

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

MEDICARE ORTHOTICS



**JUNE GIBBS BROWN
Inspector General**

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EXECUTIVE SUMMARY

PURPOSE

To determine the extent of questionable billing practices for Medicare orthotics and how it relates to the orthotics industry and to carrier policies and procedures.

BACKGROUND

An orthosis is a device, sometimes called a brace, applied to the outside of the body that supports a body part. Recent Office of Inspector General (OIG) studies have raised concerns about orthotics in general. This inspection is one of many the OIG has undertaken addressing durable medical equipment and related devices.

Any supplier with a HCFA provider number can provide and bill for orthotics. Suppliers of orthotic devices include durable medical equipment companies, orthotists, pharmacies, and doctors' offices. Some suppliers specialize in orthotics while others supply orthotics as well as a wide range of durable medical equipment. Suppliers may manufacture the devices in their own workshops or obtain devices from other companies. An orthotist is a health professional who treats musculoskeletal disorders by designing and fitting custom-made orthoses. Orthotists are certified by professional organizations. No State presently licenses orthotists but several States are currently considering licensing legislation.

We used a combination of methods in conducting this inspection. A medical records review by medical experts determined if the physical conditions of our sample Medicare beneficiaries warranted the use of an orthotic device. We then examined the billing records of each beneficiary to look at additional aspects of the use of orthotics and related Part B services. We supplemented these reviews with a mail survey to Medicare beneficiaries, a mail survey to orthotic suppliers, telephone interviews with carrier representatives, and a review of carrier policies.

FINDINGS

At Least Nineteen Percent of Orthotics Provided are Medically Unnecessary

The medical record review found that at least 19 percent of the orthotic devices provided are medically unnecessary. Some beneficiaries who received orthotics did not have conditions that warrant the use of a device. This represents \$6.4 million in Medicare payments. Many of the unnecessary orthotics are not rehabilitative, as required. Another 5 percent of orthotic devices are medically questionable, which represents \$1.5 million. In many of these cases, a more sophisticated and expensive device was provided when a lesser device would have offered the same benefit.

Our method of medical review focused on the sample device and did not address the other

devices provided to the beneficiary in the sample year. Therefore, the percent of devices that are medically unnecessary is probably understated. To gain additional insights we conducted a review of billings. We found that 54 percent of the billing cases have some type of questionable orthotic billing. The two most common problems are many devices being billed over a short time frame and several seemingly unnecessary add-on devices being billed.

Durable Medical Equipment Companies are More Likely than Orthotists to Supply Questionable Orthotics

The Medicare orthotics industry is fairly evenly divided between two very different types of suppliers: orthotists and durable medical equipment companies. According to the billing review, 68 percent of questionable cases are supplied by a durable medical equipment company, in contrast to 35 percent of orthotist cases. Devices that do not have fitting requirements, such as upper limb devices, and devices provided in the southeast region of the country are all more likely to be questionable and more likely to be supplied by durable medical equipment companies. Also, beneficiaries supplied by durable medical equipment companies are more likely than beneficiaries supplied by orthotists to report never getting the device.

Over Two-thirds of the Orthotics Billings in Nursing Facilities are Questionable

Sixty-eight percent of the cases in nursing facilities are questionable. Durable medical equipment companies are more likely than orthotists to supply orthotics to beneficiaries in nursing facilities. Orthotists generally supply orthotics to beneficiaries who live at home. Most of the questionable cases in nursing facilities involve devices that do not have fitting requirements. All four medical equipment carriers believe there are problems in the way devices are supplied to beneficiaries in nursing facilities. They are particularly concerned that residents are receiving devices that are not rehabilitative, as required. Another concern is over-utilization.

The Billing Controls of the Durable Medical Equipment Regional Carriers are Limited

The medical equipment carriers have no policies for the great majority of the orthotic billing codes. The codes that do have policies account for 38 percent of the allowed Medicare dollars for orthotics in 1995. The carriers do not have policies for upper limb devices, which we have identified as most likely to be problematic. Two main reasons cited for the paucity of policies: the complexity of orthotics and the lack of clear medical consensus on the use of orthotic devices. Due to lack of policies, carrier prepayment checks are limited to utilization and supplier screens.

All the carriers report upcoding and unbundling as major problems. The carriers say these problems exist because the current coding system is outdated and has not kept up with changes in orthotic technology.

RECOMMENDATIONS

We recognize and support the HCFA initiative underway with the Durable Medical Equipment Regional Carriers' medical directors to find better ways of assuring proper payments for orthotics. Based on the nature of unnecessary devices and questionable billing that we identified, we recommend that HCFA, in concert with the Durable Medical Equipment Regional Carriers:

- Develop guidelines that better define orthotic devices, distinguishing among categories of devices such as custom-made and off-the-shelf;
- Develop policies for orthotic codes, giving priority to upper limb devices, which we have identified as most problematic;
- Develop screens for billing many orthotic devices on the same day or within a short time frame;
- Pay special attention to billing for orthotics in nursing facilities;
- Work with the American Orthotic and Prosthetic Association to develop a table of devices that should not be used together; and
- Consider stricter standards for who is allowed to bill for orthotics, such as requiring professional credentials for orthotic suppliers.

COMMENTS

The HCFA concurred with all of our recommendations. The full text of HCFA's comments is in Appendix E.

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INTRODUCTION

PURPOSE

To determine the extent of questionable billing practices for Medicare orthotics and how it relates to the orthotics industry and to carrier policies and procedures.

BACKGROUND

Orthotic Devices

An orthosis is a device, sometimes called a brace, applied to the outside of the body that supports a body part. The practice of providing orthoses is called orthotics, which literally means the systematic pursuit of straightening or correcting. The devices are usually made of rigid materials and are customized for an individual's use. People who need orthotics range from the severely disabled, such as paraplegics or quadriplegics, to someone who requires an ankle brace for better gait. A person may need to wear the orthotic all the time for life, or every day until the condition improves, or some other time frame as prescribed by the physician. Since each orthotic is fitted for a particular patient's use, an orthotic device cannot be used properly by any one else.

Recent Office of Inspector General (OIG) studies have identified problems with certain orthotic devices and raised concerns about orthotics in general. A 1994 OIG study, "Medicare Payments for Orthotic Body Jackets" (OEI-04-92-01080), found 95 percent (\$14 million) of claims for an orthotic device called a body jacket paid by Medicare in 1992 were for non-legitimate devices. A related study, "Marketing of Orthotic Body Jackets" (OEI-04-92-01081), identified problems in the marketing of body jackets. The present inspection is a result of the questions raised in the body jacket studies, which highlighted the need to look more broadly at orthotics as a whole. It is one of many inspections the OIG has undertaken addressing durable medical equipment (DME) and related devices.

