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MEDICAID AND DURABLE MEDICAL EQUIPMENT: AN ONGOING BATTLE BETWEEN EXPENSE AND HEALTH

JENNIFER K. SQUILLARIO*

INTRODUCTION

In many states, to have an item of durable medical equipment (DME) covered by a state's Medicaid program, the item must be listed as a covered item in a state's preapproved list, and a Medicaid recipient's physician must certify that the item is medically necessary for the health of the recipient. The lists are rarely updated. In a recent case that ultimately went to the United States Supreme Court, one state's use of a preapproved list and the methodology used to establish that list was challenged. The case raises questions about how states establish lists of what kinds of DME should be covered and how beneficiaries may challenge decisions that deny coverage because an item is not on the list of covered DME, even though it meets a state's definition of DME.

The United States Court of Appeals for the Second Circuit in DeSario v. Thomas1 held that a state may use a predetermined list of DME for subsequent coverage decisions, and the state does not have to cover all "medically necessary" services as long as what the state does cover is "adequate to meet the needs of the Medicaid population of the state."2 The Health Care Financing Administration (HCFA) wrote a guidance letter in response to the Second Circuit's decision, and the letter declares that a state may use a preapproved list of DME for coverage determinations, but "[i]n evaluating a request for an

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1. 139 F.3d 80 (2d Cir. 1998).
2. Id. at 90-91. The Medicaid Act does not provide a definition for "medically necessary." DeSario v. Thomas, 963 F. Supp. 120, 132 (D. Conn. 1997). According to the district court in DeSario, the Supreme Court provided a workable definition of medically necessary in Doe v. Bolton, 410 U.S. 179 (1973) and in Beat v. Doe, 432 U.S. 438 (1977) as a "professional judgment made by a physician considering the physical, emotional, psychological, and familial factors relevant to the well-being of the patient." DeSario, 963 F. Supp. at 132. Medical necessity has, however, also been defined as "[h]ealth care provided to correct or diminish the adverse effects of a mental condition or mental illness; to assist an individual in attaining or maintaining an optimal level of health; to diagnose a condition; or prevent a medical condition from occurring." Health Advocate No. 195.12. But see infra notes 138-157 and accompanying text (describing the Medicaid population as a whole test and the departure from traditional reliance on physician's decisions).
item of [D]ME, a State may not use a 'Medicaid population as a whole' test” as the Court of Appeals had employed in DeSario. Granting certiorari, the Supreme Court in Sleekis v. Thomas vacated and remanded the case to the Court of Appeals “for further consideration in light of the interpretative guidance issued by the Health Care Financing Administration on September 4, 1998.”

According to HCFA, the Medicaid population as a whole test “requires a beneficiary to demonstrate that, absent coverage of the item requested, the needs of ‘most’ Medicaid recipients will not be met.” HCFA’s letter, however, does not explicitly provide a standard for evaluating DME requests when the equipment satisfies the definition of DME but is not on the list of covered DME. The letter, however, does declare that the criteria that a state uses should be “reasonable.” This Comment will survey cases that have dealt with the issue of coverage of DME for the Medicaid population, describe the HCFA letter of guidance and argue that eliminating the Medicaid population as a whole test but not providing a clear test in its stead only slightly decreases a state’s discretion in evaluating requests for coverage and leaves Medicaid recipients who need DME but have been denied coverage at a disadvantage.

Courts and states should place considerable weight, in the absence of clear criteria, on the medical necessity of a piece of DME for a Medicaid recipient who has been denied coverage because the particular DME is not on a preapproved list but meets the definition of DME. Medical necessity is given considerable weight when determining whether a piece of DME on a preapproved list should be covered for a specific patient. Furthermore, the burden of proof should rest on the state to prove that it is not medically necessary to cover the

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4. DeSario, 139 F.3d at 91.
6. Id. Sleekis was an intervening party in DeSario, and was the only remaining plaintiff on appeal to the Supreme Court. Id.
7. Letter from Sally K. Richardson, supra note 3, at 1.
8. Id.
9. Id.
10. States traditionally have had wide discretion in determining coverage. See DeSario, 139 F.3d at 92 (stating that “[t]itle XIX affords states great latitude in determining the scope and extent of coverage of medical services” (citing Roe v. Norton, 522 F.2d 928, 933 (2d Cir. 1975))).
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DME, and not on the Medicaid recipient or on his or her doctor.\(^\text{11}\) Additionally, a showing of the percentage of Medicaid recipients using the DME should not be a requirement. This proposed shift in the burden of proof away from the Medicaid recipient places the recipient in a better position in terms of having access to health care.

In compiling the preapproved list, a flexible standard, taking into consideration various factors, should be used in addition to a panel of experts that includes at least one doctor. The first and most important factor that should be considered is the opinion of the Medicaid recipient’s treating physician. Other factors that should be considered are the benefit to the recipient, cost to the state, the existence of alternative items that are as effective as the item in question, scientific evidence such as randomized clinical trials, and the recommendation of a panel of experts including, for example, physicians, nurses, pharmacists, and physical therapists, who could properly decipher and analyze the scientific evidence. It is, however, more likely that courts and states will use a test just short of the Medicaid population as a whole test because it is thought that relying upon a physician’s decision leads to states having to provide all medically necessary services,\(^\text{12}\) an increase in Medicaid spending, and physicians rather than states determining what will be covered.\(^\text{13}\)

The ultimate purpose of this Comment is to denounce the Medicaid population as a whole test or any variant thereof while advocating an increased reliance on a physician’s expertise in determining coverage at all levels. Part I will describe generally the Medicaid statute and the limited standards it supplies for defining medical necessity, coverage, and DME. Additionally, Part I will account the facts and reasoning of DeSario at both the district court and appellate court levels. Part II sets out the Supreme Court’s decision in DeSario and describes HCFA’s guidance letter. Part III explains the Medicaid population as a whole test, and Part IV does the same for the physician’s discretion test. Part V illustrates the many deficiencies of the Medicaid population as a whole test as evidenced in case law and by the medical profes-

\(^\text{11}\) See Sara Rosenbaum et al., Who Should Determine When Health Care is Medically Necessary?, 340 New Eng. J. Med. 229, 229 (1999) (“In our view, an insurer should be able to set aside the recommendations of a treating physician only in restricted circumstances.”).

\(^\text{12}\) Courts have supported the proposition that states do not have to provide all medically necessary treatments, and thus, states have broad discretion in determining coverage. See, e.g., Beal v. Doe, 432 U.S. 438, 444 (1977) (finding that the Medicaid statute does not require that a state fund “every medical procedure that falls within the delineated categories of medical care”); DeSario, 139 F.3d at 92 (maintaining that states do not have to “fund every medically necessary procedure or item”).

\(^\text{13}\) See DeSario, 139 F.3d at 95-96.
sion. Part V also argues that the Medicaid population as a whole test results in an extreme form of rationing and that the physician’s discretion test should be implemented instead. In addition, the section describes generally Medicare’s system of coverage and how Medicaid should adopt Medicare’s use of a hierarchy of evidence for determining coverage at the national level. Lastly, this paper advocates for the use of a flexible standard for determining which pieces of DME will be covered and takes into consideration various factors such as the physician’s discretion, which would weigh heavier than cost concerns.

I. DeSario v. Thomas

A. The Applicable Federal Medicaid Regulations and Statutes

The Medicaid program is a joint federal and state “medical assistance program that provides health care to specified categories of individuals and families who are financially and categorically eligible for these services.”\(^{14}\) The State of Connecticut participates in the program,\(^ {15}\) and therefore, must guarantee that the state plan complies with the federal Medicaid statute.\(^ {16}\) According to the Medicaid statute, Connecticut must provide services to adults with severe disabilities who are unable to work due to a medical condition.\(^ {17}\) Additionally, the statute mandates that states that participate in Medicaid must provide certain services such as home health services.\(^ {18}\) Home health services include “[m]edical supplies, equipment, and appliances suitable for use in the home.”\(^ {19}\) The statute also states that optional services exist that Connecticut may include in its medical assistance plan.\(^ {20}\) Home health services, for example, are mandatory for

14. DeSario v. Thomas, 963 F. Supp. 120, 124 (D. Conn. 1997). The program was enacted in 1965 as Title XIX of the Social Security Act. See id.; see also 42 U.S.C. §§ 1396, 1396(10)(c) (1970 ed., Supp. V) (stating that its purpose is for “enabling each State, as far as practicable under the conditions in such State, to furnish . . . medical assistance on behalf of families with dependant children and aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services . . .”).


17. 42 U.S.C. § 1396d(a).

18. Id. § 1396a(a)(13)(B)-(C).

19. 42 C.F.R. § 440.70(b)(3). Home health services also provide for nursing services and a home health aide. Id. § 440.70(b)(1)-(2).

some groups and optional for others.\textsuperscript{21} Connecticut, however, provides home health services to all Medicaid recipients.\textsuperscript{22}

Furthermore, the federal Medicaid statute mandates that in determining the extent of coverage, a state’s plan must include “reasonable standards . . . [to] the extent of medical assistance” in accordance with the purpose of the Medicaid statute,\textsuperscript{23} and that the state must furnish “safeguards as may be necessary to assure that eligibility and services under the plan be determined . . . in a manner . . . consistent with the best interests of the recipients.”\textsuperscript{24} Mandating “reasonable standards” entrusts broad discretion to determine the extent of medical assistance.\textsuperscript{25} Additionally, the federal Medicaid program has the broad primary objective “to enable each [s]tate, as far as practicable, to furnish medical assistance to individuals whose income and resources are insufficient to meet the costs of medically necessary services.”\textsuperscript{26}

It follows that Connecticut “may place appropriate limits on a [covered] service based on such criteria as medical necessity or on utilization control procedures.”\textsuperscript{27} When and if Connecticut places such limits, they must still ensure that the service provided is “sufficient in amount, duration, and scope to reasonably achieve its purpose.”\textsuperscript{28} Additionally, Connecticut “may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . [based on] diagnosis, type of illness, or condition.”\textsuperscript{29} These statutes are relevant for determining coverage of home health services including DME. From these statutes, the Court of Appeals in \textit{DeSario} concluded that the Medicaid population as a whole test is sufficient to determine whether coverage is adequate when a Medicaid beneficiary is appealing a denial of DME that is not on a state’s preapproved plan.\textsuperscript{30}

\textsuperscript{21} See \textit{DeSario} v. Thomas, 139 F.3d 80, 83 (2d Cir. 1998) (explaining that those services are “mandatory for certain groups of eligible individuals and optional for others”).

