No. 98-1131

In the Supreme Court of the United States

OCTOBER TERM, 1998

ANN WARDER, ET AL., PETITIONERS

v.

DONNA E. SHALALA, SECRETARY
OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Secretary's classification of a therapeutic seating system as "durable medical equipment," rather than as a "brace," for purposes of Medicare coverage represents a reasonable interpretation of the Medicare Act and the Secretary's implementing regulations.

2. Whether the Health Care Financing Administration ruling that announced the Secretary's interpretation embodies a substatantive rule that could be validly promulgated only through notice-and-comment rulemaking.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A44) is reported at 149 F.3d 73. The opinion of the district court (Pet. App. A45-A95) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 27, 1998. A petition for rehearing was denied on October 7, 1998. The petition for a writ of certiorari was filed on January 5, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Medicare Act, 42 U.S.C. 1395 *et seq.*, establishes a national health insurance program for the aged and the disabled. Congress has authorized the Secretary of Health and Human Services to administer the Act, in part through the issuance of both substantive regulations and other "rule[s], requirement[s], or * * * statement[s] of policy." 42 U.S.C. 1395hh.

Part B of the Act, 42 U.S.C. 1395j *et seq.*, establishes a voluntary supplemental insurance program for the elderly and the disabled. The Act covers the cost of "medical and other health services," 42 U.S.C. 1395x(s), that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," 42 U.S.C. 1395y(a)(1)(A). "Medical and other health services" are defined to include, among other things, "leg, arm, back, and neck braces," 42 U.S.C. 1395x(s)(9), and "durable medical equipment," 42 U.S.C. 1395x(s)(6).

The Act defines "durable medical equipment" (DME) to include "iron lungs, oxygen tents, hospital beds, and wheelchairs * * * used in the patient's home." 42 U.S.C. 1395x(n). The Act also provides special payment rules for certain types of DME, including equipment that is "uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment." 42 U.S.C. 1395m(a)(4). The Secretary's regulations further define "durable medical equipment" as equipment that "(1) Can withstand repeated use; (2) Is primarily and customarily used to serve a medical purpose; (3) Generally is not useful to an individual in the absence of an illness or injury; and (4) Is appropriate for use in the home."

42 C.F.R. 414.202. Thus, DME is covered only for use in the home, whereas "leg, arm, back, and neck braces" (42 U.S.C. 1395x(s)(9)) are covered regardless of where they are used.[1]

In 1990, Congress amended the Medicare statute to include, as a customized item reimbursable under 42 U.S.C. 1395m(a)(4), any wheelchair that "has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician." Pub. L. No. 101-508, § 4152(c)(4)(B)(i), 104 Stat. 1388-79 (amending 42 U.S.C. 1395m(a)(4)). The House Report accompanying the amending Act makes clear that Congress intended the amendment to cover wheelchairs that include features such as semi-or full-reclining seats, postural control devices, custom molded cushions and inserts, or lateral supports. H.R. Rep. No. 881, 101st Cong., 2d Sess. 268 (1990). The amendment provided that it would become effective on January 1, 1992, unless before that date the Secretary developed her own criteria for the treatment of wheelchairs as customized items. Pub. L. No. 101-508, § 4152(c)(4)(B)(ii), 104 Stat. 1388-79. In December 1991, the Secretary issued a regulation covering any wheelchair that is "uniquely constructed or substantially modified for a specific beneficiary" and is "so different

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[1] The Act and regulations define "home" to include "an institution used as [the patient's] home," but not hospitals or skilled nursing facilities. See 42 U.S.C. 1395x(n); 42 U.S.C. 1395x(e)(1) and 1395i-3(a)(1); 42 C.F.R. 414.202.

from another item used for the same purpose that the two items cannot be grouped together for pricing purposes." 42 C.F.R. 414.224(a).

2. Petitioner The Orthotics Center, Inc. (Ortho Concepts) designed and markets the "OrthoConcepts Seating System," which consists of a set of connected braces attached to a wheeled base, and which is used by patients with grave musculoskeletal disabilities. Pet. App. A12. In December 1989, petitioner asked a regional office of the Secretary's Health Care Financing Administration (HCFA) to establish a new billing code that would allow the OrthoConcepts system to be covered as a "brace." *Id.* at A13. The regional office advised petitioner, and the private insurance carriers that administered Part B in its region (see 42 U.S.C. 1395u), that the system would be covered under Part B only as durable medical equipment. Pet. App. A13-A14. The carrier responsible for petitioner's claims then informed petitioner that its system was classified as DME rather than as "orthotics" (braces). *Id.* at A14.

