

In the Supreme Court of the United States

OCTOBER TERM, 1998

THOMAS SLEKIS, PETITIONER

v.

JOYCE A. THOMAS, COMMISSIONER,
CONNECTICUT DEPARTMENT OF SOCIAL SERVICES

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

**BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE**

HARRIET S. RABB
General Counsel
MARCY WILDER
Deputy General Counsel
KENNETH Y. CHOE
Attorney
Department of Health and
Human Services
Washington, D.C. 20201

SETH P. WAXMAN
Solicitor General
Counsel of Record
FRANK W. HUNGER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
EDWARD C. DUMONT
Assistant to the Solicitor
General
ANTHONY J. STEINMEYER
IRENE M. SOLET
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

QUESTION PRESENTED

Whether a State that participates in the federal Medicaid program may deny coverage for an item of durable medical equipment that falls within the State's general provision for the coverage of such equipment, but is not included on the State's list of specific covered items, on the ground that a beneficiary cannot prove that in the absence of such coverage the needs of the State's Medicaid population as a whole will not be met.

TABLE OF CONTENTS

	Page
Statement	1
Discussion	7
Conclusion	16

TABLE OF AUTHORITIES

Cases:

<i>Agostini v. Felton</i> , 117 S. Ct. 1997 (1997)	14
<i>Alexander v. Choate</i> , 469 U.S. 287 (1985)	7
<i>Atkins v. Rivera</i> , 477 U.S. 154 (1986)	2
<i>Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.</i> , 467 U.S. 837 (1984)	11
<i>Harris v. McRae</i> , 448 U.S. 297 (1980)	1
<i>Lawrence v. Chater</i> , 516 U.S. 163 (1996)	15
<i>Regions Hosp. v. Shalala</i> , 118 S. Ct. 909 (1998)	10
<i>Thomas Jefferson Univ. v. Shalala</i> , 512 U.S. 504 (1994)	11
<i>Wilder v. Virginia Hosp. Ass'n</i> , 496 U.S. 498 (1990)	1

Constitution, statutes and regulations:

U.S. Const. Amend. XIV (Due Process Clause)	4
Americans With Disabilities Act, 42 U.S.C. 12101- 12213	15
Rehabilitation Act of 1973, 29 U.S.C. 701 <i>et seq.</i> : 29 U.S.C. 794	15
Social Security Act, Tit. XIX (Medicaid Act), 42 U.S.C. 1396 <i>et seq.</i>	1
42 U.S.C. 1396a	1, 2
42 U.S.C. 1396a(a)(10)(A)	2
42 U.S.C. 1396a(a)(10)(D)	2
42 U.S.C. 1396a(a)(17)	2
42 U.S.C. 1396d(a)	2
42 U.S.C. 1396d(a)(4)(A)	2

IV

Regulations—Continued:	Page
42 C.F.R.:	
Section 414.202	3
Section 430.16(a)(1)	9
Section 440.70	2
Section 440.70(b)(3)	3
Section 440.210(a)(1)	2
Section 440.220(a)(3)	2
Section 440.230(a)	2
Section 440.230(b)	3
Section 440.230(c)	3, 13
Section 440.230(d)	2
Miscellaneous:	
42 Fed. Reg. (1977):	
p. 57,351	9
p. 57,352	9

In the Supreme Court of the United States

OCTOBER TERM, 1998

No. 98-5070

THOMAS SLEKIS, PETITIONER

v.

JOYCE A. THOMAS, COMMISSIONER,
CONNECTICUT DEPARTMENT OF SOCIAL SERVICES

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

**BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE**

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States.

STATEMENT

1. The Medicaid Act, enacted in 1965 as Title XIX of the Social Security Act, as amended, 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program established "for the purpose of providing federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons." *Harris v. McRae*, 448 U.S. 297, 301 (1980). Although participation in the Medicaid program is voluntary, States that elect to participate must comply with requirements imposed by the Act and by the Secretary of Health and Human Services. See 42 U.S.C. 1396a; *Wilder v.*

Virginia Hosp. Ass'n, 496 U.S. 498, 502 (1990); *Atkins v. Rivera*, 477 U.S. 154, 157 (1986).