\textsuperscript{22} Id. (citing State of Connecticut, Department of Income Maintenance, Connecticut Medical Assistance Provider Manual for Medical Equipment, Devices and Supplies § 189.D (MAP Manual)).

\textsuperscript{23} 42 U.S.C. § 1396a(a)(17).

\textsuperscript{24} Id. § 1396a(a)(19).

\textsuperscript{25} See \textit{Beal} v. Doe, 432 U.S. 438, 444 (1977) (explaining that the statutory language “confers broad discretion”).

\textsuperscript{26} Id. (emphasis added) (citing 42 U.S.C. §§ 1396, 1396a(10)(C) (1970 ed., Supp. V)).

\textsuperscript{27} 42 C.F.R. § 440.230(d).

\textsuperscript{28} Id. § 440.230(b).

\textsuperscript{29} Id. § 440.230(c).

\textsuperscript{30} See \textit{DeSario} v. Thomas, 139 F.3d 80, 92, 96-98 (2d Cir. 1998) (discussing the objective of the Medicaid statute and its employment in deciding coverage and the use of the
B. The Facts

DeSario's focus is on Connecticut's coverage of DME in the state's Medicaid program. Connecticut broadly defines DME as follows:

"DME" means equipment which meets all of the following requirements:

a. Can withstand repeated use
b. Is primarily and customarily used to serve a medical purpose
c. Generally is not useful to a person in the absence of an illness or injury
d. Excludes items that are disposable.

Additionally, Connecticut has a list of over 100 DMEs that are covered, and coverage is limited to the list. Connecticut also has a list of DME excluded from coverage such as roomsize humidifiers, purifiers (including electronic air filters), dehumidifiers, air conditioners, and stair glides. To obtain a reimbursement for any DME, a Medicaid recipient is required to obtain prior authorization "for all DME rentals, replacement DME, and all DME costing over $100."

Medicaid population as a whole test); Letter from Sally K. Richardson, supra note 3, at 1 (stating that coverage determinations must be reasonable and consistent with the objective of the Medicaid Act and that states should not use the Medicaid population as a whole test in assessing claims for coverage of DME not on a state's preapproved list).

31. DeSario, 139 F.3d at 83. According to the Code of Federal Regulations for the Medicare Act, DME means equipment, furnished by a supplier or a home health agency 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. This is the only definition of DME available at the federal level because DME is not defined in the Medicaid Act. DeSario, 139 F.3d at 88-89. The Court of Appeals in DeSario used the Medicare definition as a reference point and to compare Connecticut's definition of DME in its Medicaid plan. Id.

32. Id. at 83 (citing MAP Manual § 189.B). The MAP Manual is the Connecticut Medical Assistance Provider Manual for Medical Equipment, Devices and Supplies and "explains Connecticut's coverage of the items listed in its title." Id. Connecticut's definition does not say that the piece of DME must be for use in the home, but does exclude disposable items unlike the definition in the Medicare Act. See supra note 31 (discussing Medicare's definition of DME). Connecticut's state agency regulations explain "disposable" as including such items as plastic bed pans, and also, excludes from the definition of DME items, which are customized or personalized such as braces and prosthetics. CONN. AGENCIES REGS. § 17-2-80B.

33. See DeSario, 139 F.3d at 83 (citing MAP Manual § 189.E.II.a).
34. Id. (citing MAP Manual § 189.E.III.a).
35. Id. (citing MAP Manual § 189.F.II.a).
The plaintiffs, "as representatives of similarly situated Medicaid recipients" sued the Commissioner of the Connecticut Department of Social Services (DSS), Joyce A. Thomas, because of DSS's denial of the plaintiff's "prior authorization requests seeking Medicaid reimbursement for certain items to which they claim[ed] entitlement as DME." The district court then certified two subclasses of plaintiffs. The first class is the "DeSario" subclass and included all of Connecticut's Medicaid recipients "who have been, or who in the future, will be denied Medicaid coverage" for equipment that the recipients claim to be DME, on the basis that the DME is not included on DSS's list for such equipment. The representative of the class was Concetta DeSario, a quadriplegic, who requested payment for an environmental control unit that controls appliances and costs about $7000 to $8000. Without the unit, she was unable to reposition her bed and relieve any respiratory distress. Additionally, the unit allowed DeSario to stay in her home rather than having to go to a long-term care facility.

The second class, the "Emerson" subclass, consisted of all of Connecticut's Medicaid recipients "who have been, or who in the future will be, denied Medicaid coverage" for equipment that the recipients claim to be DME, on the basis that DME is not included on DSS's list and has been "specifically excluded from coverage." The representatives for this class were Elizabeth Emerson, who had requested prior authorization for an air conditioner and an air purifier, and Caroline Stevenson who had requested prior authorization for an air purifier and a room size humidifier. Both Emerson and Stevenson suffered from a chemical sensitivity condition. Emerson, due to her condition, was highly susceptible "to severe reactions to air-borne environ-

36. Id. The plaintiffs based their claim on MAP Manual §§ 189.E.II.a, 189.E.III.a. Id.; see also supra notes 33-34 and accompanying text.
38. Id. In other words, this class consists of those who were or will be denied coverage based upon MAP Manual § 189.E.II.a. See DeSario, 139 F.3d at 83.
39. DeSario, 139 F.3d at 83. An environmental control unit could help DeSario to "reposition her bed, make and receive telephone calls, turn lights on and off, open her apartment door, control her heat and air conditioning, [and] control her television." DeSario, 963 F. Supp. at 129 (internal quotation marks omitted) (quoting Notice of Decision Re: Concetta DeSario, March 28, 1996).
41. Id.
42. Id. at 141 (ruling on pending motions). The "Emerson" subclass was denied coverage on the basis of MAP Manual § 189.E.III.a. DeSario, 139 F.3d at 83.
43. See DeSario, 139 F.3d at 83.
44. See id.
mental toxins” that can only be prevented by an air conditioner and an air purifier that eliminate these toxins. Without these DME, her condition would only worsen and may ultimately result in “respiratory distress.” Stevenson, due to her condition, suffered “respiratory, neurological, and allergy-like symptoms, muscle and joint pains, fatigue, weakness, digestive and absorption difficulties, and periodic depression.” Without the prescribed DME, Stevenson would have increased symptoms due to her inability to control such things as airborne molds, pollutants, and scented products.

Additionally, Thomas Slekis intervened in the action, and the district court analyzed his case separately from the two subclasses due to the “unique circumstances” of his case. Slekis was a paraplegic and receives about $600 per month in disability benefits in addition to Medicaid benefits. Due to his confinement to beds and to wheelchairs, he suffered from decubiti that often require surgery and hospitalization. Since 1985, Slekis has had fifteen to twenty flap surgeries to help his problem with decubiti. According to his physician’s testimony, however, the procedure may only be able to be completed one or two more times in the region of his buttocks before exhausting the remedy. After exhaustion of this procedure, the only remaining options would be more serious surgeries. If the decubiti is not treated, it “presents a significant risk of infection, which may lead to permanent impairment or death.”

In October 1996, Slekis had a flap procedure and an amputation of his lower left leg “to address a sore on [his] left foot that . . . showed signs of dangerous deterioration.” While the sore on his foot originated from a burn that would not heal properly, the ongoing

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46. Id. at 130.
47. Id.
48. See id.
49. See DeSario, 139 F.3d at 83.
51. See id.
52. See id. In particular, Slekis has recurrent bedsores or decubiti in his hips, buttocks, and feet. See id. The surgery requires “cleaning out the sore, shifting nearby tissue into the resulting hole, and closing the skin on top.” Id. The surgery may also require up to two weeks of hospitalization. See id.
53. See id.
54. See id. Because a patient only has a limited amount of tissue surrounding a decubitus, the flap surgery cannot be conducted indefinitely. See id.
55. See id. at 135-36. One such surgery is the “grisly ‘fillet’ procedure” which requires the sacrificing of a leg in order to obtain enough tissue to fill the wound. Id. at 136.
56. Id. at 136.
57. Id.
problems he experienced were likely related to the repeated trauma that occurred as a result of transporting himself back and forth between the wheelchair and the bed. To prevent future hospitalizations, Slekis's physician prescribed a RIK mattress. Slekis's physician testified that this mattress would help reduce Slekis's skin problems and would prevent the need for future hospital admissions.

On October 31, 1996, Connecticut Rehab and Medical Products, Inc. (Connecticut Rehab) requested prior authorization from DDS for Slekis's mattress under the Medicaid program, but, in so doing, used the appropriate Medicare code for an RIK mattress. On the same day, the mattress was delivered to Slekis. His physician testified that since Slekis had received the special bed, his "skin was in better shape than it had been for years." DSS, however, in response to Connecticut Rehab's request, sent Connecticut Rehab "a Request for Information," which stated that the code used was not valid for Medicaid recipients and that there were less expensive codes for DME that would have also met Slekis's needs. The district court stated that Slekis demonstrated that no other Medicaid codes existed for the RIK mattress or a similar DME, and concluded that the DSS response constituted a denial of prior authorization.

C. The Court's Reasoning

1. The District Court's Analysis.

   a. The Use of a DME Fee Schedule to Determine Coverage.—The district court found that the use of a preapproved DME list is not per se unlawful, but that Connecticut's list in its "present form" as an exclusive list "violates federal Medicaid law because it improperly limits the amount, duration, and scope of medically necessary durable medical

58. See id. Such trauma can be caused by banging parts of his body against the hard surfaces of a wheelchair and by "dragging his body across the surface of his bed." Id.
59. See id. The RIK mattress is "filled with an oil-based liquid and covered with exceptionally loose-fitting sheets." Id. The mattress costs $840 a month to rent. See DeSario v. Thomas, 139 F.3d 80, 83-84 (2d Cir. 1998).
60. See DeSario, 963 F. Supp. at 136.
61. See id.
62. See id.
63. Id.
64. Id. (citing Pl.'s Ex. 1).
65. See id. ("Accordingly, the Court concluded that, though denominated a 'request for information,' the defendant's response was effectively a denial of prior authorization for the RIK mattress.").
66. Id. at 131.
equipment." This decision was based on the facts that the defendant did "not have any procedure for systematically, timely, or effectively updating this dispositive list as new equipment comes on the market even if the new items meet the defendant's general definition of 'durable medical equipment,'" and that the defendant's "policies and operation of the prior approval system lack any mechanism by which a recipient can demonstrate that an item of unlisted but medically necessary equipment otherwise meets the definition of DME, such that it can be added to the list or otherwise be considered for prior approval."  

