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Orthotics Ruling Has Implications for Beneficiary Access and Federal and State Costs

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Abbreviations

ALJ	administrative law judge
BIPA	Medicare, Medicare, and SCHIP Benefits Improvement and Protection Act of 2000
CMS	Centers for Medicare and Medicaid Services
DME	durable medical equipment
DMEPOS	durable medical equipment, orthotics, prosthetics, and supplies
DMERC	durable medical equipment Regional Carrier
HCFA	Health Care Financing Administration
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
ICF	Intermediate care facility
MDS	minimum data set
NF	nursing facility
OBRA	Omnibus Budget Reconciliation Act of 1990
OEI	Office of Evaluation and Inspections
OIG	Office of Inspector General
RESNA	Rehabilitation Engineering and Assistive Technology Society of North America
SCHIP	State Children's Health Insurance Program
SNF	skilled nursing facility

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United States General Accounting Office
Washington, DC 20548

May 22, 2002

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable W. J. "Billy" Tauzin
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

In the late 1980s and early 1990s, the Health Care Financing Administration (HCFA—now called the Centers for Medicare and Medicaid Services or CMS)[1]—became concerned that some suppliers were improperly billing Medicare for certain items that attach to wheelchairs and other equipment. These suppliers were billing such items using codes for orthotic devices, which include leg, arm, back, and neck braces that provide rigid or semi-rigid support to weak or deformed body parts or restrict or eliminate motion in a diseased or injured part of the body. However, other suppliers were billing devices that served essentially the same purpose using codes for durable medical equipment (DME), which is equipment—such as wheelchairs and crutches—that serves a medical purpose, can withstand repeated use, is not generally useful in the absence

[1]On June 14, 2001, the Secretary of Health and Human Services announced that the name of the Health Care Financing Administration (HCFA) had been changed to CMS. In this report, we will continue to refer to HCFA where the actions or statements occurred before June 14, 2001.

of an illness or injury, and is appropriate for use in the home.[2] Whether an item is billed as an orthotic or DME device can affect whether such claims are paid. To clarify Medicare's payment policy on orthotics, HCFA issued Ruling 96-1 in September 1996. The ruling stated that Medicare's long-standing policy was to consider items that attach to DME (or to other equipment) as DME and not orthotics.

Medicare covers both orthotics and DME when medically necessary and prescribed by a physician, but the type of coverage depends on where the beneficiary receives care. For example, under part B, which is the part of the program that pays for physician, laboratory, and certain other services, Medicare covers both orthotics and DME for beneficiaries in their homes or in institutions that serve as their homes, but covers only orthotics for beneficiaries in a skilled nursing facility (SNF).[3] In contrast, some states' Medicaid programs cover and pay for customized DME[4] items for program beneficiaries in SNFs, including wheelchairs with attachments that have been measured and fitted to the beneficiary. Often such residents are eligible for both Medicare and Medicaid benefits.

In addition to HCFA's concerns about billing for certain items that attach to wheelchairs and other equipment as orthotic devices, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reported several times on other types of problems related to inappropriate Medicare payment for orthotic devices.[5] For example, when the OIG reviewed a sample of beneficiary medical records, it found that many

[2]42 C.F.R. § 414.202 (2001).

[3]The Medicare provision pertaining to DME does not explicitly say that a SNF can never be considered a beneficiary's home. 42 U.S.C. § 1395x(n) (Supp. IV 1998). Through cross-reference to part of the Medicare definition of a SNF, it provides that an institution (or a distinct part of an institution) "primarily engaged in providing" skilled nursing care or rehabilitation services may not be considered a beneficiary's home. 42 U.S.C. § 1395i-3(a)(1) (1994). For DME purposes, CMS interprets the definition to encompass any nursing home primarily engaged in providing skilled nursing care or rehabilitation services, whether or not it is certified as a SNF.

[4]Customized DME is uniquely constructed or substantially modified for a specific beneficiary. 42 C.F.R. § 414.224 (2001).

[5]Office of Inspector General, Department of Health and Human Services, *Medicare Payment for Orthotics: Inappropriate Payments*, OEI-02-99-00120 (Washington, D.C.: March 2000); Office of Inspector General, Department of Health and Human Services, *Medicare Orthotics*, OEI-02-95-00380 (Washington, D.C.: October 1997); and Office of Inspector General, Department of Health and Human Services, *Medicare Payments for Orthotic Body Jackets*, OEI-04-92-01080 (Washington, D.C.: June 1994).

orthotic devices were not being provided to the beneficiaries as billed. The OIG also reported that practitioners who had not been certified to dispense these items were more likely than other suppliers to bill inappropriately. To help address these program integrity concerns, in March 2000 the OIG recommended that only qualified practitioners be allowed to provide to beneficiaries custom-fabricated orthotic devices that are individually made for a specific patient.[6] In response, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) restricted payment for custom-fabricated orthotic devices that are individually fabricated over a positive model of the patient—custom-molded devices—to practitioners and suppliers meeting prescribed accreditation or other requirements.[7] The BIPA requirement applies only to custom-molded orthotic items, but not to other custom-fabricated orthotic devices.

Cognizant of program integrity issues and concerned that the HCFA ruling could have adversely affected Medicare beneficiaries, the Congress directed us in BIPA to study the ruling.[8] We addressed the following questions: (1) Why did HCFA issue its ruling and did it follow required procedures in issuing it? (2) What has been the impact of the ruling on Medicare beneficiaries? (3) If the ruling were rescinded by CMS, what would be the financial impact on Medicare and Medicaid? (4) Given the new BIPA requirement, what would be the implications for Medicare program integrity if the ruling were rescinded?

In preparing this report, we conducted interviews with officials and representatives from CMS, and from durable medical equipment regional carriers (DMERC), who are contractors that process orthotics and DME claims. We interviewed representatives from state Medicaid programs to determine the potential financial impact of changing the ruling on states' Medicaid spending for individuals dually-eligible for Medicare and Medicaid. We also interviewed representatives from the OIG, advocacy groups, orthotic industry representatives, and provider associations; reviewed federal statutes and regulations, documents related to a legal challenge to the ruling, CMS documents, and Medicare coverage policy;

[6]See OEI-02-99-00120. In 1997, the OIG made a similar recommendation—see OEI-02-95-00380.

[7]Pub. L. No. 106-554, App. F, § 427(a), 114 Stat. 2763, 2763A-520 (to be codified at 42 U.S.C. § 1395m(h)(1)(F)).

[8]BIPA § 427(c).

and analyzed data on orthotic claims and characteristics of nursing home residents. Appendix I presents the details of our methodology. We performed our work from January 2001 through March 2002 in accordance with generally accepted government auditing standards.

Results in Brief

HCFA issued Ruling 96-1 to clarify the circumstances under which certain items would be classified as orthotics or as DME for Medicare part B payment purposes. In the late 1980s and early 1990s, certain suppliers of an item that consisted of many separate supports that attached to a frame were billing part B for each support as a separate orthotic brace, using multiple orthotics billing codes that described braces expected to be used independently of other medical equipment. As DMERCs became aware of this billing practice, they began to deny these orthotics claims because the attached bracing devices[9] being provided as a group appeared to be similar in function to a seating system or customized wheelchair, which was considered DME. The distinction between orthotics and DME is significant because orthotics can be paid for beneficiaries in SNFs under part B, but DME cannot. While contractors began to deny such orthotics claims, in one significant case involving multiple claims, an administrative law judge (ALJ), who hears appeals of contractors' payment decisions, overturned some of the claims denials. In order to clarify Medicare's policy in a manner that would be binding on ALJs, HCFA ruled that leg, arm, back, and neck braces that are used independently are orthotics, whereas similar items that are attached to equipment are DME. The validity of the agency's orthotics ruling was challenged in court, with the plaintiffs charging that the ruling had been issued without following required administrative procedures. However, a federal appellate court found that HCFA had followed appropriate procedures to issue the rule as an interpretation of Medicare policy, the interpretation in the ruling was wholly supportable, and the treatment of seating systems as DME was consistent with congressional intent.[10]

[9]In this report, we are using the term "attached bracing devices" to refer to the type of items referenced in HCFA's orthotics ruling that are attached to equipment and support a body part, which is not meant to imply that they are braces or orthotics under the Medicare statute or for part B payment purposes. CMS and its DMERCs determine whether an item is a brace or orthotic under the Medicare statute or for part B payment purposes.

[10]*Warder v. Shalala*, 149 F.3d 73 (1st Cir 1998), *cert. denied*, 526 U.S. 1064 (1999).