Four years later, HCFA learned that regional carriers responsible for processing Part B claims for DME and orthotics were treating seating systems similar to petitioner's as orthotics. HCFA informed those carriers that the seating systems were to be classified as durable medical equipment. Pet. App. A14-A15.

Following the denial by three regional carriers of Part B claims relating to its seating systems, petitioner pursued two appeals. One was ultimately heard by an administrative law judge (ALJ) in one region, who ruled that the systems were "orthotic braces and not wheelchairs." The other was heard by a carrier hearing officer, who also concluded that the systems were orthotic devices, rather than durable medical equipment. Pet. App. A16-A17.

In light of these decisions, HCFA issued HCFA Ruling (HCFAR) No. 96-1 to "state[] the policy of the Health Care Financing Administration regarding the distinction between the statutory benefits of 'orthotics' and 'durable medical equipment' under Medicare Part B." Pet. App. A116-A117. By its terms, the ruling "clarifies that the 'orthotics' benefit in [42 U.S.C. 1395x(s)(9)], insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment," and that "accessories used in conjunction with, and necessary for the full functioning of durable medical equipment fall under the durable medical equipment benefits category." *Id.* at A117.

The Ruling notes that the Medicare Act classifies wheelchairs as durable medical equipment, and that "[m]any seating systems (including wheelchairs) incorporate as integral parts various rests and supporting and positional attachments that are modifications of the seating system and that are intended to be used with the seating system to which they are attached." Pet. App. A122. Citing Congress's amendment of the Medicare statute to add customized wheelchairs to the special payment provisions for durable medical equipment, the ruling concludes that "ample evidence establishes that the Congress intended sophisticated wheelchairs, including chairs with functional attachments, to be classified in their totality as durable medical equipment." *Id.* at A123.

3. Petitioners are OrthoConcepts, two of its affiliates, and two Medicare beneficiaries who used the OrthoConcepts seating system in skilled nursing facilities. They brought this suit challenging HCFAR 96-1 as procedurally invalid under the notice-and-

comment rulemaking provisions of the Administrative Procedure Act (APA), 5 U.S.C. 553, and the Medicare Act, 42 U.S.C. 1395hh, and as arbitrary and capricious under the APA, 5 U.S.C. 706(2)(A). Pet. App. A48-A49.

The district court declared HCFAR 96-1 invalid on the theory that it was a substantive rule that had been issued without compliance with applicable notice-and-comment procedures. Pet. App. A45-A95. On the basis of the ALJ and carrier hearing officer decisions holding that the OrthoConcepts system should be classified as a brace, the court concluded that the HCFA ruling on that issue represented "a substantive change from, rather than a restatement of, the earlier definition of braces." *Id.* at A74; see *id.* at A68-A78. The court also relied on the "binding" nature of the ruling (*id.* at A79-A81), and on its "substantial impact" on the public (*id.* at A81-A83).

The district court further held that HCFA could not properly treat petitioners' system as durable medical equipment under the definitions of DME and orthotics in effect before the 1996 ruling. Pet. App. A84-A93. Distinguishing between devices that enable durable medical equipment to serve its primary function and those that are attached to DME in order to perform their own primary function, the court concluded that "[t]he OrthoConcepts devices fall into the latter category and thus are properly reimbursable for their own medical function and not as accessories to" DME. *Id.* at A93. Because, in its view, "the OrthoConcepts products satisf[ied] the statutory and current regulatory definition of orthotics, and because there is no medical or orthotic basis for denying coverage to braces which are used in conjunction with other equipment," the court held that HCFA was required to cover petitioners' seating systems as "braces," at least until it had

promulgated a different rule using notice-and-comment procedures. *Id.* at A94; see *id.* at A84.

4. The court of appeals reversed. Pet. App. A1-A44. After carefully laying out the legal and factual background of the case (*id.* at A4-A20), the court first rejected (*id.* at A20-A36) petitioners' argument that HCFAR 96-1 embodies a "substantive" rule, rather than simply setting out the Secretary's interpretation of the relevant statutory and regulatory provisions as they apply to medical equipment such as petitioners' seating system. Although the court noted that the line between substantive and interpretive rules could sometimes be "far from clear," it concluded that this case is governed by "reasonably clear principles." *Id.* at A21.