It is important to note that the district court did not find that the use of a list is unlawful per se. The court asserted that the Medicaid Act has been construed to give broad discretion to states to adopt standards for the determination of the scope of medical assistance. Additionally, the court stated that HCFA has given states the authority to put "a money ceiling upon medical supplies and equipment based on a reasonable, fixed dollar amount per month or per year," and has also allowed states to require prior authorization for DME which costs a certain amount. Therefore, the court found that a list is permitted as long as there is a method for seeking modifications or alterations of the list.

b. The Categorical Exclusion of Pieces of DME.—The district court also held, however, that DSS's categorical exclusion of certain pieces of DME, in particular air conditioners, air purifiers, and room humidifiers, without considering medical necessity, violates federal Medicaid law. The district court found that DSS "may not categorically exclude a piece of DME without considering the medical neces-

67. Id. at 130 (emphasis added); see supra notes 14-30 and accompanying text (discussing the federal Medicaid program).
68. DeSario, 963 F. Supp. at 130 (citing Dodson v. Parham, 427 F. Supp. 97 (N.D. Ga. 1977)). The district court noted that the defendant's witness, Ms. Geary, testified that DSS's policies did not provide exceptions for noncovered DME, even if the noncovered DME was the only medical service available for treating a particular condition. Id. Ms. Geary also stated that even though DSS is authorized to waive application of its regulations, they have never done so "to provide Medicaid coverage for durable medical equipment not on the MEDS fee schedule." Id. (citing May 20 Hearing, Trans. at 123).
69. Id. at 131.
70. Id. (citing Beal v. Doe, 432 U.S. 438, 444 (1977)); see supra note 10 (discussing this broad discretion).
71. DeSario, 963 F. Supp. at 131 (quoting MSA Medical Assistance Manual, § 5-50.1-00 (distributed as SRS Action Transmittal SRS-AT-77-26 (Feb. 16, 1977))).
72. Id. at 132.
73. These pieces of DME were excluded under Conn. MAP Manual § 189.III.E.a. Id.
74. Id. at 132-33.
sity of an item either on a 'macro' or 'micro' level."75 The macro level refers to a legislative determination of what is medically necessary, and the micro level refers to a physician's decision "that the condition of his patient warrants the administering of a type of medical assistance which the plan makes available."76 Here, Connecticut made neither type of decision.77 The district court, therefore, appears to advocate determining coverage of medically necessary DME through the legislature or through the physician of the Medicaid recipient. Nowhere does the court refer to the number of Medicaid recipients who may require the use of the specified DME for it to be covered by a state Medicaid plan.78 In the end, the court enjoined DSS from using Conn. MAP Manual § 189.E.II.a, which permits DSS to deny coverage to Medicaid recipients for any DME not listed on the state's DME fee schedule, and § 189.E.III.a which excludes specific DME from coverage "as the exclusive determinant of plaintiffs' pre-authorization requests for" DME and granted an injunction to all of the plaintiffs.79

DSS appealed on the "claims that the district court erred in finding that plaintiffs were likely to succeed in proving DSS's regulations violated Title XIX of the Social Security Act and its regulations."80 The Court of Appeals held that the district court incorrectly construed the Medicaid Act and "miscalculated the likelihood of plaintiffs' success on the merits."81 The Court of Appeals, therefore, vacated the injunction and remanded the case.82

2. The Court of Appeals Analysis.—

a. The Need to Consider Medical Necessity before Categorical Exclusion.—The Court of Appeals first addressed the claims of the Emerson subclass whose coverage of DME was denied because the DME was specifically excluded from coverage by Connecticut's plan.83 Accord-

75. Id. at 133 (citing Preterm, Inc. v. Dukakis, 591 F.2d 121, 125 (1st Cir. 1979)).
76. Id. (quoting Preterm, 591 F.2d at 125).
77. See id. at 133-34.
78. The court did state that DSS has ignored the fact that certain DME may be medically necessary for some Medicaid recipients even though they may be only "palliative for others." Id. at 134 (internal quotation marks omitted) (quoting Jeneski v. Myers, 209 Cal. Rptr. 178 (1984)). The court, however, does not explain or define its use of the word "palliative." The court, referring to the need of "some medical recipients," implies that there would not have to be a large part of the Medicaid population that required the DME for it to be covered.
79. Id. at 120, 140, 142-43.
80. DeSario v. Thomas, 139 F.3d 80, 84 (2d Cir. 1998).
81. Id.
82. Id.
83. Id. at 88; see supra notes 42-48 and accompanying text (describing the Emerson subclass's claim).
ing to the court, the air conditioners, room size humidifiers, and air purifiers all fall outside of Connecticut’s definition of DME.\(^{84}\) Additionally, the court stated that the district court was incorrect in asserting that DSS can not exclude DME without first considering their medical necessity.\(^{85}\) Rather, the Court of Appeals reasoned that it did not matter how medically necessary something may be to an individual, noting that although “gloves are medically necessary to persons exposed to frost . . . or even to the population as a whole, the state need not (and in fact cannot) provide it unless it falls within a covered medical service.”\(^{86}\)

The Court of Appeals then stated that Connecticut had adopted “reasonable standards” as mandated by the Medicaid Act\(^{87}\) for the determination of which equipment are DME and if the DME would be covered.\(^{88}\) The Court of Appeals found that Connecticut’s definition of DME was “almost identical” to the wording of the federal regulation that defines DME for the Medicare Act as laid out in 42 C.F.R. § 414.202 (1996).\(^{89}\) The court also found that “the use of identical definitions by Connecticut and the Department of Health and Human Services (HHS) subverts the allegation that Connecticut’s definition is unreasonable.”\(^{90}\) Additionally, HHS endorsed Connecticut’s definition of DME as reasonable, which is evidenced by the Secretary of HHS’s statement to the court that Connecticut has “apparently adopted a reasonable definition of medical equipment which is based in part on the definition used by the Secretary under the Medicare program.”\(^{91}\)

The court gave significant deference to the Secretary’s assessments of Connecticut’s definition and stated that “an agency’s interpretation of the statute covering a program it administers should receive substantial deference.”\(^{92}\) The court also gave deference to

\(^{84}\) DeSario, 139 F.3d at 88.

\(^{85}\) Id. at 88-90.

\(^{86}\) Id. at 88.

\(^{87}\) Id. at 88-90 (citing 42 U.S.C. § 1396a(a)17 (1994)); see supra note 23 and accompanying text (providing relevant text).

\(^{88}\) DeSario, 139 F. Supp. at 37-38, 40.

\(^{89}\) Id.

\(^{90}\) Id. at 89; see supra notes 31-32 and accompanying text (providing the text of the definition of DME by both Connecticut and the Medicare Act).

\(^{91}\) DeSario, 139 F.3d at 89 (quoting Brief of Third-Party Defendant Donna Shalala, Secretary of HHS, at 10). Additionally, the Secretary’s brief noted that it was appropriate to compare the Medicare definition to Connecticut’s because “with respect to medical equipment, the Secretary has not required that States adopt the Medicare definitions, but has permitted States to do so in whole or in part.” Id. (internal quotation marks omitted) (quoting Brief of Third-Party Defendant Donna Shalala at 11).

\(^{92}\) Id. (citing Conn. Hosp. Ass’n v. Weiker, 46 F.3d 211 (2d Cir. 1995)).
Connecticut's distinction between equipment that is "primarily medical in nature" and equipment that is usually used for nonmedical purposes but incidentally helps someone with a medical condition.93 The court maintained that a state can reasonably refuse to cover such nonmedical equipment even if the physician who prescribed its use can show a medical need for it.94 Furthermore, the court felt that if states were required to cover whatever a physician prescribed and could show was medically necessary, the states would have to cover such equipment as heaters, vacuum cleaners, dishes, food, and bedding.95 Therefore, the court held that Connecticut's definition of DME was reasonable according to the Medicaid Act, and that the Act does not require Connecticut to cover any DME outside of that definition; air conditioners, air purifiers, and humidifiers all fell outside of the DME definition under the Act, and that DSS properly denied Emerson's and Stevenson's request for coverage of DME.96

b. The Individual Medicaid Recipient.—As for the DeSario subclass and for Slekis, the two types of DME that they requested were covered by Connecticut's DME definition but coverage was denied because the DME were not included on the DSS fee schedule.97 The Court of Appeals found that the district court erred in finding "that every medically necessary item of equipment satisfying the state’s definition of DME must be provided," and reasoned instead that for the state's coverage to be adequate, it only has to "meet the needs of the Medicaid population of the state."98

The Court of Appeals first agreed with the district court that Connecticut could use a list of covered equipment.99 The court then explained that a physician's belief that a piece of DME is medically necessary does not mean that if the state does not provide coverage, such coverage is insufficient.100 The court held that "a state need not

94. Id. at 90 (citing Dougherty v. Department of Human Servs., 449 A.2d 1235, 1238 (N.J. 1982)).
95. Id. The court stated that the plaintiffs' definition of DME "would cover all the necessities of life, and some of its amenities." Id.
96. Id.
97. See id.; supra notes 38-41, 49-56 and accompanying text (discussing the DeSario subclass and Slekis).
98. DeSario, 139 F.3d at 90-91; see also supra notes 66-68 and accompanying text (describing the district court's reasoning).
99. DeSario, 139 F.3d at 91. The court noted that a 1977 Medical Assistance Manual issued to state agencies administering HCFA medical assistance programs declares that states may limit DME. Id. (quoting MSA Medical Assistance Manual, §§ 5-50.1-00).
100. Id.
fund every medically necessary item of DME that falls within the state’s definition of DME."¹⁰¹ Rather, coverage and medical necessity are two "distinct concepts."¹⁰² According to the court, the Medicaid statute does not require "comprehensive coverage of all medically necessary services, even all of those services provided by the state."¹⁰³ Rather, the states have significant latitude to determine the scope of their coverage.¹⁰⁴ The court noted that this discretion is only slightly limited by the Medicaid Act that requires the state to have reasonable standards for determining coverage and must be "sufficient in amount, duration, and scope to reasonably achieve its purpose."¹⁰⁵

The court further averred that if states were required to provide all medically necessary services, it would constrict their ability to place limitations on coverage.¹⁰⁶ The only option would be to rely on the decisions of physicians to decide what is medically necessary, which the court believed would result in unlimited coverage because Medicaid recipients' physicians would be creating coverage and "budgeting would be by a blank check."¹⁰⁷ Therefore, the court rejected the view that states must cover all medically necessary services because the system would be "unworkable."¹⁰⁸ Rather, the objective of the state is to