Participating States must submit to the Secretary a Medicaid plan that fulfills broad requirements imposed by the Act and regulations. See generally 42 U.S.C. 1396a. The Medicaid Act specifies groups of individuals who must be made eligible under the plan, and groups that may be made eligible at the State's option. 42 U.S.C. 1396a(a)(10)(A). Similarly, the Act specifies certain medical services that must be covered for particular groups, and other services that may be covered at the State's option. *Ibid.*; 42 U.S.C. 1396d(a). As relevant here, the Act generally requires a State's plan to cover "home health services" for most Medicaid-eligible individuals. See 42 U.S.C. 1396a(a)(10)(A) and (a)(10)(D), 1396d(a)(4)(A); 42 C.F.R. 440.70, 440.210(a)(1) and 440.220(a)(3); see also Pet. App. A67, A71.¹

With respect to general categories of covered services (such as "home health services"), a State's Medicaid plan "must specify the amount, duration, and scope of each service that it provides." 42 C.F.R. 440.230(a). Subject to any specific federal requirements, the plan may generally "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 C.F.R. 440.230(d). The plan must, however, "include reasonable standards * * * for determining eligibility for and the extent of medical assistance" that are "consistent with the objectives" of the federal Medicaid program, 42 U.S.C. 1396a(a)(17); the service provided "must be sufficient in

¹ Connecticut's Medicaid plan, which respondent administers, covers "home health services" for all Medicaid recipients in the State. Pet. App. A3.

amount, duration, and scope to reasonably achieve its purpose,” 42 C.F.R. 440.230(b); and the State “may not arbitrarily deny or reduce the amount, duration, or scope of a [federally] required service * * * to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition,” 42 C.F.R. 440.230(c).

The Secretary’s regulations define “home health services” to include “[m]edical supplies, equipment, and appliances suitable for use in the home.” 42 C.F.R. 440.70(b)(3). In the absence of any more specific federal requirement, the State of Connecticut has further defined certain general characteristics that items of “durable medical equipment” (DME) must have in order to be covered by its Medicaid plan. Pet. App. A3.² In addition, respondent maintains a list of over 100 different items of DME that she has determined meet that definition. Before this litigation, respondent limited Medicaid coverage for DME to items on that pre-approved list. *Ibid.*

2. Petitioners are a class of Connecticut Medicaid recipients who were denied coverage for items of equipment that meet the State’s general DME definition, but that are not on respondent’s list of covered items.³ Pet. App. A3. As relevant here, petitioners’

² The State’s definition is essentially the same as that adopted by the Secretary under the federal Medicare program. See Pet. App. A8-A9 (quoting 42 C.F.R. 414.202).

³ The overall class certified by the district court also included a subclass of individuals who were denied Medicaid coverage for items alleged to be medically necessary, but falling outside the scope of the State’s general definition of DME. See Pet. App. A3. The petition makes clear (at 2 n.1), however, that it seeks this Court’s review only with respect to the State’s denial of coverage

complaint alleges that the State's policy of covering only items of DME on its approved list violates the Medicaid Act and the Due Process Clause of the Fourteenth Amendment. *Id.* at A20. Petitioners sought class certification and the entry of a preliminary injunction. *Ibid.*

The State filed a third-party complaint against the Secretary, who subsequently filed a brief at the district court's request. Pet. App. A20; see *id.* at A64-A78 (Secretary's brief). That brief stated that a state Medicaid plan "must delineate covered services, and may itself contain a detailed list (or may contain a more general definition which the state could then implement through a list)." *Id.* at A70. The brief noted that the Secretary had previously "specifically permitted lists to describe covered equipment under the home health benefit." *Ibid.* The brief also stated, however, that "any such list must be consistent with the federal requirements for the scope of the service" (*id.* at A70 n.3), and that "[a]n individual whose claim is denied may be entitled to a hearing consistent with federal requirements" (*id.* at A71).

