise to over $150 million per year. If 50 percent of diabetic beneficiaries received footwear, allowances could rise to more than $380 million. Finally, if 90 percent receive footwear, allowances could total between $690 million and $1 billion annually. (See computation notes in Appendix C.)

Various factors will spur future growth.

We believe HCFA's inclusion of "poor circulation" as a qualifying condition for footwear will unnecessarily contribute to future growth. "Poor circulation" is a non-clinical, "catchall" term, according to one medical advisor, which connotes a variety of symptoms, such as numbness and tingling in the extremities and a "cold" feeling. One supplier we visited stated that almost every senior citizen with diabetes has poor circulation. However, he added, that does not mean they need therapeutic shoes.

Additionally, greater awareness of the therapeutic footwear benefit among physicians and suppliers, increased public relations and advertising activity among footwear manufacturers, and more aggressive marketing and billing practices by suppliers who specialize in therapeutic footwear products may further contribute to growth in the program.

We found an example of aggressive marketing and billing practices in one area of south Texas. Though only having four therapeutic footwear suppliers and less than one-half of 1 percent of the national population, this area accounted for 9 percent of 1996 allowances. Visits to this area revealed that suppliers engage in extensive advertising and public relations efforts, such as speaking at senior citizen gatherings and personally visiting physicians to educate them about therapeutic footwear. Additionally, 30 of the 32 sampled depth shoe claims from South Texas suppliers (94 percent) had billings for the maximum number (3) of inserts. In contrast, only 57 of the 325 depth shoe claims in the sample (18 percent) from suppliers outside of South Texas had billings for three inserts. If other suppliers begin to market their products and maximize insert billings in this manner, diabetic footwear allowances could increase dramatically.

R E C O M M E N D A T I O N S

We believe that Medicare coverage as well as documentation requirements should be revised. Clearly, the lack of specific guidelines and the existence of vague and ambiguous requirements has unnecessarily contributed to the growth of Medicare expenditures for therapeutic footwear. Because the potential growth is so great, we believe it is vital for HCFA to remedy the questionable practices and irregularities uncovered in our inspection. We recommend that HCFA, in concert with the DMERCs and concerned national organizations, devise a strategy to 1) make coverage requirements more explicit and specific, 2) eliminate the documentation problems we encountered, and 3) develop a plan to ensure that the therapeutic footwear benefit contains quality assurance safeguards. Such a strategy may include:

- Revising eligibility standards to either better define "poor circulation" or eliminate it as a qualifying condition.
- Clearly delineating the various specialties eligible to sign physician certifications and

orders/prescriptions.

- **!** Stressing to footwear suppliers (perhaps through a special bulletin) the importance of the ZX modifier and compliance with documentation guidelines.
- **!** Periodically reviewing a sample of therapeutic shoe claims to ensure that appropriate documentation is on file and that the ZX modifier is being properly used.
- **!** Developing standards to govern non-physician entities which fit and provide therapeutic footwear.

AGENCY COMMENTS

The HCFA concurred with all of our recommendations. However, they indicated that implementation would be difficult owing to a lack of financial resources. In order to secure adequate funding to oversee benefits such as therapeutic footwear, HCFA has been working with Congress to explore various options.

The HCFA stated that since suppliers are not required to submit documentation to the DMERCs, it is difficult to detect any problems using the normal claims processing system. However, HCFA advocated using an educational approach with suppliers, emphasizing coverage requirements and the importance of proper documentation.

With respect to our recommendation regarding quality assurance safeguards, HCFA commented that it was unclear whether ensuring appropriate documentation would meet the goal of instituting quality assurance safeguards.

The HCFA also provided technical comments. These comments related to our projections involving potential growth in the therapeutic footwear benefit, the presence of a foot deformity as a qualifying factor to receive custom-molded shoes, and "poor circulation" as a qualifying condition. The HCFA noted that neither the Medicare Carriers Manual nor the Social Security Act lists foot deformity as a qualifying condition for eligibility for custom-molded shoes. They agreed that poor circulation is a generalized condition that could easily apply to all beneficiaries; however, efforts to modify this requirement were unsuccessful because of opposition from the podiatric community. The full text of HCFA's comments is provided in Appendix D.

OIG RESPONSE

Recommendations

We appreciate HCFA's attention and concern regarding the issues and recommendations identified in this inspection. We concur with HCFA's proposal to undertake an educational initiative for diabetic footwear. Still, we believe further efforts, such as those suggested in our recommendations, are needed to curb the questionable practices and irregularities detailed in our report. We are hopeful that HCFA can secure the resources needed to carry them out.

With regard to our recommendation on quality assurance, we would like to clarify that documentation is a separate and distinct issue. In our report, we expressed concerns regarding ill-

fitting footwear provided to beneficiaries. We also delineated concerns about the qualifications of non-physician entities who fit and furnish therapeutic footwear.