Medicare Coverage of Orthotics

Section 1834(h) of the Social Security Act (the Act) provides for payment of orthotics and prosthetics as described in section 1861(s)(9). Prosthetics is the replacement of a body part. This inspection does not address prosthetics. The Health Care Financing Administration (HCFA) explains the definition of orthotic devices in 42 CFR 414.202 of its regulations, which states, "leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition." A recent HCFA ruling clarifies that the Act's orthotics benefit regarding braces is limited to leg, arm back, and neck braces that are used independently of other medical or non-medical equipment.

Orthotic devices are mainly covered under Medicare Part B. As with all Part B Medicare services, covered orthotics must be reasonable and necessary for the diagnosis or treatment

of an illness or injury or to improve the functioning of a malformed body member. Payment is prohibited for medical services that are for prevention, palliation, research or experimentation.

In order for an orthosis to be covered by Medicare, it must be a rigid or semi-rigid device that is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Orthotics claims must have a prescription and/or a certificate of medical necessity signed by a physician. Unlike DME, orthotics may be provided in a skilled nursing facility, a nursing home, or in the beneficiary's home.

The HCFA developed a coding system called the HCFA Common Procedure Coding System (HCPCS) used for billing. The HCPCS codes L0100 through L4380, called L-codes, are designated for orthotic devices. There are other miscellaneous and temporary codes but this inspection focuses on L-codes only. There are 465 different L-codes for orthotics. In 1995, approximately \$188 million was allowed for claims for these codes.

The L-code listings give a brief description of the device and state whether the device needs to be molded to a patient model, custom fabricated, custom fitted, or have no fitting specifications. The durable medical equipment carriers explain custom fitted as when "substantial adjustments are made to a prefabricated item by a specially trained professional to meet the needs and/or unique shape of an individual patient." Custom fabricated means the "brace is made for a specific patient from his/her individualized measurements and/or pattern." Molded to patient model is the "process in which an impression is made of the specified body part. The impression is used to make a positive model of the body part. Then the orthotic is custom fabricated and/or fitted using the model." For the purposes of this inspection, we consider a device to have "HCFA fitting requirements" if the L-code definitions include the specifications of molded, custom fabricated, or custom fit.

Medicare Durable Medical Equipment Regional Carriers

Medicare Part B claims are processed by carriers under contract with HCFA. Carriers are responsible for ensuring that coverage requirements are met before approving payment. In October 1993, HCFA began processing claims for durable medical equipment, prosthetics, orthotics, and supplies through four regional carriers called the Durable Medical Equipment Regional Carriers (DMERCs). The four carriers, from regions A, B, C, and D, cover all the States, the District of Columbia, and Puerto Rico from their separate headquarters. Although fiscal intermediaries also process some claims for orthotics and other DME, this report focuses only on the Part B payments made by the regional carriers for orthotic devices.

The Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) is under contract to produce standard quarterly reports and provide analyses of claims data to identify trends and aberrancies. It also conducts postpayment medical review of national suppliers in order to determine if future corrective action is needed. All four medical equipment carriers

use these data to identify suspicious durable medical equipment and orthotic suppliers and high dollar and high volume claims for prepayment review.

Fee Schedule

The carrier determines fee schedules for most DME and prosthetic and orthotic devices. The fee schedule for orthotics gives the floor and ceiling allowed amounts for each L-code. Payment for orthotic devices is made on a lump-sum purchase basis using the lesser of the fee schedule amount or the actual submitted charge. Orthotics are not rented. Medicare pays for 80 percent of the allowed amount. The beneficiary, or the beneficiary's secondary insurance, is responsible for paying the remaining 20 percent. The cost for orthotic devices range from \$10 for a simple device to \$2800 for a more sophisticated one. A supplier is paid the same amount from the fee schedule regardless of how many support services, such as teaching and fitting the beneficiary, it provides.

Suppliers

Any supplier with a HCFA provider number can provide and bill for orthotics. Suppliers need no financial investment and experience, and little verification is done of their applications. Suppliers of orthotic devices include DME companies, orthotists, pharmacies, and doctors' offices. Some suppliers specialize in orthotics while others supply orthotics as well as a wide range of DME equipment. Suppliers may manufacture the devices in their own workshops or obtain devices from other companies.

Orthotists

An orthotist is a health professional who treats musculoskeletal disorders by designing and fitting custom-made orthoses. Two organizations offer orthotist certification: the American Board for Certification in Orthotics and Prosthetics, Inc., commonly known as ABC, and the Board of Certification (BOC). The ABC sets standards of competency and grants a Certified Orthotist (CO) credential. To qualify for ABC certification in orthotics, an individual must have a college degree, have completed a postgraduate orthotist certificate program from an accredited institution, and have at least 1 year of patient management experience. The candidate must also pass two written exams and a 3 day clinical exam that tests the ability to design, fabricate, and fit a variety of orthoses. Certified practitioners must meet continuing education requirements every 5 years to renew their credentials. Currently, there are approximately 2,124 ABC certified orthotists in the United States.

The BOC also certifies orthotists. There are more than 900 BOC certified orthotists. In order to sit for the BOC certification examination, which includes written and practical components, the applicant is required to have a high school diploma and minimum of 40 hours of unspecified formal education. In addition, all prospective BOC orthotists need to have experience fitting orthoses.

As of now, no State licenses orthotists. Several States, however, are currently considering licensing legislation.

According to ABC, the orthotist works from a physician's prescription when providing an orthosis. The physician writes the prescription and the patient then sees an orthotist for an evaluation. Ideally, the orthotist and physician work together to determine the most effective course of action. The orthotist is responsible for: formulating the orthosis's design and selecting materials and components; making all necessary casts, measurements, model modifications, and layouts; performing fittings; evaluating the orthosis on the patient; instructing the patient in its use; and maintaining patient records, all in conformity with the prescription. Since the orthotist is the supplier of the device, the orthotist can bill Medicare for it.

American Orthotic and Prosthetic Association

The American Orthotic and Prosthetic Association (AOPA) is a trade association for suppliers of orthotic and prosthetic devices. The AOPA publishes several journals and materials for patient education, lobbies for insurance reimbursement policies, monitors legislation, and conducts business education programs for members.