Following an evidentiary hearing, the district court certified the class and granted a preliminary injunction. The court enjoined respondent from using her list of covered items as the exclusive determinant of Medicaid coverage for DME, and directed her to reprocess petitioners' requests for coverage. Pet. App. A36.⁴

for items that fall within the general definition but that are not included on the State's list of specific items.

⁴ With respect to petitioner Slekis, who had intervened in this action, the court also directed respondent to pay for a specific item of DME during the pendency of the administrative process and until the State had agreed to provide either that item or some

The court reasoned that respondent's use of an exclusive list violated the Medicaid Act because it constituted "an unreasonable restriction on the amount, duration, and scope of a provided service." *Id.* at A27. On petitioners' motion for clarification, the court further held that respondents' hearing officers could not reprocess petitioners' requests under a standard that required them to demonstrate that denial of their requests would render the State's DME coverage "inadequate with respect to the Medicaid population *as a whole.*" *Id.* at A39 (emphasis added).

3. The court of appeals vacated the preliminary injunction. Pet. App. A1-A18. The court concluded that the district court had erred by implicitly ruling that the Medicaid Act required the State to provide every medically necessary item of equipment that satisfied its general definition of DME, and by holding that petitioners had demonstrated a likelihood of success on their claim that respondent's use of an exclusive list of covered items violated the Act. *Id.* at A10-A11, A18.

The Secretary did not participate in respondent's appeal.⁵ The court of appeals relied, however, on its reading of the Secretary's brief in the district court, deferring to the position expressed in that brief that a State's use of a list of covered items and services is permissible, subject to federal requirements concerning the scope of the services provided. Pet. App. A11; see

alternative item deemed sufficient to meet petitioner's medical needs. Pet. App. A37.

⁵ As the Secretary's brief in the district court noted (Pet. App. A65-A66), the Secretary maintained that she was not a proper third-party defendant in this case because of the lack of any case or controversy between her and respondent.

id. at A70 & n.3. The court rejected petitioners' argument, which it acknowledged had been accepted by some other circuits, that the Medicaid Act requires coverage of every item or service that is medically necessary for an individual Medicaid recipient so long as that item or service falls within a general category of coverage under the State's Medicaid plan. *Id.* at A12, A16. Rather, the court concluded, the State is permitted to develop reasonable standards for limiting the extent of covered services. *Id.* at A12-A13. That authority includes, the court held, the authority to impose limitations on covered services, such as the provision of DME, that result in the denial of medically necessary services to an individual recipient, "so long as the health care provided is adequate with respect to the needs of the Medicaid population as a whole." *Id.* at A14; see *id.* at A11-A16.

The court of appeals noted that, in response to the district court's preliminary injunction, respondent had begun to provide an opportunity for Medicaid recipients to challenge the denial of coverage for items not on the DME list. Specifically, respondent had provided that the hearing officer at the administrative hearing otherwise provided under the State's Medicaid plan was authorized to grant coverage for items not on the State's DME list if the recipient showed that exclusion of that item "rendered the list inadequate with respect to the needs of the Medicaid population as a whole." Pet. App. A17 n.13. Considering that procedure adequate to remedy "any imperfection in the [State's] schedule" of approved DME "through hearing-by-hearing consideration of the legality of excluding individual items" (*id.* at A18), the court specifically predicated its decision on the State's continued provision of such hearings (*id.* at A17 n.13). On that basis, the court

concluded that the district court had abused its discretion in entering the preliminary injunction. *Id.* at A18. In the court’s view, the district court had “misconceived a state’s funding obligation under [the Medicaid Act],” “lacked a basis for its finding that plaintiffs were likely to succeed on their claim that Connecticut’s * * * schedule is inadequate,” and improperly believed that petitioners should not be required “to ‘demonstrate that medical equipment covered by the [State’s plan] is inadequate with respect to the Medicaid population as a whole’ in order to obtain coverage for DME not on [respondent’s] schedule.” *Ibid.* (quoting district court’s decision).