The court explained that the HCFA ruling, which the agency itself regards as interpretive (Pet. App. A24-A25), "does not establish any new standard," but rather "addresses an area of ambiguity: whether a device comprising both orthotic and DME components should be reimbursed as a brace or as DME" (*id.* at A25-A26). Because the applicable statutory and regulatory definitions that predated the ruling were not "so complete as to provide an unambiguous answer to the question of the Seating System's classification," they "created the need for clarification—precisely the function of an interpretive rule." *Id.* at A26. Concluding that the 1996 ruling was "not inconsistent with existing law" (*id.* at A29), did not work any change in the Secretary's regulations or previous interpretations (*id.* at A31-A34), and did not purport to "bind" anyone other than the Secretary's own employees and contractors (who are always required to respect her interpretations of applicable law and regulations) (*id.* at A34-A36), the court "reject[ed] [petitioners'] argument that HCFAR

96-1 was not legally adopted because of the absence of notice and comment procedures" (*id.* at A36).

The court also rejected (Pet. App. A36-A44) petitioners' alternative argument that the interpretation set out in the HCFA ruling was not "adequately supported by the Medicare statute and regulations" (*id.* at A36). The court noted (*id.* at A37 & n.8) a divergence of views among the courts of appeals concerning a "threshold question" whether interpretive rules are entitled to judicial deference under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). It did not address that question, however, because "even assuming *arguendo* that *Chevron* deference is not applicable to interpretative rules," the court was "persuaded that HCFAR 96-1 is an appropriate construction of the statute." Pet. App. A37-A38. It therefore considered the Secretary's position only with regard to its "power to persuade." *Id.* at A39 (quoting *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944)).

The court nonetheless held that HCFAR 96-1 is not only "generally consistent with HCFA's earlier informal pronouncements," but "a persuasive reading" of the relevant law and regulations. Pet. App. A39-A40. In particular, the court observed that the Secretary's interpretation is consistent with the statutory definition of "durable medical equipment," which "unequivocally includes 'wheelchairs,'" and with the text and legislative history of Congress's 1990 amendment to 42 U.S.C. 1395m(a)(4). Pet. App. A39-A41. Noting further that HCFA had adopted its interpretation only after appropriate "deliberat[ion]" (*id.* at A42-A43) and that "the classification of medical equipment for reimbursement purposes is the sort of technical question that generally benefits from HCFA's expertise and experience" (*id.* at A43), the court held that even if it

"assum[ed] that the entire device could alternatively be reasonably construed to satisfy the [statutory] definition of a brace (which includes only examples of individual braces), there was nothing precluding HCFA from resolving the ambiguity" in the applicable definitions in favor of treating the device as DME. *Id.* at A41. "Given HCFA's expertise in administering Medicare Part B, the logic of its interpretation, and the consistency of its policy," the court concluded, "the denial of claims for reimbursement of the Seating System under the brace benefit was not arbitrary or capricious, and thus withstands [petitioners'] challenge under 5 U.S.C. § 706(2)(A)." *Id.* at A43-A44.

ARGUMENT

1. Petitioners argue (Pet. 14-17) that it is "clear that Congress did not intend" to deny Medicare Part B reimbursement for petitioners' seating system to beneficiaries resident in skilled nursing facilities (SNFs). What is clear from the Medicare Act, however, is that Congress intended to provide coverage for "braces" to all beneficiaries (where the other requirements for coverage are met), but to provide coverage for "durable medical equipment" only for beneficiaries who reside outside hospitals or SNFs. See pp. 2-3, *supra*; Pet. 16-17. It is further clear from the Act and the Secretary's substantive regulations that petitioners' seating system is properly classified, for Part B purposes, either as a "brace" or as DME. See Pet. App. A28. Contrary to petitioners' contention, however, neither the applicable statutory provisions nor the Secretary's regulations on their face clearly resolve the question whether hybrid products like petitioners' seating system are best placed in one category or the other for purposes of Medicare reimbursement. See *id.* at A29.

As the court of appeals recognized (Pet. App. A39), the Secretary's conclusion, embodied in HCFAR 96-1, that such systems are covered only as DME is "wholly supportable" as a matter of standard statutory interpretation. See *id.* at A36-A44. There can be no doubt that petitioners' system satisfies the statutory and regulatory criteria for treatment as DME; indeed, it is reasonable to view the device as fundamentally a "customized wheelchair[ ]," and Congress has explicitly indicated that such items are to be treated as DME. *Id.* at A40-A41; see also 42 U.S.C. 1395x(n) (including "wheelchairs" within the statutory definition of DME).[2] The Secretary's interpretation was, moreover, developed with due deliberation, and is one that she has consistently maintained since the introduction of petitioners' product in 1989. See Pet. App. A13-A18, A32-A34, A42-A43. The court of appeals therefore correctly held (*id.* at A44) that the Secretary's position could not be set aside as "arbitrary or capricious" under the APA, 5 U.S.C. 706(2)(A).