Operation Restore Trust

This inspection is a part of the Department of Health and Human Services anti-fraud initiative called Operation Restore Trust (ORT) designed to target fraud, waste, and abuse related to home health agencies, nursing homes, and durable medical equipment. The ORT initiative targets five States that account for 40 percent of the nation's Medicare beneficiaries and program expenditures: California, Florida, New York, Illinois, and Texas.

METHODOLOGY

We used a combination of methods in conducting this inspection. A medical record review by medical experts was done to determine if the physical conditions of sample Medicare beneficiaries warranted the use of an orthotic device. We then examined the billing records of each beneficiary to look at additional aspects of orthotics and related Part B services. We supplemented these reviews with a mail survey to Medicare beneficiaries, a mail survey to orthotic suppliers, telephone interviews with carrier representatives, and a review of carrier policies.

Sample

We selected a stratified random sample of 658 line items from Medicare claims for orthotics. Before selecting the sample, we first chose 20 orthotic L-codes. The 20 codes, which together represent approximately 50 percent of the allowed charges for all orthotics in 1995, were selected based on one or more of the following three criteria: allowed dollars; rate of growth; and/or having been identified during preinspection as potentially problematic. From the HCFA 1995 1 percent Common Working file database of claims, we identified a universe of 1,708 line items that had one of the 20 sample L-codes. A claim line item shows the L-code and number of devices billed for that code. More than one device for one code may be billed on the same line item.

The sample was stratified by seven major groupings of codes so we could compare code groups. It was not our intention to compare one specific L-code to another because the number of individual claims in the sample cells was too small. The grouping of codes was based on the part of the body the devices are supposed to support. We identified the beneficiary, the supplier, and the referring physician for each device in the sample. See Appendix A for more information on our sample selection and response rates and Appendix D for non-respondent analyses.

Medical Record Review

A medical records review was done by a medical review contractor. The review determined whether or not the records showed the beneficiary had a condition that warranted the use of the orthotic device that came up in our sample. The reviewers did not look at additional orthotic devices that may have been provided to the beneficiary throughout the year. For each beneficiary identified in the sample, we requested their medical records from their physician, home health agency, or nursing facility. We received 334 medical records for a response rate of 51 percent. Another 8 percent of the providers indicated that they did not prescribe the device. We analyzed the number of medical records received in relation to our billing history review. Those beneficiaries for whom we received no medical records, were more likely to have questionable billing histories. The records, prescriptions and certificate of medical necessity, and any other documentation received from the supplier to determine the medical necessity of the devices billed, were sent to a medical review contractor. The contractor had physical or occupational therapists screen the records and, when appropriate, refer the records for further review to a physician with a specialty in rehabilitative medicine.

Billing Review

In addition to the medical review, we also examined all orthotics billing records for each beneficiary in our sample. This review showed us additional aspects of the use of orthotic devices that the medical review could not. The billing review determined the following questionable categories:

- 1) multiple devices (more than two of the same device) or many devices billed in a short time frame,
- 2) atypical specialty for referring physician (such as pathologists who do not see patients),
- 3) many add-on devices (parts added to basic devices that seem to be duplicates of parts already on device) billed, and
- 4) a combination of the problems listed.

While the medical review focused on the sample device, the billing review included all the orthotic and related Part B services. Each sample device had a related case history that showed all 1995 orthotics billings for the beneficiary who got the sample device. This gave us 658 case histories. A beneficiary's condition may require an orthotic device and therefore the sample device would be deemed medically necessary by the medical reviewer, but if the sample device had several add-on items or if the device's components were billed separately, the case would be deemed questionable based on the billing records.

The Medicare Part B beneficiary billing records include not only the sample device, but all 1995 orthotic L-codes and related Part B services such as physical therapy, occupational therapy, and orthotic training billed for each beneficiary in the sample. See Appendix B. A registered nurse from the OIG project team reviewed the beneficiary histories, paying close attention to the diagnosis, the types and number of devices billed, the time frame for the billings, the related therapies billed, place of service, and the specialty of the referring physician. Based solely on the information in the histories, which did not include the medical records, the nurse made a judgment as to whether or not the histories raised concerns of questionable billing.

Supplier Survey

We identified the 370 different suppliers that supplied all the devices in the sample and contacted them by mail. The supplier response rate was 77 percent of the 658 cases. We asked the suppliers to send us a picture, detailed description, and any brochures of the sample device billed. We requested the certificates of medical necessity and/or prescription for each case in the sample. They were also asked to provide their most recent annual report, when applicable. We mailed the suppliers questionnaires about certain aspects of their business, such as how many orthotists they have on staff, who does the custom-fitting, who instructs the beneficiary, and how the coding and billing are done. The suppliers also identified themselves as DME companies, orthotist practices, or some other business.

Beneficiary Survey

Since the sample was picked using line items, some of the same beneficiaries were represented in more than one case. Of the 658 sample cases, 576 different beneficiaries were identified, 128 of whom are deceased. A mail questionnaire was sent to the remaining 448 beneficiaries identified in the sample. If the beneficiary was identified in more than one sample case, he or she was asked to fill out one questionnaire for each device. Beneficiaries were asked to describe the type of orthotic provided to them and compare it to a sketch of the device from the AOPA manual that is used throughout the orthotics field. The beneficiaries were also asked about the process by which the device was provided and their experience with the device. The beneficiary response rate was 61 percent.

Carrier Interviews

We interviewed representatives from all four Durable Medical Equipment Regional Carriers by telephone. We asked them to identify any prepayment screens and edits they employ regarding orthotics. We also obtained and reviewed all medical policies and educational materials the carriers have that address orthotics. We discussed each carrier's process for creating screens and edits and asked them what additional screens and edits they would like to have.

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

FINDINGS

AT LEAST NINETEEN PERCENT OF ORTHOTICS PROVIDED ARE MEDICALLY UNNECESSARY

Many beneficiaries receiving orthotics do not have conditions that warrant the use of a device

The medical record review found that at least 19 percent of the orthotic devices provided are medically unnecessary. We project that the medically unnecessary devices represent \$6.4 million in Medicare payments. See Appendix C.