HCFA's ruling that attached bracing devices were in the DME benefit category and could no longer be billed as orthotics affects beneficiaries residing in Medicare-certified SNFs and other institutions primarily engaged in providing skilled nursing care—which include most nursing homes. The ruling had no impact on beneficiaries living at home, or in settings such as assisted living facilities, because Medicare covers both orthotics and DME under part B for them. Therefore, claims for attached bracing devices are still paid as DME for such beneficiaries following the ruling. However, because Medicare part B does not cover DME in SNFs and other institutions primarily engaged in providing skilled nursing care, claims for such items are no longer paid for residents in nursing homes, who would therefore need to purchase such devices with their own resources or through other payers. Because attached bracing devices were clearly classified as DME after the ruling, Medicare part B expenditures for such devices declined by at least $1.4 million between 1996 and 1997 for beneficiaries living in nursing homes and remained lower in subsequent years. The ruling affected residents of all nursing homes, not just SNFs, because the DMERCs' practice is not to pay for DME for any nursing home residents, assuming that all nursing homes meet HCFA's criteria for institutions primarily engaged in providing skilled nursing care.

If HCFA's ruling were rescinded and Medicare's policy changed so that attached bracing devices were classified as orthotics, how much Medicare and Medicaid spending for orthotics would increase is uncertain. With a rescission of the ruling, Medicare would pay for attached bracing devices for any nursing home resident if medically necessary. The increase in Medicare spending would depend on how extensively attached bracing devices would be provided to nursing home residents following the ruling's rescission. If utilization returned to the pre-ruling level, Medicare's annual costs for attached bracing devices for nursing home residents would grow by a modest amount—about $1.8 million, given previous claims volume and current payment amounts. However, the potential exists for even greater spending increases. Estimates of the number of beneficiaries who live in nursing homes, use wheelchairs, and thus might potentially use such devices, are much higher than prior utilization levels. A payment change would provide financial incentives for suppliers to furnish attached bracing devices to such beneficiaries. Rescinding the ruling would affect individual state Medicaid programs' spending differently, depending on their existing coverage policies. States that separately cover these devices for beneficiaries in nursing homes would likely see a decrease in expenditures because most of the cost of providing the devices would shift from Medicaid to Medicare. In contrast, states not separately covering these devices would likely see some increase in

expenditures because they would be responsible for some costs not paid by Medicare, such as copayments, for beneficiaries who are covered by both programs. However, to the extent that the costs of such items were part of the per diem rates paid to nursing homes, states may decide to adjust their Medicaid per diem rates downward to reflect this coverage change, which could moderate their spending increases.

There are a number of program integrity implications should the ruling be rescinded. HCFA issued its ruling to address concerns about inappropriate billing for attached bracing devices under part B and thereby clarified the distinction between DME and orthotics. If the ruling were rescinded, the distinction between DME and orthotics would become less clear, which could lead to inappropriate billing. Should the ruling be rescinded, the requirement added by BIPA that restricts payment to qualified providers for custom-molded orthotics would not safeguard against inappropriate billing because none of the types of attached bracing devices that we identified as affected by the ruling are fabricated in this manner. Therefore, if the ruling were rescinded, additional controls, such as closely monitoring billing and reviewing medical justification for customized items prior to payment, would be vital to help curb potentially inappropriate billing.

In commenting on a draft of this report, CMS generally agreed with the report's conclusions. CMS further noted that the federal appellate court, which had held that the orthotics ruling was properly issued, had also found that the content of the ruling was wholly supportable and that the ruling well effectuated congressional intent by classifying seating systems as DME. In addition, CMS also raised concerns about the potential impact that rescinding the ruling could have on the provision of other types of equipment as orthotics in SNFs.

Background

CMS, an agency within HHS, is responsible for much of the federal government's multi-billion dollar payments for health care, primarily through the Medicare and Medicaid programs. Medicare covers about 40 million individuals 65 years old and older, as well as some disabled individuals. Eligible individuals enroll to receive part A insurance, which helps pay for inpatient hospital, SNF, hospice, and certain home health services. Most Medicare beneficiaries also elect to purchase part B insurance, which helps pay for physician, outpatient hospital, laboratory, and other services.

Medicaid is a state-administered health insurance program, jointly funded by the federal and state governments, that covers approximately 40 million eligible low-income individuals including children and their parents, the aged, blind, and disabled. Each state administers its own program and determines, under broad federal guidelines, eligibility for, coverage of, and reimbursement for specific services and items, such as orthotics and DME. In 2000, about 5.5 million low-income aged and disabled Medicare beneficiaries were also covered by Medicaid.[11] For such beneficiaries, Medicare serves as their primary health care coverage, while Medicaid pays for certain other health care costs. The extent of their Medicaid coverage is primarily dependent on their income. For the lowest income beneficiaries, Medicaid covers long-term care, prescription drugs, and their Medicare part B premiums, deductibles, and copayments, as well as other items and services not available through Medicare. For those dually-eligible beneficiaries with somewhat higher incomes, Medicaid support is limited to cost sharing and/or part B premiums.

Benefits covered by Medicare are broadly established in statute and further delineated through regulation and other means, such as rulings. Generally, a regulation is a substantive requirement promulgated by a federal agency that has the force and effect of law. Such regulations are generally first proposed, to allow for a period of public notice and comment, before they are finalized. In addition to such substantive regulations, CMS also issues interpretive rules—including administrative rulings—that are decisions of the agency's administrator that serve as final opinions and statements of policy and interpretation. They provide clarification on, and interpretation of, complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, and related matters. CMS characterizes rulings as interpreting previously promulgated policies, rather than establishing new policies. Rulings are final upon issuance without prior public notice or comment period.

Medicare pays for orthotic devices and DME under both its part A and part B benefits. Through its post-hospital extended care services benefit under part A, Medicare pays for inpatient skilled nursing care and rehabilitative services furnished by a SNF. To qualify for this benefit, a Medicare

[11]These individuals, called "dual eligibles," receive Medicare benefits and also some form of Medicaid assistance. Dual eligibles include individuals who either receive full Medicaid benefits (i.e., prescription drugs and nursing home care) and Medicaid coverage of Medicare's cost-sharing and premiums or individuals who only receive some assistance with Medicare cost-sharing and premiums.

beneficiary must be admitted to the SNF within a short period (generally 30 days) after a hospital stay of at least 3 days and receive daily skilled nursing care or rehabilitative services for a condition related to hospitalization. Medicare's part A per diem payment generally covers all necessary services and supplies provided by the SNF, such as room, board, and drugs, for as long as the need for daily skilled care continues, up to 100 days[12] of care per benefit period.[13] Medicare also covers both orthotics and DME under the part A per diem payment for a beneficiary in a SNF. HCFA considered whether orthotics should be separately reimbursed under part B when the SNF payment method was being developed. In advising the Congress on what to include in the part A per diem payment, the agency took the position that it would be appropriate to include orthotics in the SNF part A per diem payment, because orthotics were frequently used, and could be overprovided, if separately reimbursed under part B.[14]

Medicare also covers orthotic devices and DME under part B in some instances. Orthotic devices are covered under part B for a beneficiary who is not in a part A-covered SNF or hospital stay. In contrast, DME is not covered under part B for a beneficiary in a facility that is primarily engaged in providing skilled nursing or rehabilitative services. These facilities include SNFs certified for Medicare part A payment and other facilities that meet criteria developed by HCFA and used to determine whether a facility is a SNF for DME payment purposes. However, Medicare part B covers both orthotics and DME for a beneficiary living at home or in an institution (other than a Medicare-certified SNF or other facility that meets HCFA's SNF criteria) that serves as a home. Information summarizing Medicare coverage for orthotics and DME is presented in table 1.

[12]The beneficiary is responsible for up to $99 per day for days 21 through 100.

[13]A benefit period begins on the first day of an inpatient hospital stay and ends 60 days after the beneficiary is discharged from the hospital or from a SNF or other inpatient facility providing skilled nursing or rehabilitative services. There is no limit to the number of benefit periods for a beneficiary.

[14]U.S. General Accounting Office, *Skilled Nursing Facilities: Services Excluded From Medicare's Daily Rate Need to be Reevaluated*, GAO-01-816 (Washington, D.C.: Aug. 22, 2001).

Table 1: Orthotic and DME Coverage for Medicare Beneficiaries

Location of beneficiary	Medicare coverage
Skilled nursing facility or hospital (part A stay)	Medicare's per diem under part A • includes orthotics and • includes DME.[a]
Skilled nursing facility (not part A stay)	Medicare part B • covers orthotics, but • does not cover DME.[a]
Home, including an institution serving as home	Medicare part B • covers orthotics and • covers DME.

[a]Part B payment for DME is allowed within 2 days prior to discharge from a SNF to allow for fitting of equipment for use in the home and training the beneficiary in its use.

Source: GAO analysis of Medicare coverage policy.