¹⁰¹. Id. at 92.
¹⁰². Id.
¹⁰³. Id. at 93. The court, in support, referred to the Medicaid Act's requirement of reasonable standards and the objectives of the Act. Id; see supra notes 12-28 and accompanying text (providing the requirements of the Medicaid Act). The court also noted that the Secretary of HHS, in her brief, noted that 42 U.S.C. § 1396a(a)(19) states that services be furnished "in the best interests of recipients," but this statute does not mean that states cannot place "amount, duration, and scope limitations which may affect some individuals more than others." DeSario, 139 F.3d at 93 (internal quotation marks omitted) (quoting Brief of Third-Party Defendant Donna Shalala); see Alexander v. Choate, 469 U.S. 287, 303 (1985) (stating that the Medicaid Act gave "the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in 'the best interests of the recipients'" (quoting 42 U.S.C. § 1396a(a)(19))); Beal v. Doe, 432 U.S. 438, 444 (1977) (noting that the Medicaid statute does not mandate that states fund all medical procedures which "fall[ ] within the delineated categories of medical care").
¹⁰⁴. See DeSario, 139 F.3d at 92 (citing Roe v. Norton, 522 F.2d 928, 933 (2d Cir. 1975)).
¹⁰⁵. Id. at 93 (internal quotation marks omitted) (citing 42 U.S.C. § 1396a(a)(17)) (quoting 42 C.F.R. § 440.230(b) (1996) (noting further that the plaintiffs erroneously interpreted the Medicaid Act as allowing states to limit coverage based only on certain identified criteria)).
¹⁰⁶. Id. at 95 (stating a concern that such a requirement could even implicate limitations based on a "lack of medical necessity"). Id.
¹⁰⁷. Id. at 95-96 (citing Weaver v. Reagan, 886 F.2d 194, 200 (8th Cir. 1989); Pinneke v. Preisser, 623 F.2d 546, 555 (8th Cir. 1980)). The court also explained that such a situation would discourage states from adopting optional services listed in Title XIX for fear that for each such service, the state would vastly enlarge the amount of "medically necessary care" that physicians could require it to provide. Id. at 96.
¹⁰⁸. Id. at 96.
use reasonable standards to “meet the needs of the Medicaid population of the state.”\textsuperscript{109} This objective may result in “an individual with a rare condition or unusual needs, who must have a costly item of DME that Connecticut has not chosen to cover and that is needed by a handful of the Medicaid population, . . . hav[ing] to look for other sources of assistance.”\textsuperscript{110}

\textit{c. The Medicaid Population as a Whole.}—The court then discussed the Medicaid population as a whole standard.\textsuperscript{111} First, plaintiffs have the burden of proving that Connecticut’s coverage of DME does not comply with federal law.\textsuperscript{112} The court stated that the “normal assumption [is] that an applicant is not entitled to benefits unless and until he proves his eligibility.”\textsuperscript{113} The court then applied this assumption to a Medicaid recipient’s “attack [of] a plan that has been reviewed by a federal agency.”\textsuperscript{114}

The plaintiffs argued that “Medicaid recipients should only have the burden of proof as to information that is within their knowledge” and that the “Medicaid statistics needed to evaluate the adequacy of DME coverage for the Medicaid population as a whole” were not within their knowledge.\textsuperscript{115} The court essentially ignored this argument and pointed out that the plaintiffs could obtain this information through discovery and administrative hearings “and therefore [bore] no greater burden than in any other lawsuit.”\textsuperscript{116}

Due to the burden of proof required by the Medicaid population as a whole standard, the Court of Appeals found that the district court was wrong in concluding that the plaintiffs were likely to succeed in demonstrating that the fee schedule was inadequate “with respect to the needs of the Medicaid population as whole.”\textsuperscript{117} The district court came to this conclusion because there is no procedure for updating the fee schedule and for Medicaid recipients to show that an item of

\textsuperscript{109} Id. (emphasis added) (citing Alexander v. Choate, 469 U.S. 287, 303 (1985)).

\textsuperscript{110} Id. (emphasis added).

\textsuperscript{111} Id.; see infra notes 138-157 and accompanying text (defining the Medicaid population as whole standard).

\textsuperscript{112} See DeSario, 139 F.3d at 96.

\textsuperscript{113} Id. (internal quotation marks omitted) (quoting Lavine v. Milne, 424 U.S. 577, 584 (1976)).

\textsuperscript{114} Id. (citing Pinnacle Nursing Home v. Axelrod, 928 F.2d 1306, 1313 (2d Cir. 1991)). The court felt that the application of the assumption was particularly valid because Medicaid is a joint federal-state program that requires the approval of HHS. Id. (citing Perry v. Dowling, 95 F.3d 231, 236 (2d Cir. 1996)); see 42 U.S.C. § 1316; 42 C.F.R. §§ 430.12-430.15.

\textsuperscript{115} DeSario, 139 F.3d at 97.

\textsuperscript{116} Id. (citing CONN. GEN. STAT. §§ 4-177b, 4-177c).

\textsuperscript{117} Id.
DME falls within the definition of DME, and "the fee schedule was
developed and maintained with limited input from physicians having
the appropriate specializations."118 The Court of Appeals felt, how-
ever, that new DME is always entering the market with little scientific
study so that frequent updates of the fee schedule would be unneces-
sary and difficult, and physicians are not needed to make the schedule
because the committee already includes a nurse and a physical ther-
pist who are medical professionals.119 Furthermore, the court stated
that Medicaid recipients do have a method of appealing any denial at
a fair hearing where the recipient could show "that the absence of a
particular item of DME from the fee schedule renders the schedule
unreasonable and inadequate with respect to the needs of the Medi-
caid population of the state."120 The court thus concluded that using
a fee schedule to deny coverage does not violate the Medicaid Act,
and that the district court was wrong in enjoining DSS from using the
fee schedule.121

II. THE SUPREME COURT'S DECISION AND HCFA'S LETTER
OF RECOMMENDATION

The Supreme Court in Sleakis v. Thomas122 granted certiorari, va-
cated the judgment, and remanded the case to the Court of Appeals
for the Second Circuit "for further consideration in light of the inter-
pretive guidance issued by the Health Care Financing Administration
on September 4, 1998."123 HCFA'S "interpretive guidance" came in

118. Id. (citing DeSario, 963 F. Supp. at 142).
119. Id.
120. Id. The court noted that the reasonableness and adequacy of the fee schedule to
the Medicaid population of the state is usually expressed in percentage terms. Id. (citing
Charleston Mem'l Hosp. v. Conrad, 693 F.2d 324, 330 (4th Cir. 1982); Curtis v. Taylor, 625
F.2d 645, 653 (5th Cir. 1980)).
121. Id. at 98.
123. Id. at 864. It is interesting to note that DeSario died of pneumonia in February
1998. See Johnny Mason, Jr., Policies on Medicaid Spark Capitol Protest, THE HARTFORD COU-
RANT, Sept. 11, 1998. As a result of her death and the court of appeals decision, however,
over 100 people protested at Connecticut's state capitol asking for "legislative support in
asking the U.S. Supreme Court to send . . . [the] appellate court decision back to the 2nd
Circuit U.S. Court of Appeals for reconsideration." Id. Those protesting stated that they
wanted their legislature to be aware "that many people with disabilities were unable to get
the medical equipment they needed to survive." Id. Additionally, they pointed out that
only one item had been added to the list in the last five years and no methods existed "for
people with disabilities to add to the list—even when the equipment is potentially life-
saving." Id.
the form of a letter to state Medicaid directors and in response to the Court of Appeals decision in *DeSario v. Thomas*.124

HCFA wrote a letter in response to the Second Circuit Court of Appeals decision in *DeSario*, but the guidance it provides is “applicable only to [D]ME coverage policy.”125 According to HCFA, a state may use a preapproved list of DME for “administrative convenience because such a list eliminates the need to administer an extensive application process for each [D]ME request submitted.”126 Additionally, HCFA states that a DME policy must provide a “reasonable and meaningful procedure for requesting” DME that are not on the preapproved list.127 By “reasonable and meaningful procedure,” HCFA appears to mean a “fair hearing” as the Court of Appeals mandated,128 rather than the more personal system that the district court advocated.129 Additionally, the letter states that Medicaid recipients are to be informed of their right to a fair hearing.130 Therefore, the letter is rather vague as to what a “reasonable and meaningful procedure” is.

The letter also maintains that states cannot use the “Medicaid population as a whole” standard,131 as advocated by the Court of Appeals in *DeSario*.132 HCFA described this test as requiring “a beneficiary to demonstrate that, absent coverage of the item requested, the needs of ‘most’ Medicaid recipients will not be met.”133 According to HCFA, this test is inappropriate because it “establishes a standard that virtually no individual item of [D]ME can meet,” and thus mandating that a Medicaid recipient meet such a standard does not provide “meaningful opportunity for seeking modifications or exceptions to a State’s pre-approved list.”134 Therefore, the standard used by the Court of Appeals was incorrect, but HCFA does not state what test should be used instead, or if the district court’s standard should be employed.

HCFA, then, provided three conditions a state must meet “with respect to an individual applicant’s request for an item of [D]ME,” to

124. See Letter from Sally K. Richardson, *supra* note 3, at 1-2 (providing guidance on the use of exclusive lists with regards to DME).
125. *Id.* at 1.
126. *Id.*
127. *Id.*
128. *DeSario v. Thomas*, 139 F.3d 80, 97 (2d Cir. 1998).
131. *Id.* at 1.
132. *DeSario*, 139 F.3d at 96-98; see *supra* notes 105-115 and accompanying text.
134. *Id.*
be in compliance with the federal Medicaid Act. First, the process of gaining coverage must be "timely" and must use "reasonable and specific criteria" for deciding whether DME will be covered. According to HCFA, the criteria for determining whether DME will be covered "must be sufficiently specific to permit a determination of whether an item of [D]ME that does not appear on a State's preapproved list has been arbitrarily excluded from coverage based solely on a diagnosis, type of illness, or condition." Additionally, the state's preapproved list, criteria, and process must be available to the public and to Medicaid recipients. Third, Medicaid beneficiaries must be informed of their right to a fair hearing.

Lastly, HCFA provides a warning to the states "to be cognizant of the approval decisions you make regarding items of [D]ME that do not appear on a preapproved list, to ensure that the item of [D]ME is covered for all beneficiaries who are similarly situated." Also, states should update their list of preapproved DME to "reflect available technology." It appears that HCFA is simply ensuring that all Medicaid beneficiaries with the same conditions receive the DME that they need and that states have a method of updating the list. Overall, the letter does not provide much guidance. It still leaves much discretion to the states, and it does not say which standard should be employed instead of the Medicaid population as a whole standard.