Medically unnecessary orthotic devices are those that the physician medical reviewer concluded are inappropriate based on the information in the medical record. A device is labeled unnecessary for several reasons: if the beneficiary's condition does not warrant an orthotic device; if the device offers no functional benefit; if the device is for prevention; or if it is for palliation. One example that is representative is a non-weight bearing patient, demented from Alzheimer's Disease, who received two knee orthoses. The medical reviewer believes that passive range of motion exercises would be sufficient to prevent the increase of the contractures and that the orthoses were not functional devices. Another example is a patient receiving an immobilizing hand device where a cotton mitten or glove would prevent the patient from scratching herself.

Compared to the devices that were reviewed and found medically necessary, the medically unnecessary devices are more likely to have no HCFA fitting requirements, more likely to be upper limb devices, more likely to be provided in the southeast region of the country, and more likely to be provided to beneficiaries in nursing facilities. The medically unnecessary devices are also more likely to be judged problematic in our review of orthotics billing. The characteristics of the unnecessary devices will be expanded upon in the subsequent findings of this report.

Another 5 percent of orthotics are medically questionable

The 5 percent of orthotics that are medically questionable represent \$1.5 million in Medicare payments. Medically questionable orthotic devices are those where the physician medical reviewer has questions about the medical necessity of the device. Often the device provided is more sophisticated and expensive compared to the device that the beneficiary's condition actually warranted. An example is a bedbound multiple sclerosis patient who received two knee orthoses to prevent contractures of the knee joints when the reviewer felt that bivalved casts could be used just as effectively. Another example is a patient who had a stroke several years ago and the medical record showed a little tightness in the hip. This patient received a sophisticated abduction device while the medical reviewer felt a simpler device was indicated.

Like the medically unnecessary devices, the medically questionable devices also involve those with no HCFA fitting requirement, upper limb devices, and devices that were judged problematic in our review of orthotics billing.

Fifty-four percent of beneficiaries have questionable billings.

Since the medical record review looked at only the sample device billed, it probably understates the total number of devices that are medically unnecessary. Therefore, to gain additional insights, we conducted a further review of orthotic billings. Each sample device has a related case history that shows the orthotic billing for the beneficiary who received the sample device. Fifty-four percent of these cases show questionable billings. The two most common problems are many devices billed over a short time frame (43 percent of the questionable billings) and several seemingly unnecessary add-on devices billed (42 percent). Other problems were less common: 6 percent of the questionable cases are due to an atypical physician specialty, such as pathologists and psychiatrists, and 9 percent have a combination of the problems listed above. An example of questionable billing is the 86 year old nursing home resident with a diagnosis of decubitus ulcer. The devices billed for this beneficiary include three hand/wrist devices with multiple add-ons for thumb and hand and add-ons to lower limb devices. In this example a DME company supplied the devices.

DURABLE MEDICAL EQUIPMENT COMPANIES ARE MORE LIKELY THAN ORTHOTISTS TO SUPPLY QUESTIONABLE ORTHOTICS

The Medicare orthotics industry is fairly evenly divided between two very different types of suppliers: orthotists and DME companies. Orthotists account for 43 percent of Medicare orthotics supplied; DME companies account for another 50 percent. Doctor's offices, pharmacies, and rehabilitation centers supply the remaining 7 percent. The findings presented here will focus on orthotists and DME companies only. As discussed in the introduction, orthotists usually have some type of professional certification. Their offices usually have few employees. Durable medical equipment companies, on the other hand, are not certified and may or may not have a certified orthotist on staff. A few DME companies supply only orthotics, but most DME companies supply general durable medical equipment such as wheelchairs, support surfaces, and wound care supplies, as well as orthotics. In general, DME companies have more employees than orthotists' offices.

Sixty-eight percent of the cases where a DME company supplies the device are questionable, in contrast to 35 percent of orthotist cases.

Many devices billed in a short time was the most common problem noted in the questionable DME company cases. In one case, a beneficiary was billed for the same expensive upper limb device on the same day of every month for 5 consecutive months. It is important to note that orthotic devices are purchased, not rented. In another example, a 72 year old beneficiary with contractures received five orthotic devices on the same day. A few days later, the supplier billed for replacement laces. The allowed charges for the replacement laces alone total \$1,322. In many cases, multiple add-on devices were billed for a beneficiary supplied by a DME company. One beneficiary was billed a hand/wrist device,

only to get two more hand/wrist devices with multiple add-ons for the thumb and hand 6 weeks later.

Devices that do not have fitting requirements were more likely to be questionable and more likely to be supplied by DME companies

About half the devices supplied have HCFA fitting requirements and half do not. More than two-thirds (69 percent) of cases without HCFA fitting requirements, however, were questionable while 39 percent with fitting requirements are questionable.

Durable medical equipment companies supply the majority (69 percent) of the devices without HCFA fitting requirements while orthotists supply only 22 percent. The reverse is true of devices with fitting requirements: 65 percent of them are supplied by orthotists and 22 percent are supplied by DME companies.

The devices that do not have fitting requirements are often called "off-the-shelf" in the industry. These devices typically come in small, medium, and large and may have some type of strap or fastening mechanism to secure on the patient. Because these devices are not made specifically for an individual, many in the industry, especially orthotists, do not consider them to be "true" orthotics and believe they should not be included in the same category as orthotics. Orthotists supply 90 percent of the devices with the mold fitting requirement, which is the most complex fitting requirement, compared to 7 percent supplied by DME companies. Molded devices must be made specifically for an individual patient. A mold is taken of a patient's body part and the device is constructed from that mold.

Sixty-eight percent of cases where the supplier (either orthotist or DME company) buys the devices already assembled are questionable in contrast to 34 percent of the cases where suppliers make their own devices. Almost three quarters (74 percent) of orthotists report manufacturing the devices they supply whereas very few DME companies (2 percent) report manufacturing devices. The DME companies say they usually get the whole device from the manufacturer.

Cases with upper limb devices are the most likely to be questionable. Almost all upper limb devices do not have fitting requirements. Seventy-four percent of the upper limb cases have problems compared to 44 percent of the lower limb cases. Durable medical equipment companies supply the great majority (88 percent) of upper limb devices. Orthotists supply just 5 percent of the upper limb devices. Orthotists are more likely to supply lower limb devices, most of which have fitting requirements.