Suppliers and practitioners bill Medicare part B for orthotics and DME using the Healthcare Common Procedure Coding System (HCPCS) codes. Certain HCPCS codes are designated for orthotic devices, while others are designated for DME. Orthotic HCPCS code listings give a brief description of the device and state whether the device is prefabricated or custom-fabricated. Prefabricated, off-the-shelf devices are manufactured in quantity, such as an adjustable, semi-rigid, knee-joint brace. A prefabricated orthotic may be trimmed, bent, adjusted, or otherwise modified for use by a specific patient. An orthotic device that is custom assembled from prefabricated components is still considered prefabricated. Custom-fabricated devices are individually made for a specific patient, starting with basic materials, such as plastic, metal, leather, or cloth. These would include devices such as an ankle and foot brace that is attached to a shoe to control stability of the ankle and has been custom fabricated based on measurements of the patient's ankle and foot. Custom-fabricated orthotics include custom-molded devices, which are molded to a model of the patient—such as an ankle and foot brace custom-molded on a casting made from an impression of the patient's ankle and foot.[15]

Orthotics and DME suppliers and providers claim reimbursement for the services and products provided to Medicare beneficiaries under part B

[15]Molded to a patient model refers to the process in which an impression is made of a specific body part, and the impression is used to make a positive model of the body part. The orthotic device is then molded using this positive model.

from CMS's four DMERCs.[16] DMERCs are responsible for checking the validity of, and paying, orthotics and DME claims. Medicare part B has different methodologies, specified in law, for determining payment amounts for different categories of DME,[17] but generally uses separate fee schedules for each state, based on historical charges that have been updated some years to reflect inflation.[18] There are also upper and lower limits on the fees paid for DME.[19] For orthotics, Medicare uses 10 regional fee schedules, which are also based on historical supplier charges and are subject to upper and lower limits.[20] Payments for DME and orthotics are based on the lesser of the fee schedule amount or the submitted charge. DME and orthotics fee schedules include amounts for newly purchased items, rented items, and for purchase of used devices. The beneficiary is responsible for a 20 percent copayment for DME and orthotics covered under part B.

[16]In October 1993, HCFA began processing all Medicare part B claims for medical equipment, orthotics, prosthetics, and supplies through DMERCs. Each DMERC serves a separate region of the country.

[17]For DME and other covered medical supplies, there are six payment categories. These are (1) inexpensive and other routinely purchased items, (2) items requiring frequent and substantial servicing, (3) certain customized items, (4) oxygen and oxygen equipment, (5) other covered items (not DME), and (6) other DME (frequently referred to as capped rental items). 42 U.S.C. § 1395m(a)(2)-(7) (1994 & Supp. IV 1998). Separate provisions address Medicare payments for covered prosthetics and orthotics. 42 U.S.C. § 1395m(h) (1994 & Supp. IV 1998) and BIPA § 427(a).

[18]Prior to 1998, these fees were adjusted each year using formulas tied to the Consumer Price Index. No update was provided from 1998 through 2000 or in 2002, although updates were provided in 2001. 42 U.S.C. § 1395m(a)(14) (Supp. IV 1998); Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, App. F, § 228, 113 Stat. 1501, 1501A-356; and BIPA § 425.

[19]The upper limit is equal to the median or midpoint of the statewide fee schedule amounts. The lower limit is equal to 85 percent of the median of the statewide fee schedule amounts.

[20]For orthotics, the upper limit is based on 120 percent of the average of the regional statewide fees. The lower limit is based on 90 percent of the average of the regional statewide fees.

HCFA's Ruling Issued to Clarify Medicare Policy for Orthotics and DME

HCFA issued its orthotics ruling in September 1996 to clarify the distinction between certain DME and orthotics for Medicare part B billing purposes. HCFA's ruling helped address concerns about the manner in which some suppliers were billing Medicare for a system consisting of leg, arm, neck, and back supports that attached to a base. These suppliers were billing for each attached support as a separate orthotic brace. HCFA's ruling stated that it has been Medicare's longstanding policy to treat braces attached to DME or other medical or nonmedical equipment as DME. The ruling also said that only braces that could be used independently qualified as orthotics. Attached devices that brace individuals, such as items that attach to wheelchairs, would not be paid under Medicare's orthotics benefit. Shortly after it was issued, several beneficiaries, a manufacturer, and several suppliers of attached bracing devices challenged the ruling in court, claiming HCFA did not follow appropriate procedures because it should have promulgated this decision as a regulation after public notice and comment. However, a federal appellate court found that HCFA had acted properly in issuing it as a ruling, which is an appropriate way to interpret existing policy. The court also found that the interpretation in the ruling was wholly supportable and that the treatment of seating systems as DME was consistent with congressional intent.

HCFA's Ruling Clarified the Distinction Between Orthotics and DME

In the late 1980s and early 1990s, HCFA and its contractors had become increasingly concerned about how certain suppliers were billing Medicare. Particular concern was raised by the way in which suppliers of an item manufactured by a company called OrthoConcepts[21] were billing Medicare. The OrthoConcepts system consisted of leg, arm, neck, and back supports that attached to a base that could be put on wheels. OrthoConcepts said that its adjustable system of multiple supports provided orthotic support to the body, which would be particularly helpful to individuals with severe neurological problems who needed to be properly positioned. Suppliers of its system were billing each attached support as a separate orthotic brace, using multiple orthotics billing codes that described braces expected to be used independently of other medical equipment. As DMERCs became aware of this billing practice, they began to deny these orthotics claims because the attached bracing devices being provided as a group appeared to be similar in function to a seating system or customized wheelchair,

[21]OrthoConcepts is an orthotic management company that has developed an adjustable seating system for nursing home residents.

which were both considered DME. However, some of the claims denials were subsequently overturned by an ALJ, who hears Medicare appeals on denied claims.

These decisions by an ALJ prompted HCFA to issue its September 1996 ruling, which is binding on these judges. HCFA's ruling limited payment for orthotics under Medicare part B to leg, arm, back, and neck braces that can be used independently of other equipment. (See app. II for an excerpt from the *Conclusions and Illustrations* section of the ruling to demonstrate its practical application.) As a result of the ruling, attached bracing devices, such as OrthoConcepts' items and other attached devices, were placed in the DME benefit category and could no longer be billed as orthotics.

The ruling cited the Congress' action in the Omnibus Budget Reconciliation Act of 1990 (OBRA) as evidence for Medicare's policy on whether attached items could be considered orthotics. OBRA provided that wheelchairs measured, fitted, or adapted for a particular patient, and assembled or ordered with customized features, modifications, or components intended for a specific patient's use, were considered customized DME.[22] A committee report on the OBRA legislation discussed how wheelchairs could be customized by adding attachments, such as postural control devices and custom-molded cushions, inserts, or lateral supports designed to brace the individual using the wheelchair.[23] HCFA concluded in its ruling that, while the Congress specifically addressed only customized wheelchairs and their accessories in OBRA, it also intended that devices attached to noncustomized wheelchairs be considered part of the wheelchair and, therefore, DME.

Court Finds HCFA Acted Properly in Issuing the Ruling

Concern about whether HCFA's issuance of its ruling violated statutory requirements was the focus of a court challenge in 1997. The ruling was challenged by OrthoConcepts, whose seating system was affected by the ruling; two Medicare beneficiaries, who used the OrthoConcepts product;

[22]Pub. L. No. 101-508, § 4152(c)(4), 104 Stat. 1388, 1388-79. The law established relevant criteria applicable to items furnished after January 1, 1992, unless regulations establishing other criteria were developed before that date. Regulations establishing other criteria, closely related to those in the law, 42 C.F.R. § 414.224 (2001), were finalized on December 20, 1991. 56 Fed. Reg. 65,995.

[23]H. R. Rep. No. 101-881, at 268 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2270.

and three DME suppliers of the OrthoConcepts product. These parties argued that the ruling was invalid because it was adopted without following the prescribed notice and comment procedures for a substantive rule and that the agency's refusal to classify the OrthoConcepts seating system as orthotics was arbitrary and capricious.

After these parties were initially successful in challenging the ruling in the United States District Court for the District of Massachusetts, HCFA appealed the lower court's decision. On July 27, 1998, the United States Court of Appeals for the First Circuit found that HCFA's characterization of the OrthoConcepts seating system as DME was consistent with the agency's earlier stated position covering such devices and that the agency had merely clarified its policy. Further, the court held that HCFA was not required to provide for public notice and comment before issuing the ruling because it was interpretive rather than legislative or substantive. Because HCFA had followed federal requirements for an interpretive rulemaking, the court also held that the agency had not acted in an arbitrary and capricious manner in issuing the ruling. Furthermore, the court found that the interpretation in the ruling was wholly supportable and that the ruling's treatment of seating systems as DME was consistent with congressional intent. The Supreme Court denied a request to hear a further appeal.

HCFA's Ruling Affects Beneficiaries Who Reside in Nursing Homes

As a result of HCFA's ruling, attached bracing devices are now clearly classified as DME and cannot be billed as orthotics, which affects beneficiaries who live in nursing homes. Part B no longer pays claims for attached bracing devices for beneficiaries in institutions primarily engaged in providing skilled nursing care because part B does not cover DME in these settings. HCFA and the DMERCs developed criteria and guidance on how to define such institutions that prohibit payment for DME for beneficiaries in most nursing homes—not just Medicare-certified SNFs. These beneficiaries would need to purchase such devices with their own resources or through other payers.