DISCUSSION

1. As the Secretary explained in the brief she filed in this case at the request of the district court (Pet. App. A64-A78), a State that participates in the federal Medicaid program has considerable flexibility in defining the scope of coverage under the State’s Medicaid plan, subject to certain minimum federal requirements. See, e.g., *id.* at A67-A70; *Alexander v. Choate*, 469 U.S. 287, 303 (1985) (“The [Medicaid] Act gives the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage.”). In determining what items of “durable medical equipment” will be covered under Connecticut’s Medicaid plan, respondent makes use of both a general definition and a specific list of covered items. See Pet. App. A3. In the brief she submitted to the district court, the Secretary advised that the general definition used by respondent appears to be a reasonable one. *Id.* at A10. The Secretary’s brief further indicated that the use of a specific list of items or services, whether or not in conjunction with such a general definition, to help

define the scope of coverage under a state plan would generally be “consistent with the requirements of federal law.” *Id.* at A70. With specific respect to this litigation, the Secretary noted that she “ha[d] made no finding that the State’s policies on medical equipment, or use of such lists, [were] out of compliance with federal statutory requirements.” *Id.* at A71 n.4; see also *id.* at A76.

The Secretary’s brief explicitly cautioned, however, that any list of covered items “must be consistent with the federal requirements for the scope of the service” involved. Pet. App. A70 n.3. The Secretary noted that, to the extent a list “ends up defining the scope of coverage under a benefit category, the services described must be sufficient in amount, duration, and scope to reasonably achieve its purpose.” *Ibid.* In addition, she observed that “[a]n individual whose claim is denied may be entitled to a hearing consistent with federal requirements * * * [to] establish that the item or service is covered under the State Medicaid plan.” *Id.* at A71.

The court of appeals relied heavily on the Secretary’s district-court submission in reaching its decision in this case. See Pet. App. A9, A11-A13, A17. The court overread the Secretary’s brief, however, to the extent that it interpreted her statements to the effect that she had “made no finding that the referenced State policies are contrary to federal Medicaid law” (*id.* at A76) as an affirmative validation or endorsement of the State’s procedures. See *id.* at A16 (applying standard for “a plan that has been reviewed by a federal agency”), A17 (quoting Secretary’s brief and concluding that State’s

plan “has withstood regulatory oversight”).⁶ Moreover, the court appears to have read the Secretary’s brief to support the court’s conclusion that a recipient may be required to show, in order to obtain coverage for an item of medically necessary equipment not included on the State’s DME list, that failure to provide that item would render the State’s Medicaid plan “[in]adequate with respect to the needs of the Medicaid population as a whole.” *Id.* at A14; see *id.* at A16-A18 & n.13. The Secretary’s brief did not address that point, and the court’s conclusion is not consistent with her views.

2. After the court of appeals rendered its decision, the Health Care Financing Administration (HCFA), to which the Secretary has delegated primary responsibility for the administration of the Medicaid program (see 42 Fed. Reg. 57,351, 57,352 (1977)), received a number of inquiries concerning Medicaid coverage of medical equipment and the use of lists in making coverage determinations. See App., *infra*, 1a. On September 4, 1998, HCFA responded to those inquiries by sending all state Medicaid directors a letter setting out new interpretive guidance to clarify the Secretary’s position on those issues. We have reprinted a copy of that letter as an appendix to this brief. *Id.* at 1a-4a.

After noting various relevant federal statutory and regulatory provisions, HCFA’s letter observes that any State “may develop a list of pre-approved items of [medical equipment (ME)] as an administrative convenience because such a list eliminates the need to

⁶ As the court of appeals noted (Pet. App. A16), although state Medicaid plans must be submitted to the Secretary for review, a plan is “considered approved” unless the Secretary disapproves it, or requests additional information, within 90 days of its submission. 42 C.F.R. 430.16(a)(1).

administer an extensive application process for each ME request submitted.” App., *infra*, 1a-2a. The letter advises, however, that “[a]n ME policy that provides no reasonable and meaningful procedure for requesting items that do not appear on a State’s pre-approved list[] is inconsistent with * * * federal law.” *Id.* at 2a.