Durable medical equipment companies provide fewer services than orthotists; and suppliers that provide few services are more likely to supply questionable orthotics

Most cases (83 percent) with suppliers that report they do not teach patients how to use devices are questionable and a little less than half (49 percent) the cases with suppliers that did report teaching are questionable. Only 20 percent of beneficiaries supplied by DME companies say they were taught to use the devices and many of these beneficiaries were

taught by nurses or therapists who are not associated with the supplying company. Another 12 percent of beneficiaries supplied by DME companies say that no one taught them how to use the device. In contrast, 60 percent of beneficiaries supplied by orthotists say they were taught.

We found that over three quarters (78 percent) of cases with suppliers that report they do not fit devices on patients are questionable. Durable medical equipment companies usually do not fit the devices. Only one quarter of the beneficiaries supplied by DME companies report being fit by a company representative. Almost 75 percent of the beneficiaries supplied by orthotists, however, report being fit with the device by the orthotist. According to beneficiary responses, orthotists are also more likely than DME companies to take measurements before supplying the device. If a DME company has an orthotist on staff, however, it is more likely than companies that have no orthotists on staff to offer more services, such as fitting devices and teaching patients.

Beneficiaries supplied by DME companies are more likely to report never getting the device

Twenty-three percent of the beneficiaries supplied by DME companies report never receiving any type of device or receiving a device that looked nothing like the sketch in the American Orthotic and Prosthetic Association manual that we sent them. The sketches in the manual are used throughout the industry to identify devices under L-codes. Only 5 percent of the beneficiaries supplied by orthotists report never receiving a device or receiving one that looked nothing like the sketch.

Orthotics provided in the southeast region of the country are more likely to be questionable

Sixty-one percent of the cases in the southeast, compared to 48 percent in the rest of the country, are questionable. Usually, this is because too many devices are billed in a short time period. The devices provided in the southeast are more likely to be supplied by DME companies and more likely to have no fitting requirements.

OVER TWO-THIRDS OF THE ORTHOTICS BILLINGS IN NURSING FACILITIES ARE QUESTIONABLE

Sixty-eight percent of the orthotics in nursing facilities are questionable and DME companies are more likely than orthotists to supply to beneficiaries in nursing facilities

Overall, two-thirds of the beneficiaries getting orthotic devices live at home and one-third live in some type of nursing facility. Orthotists generally supply to beneficiaries who live at home and DME companies generally supply to beneficiaries in nursing facilities. Of those beneficiaries at home, 60 percent are supplied by orthotists and 33 percent are supplied by DME companies. Of those beneficiaries in facilities, however, 11 percent of the beneficiaries are supplied by orthotists while a far greater percentage (82 percent) are supplied by DME companies. The beneficiaries supplied by DME companies seem to include more of those in poor health: 71 percent of the beneficiaries who are now deceased had been supplied by DME companies whereas 15 percent had been supplied by orthotists.

Most of the questionable cases in nursing facilities (72 percent) involve devices that do not have fitting requirements. A common problem noted in nursing facilities is the billing of multiple hand/wrist devices on the same day or within a very short time period.

The majority of DME companies (74 percent) report that they get referrals from physical or occupational therapists and nursing facilities. In contrast, only 7 percent of orthotists say that therapists and nursing facilities are referral sources. Orthotists are more likely to get physician referrals than are DME companies. A great majority of orthotists (92 percent) report that they most often get their referrals from physicians, while just 13 percent of the DME companies report the same.

Medical equipment carriers have concerns about the use of orthotics in nursing facilities

All four medical equipment carriers believe there are problems in the way devices are supplied to beneficiaries in nursing facilities. A major concern is whether the residents receiving orthotic devices are rehabilitative, as required. The carriers believe that many devices supplied are not medically necessary. For instance, a rolled up wash cloth might be better for certain hand contractures than a sophisticated, cumbersome, and expensive wrist/hand device. A few carriers point out that a lot of orthotic devices, especially in nursing facilities, are prescribed by general physicians who give vague descriptions such as "ankle brace," then it is left up to the supplier to decide exactly what to supply and bill.

Another concern in nursing facilities is over-utilization. One carrier representative reports, "In one case, the same knee and lower back orthotics were issued to every patient in a particular nursing facility." At least one supplier agrees with the carriers by saying, "individuals or companies have sales people on a quota and all they care about is putting orthotic devices on anybody. They just go in a nursing home and tell nursing [staff] that these people need splints and most of them don't."

The carriers also complain that contradictory devices are commonly billed to a single nursing home patient. The AOPA is currently developing a table that show codes that should not be used in combination with each other.

THE BILLING CONTROLS OF THE DURABLE MEDICAL EQUIPMENT REGIONAL CARRIERS ARE LIMITED

The medical equipment carriers have no policies for the great majority of the orthotic L-codes

The medical equipment carriers have specific medical policies addressing only 15 percent of the orthotic L-codes. These codes account for 38 percent of the allowed Medicare dollars for orthotics in 1995. Presently the carriers have published policies for spinal, ankle-foot, knee-ankle-foot, and ankle positioning orthoses. They do not have policies for upper limb devices, which we have identified as most likely to be problematic.

The policies the carriers do have offer general definitions of devices that could be billed under the codes. The policies also give indications for the general purpose and use of the devices. For example, a policy indication would be "to reduce pain by restricting the mobility of the trunk." Some policies also have requirements for supplemental documentation, such as photographs of the device, or medical documentation to justify the prescription of a particular device.

The carriers cite two primary reasons for the paucity of policies: the complexity of orthotics and the lack of clear medical consensus on the use of orthotic devices. However, policies for other durable medical equipment groups such as support surfaces have been developed despite the complexity of the issue and lack of medical consensus. The carriers explain that orthotics is a complicated subject due to the large number of devices and various L-codes and because there are significant differences between devices fabricated from raw materials for a particular individual and the "off-the-shelf" devices. These differences have yet to be defined. According to the carriers, they are currently working on developing policies for more orthotic codes and much of that work is directed towards delineating between the custom-fabricated and "off-the-shelf" devices. The carriers also say that the medical community, orthotists, and suppliers have not been able to build consensus on the proper use of orthotic devices. This disagreement makes it all the more difficult to develop policies. One carrier representative noted, "Without a medical consensus, it is a very complicated, slow process."

Due to lack of policies, carrier prepayment checks are limited to utilization and supplier screens

A carrier cannot implement widespread procedures for processing claims without a corresponding published policy. Therefore, claims are generally paid in good faith for those L-codes that are not addressed in a policy. When policies do exist, guidelines for that code are usually automated to assist the claims processor. Carriers have utilization screens that target billing for a particular code. An example of this type of screen is a limit of one particular device in the same year for the same beneficiary.