When Medicare was established in 1965, facilities providing skilled nursing care under part A were expected to serve as a bridge between the hospital and other, less skilled care or home.[24] Medicare part B did not cover medical and other health services—such as DME—provided in what were

[24]S. Rep. No. 89-404, pt. 1, at 30 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1971.

then called extended care facilities and are now called SNFs.[25] Medicare part B did pay for DME in facilities that provide a lesser level of care, but as the nursing home industry evolved, fewer did not provide skilled care. In 2001, most nursing homes were certified as SNFs. A significant number of Medicare beneficiaries reside more or less permanently in SNFs or other nursing homes that DMERCs consider as meeting HCFA's criteria for a SNF for DME payment purposes. Such beneficiaries are therefore unable to obtain Medicare coverage for DME, while other beneficiaries living in congregate settings such as assisted living facilities, as well as those living at home, do receive DME coverage.

HCFA's Ruling Reduced Medicare Payments For Beneficiaries in Nursing Homes by at Least $1.4 Million

Following the ruling, claims were no longer paid for attached bracing devices for beneficiaries living in nursing homes, which caused a drop in the number and amount of such claims paid by Medicare. Medicare expenditures for such devices declined by at least $1.4 million[26] between 1996 and 1997, and expenditures remained lower in subsequent years. Prior to the ruling, the HCPCS coding system had nine codes that described bracing devices that attached to wheelchairs.[27] Suppliers used these codes to bill for such items under Medicare's orthotics benefit category and DMERCs paid such claims. These devices included one back support to position wheelchair users and eight mobile arm supports to assist them in moving their hands and arms. (See table 2 for information on these nine devices.) These codes were unlike other orthotics codes because most of the other HCPCS orthotics codes were for braces designed to be used independently of other equipment. In addition, most other items that attached to wheelchairs—such as special headrests to provide postural support—had codes that categorized them as DME and were paid under the DME benefit category.

[25]Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), sec. 1861(s), 79 Stat. 286, 321.

[26]This amount is based on the difference between calendar year 1996 and 1997 claims payment for nine codes that described attached bracing devices that were classified as DME after the ruling.

[27]Having applicable codes does not mean that items are covered by Medicare, or that they are in the appropriate benefit category.

Table 2: Attached Bracing Devices HCFA's Coding System Classified as Orthotics Prior to the Ruling

Device name	HCPCS code	Description	Fee schedule amount[a] (floor-ceiling)
Back support system	K0114	Prefabricated back support system, with inner frame, for use with wheelchair.	$616.56-725.36
Shoulder elbow orthosis	L3964	Prefabricated mobile arm support attached to wheelchair. Cost includes fitting and adjustment.	$505.08-594.21
Shoulder elbow orthosis	L3965	Prefabricated Rancho type mobile arm support attached to wheelchair. Cost includes fitting and adjustment.	$805.96-948.19
Shoulder elbow orthosis	L3966	Prefabricated mobile arm support attached to wheelchair. Cost includes fitting and adjustment.	$607.16-714.31
Shoulder elbow orthosis	L3968	Prefabricated mobile arm support attached to wheelchair. Cost includes fitting and adjustment.	$768.34-903.93
Shoulder elbow orthosis	L3969	Prefabricated mobile arm support attached to wheelchair. Cost includes fitting and adjustment.	$537.30-632.12
Shoulder elbow orthosis	L3970	Addition to mobile arm support, which elevates arm.	$214.93-252.86
Shoulder elbow orthosis	L3972	Addition to mobile arm support.	$136.67-160.79
Shoulder elbow orthosis	L3974	Addition to mobile arm support.	$115.92-136.38

[a]Fee Schedule amount is for new item.

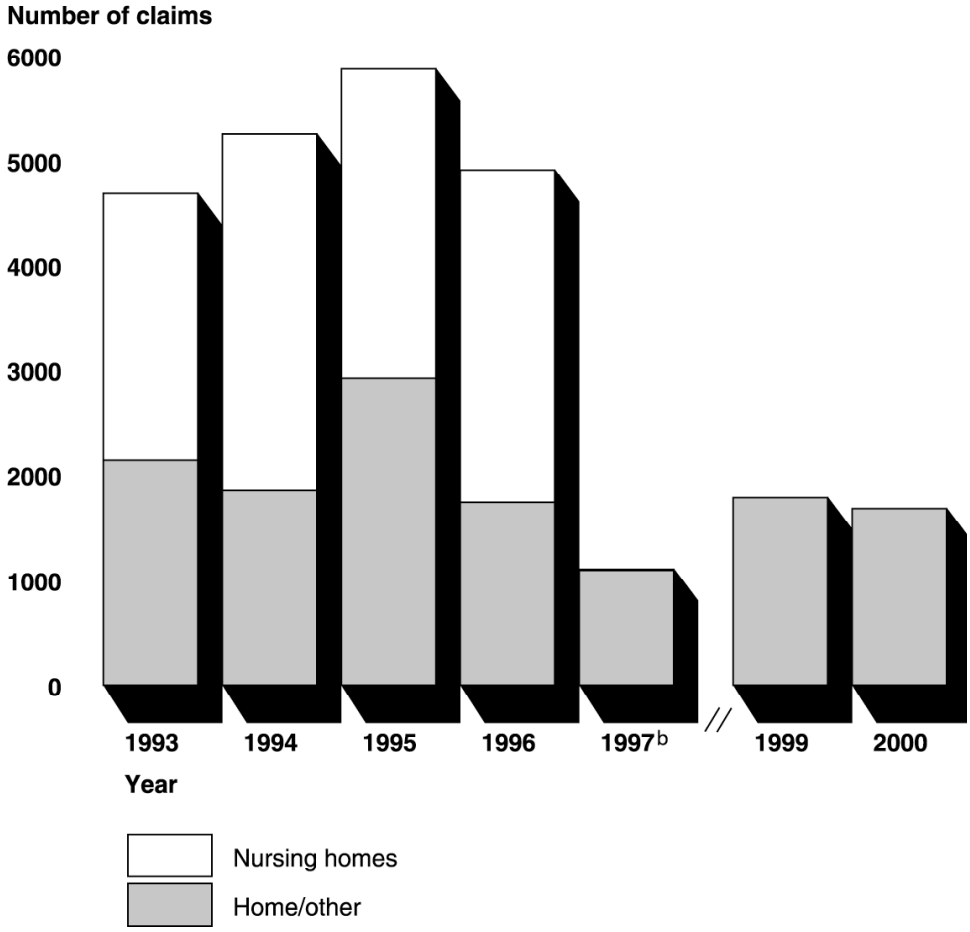
Source: 2001 Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule.

To develop a conservative assessment of the effect of the ruling on claims payment, we analyzed Medicare claims data for the nine attached bracing devices that were classified in the DME—rather than the orthotic—benefit category as a result of the clarification in the ruling. Our analysis showed that Medicare part B expenditures for the nine attached bracing devices provided to beneficiaries in nursing homes dropped by about $1.4 million

between 1996 and 1997[28] and the number of claims paid for these beneficiaries for such devices declined from about 3,200 claims in 1996 to only 11 claims in 1997. Furthermore, the reduction has continued, with no claims paid for the nine attached bracing devices for beneficiaries in nursing homes in either 1999 or 2000. (See fig. 1.) However, our estimate of the change in Medicare spending for attached bracing devices for nursing home residents prior to and after the ruling is conservative because payment under the nine codes we analyzed does not represent all payments for such devices. Some suppliers—such as those providing OrthoConcepts' products—were billing for attached bracing devices using codes for nonattached braces. Because both attached and nonattached items were being billed using these codes, we could not isolate the claims for attached items from claims for nonattached items. As a result, we could not analyze all billing in the orthotics benefit category for attached bracing devices prior to the ruling.

[28]The total decrease in expenditures for the nine attached bracing devices is based on 1996 and 1997 claims for beneficiaries in nursing homes. We used data from 1996 and 1997 because payment changes for the nine devices were implemented on January 1, 1997.

Figure 1: Total Part B Annual Claims for Nine Attached Bracing Devices Affected by the Ruling from 1993 through 2000[a]



[a]Calendar year data for 1998 were not available in CMS's Medicare part B extract and summary system for all nine devices.

[b]Eleven claims were paid for beneficiaries in nursing homes in 1997.

Source: GAO analysis of data from CMS's Medicare part B extract and summary system.