The HCFA guidance goes on to clarify that “[i]n evaluating a request for an item of ME, a State may not use a ‘Medicaid population as a whole’ test, which requires a beneficiary to demonstrate that, absent coverage of the item requested, the needs of ‘most’ Medicaid recipients will not be met.” *Ibid.* The letter explains that such a test, in the medical equipment context, “establishes a standard that virtually no individual item of ME can meet,” and therefore “fails to provide a meaningful opportunity for seeking modifications of or exceptions to a State’s pre-approved list.” *Ibid.* Accordingly, under the Secretary’s interpretation of the Medicaid Act and her implementing regulations, “a State will be in compliance with federal Medicaid requirements only if, with respect to an individual applicant’s request for an item of” medical equipment, the State (1) provides a timely response and “employs reasonable and specific criteria by which an individual item of ME will be judged for coverage”; (2) makes its process and criteria, as well as its list of pre-approved items, available to beneficiaries and the public; and (3) informs beneficiaries of their right to a fair hearing to determine whether an adverse decision is contrary to federal law. *Id.* at 2a-3a.

3. The interpretation of the Medicaid Act and its implementing regulations by the Secretary of Health and Human Services is entitled to substantial deference from the courts. See, e.g., *Regions Hosp. v. Shalala*, 118 S. Ct. 909, 915 (1998); *Thomas Jefferson Univ. v.*

Shalala, 512 U.S. 504, 512 (1994); *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984). The authoritative administrative guidance provided by the Secretary in the September 4 HCFA letter applies to the situation at issue in this case, and significantly undermines the court of appeals' rationale for vacating the preliminary injunction entered by the district court.

In holding that the district court had abused its discretion by enjoining respondent from using a list of pre-approved items as the "primary determinant" of coverage for medical equipment, the court of appeals specifically relied on Connecticut's continued provision of a "fair hearing" at which a Medicaid recipient "may demonstrate that the absence of a particular item of [durable medical equipment] from the [pre-approved] schedule renders the schedule unreasonable and inadequate with respect to the needs of the Medicaid population of the state." Pet. App. A17-A18 & n.13. The requirement that the State provide such a hearing is consistent with the Secretary's recent guidance. In vacating the preliminary injunction, however, the court held that the district court should have evaluated petitioners' chances of success on the merits using a standard that would require them to show that the failure to provide specific items would render the State's list of covered medical equipment "inadequate to serve the needs of the [State's] Medicaid population *as a whole*." *Id.* at A18 (emphasis added).

The "Medicaid population as a whole" test, as evidently conceived by the court of appeals—*i.e.*, as applied to preclude a successful challenge to the failure to provide a particular piece of equipment, so long as the other equipment provided would be adequate to meet the needs of "most" eligible recipients (see Pet.

App. A14-A15 (citing cases))—is not consistent with the Secretary’s interpretation of the Medicaid Act and regulations. As the HCFA letter explains (App., *infra*, 2a), in the present context, such a test “establishes a standard that virtually no individual item of [medical equipment] can meet.” Such items are typically prescribed to treat specific illnesses or conditions. No single illness or condition characterizes “most” of the Medicaid population, or even “most” of the Medicaid population that needs some form of medical equipment. Even the most common conditions affect only a small minority of Medicaid recipients; and while some items of medical equipment are prescribed to treat more than one condition, few if any would be prescribed for “most” beneficiaries who need some form of equipment. It is therefore highly unlikely that a Medicaid recipient would ever be able to demonstrate that a State’s failure to provide any particular item would render its plan inadequate with respect to “most” of the State’s Medicaid beneficiaries. The Secretary has, accordingly, reasonably concluded that the application of any such standard would itself violate federal requirements, because it would deny a beneficiary any “meaningful opportunity for seeking modifications of or exceptions to a State’s pre-approved list” of covered medical equipment. *Ibid.*

Moreover, the Secretary’s guidance requires that a State’s criteria for determining whether particular items of medical equipment will be covered under its Medicaid plan be “sufficiently specific to permit a determination of whether an item of ME that does not appear on a State’s pre-approved list has been arbitrarily excluded from coverage based solely on a diagnosis, type of illness, or condition.” App., *infra*, 3a. That requirement seeks to facilitate enforcement of the

federal regulatory prohibition against such exclusions from the scope of mandatory Medicaid coverage. 42 C.F.R. 440.230(c). If an item of medical equipment appears to fall within a State's categorical definition of covered equipment, but is omitted from the State's list of pre-approved items, the procedures required by the Secretary's guidance provide a means for assuring that any continued denial of that item is based on some appropriate ground.