The carriers also develop screens if they conclude there is a problem supplier. When a supplier is under review, all claims from that supplier are evaluated. Usually medical justification is required for each claim. Problem suppliers are generally identified through beneficiary complaints, utilization screens or post-payment reviews.

The carriers cite problems with coding

All the carriers report upcoding and unbundling as problems. Upcoding is the practice of billing the device provided under a more expensive code than that device merits. Unbundling is the separate billing of components, such as add-ons, that make up a single device. The carriers say upcoding and unbundling have become problems because the existing coding system is outdated and has not kept up with changes in orthotic technology. They say the L-codes were established when most orthotic devices were individually

manufactured or if the device was already made, it was substantially customized for the patient. Now the devices are increasingly "off-the-shelf" in nature.

Carriers believe it is relatively easy to receive a provider number and supply orthotics. They suggest that the review of prospective suppliers be more rigorous. Another common recommendation was that provision of complicated, molded devices be limited to certified orthotists.

RECOMMENDATIONS

We recognize and support the HCFA initiative underway with the Durable Medical Equipment Regional Carriers' medical directors to find better ways of assuring proper payments for orthotics. Based on the nature of unnecessary devices and questionable billing that we identified, we recommend that HCFA, in concert with the Durable Medical Equipment Regional Carriers:

- Develop guidelines which better define orthotic devices, distinguishing among categories of devices such as custom-made and off-the-shelf;
- Develop policies for orthotic codes, giving priority to upper limb devices, which we have identified as most problematic;
- Develop screens for billing many orthotic devices on the same day or within a short time frame;
- Pay special attention to billing for orthotics in nursing facilities;
- Work with the American Orthotic and Prosthetic Association to develop a table of devices that should not be used together; and
- Consider stricter standards for who is allowed to bill for orthotics, such as requiring professional credentials for orthotic suppliers.

COMMENTS

The HCFA commented on our draft report and concurs with all of our recommendations. The full text of HCFA's comments is in Appendix E.

The HCFA agrees with our recommendation to better define orthotic devices, and is preparing a report to Congress that describes prosthetic devices, orthotics, and prosthetics covered under Part B that do not require individualized or custom fitting and adjustment. This report is recommending that the Medicare statute be revised to change the payment methodology for all prosthetic devices, orthotics, and prosthetics.

The HCFA agrees with our recommendation to develop policies for orthotic codes, and is currently working with the durable medical equipment carriers (DMERCs) on the feasibility of issuing revised regional medical review policies.

The HCFA agrees with our recommendation to develop billing screens for orthotic devices, and will work with the DMERCs to ensure that utilization/frequency edits are in place after the development and implementation of the new medical review policies.

The HCFA agrees with our recommendation to pay attention to billing in nursing facilities and believes that the development of policies and edits will strengthen their ability to control inappropriate billings for orthotics in nursing facilities.

In addition, the Balance Budget Act of 1997 contains a number of nursing home reforms including creating a prospective system for Part A covered services. This bundled payment will eliminate separate payment for orthotics as provided under a Part A stay. Also, for stays not covered by Part A, the statute requires the nursing facility to bill for items such as orthotics. When implemented, these reforms should help control inappropriate billings in nursing facilities.

The HCFA agrees with our recommendation to work with the American Orthotic and Prosthetic Association to identify devices that should not be used together. The HCFA indicates that they are consulting with them and other relevant professional organizations in developing the regional medical review policies.

The HCFA agrees with our last recommendation, to consider stricter standards as to who can bill for orthotics. Since HCFA traditionally relied upon States to determine the extent to which physicians and other health care professionals must be licensed in order to furnish health care services there is no explicit Medicare statutory authority in this regard. However, there is authority under section 1662(a)(A) of the Medicare statute to develop standards for "reasonable and necessary" medical services. Using this statute, HCFA expects to establish more stringent standards where State licensure is found to be inadequate. The HCFA is also considering limiting who will be eligible to supply orthotics in the proposed regional medical review policies.

APPENDIX A

L-CODES INCLUDED IN SAMPLE

CODE	HCFA DESCRIPTION
L0420	- Thoracic-Lumber-Sacral Orthoses (TLSO), two piece construction, molded to patient model
L0430	- TLSO, with interface material custom-fitted
L0700	- Cervical-TLSO, molded to patient model (Minerva type)
L1680	- Hip Orthoses (HO), abduction control of hip joints, dynamic pelvic control, adjustable hip motion control, thigh cuffs
L1686	- HO, Abduction control of hip joint, post-operative abduction hip type, custom-fitted
L1832	- Knee Orthoses (KO), adjustable knee joints, positional orthoses, rigid support, custom fitted
L1844	- KO, single upright, thigh and calf, with adjustable flexion and extension joint, medial-lateral and rotation control, molded to patient model
L1845	- KO, double upright, thigh and calf, with adjustable flexion and extension joint, medial-lateral and rotation control, custom fitted
L1855	- KO, molded plastic, thigh and calf sections, with double upright knee joints
L1960	- Ankle-Foot Orthoses (AFO), posterior solid ankle, molded to patient model, plastic
L1970	- AFO, plastic, molded to patient model, with ankle joint
L1990	- AFO, double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (Double Bar BK Orthoses)
L2036	- Knee-Ankle-Foot Orthoses full plastic, double upright, free knee, molded to patient model
L3730	- Elbow Orthoses (EO), Double upright with forearm/arm cuffs, extension/flexion assist
L3740	- EO, Double upright with forearm/arm cuffs, adjustable position lock with active control
L3805	- Wrist-Hand-Finger-Orthoses (WHFO), long opponens, no attachment
L3860	- WHFO, addition to short and long opponens, adjustable M.P. flexion control and I.P.
L3904	- WHFO, electric powered
L3963	- Shoulder-Elbow-Wrist-Hand Orthoses, molded shoulder, arm, forearm, and wrist, articulating elbow joint
L4310	- Multi-podus or equal orthotic preparatory management system for lower extremities

TABLE A-1

SAMPLE STRATIFICATION

STRATA	DESCRIPTION OF STRATA	Number in Universe	Number in Sample
1	Body	89	60
2	Upper limb; more expensive	102	102
3	Upper limb; less expensive, line item allowed charge is more than \$280*	33	33
4	Upper limb; less expensive, line item allowed charge less than or equal to \$280	396	80
5	Lower limb; more expensive	154	154
6	Lower limb; less expensive, line item allowed charge is more than \$740*	79	79
7	Lower limb; less expensive, line item allowed charge is less than or equal to \$740	855	150
TOTAL		1,708	658

* In the majority of the cases, the line item was higher than the ceiling price listed in the HCFA schedule because more than 1 device was billed on that line of the claim.