A. The Medicaid Population as a Whole Test

According to HCFA, the Medicaid population as a whole test "requires a beneficiary to demonstrate that, absent coverage of the item requested, the needs of 'most' Medicaid recipients will not be met." HCFA, though, does not define what "most" is. Is it 50%, 70%, or ...

135. Id.
136. Id. at 2.
137. Id.; see 42 C.F.R. § 440.230(c) (stating that a "Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition").
138. See Letter from Sally K. Richardson, supra note 3, at 2.
139. See id.
140. Id.
141. Id.; see DeSario, 963 F. Supp. at 130 (finding that Connecticut did not have, but should have had, a system for updating their preapproved list). But see DeSario, 139 F.3d at 97 (stating that updating the preapproved list is difficult because new DME are constantly being produced with little scientific study).
142. Letter from Sally K. Richardson, supra note 3, at 1. The Medicaid population as a whole standard is also referred to as the "generalized evidence of medical necessity" test. Rosenbaum, supra note 11, at 230. This test is described as "link[ing] medical necessity to broad standards based on evidence involving large groups of patients rather than to clinically derived professional standards applied to particular patients." Id.
90% of the population? The Court of Appeals in *DeSario v. Thomas*\(^{143}\) described the test as the state's coverage being able to provide DME "adequate to meet the needs of the Medicaid population of the state."\(^{144}\) The test does not require that the state cover all medically necessary services, and, therefore, DME that a Medicaid beneficiary's physician has determined to be medically necessary, does not have to be covered by the state plan and Medicaid recipients may not always receive the DME that they medically need.\(^{145}\) Additionally, the court noted that the standard requires the Medicaid recipients to prove that the state's DME coverage does not comply with federal law,\(^{146}\) and it is appropriate to show the "reasonableness and adequacy" of the pre-approved list to the Medicaid population of the state in terms of a percentage.\(^{147}\) The court, however, does not describe how large the percentage has to be to gain coverage. The court also stated that a cost-benefit analysis could be used to justify denial of coverage.\(^{148}\) The court, though did not explain how a cost-benefit analysis would be used in conjunction with a percentage.

The Court of Appeals of the Fifth Circuit in *Curtis v. Taylor*\(^{149}\) employed similar reasoning in upholding the Medicaid population as a whole standard. In *Curtis*, Florida decreased the number of physician visits that it would cover to three visits and to emergencies.\(^{150}\) The plaintiffs argued that this decrease violated the federal Medicaid Act,\(^{151}\) and that the services provided "must be determined with regard to each individual who receives medical services."\(^{152}\) The statistics submitted to the court illustrated, however, that "most Medicaid recipients do not require more than three visits in any calendar

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\(^{143}\) 139 F.3d 80 (2d. Cir. 1998).

\(^{144}\) Id. at 90-91.

\(^{145}\) See id. at 91-92. The court stressed that a state does not have to cover all medically necessary services and even noted that they understood that this means that some DME that are medically necessary to a "particular Medicaid recipient" will not be covered by Medicaid. Id. at 91; see Virginia Hosp. Ass'n v. Kenley, 427 F. Supp. 781, 784 (1977) (upholding a limit of 21 days for hospitalization for Medicaid recipients while realizing that some Medicaid recipients may require longer than 21 days of hospitalization); see also Beal v. Doe, 432 U.S. 438, 444 (1977) (finding that the Medicaid Act does not require a state to cover "every medical procedure falling within the delineated categories of medical care"). *But see* Weaver v. Reagan, 886 F.2d 194, 198 (8th Cir. 1989) (finding that a state must provide all medically necessary services in order to meet the purpose of the Medicaid Act).

\(^{146}\) DeSario, 139 F.3d at 96.

\(^{147}\) Id. at 97 (citing Charleston Mem'l Hosp. v. Conrad, 693 F.2d 324, 330 (4th Cir. 1982); Curtis v. Taylor, 625 F.2d 645, 653 (5th Cir. 1980)).

\(^{148}\) Id. at 98, 98 n.14.

\(^{149}\) 625 F.2d 645 (5th Cir. 1980).

\(^{150}\) Id. at 647.

\(^{151}\) Id. at 650.

\(^{152}\) Id. at 651.
The court upheld the reduction in coverage because other circuits have permitted it, and because this limitation is not based "solely upon the 'diagnosis, type of illness, or condition' of the recipient." The state regulation, however, may not explicitly base the limit on the type of diagnosis or condition, but instead the limitation is based implicitly on all those medical conditions that require more than three physician visits per month. The court concluded by stating that the coverage just needs to provide "adequate" services for the "medical needs of most of the individuals eligible for Medicaid assistance." It appears then that if more Medicaid recipients had required more than three visits per month, then the limitation would not have been permitted.

The Supreme Court in *Alexander v. Choate* also supported the Medicaid population as a whole test, albeit with different language. In *Alexander*, the plaintiffs brought an action against the State of Tennessee for proposing to reduce the number of inpatient days Medicaid would cover because it would violate section 504 of the Rehabilitation Act of 1973 and put the handicapped at a disadvantage. The Court held that the proposal would not violate the Act. Statistical evidence was introduced to show that "27.4% of all handicapped users of hospital services who received Medicaid required more than 14 days of care, while only 7.8% of nonhandicapped users required more than 14 days of inpatient care." The Supreme Court noted these percentages, but stated that the Medicaid Act does not assure that each

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153. *Id.* (emphasis added). The statistics showed that "[i]n Florida, only 3.9% of the second quarter 1977 Medicaid population required more than three physicians' visits in any month of that quarter." *Id.* at 651 n.10. Additionally, only .5% needed more than three visits in one month. *See id.* The plaintiffs, however, provided documentation that they would need more than three visits per month. *See id.* at 651 n.11. One of the plaintiffs had cirrhosis of the liver, tuberculosis, and chronic anemia, and his physician stated that he could not treat his patient properly with the limit of three visits per month. *See id.* Additionally, physicians testified that some conditions such as asthma, urinary tract infections, pneumonia, and acute tonsillitis could not be treated with this restriction. *See id.*

154. *Id.* at 651-52 (quoting 42 C.F.R. § 440.230).

155. *Id.* at 653 (emphasis added) (citing Virginia Hosp. Ass'n v. Kenley, 427 F. Supp. 781, 786 (E.D. Va. 1977)). In *Virginia Hospital Ass'n*, the court found that a reduction in coverage to 21 days would meet the needs of 92% of the Medicaid population. *Virginia Hosp. Ass'n*, 427 F. Supp. at 786; *see also* David M. Eddy, *Rationing Resources While Improving Quality: How to Get More for Less*, 272 JAMA 817, 820 (1994) (advocating the identification of "no-value or low-value practice[s]" and developing guidelines for discouraging their use and understanding that this practice may deny coverage from those who may benefit from "no-value or low-value practice[s]").


157. *See id.* at 289, 290. The state proposed a reduction from 20 to 14 days. *See id.*

158. *Id.* at 289.

159. *Id.* at 290.
Medicaid recipient will receive "that level of health care precisely tailored to his or her particular needs. Instead, the benefit provided through Medicaid is a particular package of health care services . . . ." Therefore, the Court implied that not enough of the Medicaid population is affected to warrant denying the proposal, and thus the Medicaid Act does not mandate tailored care to individual recipients. It appears that if the statistics had shown that a larger part of the Medicaid population would have been affected or that the affected handicapped individuals made up a large portion of the Medicaid population as a whole, then the proposal would not have been acceptable.

B. Physician’s Discretion Test

The physician’s discretion test has been used primarily to determine medical necessity when a covered procedure or DME is denied to a particular Medicaid beneficiary. This Comment argues that the physician’s discretion should be given more weight in determining whether a state should cover certain DME and procedures and should be used within certain limitations in place of the Medicaid population as a whole test.

In its simplest terms, the physician’s discretion test provides coverage of services that physicians determine are medically necessary in an individual case. For example, the district court in *DeSario v. Thomas*, advocated the reliance on physicians to determine what is medically necessary and thus what Medicaid covers. The *DeSario* court found that the state plan was sufficient because it would meet the needs of most Medicaid recipients. *Id.; see supra* note 144.

160. *Id.* at 303. An earlier court of appeals case made a similar finding in a case where the state plan was limiting the number of inpatient and outpatient hospital days covered by Medicaid. *Charleston Mem'l Hosp. v. Conrad*, 693 F.2d 324, 329 (1982). Statistical evidence presented demonstrated that the limit on inpatient days would fully meet the needs of 88% of Medicaid recipients, and the limit on the outpatient days would fully meet the needs of 99% of the Medicaid recipients. *See id.* at 330. Because of these percentages, the court found that the state plan was sufficient because it would meet the needs of "most" Medicaid recipients. *Id.; see supra* note 144.

161. This contention appears to be true also with the case of *Charleston Memorial Hospital* because the Court was so concerned with percentages affected by the limitation. 469 U.S. at 330; *see supra* note 156 (discussing *Charleston Memorial Hospital v. Conrad*).

162. *See Rosenbaum, supra* note 11, at 230 ("Traditionally, insurers considered care and services medically necessary whenever treating physicians said they were necessary."). As health care costs rose, Medicare and Medicaid "began to review the medical necessity of physicians' treatment recommendations as the basis for determining which procedures and services would be covered." *Id.* (citing Bergthold LA. Medical necessity: do we need it? Health Aff (Millwood) 1995; 14(4):180-90).


164. *Id.* at 133. The district court incorrectly put coverage and medical necessity together while the court of appeals properly distinguished the two concepts from each other. *See DeSario v. Thomas*, 139 F.3d 80, 92 (1998) (stating that "medical necessity and cover-
district court also maintained that the state must examine the medical necessity of an item before excluding it from coverage.\textsuperscript{165} This process would thus require determining the medical necessity of each claim for each individual rather than basing coverage on the percentage of the Medicaid population that uses the item.