4. The Secretary's September 4 administrative guidance clarifies the state of the law relevant to this case in important ways that the court of appeals has had no chance to consider. For that reason, whatever the original merits of the certiorari petition in this case, the matter is not presently ripe for review by this Court. Indeed, petitioners themselves have suggested that, rather than granting plenary review, the Court should vacate the judgment below, and remand the case to the court of appeals for further consideration in light of the Secretary's intervening interpretive guidance. Pet. Supp. Memo. Pursuant to Rule 15.8, at 8.

Respondents have opposed that suggestion on the ground that the court of appeals ruled only on the propriety of granting preliminary injunctive relief, and that the district court is in the best position to consider, in the first instance, whether the Secretary's intervening guidance renders the court of appeals' decision "not definitive as to [petitioners'] claims" on the merits. Resp. Supp. Memo. Opposing Pet. Supp. Memo. 2. We respectfully disagree with that assessment in the circumstances of this case.

The court of appeals' decision that the district court abused its discretion in granting a preliminary injunction rested, not on some ground relatively unaffected by the merits of the case (such as the balance of harms),

but on the ground that the district court “misconceived” the State’s obligations under applicable federal law, “lacked a basis for its finding that plaintiffs were likely to succeed” on the merits under what the court of appeals believed to be a correct understanding of that law, and erred by precluding respondent from requiring petitioners to satisfy the “Medicaid population as a whole” test in order to obtain coverage for items not on the State’s pre-approved list. Pet. App. A18. The Secretary’s subsequent guidance calls those legal conclusions into significant doubt, particularly given the court of appeals’ explicit—but, it now appears, incorrect—understanding that it was deferring substantially to the Secretary’s interpretations of federal law. See, *e.g.*, *id.* at A9. Requiring this case to return directly to the district court pursuant to the mandate of the court of appeals’ decision, without first giving the court of appeals an opportunity to consider the Secretary’s intervening guidance, would unnecessarily place the district court in the awkward—and perhaps improper—position of attempting to second-guess legal principles previously articulated by a superior court, in the very case in which those principles were announced. Cf. *Agostini v. Felton*, 117 S. Ct. 1997, 2017 (1997).

The Second Circuit’s exposition of applicable legal principles binds all district courts in three States, and may be expected to be influential in many other courts. The Secretary is therefore concerned that allowing the appellate decision in this case to stand while litigation proceeds in the district court may impede nationwide implementation of the contrary interpretive guidance she has now provided through the September HCFA letter. We therefore suggest that the Court grant the petition, vacate the court of appeals’ judgment, and remand the matter to the court of appeals for further

consideration in light of the Secretary's intervening clarification of her interpretation of applicable federal law. Compare *Lawrence v. Chater*, 516 U.S. 163 (1996).⁷ Of course, the court of appeals, rather than addressing the matter further at that stage, might then remand the case to the district court to allow that court to consider the impact of the Secretary's new guidance in the first instance.

⁷ The petition also seeks (at 32-38) to raise, for the first time in this litigation, questions under the Americans With Disabilities Act, 42 U.S.C. 12101 *et seq.*, and the Rehabilitation Act, 29 U.S.C. 794. In light of our suggestion that the court remand this case for reconsideration of the central issues litigated below, we express no view on those aspects of the petition.

CONCLUSION

The petition for a writ of certiorari should be granted, the judgment of the court of appeals should be vacated, and the case should be remanded to the court of appeals for further consideration in light of the interpretive guidance issued by the Health Care Financing Administration on September 4, 1998.

Respectfully submitted.