The effect of the ruling was to make beneficiary place of residence pivotal as to whether Medicare would reimburse for attached bracing devices under part B. HCFA's ruling did not affect Medicare beneficiaries living in their own homes, or settings such as assisted living facilities, because

attached bracing devices that are considered DME are covered for beneficiaries in those settings.[29] The ruling affected beneficiaries who are long-term residents of SNFs and other institutions primarily engaged in providing skilled nursing care because DME is not covered by part B for beneficiaries in these facilities. If the beneficiary is in a part A-covered stay, both orthotics and DME are included in the per diem part A payment. However, when a beneficiary is not in a Medicare part A-covered stay, part B will cover orthotics, but not DME, including customized DME items that are uniquely constructed or substantially modified for a specific beneficiary.

Some beneficiaries who reside in SNFs and other institutions primarily engaged in providing skilled nursing care and need attached bracing devices that are not paid for through Medicare can obtain them through other sources. For example, certain state Medicaid programs separately cover attached bracing and similar devices as customized DME for nursing home residents, and other Medicaid programs may include payment for these devices in their per diem rates. However, other beneficiaries may have to pay out of pocket or forgo using such devices.

DME Coverage Policy Predates Evolution of Nursing Home Industry

The policy of not covering DME for beneficiaries in facilities primarily engaged in providing skilled nursing care has its roots in the early years of the Medicare program. When the Congress created the Medicare program in 1965, part A was designed to cover only hospitalizations and relatively short-term, post-hospital care in the home or in a facility that provided skilled nursing care.[30] Part A post-hospital care in such a facility was expected to involve skilled nursing or rehabilitative care, which would serve as a bridge between the hospital and other, less intense nursing care or therapy. In this skilled nursing home environment, Medicare did not pay for any service, drug, or other items under part A—including DME and orthotics—that could not be paid for if furnished in a hospital. Payment under part A for a beneficiary's SNF stay would cover only such needs as would be covered for a beneficiary's hospital stay. When the Medicare

[29]Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2321, 98 Stat. 494, 1085 (codified as amended at 42 U.S.C. § 1395x(n) (1994)) explicitly defined DME to include certain items used in the home, including in an institution used as a home, other than one primarily providing hospital or skilled nursing facility services.

[30]Outpatient hospital diagnostic services were originally covered under part A also. Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 102(a), § 1812(a)(4), 79 Stat. 286, 291-92.

program began, facilities providing skilled nursing care were not expected to serve as patients' residences past the immediate recovery from their hospitalization.

Medicaid's coverage of nursing home care is broader than Medicare's, because Medicaid also covers institutional care for beneficiaries who do not need skilled nursing care. In 1971, the Congress expressly designated intermediate care facilities (ICF) as a service states could cover under Medicaid. ICFs were defined as providing regular health-related care and services to individuals who needed institutional care and services above the level of room and board, but not the level of care a hospital or a SNF would provide.[31] State Medicaid policies, rather than the statute's distinction in the types of care provided, determined whether nursing homes were designated as SNFs or ICFs. In some states, almost all nursing homes were designated as SNFs, although many of these SNFs served longer term residents who would be receiving care similar to that provided by ICFs in other states.

Under the original 1965 Medicare statute, part B did not pay for medical and health services provided by hospitals, extended care facilities (now known as SNFs), or home health agencies.[32] As a result, DME and other ancillary services—such as physical therapy—were not paid for under part B in a SNF. In 1967, the law was changed to eliminate the prohibition on part B payment for certain ancillary services provided in a SNF. In a report accompanying the 1967 legislation, the Senate Finance Committee noted that retaining a sweeping part B prohibition against paying for any services under part B in a SNF would deprive a beneficiary who had exhausted, or never qualified for, part A benefits of any payment for services that—in another setting—would be separately coverable under part B.[33] However, the Congress added language that retained the prohibition on paying for

[31]H.R. Conf. Rep. 92-747 at 9 (1971), *reprinted in* 1971 U.S.C.C.A.N. 2436, 2439. This included services in a public institution for the mentally retarded if the primary purpose of such an institution was to provide health or rehabilitative services—therefore, the provision of rehabilitative services did not exclude a facility from being designated as an ICF.

[32]Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), sec. 1861(s), 79 Stat. 286, 321.

[33]S. Rep. No. 90-744, at 85 (1967), *reprinted in* 1967 U.S.C.C.A.N. 2834, 2908.

DME under part B in a SNF, at the same time that it allowed part B payment in a SNF for other ancillary services.[34]

HCFA and its carriers had to delineate when a facility was primarily engaged in providing skilled nursing care, particularly for facilities that were not Medicare- or Medicaid-certified SNFs, such as ICFs. In 1982 and 1984, HCFA published rulings with criteria to determine under what circumstances a facility would be classified as primarily engaged in providing skilled nursing care.[35] A facility has to meet five criteria to be considered as primarily engaged in providing skilled nursing care:

- Nursing services are provided under the direction or supervision of one or more registered, licensed practical, or vocational nurses.
- Nursing personnel, including nursing aides or orderlies, are on duty on a 24-hour basis.
- On average, the ratio of full-time equivalent nursing personnel to the number of beds (or average patient census) is no less than 1 to 15 per shift.
- Bed and board are provided to inpatients in connection with the furnishing of nursing care, plus one or more medically related health services, such as physicians' services; physical, occupational, or speech therapy; diagnostic and laboratory services; and administration of medication.
- The facility is not licensed or certified solely as an ICF.

These criteria provided a means for identifying facilities that may not meet all of the requirements for SNFs but could be classified as primarily engaged in providing skilled nursing care for the purposes of prohibiting part B DME coverage.[36] In a 1985 court case, HCFA indicated that about 90 percent of the 11,000 ICFs were classified as primarily providing skilled nursing care, leaving about 10 percent of ICFs as being facilities in which beneficiaries could have part B coverage for their DME.

[34]Social Security Amendments of 1967, Pub. L. No. 90-248, § 144(a) and (d), 81 Stat. 821, 859.

[35] 47 Fed. Reg. 54,551 (Dec. 3, 1982) and 49 Fed. Reg. 10,710 (Mar. 22, 1984). According to HCFA, the first four criteria outlined in the 1982 ruling had been in use since 1966. *Miller v. Heckler*, 601 F. Supp. 1471, 1475 (E.D. Tex. 1985). The fifth criterion was added through the 1984 ruling as a result of a court order in *Kron v. Heckler*, Civil Action No. 80-1332 (E.D. La., Oct. 17, 1983).

[36]The full statutory definition of a SNF includes being primarily engaged in providing skilled nursing care, but includes other requirements as well. The prohibition on providing DME is tied only to the first part of the statutory definition.

ICF as a category of nursing home distinct from a SNF under Medicaid disappeared when the Omnibus Budget Reconciliation Act of 1987 combined them into a single category, nursing facility (NF).[37] A single set of requirements was developed for all nursing homes participating in Medicare and Medicaid. With the single set of participation requirements and more generous Medicare coverage of stays, many more nursing homes became wholly or partially[38] certified as Medicare SNFs to be eligible for part A payment.[39] Most of their residents would, however, still need longer term less skilled services that would not qualify for part A coverage.

In 2001, most nursing home residents were in SNFs, including Medicare beneficiaries who were long-term residents.[40] Although they are in SNFs, these Medicare beneficiaries may not be receiving a level of care that would qualify them for the Medicare part A-covered SNF benefit or otherwise might not be eligible for this coverage, which is only post-hospital and for a maximum of 100 days. Such beneficiaries who are paying for their care out of their own pockets or through other payers are not eligible for part B DME benefits that they could receive if living at home or in an assisted living facility. This prohibition includes even paying for items that need to be customized for them, such as customized wheelchairs.

Beneficiaries in NFs are also included in the group for which DME is not payable under part B. The four DMERCs have issued guidance to suppliers indicating that they will not pay for DME under part B in any nursing home. For example, the region B DMERC supplier manual, dated June 2000, states "DME and related supplies and accessories are not covered by

[37]Pub. L. No. 100-203, § 4211, 101 Stat. 1330, 1330-182 (codified at 42 U.S.C. 1396r(a)(1) (1994). A NF is defined somewhat more broadly than a SNF. A NF includes an institution (or distinct part of an institution) primarily engaged in providing skilled nursing care or rehabilitative services. A NF also includes an institution primarily engaged, on a regular basis, in providing health-related care and services to individuals who, because of their physical or mental condition, require care and services (above the level of room and board) that can be made available to them only through institutional facilities, which were formerly called ICFs. 42 U.S.C. § 1396r(a)(1).

[38]Medicare allows nursing facilities to designate some beds as a distinct part that qualifies as a SNF. Beneficiaries in those beds may be eligible for part A coverage and payment.

[39]Between 1989 and 1997, the number of SNFs participating in the program increased from 8,638 to 14,619.

[40]About 80 percent of federally-certified nursing homes are certified as both SNFs and NFs, about 7 percent only as SNFs, and about 13 percent as only NFs.