TABLE A-2

RESPONSE RATES

STRATA	Questionnaires Received		Medical Records
	Beneficiary*	Supplier	Received**
1	30 (53%)	31 (52%)	22 (37%)
2	39 (47%)	77 (75%)	58 (57%)
3	14 (61%)	27 (82%)	12 (36%)
4	25 (47%)	71 (89%)	42 (53%)
5	82 (68%)	119 (77%)	77 (50%)
6	35 (56%)	65 (82%)	41 (52%)
7	99 (76%)	114 (76%)	82 (55%)
Total:	324 (61%)	504 (77%)	334 (51%)

* Beneficiary response rates are based on questionnaires received from the 530 live beneficiaries.

** In an additional 52 (8 percent) of the cases, the referring physician on HCFA's record did not prescribe the device.

APPENDIX B

PART B SERVICES INCLUDED IN BILLING RECORDS

Code	Description
97110 -	Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility.
97112 -	Neuromuscular reeducation of movement, balance coordination, kinesthetic sense, posture and proprioception.
97113 -	Aquatic therapy with therapeutic exercises
97116 -	Gait training (includes stair climbing)
97139 -	Unlisted therapeutic procedure
97150 -	Therapeutic procedure(s), Group (two or more individuals)
97500 -	Orthotics training (dynamic bracing, splinting upper and/or lower extremities; initial 30 minutes, each visit
97501 -	Each additional 15 minutes
97530 -	Therapeutic activities, direct (one on one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes
97535 -	Self care/home management training (eg. activities of daily living [ADL] and compensatory training, meal preparation, safety procedures, and instructions in use of adaptive equipment) direct one on one contact with provider, each 15 minutes
97703 -	Checkout for orthotic/prosthetic use, established patient, each 15 minutes
97799 -	Unlisted physical medicine/rehabilitation service or procedure
99002 -	Handling, conveyance, and/or any other service in connection with the implementation of an order involving devices (eg. designing, fitting, packaging, handling, delivery or mailing) when devices such as orthotics, protectives, prosthetics are fabricated by an outside laboratory or shop which items have been designed, and are to be fitted and adjusted by the attending physician

APPENDIX C

CHI-SQUARE TESTS AND CONFIDENCE INTERVALS

Chi-Square Values

We computed chi-square values for differences in questionable billing histories for the five variables upon which our major findings are based. Chi-square values show that differences on all five variables were significant at the 95 percent confidence level.

Table C-1

CHI-SQUARE Values for Testing Significance of Differences in Questionable Billing Histories for Type of Supplier, Type of Device, Fitting Requirements, Region, and Residence

VARIABLE	DF*	CHI-SQUARE
Type of Supplier	2	42.15
Type of Device	2	50.27
Fitting Requirements	1	51.42
Region	1	9.04
Residence	1	20.65

*Degrees of Freedom

Table C-2

***Projections of Cost Savings
Based on Unnecessary and Questionable Services***

Service Outcomes	Sample Size	Weighted Projections	Boundaries for 95 % Confidence Interval
1) services medically unnecessary (n= 61)	334	\$6,437,786	+/- \$1,871,542
2) services medically questionable (n= 20)	334	\$1,532,776	+/- \$703,498

APPENDIX D

NON-RESPONDENT ANALYSES

An important consideration in studies of this type is the bias that may be introduced into the results if non-respondents differ from respondents to the data collection instruments. To test for the presence of any bias, we first obtained information from the HCFA's one percent Common Working File (CWF) for all 658 beneficiaries in our sample, including both respondents and non-respondents. We then analyzed the variables that might influence whether an individual would respond to the survey or that might affect the responses given. For our sample, we looked at place of residence (home vs facility), region of the country (Southeast vs rest of U.S.), and device fitting requirements (special requirements vs none). Differences between respondents and nonrespondents for each of the three variables were tested for significance using Chi-square with the appropriate degrees of freedom. Analyses of respondents and non-respondents are presented separately for the medical records review and the orthotics supplier survey.

A. Medical Records Review

For this portion of the inspection, a beneficiary whose medical records were not obtained and reviewed is a non-respondent. There were 324 non-respondents, including 272 beneficiaries for whom we received no records and another 52 whose physicians indicated that no orthotic devices were ordered (and, therefore, no relevant records existed). The remaining 334 beneficiaries for whom records were received and reviewed are our respondents.

The results of this analysis are presented in Tables D-1, D-2, and D-3 below. The Chi-square values given in the tables provide a test of significance for the differences in the distribution of respondents and non-respondents for each variable of interest. Also provided in the tables are the response rates for the different values of the variables.

Tables D-1 and D-3 show no statistically significant differences between respondents and non-respondents for the variables tested.

Table D-2 shows a statistically significant difference between respondents and non-respondents with respect to the region of the country in which they live (Southeast vs rest of U.S.). In order to test whether this difference introduced any bias, we analyzed answers to two key medical record review questions for differences between regions: 1) whether the claim was medically questionable (e.g., a simpler device was indicated), and 2) whether the device was medically unnecessary.

The proportion of claims deemed medically questionable in the Southeast was within 1 percentage point of that for the rest of the country, a statistically insignificant difference. However, the proportion of orthotics determined to be medically unnecessary differed by 12

percentage points between regions, so further analysis was required. Assuming that non-respondents and respondents from the same geographic region had the same proportion of medically unnecessary devices, we calculated a hypothetical global rate for medically unnecessary devices for all 658 beneficiaries in the sample. This calculation gave only a slightly higher medically unnecessary rate of 20 percent (compared to 19 percent for respondents). This difference is not statistically significant.