2. For similar reasons, there is no force to petitioners' argument (Pet. 17-20) that the reimbursement policy set out in HCFAR 96-1 amounts to a "substantive" or "legislative" rule that could be validly promulgated only through notice-and-comment rulemaking. Petitioners contend that the HCFA ruling "imposes obligations, the basic tenor o[f] which is not already outlined in the law itself." Pet. 18 (citation omitted). In fact, however, the ruling imposes no obligations of any

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[2] As the court of appeals observed, "it is not inconsistent to treat the Seating System—which is, after all, a wheeled device in which a patient sits—as a customized wheelchair, a piece of equipment specifically identified as DME." Pet. App. A29 (citing 42 U.S.C. 1395x(n) and 42 C.F.R. 414.224).

kind; it merely clarifies which of two possible Medicare reimbursement categories applies to a particular type of medical equipment. See Pet. App. A25-A27. Moreover, as the court of appeals recognized (*id.* at A29-A34), nothing in HCFAR 96-1 is inconsistent with "any of the existing statutory or regulatory definitions" relevant to Medicare reimbursement (*id.* at A29), or even with any interpretation of those provisions that had been previously adopted by the Secretary (see *id.* at A31-A34).[3]

HCFAR 96-1 was issued because "the extant [statutory and regulatory] definitions were ambiguous in respect to the category within which [petitioners'] Seating System best fit." Pet. App. A29. That ambiguity had produced some administrative reimbursement determinations that the Secretary considered inappropriate (see *id.* at A14-A17)—not a surprising or unusual development in a large, complex, and relatively decentralized federal benefit program, and one that those ultimately charged with administering such a program must be able to address. Seeing a need for a clear and uniform interpretation of the relevant provisions in this context, the Secretary promulgated HCFAR 96-1. By announcing the Secretary's determination as to the correct application of the existing statutory and regulatory provisions to a particular sort of medical device, that ruling functions much like the Medicare Provider

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[3] As the court of appeals also made clear (Pet. App. A30-A31), even if the Secretary's present interpretation had displaced an earlier one, that would not make it any less "interpretive." See *id.* at A31 (quoting *White* v. *Shalala*, 7 F.3d 296, 304 (2d Cir. 1993) ("If the rule is an interpretation of a statute rather than an extra-statutory imposition of rights, duties or obligations, it remains interpretive even if the rule embodies the Secretary's changed interpretation of the statute.")).

Reimbursement Manual provision that this Court considered in *Shalala* v. *Guernsey Memorial Hospital*, 514 U.S. 87 (1995). And, like that provision, the HCFA ruling is "a prototypical example of an interpretive rule '"issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers."'" *Id.* at 99 (quoting *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 302 n.31 (1979), in turn quoting United States Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 30 n.3 (1947)); see also Pet. App. A29 (quoting *Orengo Caraballo* v. *Reich*, 11 F.3d 186, 195 (D.C. Cir. 1993) ("'the quintessential example of an interpretive rule' is '[a] statement seeking to interpret a statutory or regulatory term.'")).

3. Finally, petitioners argue (Pet. 20-23) that if HCFAR 96-1 is an interpretive ruling, it is not entitled to the same measure of judicial deference that a substantive or "legislative" rule would receive under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). This case does not present that question, however, because the court of appeals expressly declined to reach it. Pet. App. A37-A38. The court instead "assum[ed] *arguendo* that *Chevron* deference is not applicable to interpretative rules" (*id.* at A37), and accorded the Secretary's position only the "power to persuade" that this Court itself has long recognized is appropriate for any considered agency interpretation, because of the agency's "body of experience and informed judgment" on matters within its jurisdiction. *Id.* at A38-A39 (quoting *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944)). Considering the matter only from that perspective, and exercising its independent judgment, the court of appeals found itself "persuaded that HCFAR 96-1 is an appropriate con-

struction of the statute" and the Secretary's substantive regulations. *Id.* at A37-A38; see *id.* at A39-A40. In the absence of a contrary determination by any other court of appeals, that conclusion does not warrant further review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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MARCH 1999