Medicare part B and claims must not be submitted to the DMERC for patients in a SNF or NF, regardless of whether the patient is in a Medicare covered stay or not. This is true even if the nursing facility could be considered the patient's permanent residence." CMS officials noted that DMERCs do not pay for DME in nursing homes because DMERCs presume that these facilities meet the criteria for being primarily engaged in providing skilled nursing care for DME part B payment purposes and, therefore, cannot be considered as a beneficiary's home.

Rescinding the Ruling Would Increase Medicare Payments, But Financial Impact on States Would Vary

If the ruling were rescinded by CMS and attached bracing devices were paid as orthotics, annual spending under Medicare part B for such devices for beneficiaries in nursing homes would increase modestly if utilization returned to the pre-ruling level. However, several factors suggest that utilization could increase more with the ruling's rescission. The effect on Medicaid expenditures is less certain. Because state Medicaid coverage policies are not uniform, rescinding the ruling would have a varying effect on states' Medicaid expenditures.

It is difficult to predict with confidence how much Medicare payments might increase if the ruling were rescinded. For example, if the utilization level returned to the pre-ruling level, spending increases would be modest. Rescinding the ruling would move the nine HCPCS codes for attached bracing devices back into the orthotics benefit category. If the change were limited to billing under those nine codes and we assumed no growth in future billing, claims volume might only return to the pre-ruling level. This would be an increase of about 3,000 claims, and payment increases of about $1.8 million per year—given the amounts Medicare currently pays for these items, which generally now cost between $500 and $800.[41] However, as discussed above, this estimate is based on a claims analysis that does not include all the billing for attached devices that occurred before the ruling. Because some suppliers billed attached bracing devices using codes that were not specific for such devices, all of the claims paid prior to the ruling for attached bracing devices cannot be identified with certainty.

[41]This estimate is based on 1996 claims volume for these nine devices for beneficiaries in SNFs and NFs and 2001 fee schedule amounts for these items. We used 1996 data on claims volume because payment changes for the nine devices were implemented on January 1, 1997.

Moreover, several factors could lead to considerable growth in the use of such devices, which would increase Medicare costs more substantially than our conservative estimate. First, the number of Medicare beneficiaries is likely to grow significantly over time, with the number over age 85 growing fastest, which would likely increase demand for bracing devices in nursing homes.[42] In addition, estimates of the number of beneficiaries who might use attached bracing devices are higher than the prior utilization levels for the devices we identified. Our analysis of data maintained by CMS on characteristics of nursing home residents identified about 53,000 nursing home residents from July 1999 through June 2000 who at that time were 65 years and older, were likely eligible for Medicare part B, and were wheelchair-bound with disabling medical conditions, pressure ulcers, and functional limitations. Others have also developed estimates on the number of elderly nursing home residents with characteristics that indicate that they could potentially use attached bracing devices. These estimates vary considerably—ranging from 35,000 individuals by OrthoConcepts[43] to almost 170,000 individuals by researchers at the University of Pittsburgh.[44] HCFA developed an estimate of as many as 80,000 individuals who might potentially use these attached bracing devices.

Second, should the ruling be rescinded, Medicare part B would pay for attached bracing devices for nursing home residents, providing financial

[42]According to estimates by the Urban Institute, assuming no change in the eligibility rules, the number of beneficiaries in the Medicare program will grow by 77 percent by the year 2025, from about 40 million to an estimated 70 million. The Institute of Medicine estimated that if current trends continue, the number of people over age 85 will triple by 2030, reaching about 8.8 million. This rapid growth in the oldest population will have a major effect on the demand for long-term care services.

[43]OrthoConcepts officials estimated that about 10 percent of these individuals—or about 3,500 residents of nursing homes—would be suitable candidates for their seating system, which is designed to meet the needs of the most severely disabled with complex seating needs.

[44]Geyer, et al, *Efficacy of Seat Cushions in Preventing Pressure Ulcers for At Risk Elderly Nursing Home Residents: Research Issues*, Departments of Rehabilitation Science and Technology and Epidemiology, University of Pittsburgh, (Pittsburgh: June 26-30, 1998) pp. 122-124.

incentives that could lead to increased utilization.[45] For example, suppliers who could profitably furnish attached bracing and related devices to beneficiaries in nursing homes would have a financial incentive to supply that market. Manufacturers would have incentives to develop new products that fit within the orthotics definition—such as chairs that provide "orthotic" support—if such items could be paid for under part B. Many items that support and position wheelchair-bound individuals could be described as having an orthotic benefit, including the chair itself. Furthermore, some nursing homes might shift a portion of the costs of their beneficiary services to Medicare. For example, to increase their revenues, nursing homes could substitute orthotics devices that could be paid separately under part B for items of DME that are not separately paid under part B. Finally, if the ruling were rescinded, the distinction between DME and orthotic devices would be blurred, making it more confusing for providers who are trying to bill appropriately and more difficult for DMERCs to identify and deny claims that were inappropriately billed.

In addition to increasing Medicare expenditures, rescinding HCFA's ruling would also affect state Medicaid expenditures for beneficiaries who are dually eligible for Medicare and Medicaid.[46] These effects also cannot be quantified with certainty. The impact on a particular state's spending would depend on its current coverage policies for customized DME, increases in the use of such items, and changes in state reimbursement policies. For example, states paying separately for customized DME—for example, Michigan, Ohio, and Washington—would likely see their expenditures decrease. Since Medicare would become the primary payer for such items, these states would be responsible only for the copayments and deductibles for these beneficiaries. However, increases in the use of such devices could significantly affect potential Medicaid cost savings. Other states—such as Florida—do not separately cover customized DME. If the ruling were rescinded, these states would become responsible for

[45]For examples of changes in provider and supplier behavior associated with changes in financial incentives, see U.S. General Accounting Office, *Medicare Home Health Care: Prospective Payment System Could Reverse Recent Declines in Spending*, GAO/HEHS-00-176 (Washington, D.C.: Sept. 8, 2000); U.S. General Accounting Office, *Medicare: HCFA Faces Challenges to Control Improper Payments*, GAO/T-HEHS-00-74 (Washington, D.C: Mar. 9, 2000); and Technical Review Panel on the Medicare Trustees Report, *Review of the Assumptions and Methods of the Medicare Trustees' Financial Projections*, Dec. 2000.

[46]There are 1.5 million residents of nursing homes, and about 75 percent are covered by Medicare, Medicaid, or both programs.

copayments and deductibles for Medicaid-eligible beneficiaries, which could cause states' payments to increase. However, these states may offset potential cost increases if they reduced their Medicaid per diem rates. Such reductions could be justified because these states would now be required to separately cover a portion of the cost of items that had been previously covered in their nursing homes' per diem rate.

Ruling's Rescission Would Have Implications for Medicare Program Integrity

The rescission of HCFA's ruling on orthotics would raise program integrity concerns. If HCFA's ruling on orthotics were rescinded by CMS, the requirement in BIPA aimed at increasing program integrity by restricting payment for custom-molded orthotics to qualified providers would not apply to the attached bracing devices we identified as being affected by the ruling. Even if some attached bracing devices were affected by the new BIPA requirement after the ruling's rescission, this requirement may have limited potential for curbing inappropriate orthotic payments because most Medicare payments are for orthotics not covered by the requirement and, if industry trends continue, proportionally fewer devices may be covered by the requirement in the future. In addition, the ruling's rescission could lead to inappropriate billing because suppliers would have more difficulty determining if items should be billed as orthotics or DME, given that the distinction between some items in these two benefit categories would be less clear. Furthermore, Medicare beneficiaries in nursing homes have been the target of fraudulent or abusive billing in the past for orthotics, DME, and other services. Therefore, should the ruling be rescinded, additional controls would be needed.

BIPA Requirement Added to Safeguard Orthotics Payments

The BIPA requirement was developed because the HHS OIG had reported on problems related to Medicare orthotics in recent years, including inappropriate billing practices associated with these devices.[47] For example, the OIG found that, compared to certified suppliers, noncertified suppliers are more likely to inappropriately provide or bill for orthotics. The OIG recommended that HCFA require that only qualified practitioners provide beneficiaries with certain kinds of orthotic devices.

BIPA modified the Medicare requirements related to customized items to stipulate that Medicare will pay for custom-molded orthotics only if furnished by a qualified practitioner and fabricated by a qualified

[47]OEI-02-99-00120, OEI-02-95-00380, and OEI-04-92-01080.

practitioner or supplier.[48] The statutory definition of qualified practitioner includes a physician; an orthotist who is licensed, certified, or has credentials and qualifications approved by the HHS Secretary; or a qualified physical therapist or occupational therapist. The language added by BIPA describes a custom-fabricated orthotic as an item that (1) requires education, training, and experience to fabricate, (2) is included in a list of items to be developed by CMS, and (3) is individually fabricated over a positive model of the patient. CMS will be working with experts in the field of orthotics, using a negotiated rulemaking process,[49] to develop the list of custom-fabricated orthotic items subject to the new requirement.[50]

Professionals in the field of customized seating and orthotics told us that they believe the new BIPA requirement relating to qualified providers will help address some problems related to inappropriate billing. They also said that the requirement will improve the quality of care provided to beneficiaries by ensuring that providers have the knowledge and skills needed to craft and fit custom-molded orthotic devices.