As we indicated in our recommendation, we believe that HCFA, working with the DMERCs and interested national organizations, should develop a plan to ensure that the therapeutic footwear benefit contains quality assurance safeguards. The HCFA may wish to explore a number of options with these organizations before deciding on a specific course of action. Hopefully, collaboration with the DMERCs and industry organizations will lead to acceptable and effective safeguards.

Technical Comments

In response to HCFA's comments about future costs, we simply wanted to show what the cost could be if the large number of beneficiaries who were potentially eligible for therapeutic footwear began to use the benefit. The estimates were meant only to illustrate the cost of the benefit at potential utilization levels. We felt it would be prudent to consider the full potential impact of the vulnerabilities we have uncovered, especially the costs that could arise as a result of aggressive marketing practices such as those we have seen on certain kinds of Medicare benefits. The HCFA will have to monitor future increases in annual allowances to determine if utilization levels are increasing. In updating our work, we have already identified a significant growth in the program from 1996 to 1997. We found that 1997 allowances, which are 98 percent complete, show total allowances of about $19.5 million, an increase of approximately 40 percent over 1996 totals and almost a three-fold increase over 1994 levels.

With regard to the requirement that a beneficiary must have a foot deformity to qualify for custom-molded shoes, HCFA commented that this requirement is not specified in the Medicare Carriers Manual or the Social Security Act. However, we found this requirement in all four DMERC manuals, and we have included wording in the report to reflect this.

A P P E N D I X A

Statement of Certifying Physician for Therapeutic Shoes

Patient Name:_____

HIC #:_____

I certify that all of the following statements are true:

1) This patient has diabetes mellitus.

2) This patient has one or more of the following conditions: (circle all that apply):

a) History of partial or complete amputation of the foot
b) History of previous foot ulceration
c) History of pre-ulcerative callus
d) Peripheral neuropathy with evidence of callus formation
e) Foot deformity
f) Poor circulation

3) I am treating this patient under a comprehensive plan of care for his/her diabetes.

4) This patient needs special shoes (depth or custom-molded shoes) because of his/her diabetes.

Physician Signature:_____

Date Signed:_____

Physician Name (printed):_____

Physician Address:_____

_____

_____

Physician UPIN:_____

A P P E N D I X B

POINT ESTIMATES, CONFIDENCE INTERVALS, AND CHI-SQUARES

The tables below contain statistical estimates presented in the Findings section of the report. Chi-square statistics, point estimates and corresponding confidence intervals were computed using standard statistical formulas for a systematic random sample. For all categorical variables, the sample size was calculated to produce estimates within 5 percent of the true value at the 95 percent confidence level.

Medicare paid $6.2 million of the $11.3 million on which our sample was based for claims that did not have the proper documents to support medical need.

Point Estimate	95% Confidence Interval
$6,213,211	$5,595,101 - $6,831,321

When applied to the $13.9 million allowed for the 3 codes in 1996, allowances for claims without the required supporting documentation totaled $7.7 million.

Point Estimate	95% Confidence Interval
$7,650,418	$7,102,729 - $8,198,106

Medicare allowed $1.1 million in 1996 for shoes which beneficiaries rarely or never wear.

Point Estimate	95% Confidence Interval
$1,132,242	$781,392 - $1,483,093

Claims from suppliers who did not provide professional credentials were significantly more likely to have improper documentation.

	Improper Documentation	Proper Documentation	Total	% Improper Documentation
Credentials Not Provided	56	18	74	76%
Credentials Provided	178	149	327	54%
Overall	234	167	401	58%

CHI-SQUARE = 11.20 DEGREES OF FREEDOM=1 PROBABILITY=.001[2]

[1] This chi-square statistic indicates that we can reject the null hypothesis that providing credentials and having proper documentation are independent at the 99.9 percent confidence level.

A P P E N D I X C

CALCULATIONS ILLUSTRATING GROWTH POTENTIAL OF SHOE BENEFIT

Comparing claims data for therapeutic footwear with demographic information on Medicare beneficiaries indicates that the potential number of eligible beneficiaries has barely been tapped. Approximately 3.2 million Americans over the age of 65 have diabetes. If we assume that all these persons are Medicare-eligible, then less than one out of 50 received therapeutic footwear in 1996. To illustrate the potential cost to the program for therapeutic footwear, we calculated cost estimates assuming between 20 and 90 percent of diabetic beneficiaries may receive shoes and inserts. We calculated that if 20 percent of diabetic beneficiaries received footwear, allowances would most likely rise to over $150 million per year. If 50 percent of diabetic beneficiaries received footwear, allowances would rise to more than $380 million. Finally, if 90 percent receive shoes, allowances could total between $690 million and $1 billion annually.

We first calculated the cost of the average claim by dividing total allowances in our sample by the number of beneficiaries in our sample. We then used this number to estimate the number of beneficiaries receiving shoes in the entire population. Next, the incidence was calculated by dividing the number of beneficiaries who received shoes in 1996 into 3.2 million. Because some suppliers always maximized allowances by billing for three pairs of inserts, we also determined a maximum reimbursement per claim. Finally, we took these reimbursement estimates and multiplied them by the number of beneficiaries who would receive shoes at the 20 percent, 50 percent, and 90 percent level. The calculation steps are outlined below.