The DeSario court based this reasoning, in part, on Preterm, Inc. \textit{v. Dukakis},\textsuperscript{166} a First Circuit Court of Appeals decision.\textsuperscript{167} \textit{Preterm} involved Medicaid coverage of abortions that had been limited by state statute.\textsuperscript{168} The court found that there were two levels of judgment in assessing medical necessity.\textsuperscript{169} One is the “macro-decision,” which the legislature makes as to what the Medicaid plans cover, and the second is the “micro-decision,” which the physician makes as to whether his patient requires a specific service “that [a] plan makes available.”\textsuperscript{170} The court did not apply the micro-decision because the case concerned a state’s statute.\textsuperscript{171} The court in \textit{Preterm}, unlike the DeSario district court, recognized that a physician’s discretion traditionally comes into play when considering when a Medicaid recipient should receive a covered service, not what services a state should cover. This case is important, however, in making the distinction between coverage and medical necessity and for recognizing the importance of a physician’s discretion.\textsuperscript{172}

Additionally, the Eighth Circuit has been particularly friendly to the physician’s discretion test. For example, in \textit{Pinneke v. Preisser},\textsuperscript{173} the Eighth Circuit Court of Appeals found that the state Medicaid plan must cover “sex reassignment surgery,” which was not covered at all by the state’s plan because it is the only procedure available for the condition of transsexualism and was deemed medically necessary for

\textsuperscript{165} 963 F. Supp. at 134.
\textsuperscript{166} 591 F.2d 121 (1st Cir. 1979).
\textsuperscript{167} \textit{See DeSario}, 963 F. Supp. at 133 (discussing \textit{Preterm, Inc.}).
\textsuperscript{168} \textit{See Preterm, Inc.}, 591 F.2d at 122.
\textsuperscript{169} \textit{Id.} at 125.
\textsuperscript{170} \textit{Id.}
\textsuperscript{171} \textit{See id.} (“Our task here is to test the judgment of the Massachusetts legislature as to medical necessity . . . .”).
\textsuperscript{172} \textit{See id.} (recognizing the importance of a physician’s opinion but realizing that a state plan cannot cover all services deemed medically necessary by a physician because the variations of medically necessary services would be “limited only by the diversity of physicians”).
\textsuperscript{173} 623 F.2d 546 (8th Cir. 1980).
the plaintiff by her physician.\textsuperscript{174} The court noted that professional medical judgement is extremely important in determining medical necessity and \textit{coverage}.	extsuperscript{175} Additionally, the court stated that the legislative history supports the conclusion that a physician's judgement is particularly important and shows that "Congress intended medical judgments to play a \textit{primary} role in the determination of medical necessity."\textsuperscript{176} Therefore, the court held that "the decision of whether or not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or government officials" and thus the state must provide coverage for the previously noncovered service.\textsuperscript{177}

\textbf{C. Analysis}

\textit{1. The Problems with the Medicaid Population as a Whole Test.}—The HCFA letter clearly states that the Medicaid population as a whole test is no longer to be employed in determining coverage of DME.\textsuperscript{178} The standard, however, may still be applied by states to Medicaid coverage

\textsuperscript{174} Id. at 548.
\textsuperscript{175} Id. at 549 (citing Beal v. Doe, 432 U.S. 438, 445 n.9 (1977)). But see DeSario, 139 F.3d at 97 (finding that a physician does not have to be included in determining what a state Medicaid plan should cover as long as medical professionals such as a nurse and physical therapist are included in the decision making process). The \textit{Pinneke} court, like the \textit{DeSario} district court, meshed together the concepts of coverage and medical necessity by applying the medical necessity to determine whether a noncovered procedure should be covered by a state plan. In doing so, however, the court appears to be saying that it is logical that to some extent medical necessity should be considered, not only when determining if a Medicaid recipient should receive a covered service, but also when a state decides what services to cover.

\textsuperscript{176} \textit{Pinneke}, 623 F.2d at 549-50 (emphasis added) (citing S. REP. No. 404, 89th Cong., 1st Sess., \textit{reprinted in} U.S. CODE CONG. & ADMIN. NEWS 1943, 1986-89 (1965). This Senate report states that:

\textit{\textbf{3(a)}} Conditions and limitation on payment for services.

\textbf{(1) Physicians' role}

The committee's bill provides that the physician is to be the key figure in determining utilization of health services and provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs and treatments, and determine the length of stay. For this reason the bill would require that payment could be made only if a physician certifies to the medical necessity of the services furnished.


\textsuperscript{177} \textit{Pinneke}, 623 F.2d at 550; see also Weaver v. Reagen, 886 F.2d 194, 199 (8th Cir. 1989) (using \textit{Pinneke} to find that a state plan must provide the drug AZT to all Medicaid recipients with the AIDS virus whose physicians have certified the treatment as medically necessary because AZT is the only available treatment and denying coverage creates "an irrebuttable presumption that AZT can never be medically necessary treatment for AIDS patients").

\textsuperscript{178} Letter from Sally K. Richardson, \textit{supra} note 3, at 1.
of other services or equipment. Additionally, HCFA did not provide an alternative standard, so states may adopt similar standards that have the same negative consequences as the Medicaid population as a whole test. Therefore, it is important to note the shortcomings of using such a test in the future. The most glaring detriment of the standard is the burden it places on the Medicaid beneficiary to show, through statistical evidence, that the DME provides a benefit to the Medicaid population as a whole. Additionally, the standard, or a version of it, results in the practice of bad medicine, violations of the Medicaid Act, and the rationing of health care.

2. The Test's Detriments as Evidenced in Case Law.—The Medicaid population as a whole test was used by the Second Circuit Court of Appeals in denying coverage to Medicaid beneficiaries for DME not included in a state's preapproved plan. According to the Court of Appeals, this test was the appropriate one under the Medicaid Act for determining a state plan's coverage. The district court, however, was firmly opposed to the use of the Medicaid population as a whole test. The district court stated that in relation to the intervenor Sleekis it was "self-evident that the fee schedule does not provide a meaningful medical benefit for the Medicaid population as a whole 'who is at risk of experiencing' skin breakdowns." Additionally, the district court noted that the test requires the Medicaid beneficiary to support the showing that the DME benefits the Medicaid population as a whole with statistical data that DSS does not even have. Finally, the district court concluded that placing such a harsh requirement on a Medicaid recipient seeking coverage for DME, not on the fee sched-

179. Cf. id. (stating that this burden "establishes a standard that virtually no individual item of [D]ME can meet").
180. See DeSario v. Thomas, 139 F.3d 80, 96-98 (2d Cir. 1998).
181. Id. at 96.
182. DeSario v. Thomas, 963 F. Supp. 120, 142 (D. Conn. 1997) (Plaintiffs' Motion for Clarification (Doc. 86)). The district court described the Medicaid population as a whole test as placing the burden of proof on the Medicaid beneficiary to show that "the MEDS fee schedule is inadequate to meet the medical equipment needs for the Medicaid population as a whole, or alternatively ... that the medical equipment covered by the Department [DSS] is inadequate to provide a meaningful medical benefit for the Medicaid population as a whole who is experiencing, or at risk of experiencing skin breakdowns [like Sleekis]." Id.
183. Id. The court also noted that part of the problem with the Medicaid population as a whole test was wrapped up in the shortcomings of using a DME fee schedule or pre-approved list without also considering medical necessity. Id.; see supra notes 64-78 and accompanying text.
ule, "virtually . . . restore[s] the MEDS fee schedule as a dispositive criterion in evaluating requests for prior authorization" which the district court clearly prohibited in granting the preliminary injunction.185

Thus, the district court believed that such a burden would be almost impossible to meet and that DSS cannot request the Medicaid recipient to provide information that it cannot provide itself. The practical result of having a Medicaid population as a whole test is an immutable preapproved list; the only entities capable of changing this list and the most unlikely to do so are the DSS or Congress who can change the Medicaid Act.186 Additionally, such an immutable preapproved list contradicts the objective of the Medicaid Act because it can not be considered a reasonable standard for determining coverage.187 The preapproved list is not reasonable because it is a static standard that does not allow for updating the list to accommodate positive changes in the medical field, and it does not provide a method for determining if a state has arbitrarily left a piece of DME off of the list.188

3. The Test's Detriments as Evidenced by the Medical Profession.—The use of the Medicaid population as a whole test can produce adverse medical results and ultimately result in rationing. An article in The

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185. Id. at 142-43. The court is referring to its finding that the exclusive list violates the Medicaid Act because with the exclusive list there was no proper way of updating the list or showing that an unlisted DME should be covered, and therefore DSS should add to the list any DME which is shown to be medically necessary. Id. at 130 (Ruling on Plaintiffs' Motions for Preliminary Injunction (Docs. 3 & 68)); see supra notes 64-78 and accompanying text (describing the court's reasoning in more detail). But see DeSario, 139 F.3d at 91 (stating that a state plan does not have to provide a method for reviewing new DME products "or allow[ing] an individual applicant for prior authorization to make [the] showing" that a noncovered DME meets the definition of DME and should be covered because a state has discretion in determining coverage and does not have to provide all DME which are medically necessary).

186. See Letter from Sally K. Richardson, supra note 3, at 1 ("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.").

187. See 42 U.S.C. § 1396a(a)(17) (requiring reasonable standards for states in determining coverage); DeSario, 963 F. Supp. at 131 (stating that the preapproved list violates the Medicaid Act because it was an "unreasonable restriction on the amount, duration, and scope of a provided service").

188. See Letter from Sally K. Richardson, supra note 3, at 2 (maintaining that the states in determining coverage should have reasonable criteria for determining coverage and for judging coverage, and "these criteria must be sufficiently specific to permit a determination of whether an item of DME that does not appear on a State's preapproved list has been arbitrarily excluded from coverage based solely on a diagnosis, type of illness, or condition").
New England Journal of Medicine argues against the use of generalized evidence as required by the Medicaid population as a whole test, because such evidence opposes the practice of good medicine. The article contends that the predominant use of generalized evidence “is at odds with good medical practice,” it is practically impossible to design studies “that can answer all clinical questions,” and “much of the existing evidence that might be used to justify wholesale, nonreviewable exclusions of coverage is of insufficient scientific quality to displace clinical judgement.”

The article continues by stating that the practice and ethics of medicine require the physician to take into account the particular patient when deciding his treatment and not to apply “general rules arbitrarily to all cases” because general rules do not always help the individual patient. Thus, this “one size fits all” practice of medicine does not actually fit all, and therefore, some patients do not receive the services that they need. The Medicaid population as a whole test used in conjunction with a preapproved list results in “one size fits all” medicine, which is inadequate medicine because recipients who do not fit into the generalizations do not receive proper care and have no true method of appealing the denial of coverage. These results thus contradict the stated purpose of the Medicaid Act to provide services “in the best interest of the recipient.”