However, the BIPA requirement regarding qualified practitioners and suppliers may have limited potential for curbing inappropriate orthotic payments in the program as a whole for several reasons. Medicare expenditures for custom-molded orthotics amounted to less than 30 percent of Medicare spending for orthotics in 2000.[51] Furthermore, the requirement may apply to an even smaller percentage of covered orthotic devices in the future, because due to technological advances, more prefabricated devices that can serve functions similar to customized

[48]BIPA § 427(a) (to be codified at 42 U.S.C. § 1395m(h)(1)(F)).

[49]Negotiated rulemaking is a process for developing a proposed rule using a committee of representatives with interests that may be significantly affected by the rule, chartered as an advisory committee under the Federal Advisory Committee Act. The committee works to reach consensus on key elements of the rule before it is formally published as a proposal. An impartial mediator assists the committee, which is open to the public.

[50]BIPA required that CMS publish a regulation with a list of specific items by December 21, 2001. On March 22, 2002, CMS published a notice of intent in the *Federal Register* to form a negotiated rulemaking committee. CMS has begun the chartering process for the committee, and agency officials do not anticipate that the committee will begin the required negotiations to develop a list of custom-fabricated orthotic items subject to the new BIPA requirement before the summer of 2002.

[51]For items covered by the BIPA requirement—custom-molded orthotic devices—Medicare paid practitioners and suppliers approximately $70 million. In contrast, expenditures in 2000 for orthotic devices not covered by the requirement amounted to more than $184 million.

components with little or no alteration are entering the market. Therefore, if this trend continues, proportionately fewer devices will be covered by the new BIPA requirement because the payment restriction is limited to custom-molded orthotics. Finally, limiting payment to qualified practitioners and suppliers does not, in itself, completely resolve questionable billing practices because some of these providers have also billed Medicare inappropriately. For example, in 1997, the HHS OIG reported that certified orthotists billed improperly for items that were not medically necessary or not provided as billed, but to a lesser degree than other suppliers. In 1999, the OIG also reported on instances of improper billing for therapy by physical and occupational therapists working in SNFs[52] —professionals who can be considered qualified practitioners and may supply custom-molded orthotics under the BIPA requirement.

Further Controls Would Better Ensure Program Integrity If The Ruling Were Rescinded

If the ruling were rescinded, the new requirement in BIPA that Medicare pay only qualified practitioners and suppliers for custom-molded orthotics would not apply to the attached bracing devices that we identified as affected by the ruling. BIPA's requirement applies only to custom-molded orthotic devices, not all custom-fabricated ones. The devices we identified as being affected by the ruling are not custom-molded because they are not made over a positive model of the patient's body part.

If HCFA's ruling on orthotics were to be rescinded, a heightened level of oversight of orthotics billing would be critical to safeguard program dollars. Concerns about improper billing prompted HCFA to issue its orthotics ruling to clarify the distinction between DME and orthotics for Medicare part B billing purposes in the first place. Rescinding the ruling would once again blur the distinction between DME and orthotics, increasing the potential for inappropriate billing—both intentional and unintentional.

A heightened level of oversight would be also be critical, because the OIG and we have reported that Medicare beneficiaries in nursing homes can be an attractive target for fraudulent or abusive billing for orthotics, DME,

[52]Office of Inspector General, Department of Health and Human Services, *Physical and Occupational Therapy in Nursing Homes: Medical Necessity and Quality of Care*, OEI-09-97-00121 (Washington, D.C.: August 1999).

and other services.[53] Because nursing homes are institutions with a large number of co-located beneficiaries, providing services to multiple individuals in this setting can help maximize profits for providers and suppliers. Although most providers and suppliers are honest and bill appropriately,[54] some, including certain durable medical equipment and orthotics suppliers, have been involved in fraudulent or abusive billing of Medicare for services and supplies furnished to nursing home residents.[55]

Other controls could enhance safeguards associated with Medicare reimbursement for orthotics, should the ruling be rescinded. In the past, Medicare expenditures have increased more than anticipated after a coverage policy change, due, in part, to inappropriate billing.[56] Without adequate monitoring of orthotics payments, rescinding the ruling could have a similar outcome. DME claims are currently monitored so that DMERCs can follow payment trends over time for groups of codes for similar types of items (such as leg braces). If the ruling were rescinded, DMERCs might have to extend their monitoring in order to analyze payment trends for attached devices. Through monitoring claims billing, DMERCs would be more likely to spot any questionable trends. If such trends were identified, DMERCs could examine a sample of questionable claims and their related medical records and take other steps as needed to determine if the items were medically necessary and provided as billed.

A prior authorization process, such as those used by some state Medicaid programs for higher priced or other selected orthotic or DME items, may also provide better control, should the ruling be rescinded. These

[53]Office of Inspector General, Department of Health and Human Services, *Part B Services in Nursing Homes*, *An Overview*, OEI-06-92-00865 (Washington, D.C.: March 1996); U.S. General Accounting Office, *Nursing Homes: Too Early to Assess New Efforts to Control Fraud and Abuse*, GAO/T-HEHS-97-114 (Washington, D.C.: April 16,1997); and U.S. General Accounting Office, *Fraud and Abuse: Providers Target Medicare Patients in Nursing Facilities*, GAO/HEHS-96-18 (Washington, D.C.: Jan. 24, 1996).

[54]The OIG reported that the majority of health care providers submit claims to Medicare for services that are medically necessary, billed correctly, and documented properly. See Office of Inspector General, Department of Health and Human Services, *Improper Fiscal Year 2000 Medicare Fee-for Service Payments*, A-17-00-02000 (Washington, D.C.: February 2001).

[55]GAO/HEHS-96-18.

[56]U.S. General Accounting Office, *Medicare: Lessons Learned From HCFA's Implementation of Changes to Benefits*, GAO/HEHS-00-31 (Washington, D.C.: Jan. 25, 2000).

Medicaid programs review medical justifications and a description of the orthotic or customized DME item before it is provided to the beneficiary. If the item is justified, Medicaid notifies the supplier in advance that it will pay for the item and the amount it will pay. The Medicaid prior authorization process helps ensure program integrity because it establishes that the device is medically necessary. Some providers and suppliers also noted that prior authorization protects them from the risk of supplying devices without knowing whether and what they will be paid. However, the use of the prior authorization process by the Medicaid program involves an investment of time and resources for prior review of supporting documentation.

For Medicare, DMERCs do not use all the elements of a prior authorization process. However, they have begun to use a process for determining coverage—but not payment—in advance for a few items of DME. As of October 1, 2001, as part of ongoing program integrity efforts, DMERCs will accept requests from beneficiaries and suppliers for an advance determination of Medicare coverage for customized DME, which is an item that has been uniquely constructed or substantially modified for a specific beneficiary.[57] This process differs from the prior authorization used by Medicaid programs in the states whose processes we reviewed because an advance determination of Medicare coverage does not guarantee a specific amount that Medicare will pay for an item. As a result, suppliers will be uncertain about how much reimbursement to expect for customized wheelchairs and accessories that they supply to beneficiaries. Practitioners reported that such uncertainty affects suppliers' willingness to provide customized items to beneficiaries.[58]

Concluding Observations

HCFA's 1996 ruling on orthotics more clearly delineated the circumstances under which Medicare would consider an item as an orthotic or DME for payment policy, and HCFA's issuance of the ruling was found to be proper in court. The ruling affected relatively few devices and only a small percentage of overall Medicare program expenditures. Without the ruling,

[57]Previously, there was a process that only considered whether power-driven vehicles, seat-lift mechanisms, and transcutaneous electrical nerve stimulators would be covered.

[58]Prior to this, suppliers had to code customized wheelchairs and accessories as miscellaneous items and DMERCs made individual coverage and payment decisions after the items were supplied to beneficiaries. As a result, suppliers had no guarantee that Medicare would reimburse them for an item at all.

there would be some confusion for suppliers about whether bracing devices that are attached to wheelchairs should be billed as DME or orthotics and for DMERCs about whether particular claims should be paid. Revising Medicare payment policy to treat attached bracing devices as orthotics would likely increase program expenditures, although to what degree is uncertain. We would caution that taking such a step without addressing program integrity concerns could lead to an increase in inappropriate payments by Medicare and Medicaid.

Agency Comments and Our Evaluation

We provided a draft of this report to CMS for its review and comment. (See app. III for CMS's comments.) CMS generally agreed with our conclusions. In its comments, CMS observed that, in addition to holding that the orthotics ruling had been properly issued, the U.S. Court of Appeals decision in *Warder v. Shalala* had also found that the content of the ruling was wholly supportable and that the ruling well effectuated congressional intent by classifying seating systems as DME. We agreed and added language to that effect to our final report.