HARRIET S. RABB
General Counsel
MARCY WILDER
Deputy General Counsel
KENNETH Y. CHOE
Attorney
Department of Health and
Human Services

SETH P. WAXMAN
Solicitor General
FRANK W. HUNGER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
EDWARD C. DUMONT
Assistant to the Solicitor
General
ANTHONY J. STEINMEYER
IRENE M. SOLET
Attorneys

DECEMBER 1998

APPENDIX

[seal omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration
Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850

SEP 4 1998

Dear State Medicaid Director:

We have received a number of inquiries regarding coverage of medical equipment (ME) under the Medicaid program in light of the ruling of the United States Court of Appeals for the Second Circuit in *DeSario v. Thomas*. In that case, the court examined the circumstances under which a State may use a list to determine coverage of ME and offered its interpretation of HCFA's policies. We have concluded that it would be helpful to provide States with interpretive guidance clarifying our policies concerning ME coverage under the Medicaid program and the use of lists in making such coverage determinations. This guidance is applicable only to ME coverage policy.

As you know, the mandatory home health services benefit under the Medicaid program includes coverage of medical supplies, equipment, and appliances suitable for use in the home (42 C.F.R. § 440.70(b)(3)). A State may establish reasonable standards, consistent with the objectives of the Medicaid statute, for determining the extent of such coverage (42 U.S.C. § 1396(a)(17)) based on such criteria as medical necessity or utilization con-

trol (42 C.F.R. § 440.230(d)). In doing so, a State must ensure that the amount, duration, and scope of coverage are reasonably sufficient to achieve the purpose of the service (42 C.F.R. § 440.230(b)). Furthermore, a State may not impose arbitrary limitations on mandatory services, such as home health services, based solely on diagnosis, type of illness, or condition (42 C.F.R. § 440.230(c)).

A State may develop a list of pre-approved items of ME as an administrative convenience because such a list eliminates the need to administer an extensive application process for each ME request submitted. An ME policy that provides no reasonable and meaningful procedure for requesting items that do not appear on a State's pre-approved list, is inconsistent with the federal law discussed above. In evaluating a request for an item of ME, a State may not use a "Medicaid population as a whole" test, which requires a beneficiary to demonstrate that, absent coverage of the item requested, the needs of "most" Medicaid recipients will not be met. This test, in the ME context, establishes a standard that virtually no individual item of ME can meet. Requiring a beneficiary to meet this test as a criterion for determining whether an item is covered, therefore, fails to provide a meaningful opportunity for seeking modifications of or exceptions to a State's pre-approved list. Finally, the process for seeking modifications or exceptions must be made available to all beneficiaries and may not be limited to sub-classes of the population (e.g., beneficiaries under the age of 21).

In light of this interpretation of the applicable statute and regulations, a State will be in compliance with federal Medicaid requirements only if, with respect to

an individual applicant's request for an item of ME, the following conditions are met:

- The process is timely and employs reasonable and specific criteria by which an individual item of ME will be judged for coverage under the State's home health services benefit. These criteria must be sufficiently specific to permit a determination of whether an item of ME that does not appear on a State's pre-approved list has been arbitrarily excluded from coverage based solely on a diagnosis, type of illness, or condition.
- The State's process and criteria, as well as the State's list of pre-approved items, are made available to beneficiaries and the public.
- Beneficiaries are informed of their right, under 42 C.F.R. Part 431 Subpart E, to a fair hearing to determine whether an adverse decision is contrary to the law cited above.

We encourage you to be cognizant of the approval decisions you make regarding items of ME that do not appear on a pre-approved list, to ensure that the item of ME is covered for all beneficiaries who are similarly situated. In addition, your list of pre-approved items of ME should be viewed as an evolving document that should be updated periodically to reflect available technology.

HCFA's Regional Offices will be monitoring compliance with the statute and regulations that are the subject of

4a

this guidance. Any questions concerning this letter or the ME benefit may be referred to Mary Jean Duckett of my staff at (410) 786-3294.

Sincerely,

/s/ SALLY K. RICHARDSON
SALLY K. RICHARDSON
Director

cc: All HCFA Regional Administrators

All HCFA Associate Regional Administrators for
Medicaid and State Operations

Lee Partridge
American Public Human Services Association

Nolan Jones
National Governors Association

Joy Wilson
National Conference of State Legislatures