Furthermore, the Medicaid population as a whole test used in conjunction with a predetermined list may eliminate physician discre-
tion entirely; the physician's "knowledge of the individual patient is rendered irrelevant."195 Those with the most expertise are replaced by statistics or by those in the medical field who have less knowledge of the patient than his or her physician, such as nurses or physical therapists.196 Even with HCFA eliminating the Medicaid population as a whole test and mandating a method for appeal, physicians may be kept out of the system. Because HCFA does not provide an alternative standard nor define precisely how large the Medicaid population as a whole is,197 states may decide to implement an appellate process and put the burden of proof on the Medicaid recipient to show that at least fifty percent of the Medicaid population require the DME or service. This burden is still hard to meet, and the physician is still absent from the process except for initially prescribing the service or DME to the Medicaid patient. Leaving out the most important and most knowledgeable person, the physician, to a Medicaid patient's health, is not in the recipient's best interest and thus, again, violates the objective of the Medicaid Act.198

The Court of Appeals in DeSario noted that it is unrealistic and difficult to continuously be required to update the preapproved DME list because new DME are always coming onto the market with little scientific study.199 Therefore, requiring a Medicaid recipient to show that most of the Medicaid population would receive a benefit from the DME is a method of avoiding updating the list and mistakenly adding an item of DME that has had little scientific study and may eventually be proven unbeneificial. The Court of Appeals, however, did not consider that the evidence that the Medicaid recipient employs to demonstrate that the Medicaid population as a whole test could be faulty and just as unreliable as scientific studies for new equipment.200 Demanding the showing of such evidence also requires

195. Rosenbaum, supra note 11, at 231.

196. See DeSario, 139 F.3d at 97 (stating that a state's method of deciding what was to be covered was sufficient without requiring the input of a physician because the committee that determined coverage had a nurse and physical therapist).

197. See Letter from Sally K. Richardson, supra note 3, at 1 (stating that the Medicaid population as a whole test means showing that "most" of the Medicaid population would benefit and not providing an alternative standard for the Medicaid population as a whole standard).

198. See 42 U.S.C. § 1396a(a)(19) (requiring, among other things, that all "care [be given] . . . in a manner consistent with . . . the best interests of the recipients").

199. DeSario, 139 F.3d at 97.

200. See Rosenbaum, supra note 11, at 231 (questioning the reliability of most medical studies because they are done in controlled situations or isolation and not in actual practice and the most effective studies, "randomized clinical trials," are too expensive to conduct).
a standard for the type of evidence provided to ensure quality, thus making the Medicaid population as a whole standard even more difficult to satisfy. Therefore, a physician's opinion should be taken into account when deciding coverage in addition to scientific studies particularly because "[m]uch of medical practice is the result of tradition and collective experience" and not solely of scientific studies and statistics.\textsuperscript{201}

4. \textit{Rationing Effects}.—The Medicaid population as a whole test, or a test with a similar burden, used in conjunction with a predetermined list of covered services results in the rationing of health care. The Court of Appeals in \textit{DeSario} noted that the Medicaid Act does not require the states to cover all medically necessary services and stated that the result is that "an individual with a rare condition or unusual needs, who must have a costly item of DME that ... [the state] has not chosen to cover and that is needed by a handful of the Medicaid population, will have to look for other sources of assistance."\textsuperscript{202} It follows that the Court of Appeals believed it was satisfactory for some of the Medicaid population not to receive treatment while most of the population did, which is rationing.

The rationing of health care is not entirely an abominable practice and "is inevitable in any responsible kind of financial protection against unpredictable health care costs."\textsuperscript{203} The Medicaid Act attempts to avoid such unpredictable health concerns. Medicaid recipients who are denied coverage, however, often cannot afford to pay for coverage elsewhere as the Court of Appeals implied a recipient should when it stated that they could "look for other sources of assistance."\textsuperscript{204} When a Medicaid recipient is forced to use the Medicaid population as a whole test, or a version of it, he or she does not have the ability to show that he or she medically needs the denied service or DME, or that the DME or service is actually cost-effective compared to another

\textsuperscript{201} Id. \textit{But see} Eddy, \textit{supra} note 155, at 820 (stating that physicians are poor at prescribing services that provide a high value and often prescribe those that have a low value).

\textsuperscript{202} \textit{DeSario}, 139 F.3d at 96.


\textsuperscript{204} \textit{DeSario}, 139 F.3d at 97.
covered service. Therefore, the rationing becomes based on purely economic, and not medical, grounds.

As has been demonstrated, it is well established that the Medicaid Act does not require a state to provide all services and DME determined to be medically necessary. The Medicaid population as a whole test, however, goes a step further and eliminates the possibility that those with unusual needs, such as Sleks, will ever be able to receive coverage. A right to health care has not been recognized by the Supreme Court and thus “the legitimacy of restrictive rules cannot be questioned; the public has a clear right to limit any entitlements it democratically creates.” A Medicaid recipient with the help of his physician, however, should be given the opportunity not to show that the Medicaid population as a whole will benefit but that the particular Medicaid recipient has a strong medical need, such as Sleks and DeSario, for a particular DME and service and that for him or for her it is more cost-effective and beneficial than any other remedy.

D. The Benefits of the Physician’s Discretion Test

Physicians work most closely with the Medicaid patient and know the patient’s health needs and how best to meet these needs. According to Rosenbaum, “[t]he practice of medicine has a core ethical dimension and requires that the physician use his or her knowledge of the particular patient in deciding on the course of treatment along with the patient.” The Medicaid population as a whole test takes this ability away from the physician. The physician’s opinion should be taken into account both when deciding whether a service or DME that is not covered by a predetermined list should be covered for a particular Medicaid patient, and when deciding what the fee schedule will cover just as the physician’s opinion is used in deciding the medi-

205. See supra notes 47-60 and accompanying text (describing the condition of Sleks). Havighurst noted that most public-provided health care does have some form of utilization management but states that “these cost-containment programs are tolerable because, ostensibly at least, they seek only to eliminate care that is inappropriate by medical standards or to ensure that lower-cost methods are used when medically equivalent.” Havighurst, supra note 205, at 1761. With the Medicaid population as a whole test, however, someone like Sleks who showed that the denied DME was more cost-effective than his current treatment can still be denied coverage because he did not meet the burden of the test.

206. See Havighurst, supra note 203, at 1761 (“The controls on health care financing that are most threatening to patients are those that threaten to deny payment for specific services on economic rather than purely medical grounds.”).

207. See supra note 99 and accompanying text.

208. Havighurst, supra note 203, at 1762.

209. Rosenbaum, supra note 11, at 230.
cal necessity of a service or DME for a Medicaid recipient who has been denied coverage of a covered service.\textsuperscript{210}

For example, in \textit{Jeneski v. Myers},\textsuperscript{211} the California Court of Appeals recognized the importance of a physician's expertise and found that prior authorization procedures, mandatory by Medi-Cal and necessary for obtaining certain drugs, were prohibited because a doctor of pharmacy, rather than a physician, made the decision whether or not to approve the prior authorization.\textsuperscript{212} The court stated that it was illogical to believe that a doctor or pharmacy "is capable of making that type of informed judgment which is necessary to ultimately review any request for prior approval for a drug which the requesting physician in his experience has found to be medically necessary and indicated for a patient with whom he is intimately familiar."\textsuperscript{213} Additionally, the court asserted that coverage and prior approval decisions should reflect "the practical experience only possessed by one who is skilled in the medical field and perhaps even in certain specialties."\textsuperscript{214}

This decision recognizes the importance of a physician's medical judgment and that by making certain drugs \textit{totally} unavailable, the state fails to recognize "the necessity that some patients have for drugs that might be merely palliative for others" and that these decisions need to be made on a "patient-by-patient basis."\textsuperscript{215} The Medicaid population as a whole test essentially assures that DME not on the list are \textit{totally} unavailable and takes the physician out of the decision. The physician is an essential part of the system due to his experience and expertise and thus should be taken into account when a state decides what to cover and when deciding whether to cover, for a particular Medicaid recipient, a service or DME that is not a covered item.

\textsuperscript{210} See DeSario v. Thomas, 963 F. Supp. 120, 132 (D. Conn. 1997) (finding that "categorical exclusion of certain pieces of DME without considering medical necessity violates federal Medicaid law"). \textit{But see} Alexander v. Choate, 469 U.S. 287, 303 (1985) ("Medicaid programs do not guarantee that each recipient will receive that level of health care precisely tailored to his or her particular needs.").


\textsuperscript{212} \textit{Id.} at 31-32. The California regulation removed antihistamines, topical dermatological preparations, cough and cold preparations, and other prescription drugs from a list of covered drugs. \textit{Id.} at 24. Some physicians revolted against this new regulation by making such comments as the system is a "mockery of any attempt to impart any rational health care to the needy" and is "a clear class system of medical treatment." \textit{Id.}

\textsuperscript{213} \textit{Id.} at 32 (internal quotation marks omitted) (quoting Dodson v. Parham, 427 F. Supp. 97, 108 (N.D. Ga. 1977)).

\textsuperscript{214} \textit{Id.} (internal quotation marks omitted) (quoting \textit{Dodson}, 427 F. Supp. at 108).

\textsuperscript{215} \textit{Id.} at 33. As an example, the court noted that the elderly and infants may suffer from conditions that are considered minor by other parts of the population. \textit{Id.}
E. Medicare Coverage of Medical Equipment

In determining the coverage standards of DME for Medicaid, it may be useful to look at how DME is covered under Medicare. The Medicare program appears to give significant weight to the physician’s determination of medical necessity or to a physician’s expertise in all aspects of deciding coverage and does not require a showing that the DME will benefit the Medicare population as a whole. It is necessary, however, to note that the differences between the two systems’ type of coverage may be because Medicare covers the elderly while Medicaid covers the poor, and Medicare is run solely by the federal government while Medicaid is run by both state and federal governments.

DME is covered by Medicare Part B and is defined as “equipment which can withstand use; is primarily and customarily used to serve a medical purpose; is generally not useful to a person in the absence of an illness or injury; and is appropriate for use in the home.” Additionally, the Medicare statute provides a list of items that the term durable medical equipment includes such as “iron lungs, oxygen tents, hospital beds, and wheelchairs.” In essence, the statute provides a predetermined list of what will be covered. The list, however, is not exhaustive but merely provides examples of covered items, unlike the predetermined list in DeSario that was meant to be exhaustive and makes it very difficult for a Medicaid beneficiary to receive coverage for an item of DME not on the list.