CMS also suggested that our report clearly indicate the precedent-setting effect that rescinding the ruling could have on the provision of certain types of equipment as DME in SNFs. For example, CMS said that if the ruling were rescinded, other components of a wheelchair could be construed to be an orthotic, such as the backrest of a wheelchair. In our report, we discuss and provide examples of the potential impact of rescinding the ruling, stating that there would be financial incentives that could lead to increased utilization if Medicare part B paid for attached bracing devices for nursing home residents. We also note that, if the ruling were rescinded, the distinction between DME and orthotic devices would be blurred, making it more confusing for providers who are trying to bill appropriately and more difficult for DMERCs to identify and deny claims that were inappropriately billed. In general, we agree with CMS's comments, but we did not change the report because we believe that we had adequately addressed the concerns. CMS also provided technical comments that we incorporated as appropriate.

We are sending copies of this report to the Administrator of the Centers for Medicare and Medicaid Services, appropriate congressional committees, and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please call me at (312) 220-7600 or Sheila K. Avruch at (202) 512-7277. Other key contributors to this report were Barrett Bader, Sandra Gove, and Craig Winslow.

Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues

Appendix I: Scope and Methodology

To determine why the Health Care Financing Administration (HCFA) issued its orthotics ruling and if the agency followed required procedures in issuing it, we conducted interviews with officials and representatives from the agency, two Durable Medical Equipment Regional Carriers (DMERC), and reviewed the ruling and agency documents related to its development and issuance. We also interviewed a plaintiff and legal representatives involved in the legal challenge to the ruling and reviewed relevant documents, including the federal district and appellate courts' decisions on whether HCFA had appropriately followed the proper statutory procedures in issuing the ruling.

To assess the impact of the ruling on Medicare beneficiaries, we reviewed Medicare payments and coverage policies for orthotics and durable medical equipment (DME). We analyzed Medicare claims data from the Medicare part B extract and summary system for the Healthcare Common Procedure Coding System (HCPCS) codes associated with the nine attached bracing devices moved from the orthotic to the DME benefit category as a result of the ruling. We also discussed the impact of the ruling on beneficiaries living in nursing homes with Centers for Medicare and Medicaid Services (CMS) officials, and state Medicaid officials in Florida, Indiana, Michigan, Ohio, Pennsylvania, and Washington. We judgmentally chose these states to attain geographic diversity and because these states have a large proportion of elderly Medicare beneficiaries.

We also discussed the impact of the ruling with four providers and suppliers of attached bracing and other customized seating accessories, in addition to national organizations representing them,[1] seven clinicians with experience in the seating and positioning needs of elderly and disabled individuals, and two manufacturers of attached bracing and similar devices. We chose the clinicians, providers, suppliers, and manufacturers to interview based on those recommended for their expertise by the national organizations.

To assess the financial impact of rescinding the ruling, we reviewed Medicare and Medicaid coverage and payment policies and then interviewed representatives from CMS and Medicaid programs in Florida, Indiana, Michigan, Ohio, Pennsylvania, and Washington. We also developed an estimate of the number of beneficiaries who could use these

[1]These included the American Orthotic and Prosthetic Association, the American Occupational Therapy Association, and the American Physical Therapy Association.

devices by analyzing national data on nursing home residents from the minimum data set (MDS),[2] and we reviewed demographic findings from other studies. Our MDS analysis used data from July 1999 through June 2000 and was limited to Medicare beneficiaries with all of the following characteristics: (1) functional limitations that required the use of wheelchairs as their primary means of locomotion, (2) one or more of eight neurological conditions[3] that experts told us could indicate a need for attached bracing devices because individuals with such conditions can have poor motor control and may not be able to readily brace or re-position themselves in their wheelchairs, (3) pressure ulcers ranging from mild to severe, and (4) limited ability to move while in bed or get out of bed without requiring extensive assistance from either one or two other people.

To evaluate the implications for Medicare program integrity if the ruling were rescinded, we interviewed officials from the Department of Health and Human Services Office of the Inspector General (HHS-OIG) and reviewed pertinent OIG reports. In order to assess the scope of the requirement and its possible effect on attached bracing devices, we analyzed claims data from the statistical analysis durable medical equipment regional carrier[4] associated with custom-fabricated orthotics as defined by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. We also interviewed providers and suppliers and

[2]Since 1991, nursing homes have been required to periodically collect information on all residents using MDS, a uniform assessment instrument. The MDS contains over 500 individual assessment items regarding a resident's medical condition, cognitive and motor skills, and expected use of other services. MDS assessments are conducted within 14 days of admission and at routine intervals thereafter unless there is a significant change in condition.

[3]These conditions were cerebral palsy, multiple sclerosis, osteoporosis, paraplegia, Parkinson's disease, quadriplegia, stroke, and traumatic brain injury. Individuals with these conditions are susceptible to a number of secondary complications, including pressure ulcers. About 456,000 nursing home residents were aged 65 years and older and may have been eligible for part B coverage, had one or more of these eight conditions, and used wheelchairs as their primary means of locomotion.

[4]The statistical analysis durable medical equipment regional carrier is under contract with CMS to produce standard quarterly reports and provide analyses of claims data to identify trends and aberrant billing patterns. It also conducts postpayment review of national suppliers in order to determine if future corrective action is needed. The four DMERCs use these data to identify for prepayment review those DME and orthotic suppliers who have unusual billing patterns or high-dollar and high-volume claims.

organizations representing them and reviewed documents that they provided to us to further assess the effect of the requirement on these devices. We performed our work from January 2001 through March 2002 in accordance with generally accepted government auditing standards.

Appendix II: Excerpt from HCFA's Ruling 96-1

The following discussion is excerpted from the *Conclusions and Illustrations* section of HCFA's ruling to demonstrate its application.

"A supplier manufactures and supplies medical devices to individuals who are generally elderly and suffer from Alzheimer's or other debilitating neuromuscular diseases that have caused them to be non-ambulatory, immobile, and confined to a chair or bed. Due to their immobility, these patients may suffer from secondary complications, such as pressure sores, multi-sited contractures, musculoskeletal degeneration and deformities, and circulatory problems.

Under a physician's order, the supplier furnishes individually fitted attachments designed to be used in conjunction with a chair to seat and position the patient. The attachments, which the supplier labels "orthotic braces," are alleged to position limbs and other body parts properly; restrict motion or weight bearing; immobilize and protect weak musculoskeletal segments; reduce load; retard progression of musculoskeletal deformity; and improve function. The design of the supplier's "orthotic braces" requires them to be attached to the chair frame, and the "orthotic braces" cannot function or be used apart from the chair to which they are attached.

Discussion: Although the devices in question may support or restrict movement in parts of the body, they are not braces within the meaning of [42 U.S.C. § 1395x(s)(9)] because they are integral parts of a seating system and are not designed or intended to be used apart from the seating system."

Appendix III: Comments from the Centers for Medicare and Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

MAY - 6 2002

TO: Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues
General Accounting Office

FROM: Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: General Accounting Office (GAO) Draft Report: *Medicare: Orthotics Ruling Has Implications for Beneficiary Access and Federal and State Costs* (GAO-02-330)

Thank you for the opportunity to review the above-referenced GAO draft report. While generally we agree with the report's conclusion, we ask that the conclusion specify that the U. S. Court of Appeals decision in Warder v. Shalala not only held that the ruling was properly promulgated, but also found that the content of the ruling was wholly supportable and it well effectuated congressional intent by classifying seating systems as durable medical equipment (DME). Also, we ask that the conclusion more clearly indicate the precedent setting effect on other types of equipment that could result from rescinding this ruling. It is uncertain to what extent such a revision would logically lead to covering other accessories and attachments to medical equipment (such as beds, wheelchairs, and walkers) as braces rather than as DME. For example, to circumvent the statutory requirement that DME is not covered by Medicare Part B in skilled nursing facilities (SNFs), it could be argued that attachments to posture chairs and beds provide support to the patient and, therefore, should be covered as orthotics rather than being considered as DME accessories. In addition, if this ruling is rescinded, other components of a wheelchair could be construed to be an orthotic, such as the backrest of a wheelchair.

According to the ruling and the court case, the devices in question are DME accessories and not braces. However, throughout the report and in the conclusion these devices are described as bracing devices, but we believe it would be more appropriate to refer to these items as supporting devices. We also ask that the report more explicitly explain that the Medicare statute is so structured that authorized benefit categories are the key for determining the scope of Medicare coverage. Therefore, it is important to have workable and supportable criteria for determining which benefit category may apply to a particular item or service.

We appreciate the effort that went into this report and the opportunity to provide comments. We look forward to working with GAO on this and other issues.

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