STEP 1

Sample Beneficiaries	Sample Allowances	Allowance per Beneficiary
474	$113,469	$239.39

STEP 2

Population Estimate	Allowance Estimate	Allowance per Beneficiary
47,400	$11,346,900	$239.39
58,364	$13,971,641	$239.39

STEP 3

Population Estimate	# of Diabetics Over 65	% of Older Diabetics Receiving Shoes	Incidence
58,364	3,200,000	1.8%	1 out of 55

STEP 4

	Max Expenditure Shoes and Inserts	Estimated Usage	Max Expenditure Per Beneficiary
Depth Shoes	$309	80%	$247.20
Custom Shoes	$492	20%	$98.40
Total		100%	$345.60

STEP 5

% of 3.2 Million Diabetics Over 65 Potentially Receiving Footwear	# of 3.2 Million Diabetics Over 65 Potentially Receiving Footwear	Projected Allowances at Current Reimbursement ($239.39)	Projected Allowances at Maximized Reimbursement ($345.60)
20%	640,000	$153,209,600	$221,184,000
50%	1,600,000	$383,024,000	$552,960,000
90%	2,880,000	$689,443,200	$995,328,000

A P P E N D I X D

HEALTH CARE FINANCING ADMINISTRATION COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

RECEIVED
1998 JUN 15 A 11:27
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DATE: JUN 11 1998

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Payments for Therapeutic Shoes" (OEI-03-97-00300)

We reviewed the above-referenced report that identifies questionable billing practices relating to therapeutic footwear provided to Medicare beneficiaries with diabetes. The audit found that Medicare allowed more than $7 million for therapeutic footwear claims with missing or inadequate documentation. The audit also found the lack of specific guidelines and standards has unnecessarily contributed to the growth of expenditures for therapeutic footwear.

Although the Health Care Financing Administration (HCFA) concurs with all of the OIG recommendations, implementation would be difficult. Our detailed comments are as follows:

OIG Recommendation 1
HCFA, in concert with the durable medical equipment regional carriers (DMERCs) and concerned national organizations, should devise a strategy to make coverage requirements more explicit and specific.

HCFA Response
We concur with the intent of the recommendation. However, given our limited resources, HCFA and the DMERCs may not be able to address the therapeutic footware issue in the near future. We have proposed to Congress various user fees which would help to provide adequate funding for administration of remedial programs such as this one.

OIG Recommendation 2
HCFA, in concert with the DMERCs and concerned national organizations, should eliminate the documentation problems encountered.

HCFA Response

We concur with the intent of the recommendation. It is difficult, however, to detect documentation problems through the DMERCs' normal claims processing system since the supplier is not required to submit documentation to the DMERCs, but must keep it on file for inspection. At present, we do not have the financial resources available to complete a substantial number of post-payment claims reviews that could identify documentation deficiencies in the information that is submitted by suppliers for reimbursement. However, we are working with Congress to obtain funding that may enable us to do this. In the meantime, we will remind suppliers of the importance of complying with documentation guidelines and of using the ZX modifier.

OIG Recommendation 3

HCFA, in concert with the DMERCs and concerned national organizations, should develop a plan to ensure that the therapeutic footwear benefit contains quality assurance safeguards.

HCFA Response

The OIG recommendation suggests we institute quality assurance safeguards and conduct periodic sample reviews of therapeutic shoe claims to ensure appropriate documentation is on file and the ZX modifier is being properly used. It is unclear whether ensuring appropriate documentation will meet the goal of instituting quality assurance safeguards.

Technical Comments

There is concern among our DMERC staffs that the projections in this report are somewhat excessive. For example, the report suggests that through extensive marketing by the suppliers, the increase of potential benefits would rise substantially. In spite of increased marketing efforts by suppliers, physicians or podiatrists must still certify the medical necessity of the shoes. The report states that if 90 percent of the diabetic population were to receive footwear, Medicare allowances could total between $690 million to $1 billion annually. However, based on our experience with Medicare beneficiaries with diabetes there is only a very small percentage who would want to receive these shoes.

The report states in several places that the beneficiary must have a foot deformity to qualify for custom shoes. However, neither the Medicare Carriers Manual (section 2134) nor the Social Security Act (section 1861(s)(12)) lists foot deformity as one of a list of qualifying criteria. Only one of these conditions is necessary, and it is not specified that foot deformity is required, unless it is the only condition the beneficiary presents. Nor is it necessary to have an amputation (as stated on page 8 of the report) if other qualifying

conditions are present. If there is another source for this information, perhaps in the DMERC manual, it would be helpful if the source were stated in the report.

We agree poor circulation is a generalized condition that could easily apply to all beneficiaries. However, HCFA's attempts to modify section 2323 of the carriers manual to clarify the conditions necessary to qualify for foot care have met with opposition from the podiatric community.

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