TABLE D-1

BENEFICIARY PLACE OF RESIDENCE						
	Respondents		Non-respondents		Total	Response Rate
Home	234	70%	209	65%	443	53%
Facility	100	30%	115	35%	215	47%
Total	334		324		658	51%
CHI-SQ = 2.306 Degrees of Freedom = 1						

TABLE D-2

BENEFICIARY REGION OF COUNTRY						
	Respondents		Non-respondents		Total	Response Rate
Southeast	107	32%	160	49%	267	40%
Rest of U.S.	227	68%	164	51%	391	58%
Total	334		324		658	51%
CHI-SQ = 20.524 Degrees of Freedom = 1						

TABLE D-3

DEVICE FITTING REQUIREMENTS						
	Respondents		Non-respondents		Total	Response Rate
Has requirement	187	56%	195	60%	382	49%
No requirement	147	44%	129	40%	276	53%
Total	334		324		658	51%
CHI-SQ = 1.190 Degrees of Freedom = 1						

B. Beneficiary Survey

For this part of the inspection, a beneficiary for whom a survey was not received is a non-respondent. There were 324 non-respondents and 206 respondents.

The results of this analysis are presented in Tables D-4, D-5, and D-6 below. The Chi-square values given in the tables provide a test of significance for the differences in the distribution of respondents and non-respondents for each variable of interest. Also provided in the tables are the response rates for the different values of the variables.

All three tables show statistically significant differences between respondents and non-respondents with respect to each of the three variables analyzed. In order to test whether these differences introduced any bias, we analyzed answers to the key beneficiary survey question used in our findings: whether or not the beneficiary received a device which looked like the one for which Medicare was billed. For each variable analyzed (e.g., place of residence), the distribution of answers given by different segments of the sample (e.g., at home vs in facility) were within two percentage points of each other. These differences are not statistically significant.

TABLE D-4

BENEFICIARY PLACE OF RESIDENCE						
	Respondents		Non-respondents		Total	Response Rate
Home	260	80%	130	63%	390	67%
Facility	64	20%	76	37%	140	46%
Total	324		206		530	61%
CHI-SQ = 19.034 Degrees of Freedom = 1						

TABLE D-5

BENEFICIARY REGION OF COUNTRY						
	Respondents		Non-respondents		Total	Response Rate
Southeast	126	39%	98	48%	224	56%
Rest of U.S.	198	61%	108	52%	306	65%
Total						
	324		206		530	61%
CHI-SQ = 3.892 Degrees of Freedom = 1						

TABLE D-6

DEVICE FITTING REQUIREMENTS						
	Respondents		Non-respondents		Total	Response Rate
Has requirement	211	65%	114	55%	325	65%
No requirement	113	35%	92	45%	205	55%
Total						
	324		206		530	61%
CHI-SQ = 5.082 Degrees of Freedom = 1						

APPENDIX E

COMMENTS ON THE DRAFT REPORT

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: AUG 11 1997

TO: June Gibbs Brown
Inspector General

FROM: Bruce C. Vladeck 
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Orthotics,"
(OEI-02-95-00380)

We reviewed the above-referenced report that examines the extent of questionable billing practices for Medicare orthotics and how it relates to the orthotics industry and to carrier policies and procedures.

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

Attachment

Comments of the Health Care Financing Administration (HCFA) on
Office of Inspector General (OIG) Draft Report Entitled:
"Medicare Orthotics." (OEI-02-95-00380)

HCFA should, in concert with the durable medical equipment regional carriers (DMERCs):

OIG Recommendation

Develop guidelines that better define orthotic devices, distinguishing among categories of devices such as custom-made and off-the-shelf.

HCFA Response

We concur. As required by section 131(c) of the Social Security Act Amendments of 1994, we are preparing a report to Congress that describes prosthetic devices, orthotics, and prosthetics covered under Part B of the Medicare program that do not require individualized or custom fitting and adjustment. This report, presently in final Departmental clearance, provides a list of devices that are not prefabricated for proper fit or require individualized modification or custom fitting. In addition, a listing is provided of those products that need fairly minor adjustments and generally do not require the expertise of an orthotist. The report recommends the Medicare statute be revised to change the payment methodology for all prosthetic devices, orthotics, and prosthetics, regardless of whether they require fitting or adjustments. It also recommends the fee schedules be recomputed from the base year, and regional fee schedules be estimated. Accordingly, the median value would be used as a payment limit, as in the current methodology for DME covered under the Medicare program. We estimate these recommendations could save up to \$390 million over the next 5 years.

OIG Recommendation

Develop policies for orthotic codes, giving priority to upper limb devices, which we identified as most problematic.

HCFA Response

We concur. We are currently working with the DMERCs on the feasibility of issuing revised regional medical review policies (RMRPs) that will provide further guidance on the scope and meaning of prosthetics and orthotics as a Medicare benefit. The

development of these revised RMRPs are in the preliminary stages. The DMERCs are holding fact gathering meetings with various representatives of the medical community on the use of prosthetics and orthotics in various settings. We expect to issue draft policies for public comment early next year.

OIG Recommendation

Develop screens for billing many orthotic devices on the same day or within a short time frame.

HCFA Response

We concur. Subsequent to development and implementation of new medical review policies and procedure codes, HCFA will work with the DMERCs to ensure that utilization/frequency edits are in place. We agree that edits will limit the supplier's ability to upcode or unbundle when billing Medicare for orthotic equipment.

OIG Recommendation

Pay special attention to billing for orthotics in nursing facilities.

HCFA Response

We concur. Based on the findings in the OIG report, we recognize there is a need to closely monitor billing practices in nursing homes. We believe the development of policies and edits will strengthen our ability to control inappropriate billings for orthotics in nursing facilities. Additionally, we will continue to work with the DMERCs to determine the other methods for ensuring that orthotics billed to Medicare meet medical necessity requirements.

OIG Recommendation

Work with the American Orthotic and Prosthetic Association to develop a table of devices that should not be used together.

HCFA Response

We concur. We are consulting with the American Orthotic and Prosthetic Association, as well as other relevant professional organizations, as part of the development of the RMRP on prosthetics and orthotics previously mentioned

OIG Recommendation

Consider stricter standards for who is allowed to bill for orthotics, such as requiring professional credentials for orthotic suppliers.

HCFA Response

We concur. Because there is no explicit Medicare statutory authority in this regard, we traditionally relied upon states to determine the extent to which physicians and other health care professionals must be licensed in order to furnish health care services. In this respect, all health care providers under Medicare are required to meet any applicable state licensure requirements. There is, however, authority under section 1962(a)(1)(A) of the Social Security Act to develop standards for what is reasonable and necessary medical services. Under this authority, we expect to establish more stringent standards where state licensure is found to be inadequate for Medicare purposes. In this context, we are also considering limiting who will be eligible to supply orthotics in the proposed RMRP for prosthetics and orthotics.