Some have argued that the use of the term “durable medical equipment” in the Medicare Act is outdated and therefore results in the denial of coverage of new DME because the DME industry uses the term “‘home medical equipment’ . . . [which] reflect[s] the fact

216. See Kinney, supra note 225, at 892 (noting that “[a]lthough HHS has assumed a more aggressive role in formulating coverage policy in recent years, the agency still relies heavily on insurance companies to make most coverage decisions and coverage policy, and on physicians for their expertise in formulating specific coverage policies” (citation omitted)).
217. See Miller v. Heckler, 601 F. Supp. 1471, 1472 (E.D. Tex. 1985) (“The Medicare program was enacted in 1965 to furnish federal health insurance to the elderly and disabled.”).
218. 42 C.F.R. § 405.524(b) (1991); see supra notes 29-30 and accompanying text (noting the Medicare definition of DME and that Medicaid does not have a definition). Medicare Part A provides insurance for the cost of hospital and related post-hospital services. 42 U.S.C. § 1395c. Medicare Part B is a voluntary program of supplemental medical insurance which covers expenses not covered by Part A such as durable medical equipment. 42 U.S.C. § 1395j.
220. See supra notes 64-117 and accompanying text.
that significant technological advances have occurred since the days of the iron lung."²²¹ Weitzman, in *Legal and Policy Aspects of Home Care Coverage*, contended that these examples of DME appear "restrictive and similarly outmoded," and therefore, the statute should not have specific examples but should "provide for any 'certifiably effective' home medical equipment currently available or developed in the future."²²² This proposition is beyond the scope of this Comment, which does not argue that predetermined lists should be prohibited. Rather, this Comment finds the lists administratively efficient as HCFA points out,²²³ and merely calls for consideration of the physician's determinations in deciding coverage and in appeals for denied coverage of items not covered by preapproved lists.

Coverage determinations under the Medicare Act are complicated.²²⁴ They are made at two levels. The first level of determination is whether a technology, procedure, or service "should be covered as a matter of general policy."²²⁵ This situation occurs when coverage questions arise from carriers or from HCFA, and HCFA decides to expand Medicare coverage.²²⁶ Often, physicians will be consulted at this stage.²²⁷ The second level of coverage determinations is the "individual beneficiary level."²²⁸ The coverage determinations, in individual cases, require a decision based on medical criteria that establishes whether the benefit was either necessary and reasonable in a specific instance or provided in an appropriate setting.²²⁹ Because DME fall under Part B, carriers make this second level coverage determina-


²²² *Id.*

²²³ See Letter from Sally K. Richardson, *supra* note 3, at 1 ("A State may develop a list of pre-approved items of [D]ME as an administrative convenience because such a list eliminates the need to administer an extensive application process for each [D]ME request submitted.").

²²⁴ See, e.g., Laura Callahan, Medicare Coverage Policy (Fall 1998) (on file with author) (describing Medicare's coverage policy); Eleanor D. Kinney, *The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint*, 1 ADMIN. L.J. 1, 14-15 (1987) (noting that "[d]ue to the inherent uncertainty in these types of coverage decisions, Congress authorized the Secretary of HHS to waive a beneficiary's or provider's liability for services not covered on the basis of medical criteria if the beneficiary or provider did not know or have reason to know that such services were not covered" (footnote omitted)).


²²⁶ *Id.*

²²⁷ *Id.* at 13-14.

²²⁸ *Id.* at 14.

²²⁹ *See id.*
It is questionable as to how much input physicians have at the individual level because physicians have expressed concern that at the individual beneficiary level carriers do not take into account the "specific circumstances of the individual patients involved." At the national level, however, physicians are quite satisfied with how HCFA makes coverage determinations, particularly because of the influence that physicians have over the decisions. It appears that the Medicare coverage decisions at the individual beneficiary levels have the same problem of lack of physician involvement as Medicaid does at deciding whether to cover a noncovered DME for a single beneficiary. Congress and States, however, should follow how the Medicare system operates at the national level and mandate that states participating in Medicaid must take into consideration a physician's opinion in determining coverage at all times.

The standard for determining coverage at both levels is whether the item of DME is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." This standard, however, is not necessarily any clearer than that of the Medicaid standard, or lack thereof, for the Medicaid and the Medicare standard result in different decisions regarding the same questions of coverage. For example, because DME is covered under Part B of the Medicare Act, coverage decisions are made on a case-by-case basis by individual HCFA carriers and not on a national level, and therefore discrepancies will exist between different carries. Because Medicaid is a state and federal program, dispari-


232. See id.

233. Note that Medicare has a Practicing Physicians Advisory Council that is to "meet once during each calendar quarter to discuss certain proposed changes in regulation and carrier manual instructions related to physician services identified by the Secretary." 42 U.S.C. § 1395ee.

234. 42 U.S.C. § 1395y(a)(1)(A); see also Quality of Care Information, Medicare Coverage Process, Medicare Coverage Advisory Committee (MCAC) (visited Apr. 24, 1999) <http://www.hcfa.gov/quality/8b1-a.htm> (stating that "[t]he Secretary, and by delegation, the Administrator of the Health Care Financing Administration (HCFA), and the Director of the Office of Clinical Standards and Quality, (OCSQ) HCFA are charged with deciding which medical services and items are reasonable and necessary for Medicare beneficiaries under Title XVIII of the Social Security Act").

235. See Kinney, supra note 231, at 906 ("Beneficiaries ... question the current decentralized policymaking process that results in beneficiaries in different parts of the country getting different benefits.")
ties are going to exist among the states because they have wide discretion in coverage policy and implement their programs differently. Therefore, the system should at least provide a fair method for coverage appeals for those items that are not covered by preapproved lists. A fair system for coverage appeals includes placing the burden of proof on the state and including physicians' expert opinions in the decision.

Additionally, states should consider implementing the same system for considering coverage of Medicaid services as Medicare has implemented for its coverage at the national level. HCFA has issued "a general guidance document describing in detail the rules and criteria HCFA uses in its coverage reviews." First, HCFA "weighs the medical and scientific evidence in accordance with a fairly standardized hierarchy that ranks the relative authority given to various types of studies." Therefore, controlled clinical trials that are published in peer-reviewed medical and scientific journals will carry more weight than assessments issued by HCFA. Having a hierarchy of evidence will eliminate some of the problems with having general evidence tests because it assures that decisions will not rely solely on weak or unsupportable evidence.

Furthermore, HCFA has established an Advisory Committee that "will have open meetings and will discuss technical issues of major importance or controversy relating to issues subject to the coverage review process." The Committee is to have a large contingency "representing a broad range of disciplines, including industry and consumers" and may include experts in the medical and scientific fields, beneficiary and consumer experts, medical ethics experts, epidemiologists, and experts in health policy and law, among others. Even though the Committee is only advisory to HCFA, it appears

237. White Paper, supra note 236.
238. See id.
239. See supra notes 185-192 and accompanying text (describing the problems of using generalized evidence).
241. White Paper, supra note 236.
242. See id.
that the Committee has the ability to represent the views of those who are affected by Medicare coverage and to have a positive influence on HCFA's coverage decisions. State Medicaid plans should be required to have a Committee with such high credentials and not be able to get away with having only a nurse and a physical therapist and no physician aid in the coverage decisions.243

F. The Proposed Solution: A Flexible Standard

HCFA did not provide a standard to be used in place of the Medicaid population as a whole test. Therefore, states may attempt to use a similar standard because it is most beneficial to them.244 However, the test used for determining if a noncovered service or DME should be covered for an individual Medicaid recipient should be based on a number of factors, including benefit to the beneficiary and cost to the state. The test should also be conducted on a case-by-case basis because these claims often involve a person's health and possibly his or her life.245 Neither the state nor the physician should be the sole decision-maker as to what should be covered. Rather, the two parties should collaborate while taking into consideration the best interests of the Medicaid recipient.246

If the physician is the sole decision-maker, then anything and everything could be covered by Medicaid including houses and swimming pools.247 Coverage would become "unlimited and budgeting would be by blank check."248 Endless coverage would be catastrophic to the Medicaid system because states do not have the funds to cover all of these services, and "the only cost control measure available to a state would be to avoid adopting new optional services under its Medicaid program, and to end some of the optional services that it already

243. See supra notes 79-117 and accompanying text (describing how Connecticut had a nurse and physical therapist on their coverage committee).

244. See supra notes 10-11 and accompanying text.

245. See, e.g., Mason, supra note 123 (stating that an item of DME can be "potentially life-saving").

246. See generally Rosenbaum, supra note 11, at 229 (stating that coverage criteria should include professional standards of clinical practice, but the treating physician should not have total autonomy in making coverage decisions and that "[t]his middle position requires insurers to act reasonably and weighs the reasonableness of their conduct against professional standards of practice as reflected by valid reliable evidence").

247. See DeSario v. Thomas, 139 F.3d 80, 95-96 (2d Cir. 1998) (stating that permitting physicians solely to decide coverage results in a "Medicaid recipient's physician ... be[ing] able to create coverage by prescribing a particular procedure or item of equipment").

248. Id. at 96.
Therefore, the physician's opinion should be a significant factor in establishing coverage, but it must also be balanced against the funding needs of the Medicaid program. Furthermore, the coverage decision should consider how medically necessary the service or DME is to the Medicaid recipient. For example, whether the physician believes that the DME or service greatly increases the patient's health, well-being, or quality of life, or has the potential to save the patient's life should be considered.

The state or DSS also should not be the sole decision-maker because they simply do not have the medical expertise, without the help of a panel of experts, to make the proper decision or to understand correctly any medical evidence that they use to make determinations. Additionally, in individual coverage decisions, the state or DSS has no first-hand understanding of the individual patient's health needs or circumstances. It appears that their main source of information regarding a DME or a service is generalized evidence that can often be unreliable. Therefore, standards need to be set as to which types of evidence are more reliable and deserve more weight. It has been argued that all Medicaid recipients need is the ability to appeal coverage decisions. Procedural reform alone, however, cannot aid Medicaid beneficiaries if states and DSS are given broad discretion to determine what standards will be employed in coverage decisions because "such protection would be an instance of winning a battle but losing a war." In other words, an individual may be able to gain coverage through procedural reform alone, but ultimately, there needs to be a system where the standard is set and physicians' expertise are taken into account so all recipients have the ability to win.

Therefore, this Comment advocates the adoption of a flexible standard that balances various factors as a mechanism for determining coverage of DME. First, the burden of proof should lie with the state to show why it should not cover the DME or service in question and

249. Id.; see also Preterm, Inc. v. Dukakis, 591 F.2d 121, 125 (1st Cir. 1979) (stating that a state plan cannot cover all medically necessary services because variations of medically necessary services would be "limited only by the diversity of the physicians").

250. See supra note 2.

251. See supra notes 185-197 and accompanying text (discussing the unreliability of generalized evidence).

252. See supra notes 224-231 and accompanying text (discussing the Medicare coverage systems and its hierarchy of evidence).

253. See Rosenbaum, supra note 11, at 229 ("Groups such as the Advisory Commission on Consumer Protection and Quality in the Health Care Industry have recommended only procedural protection for patients, such as the right to a timely review of an adverse decision about coverage.").

254. Id.
not on the Medicaid recipient to show that the DME or service benefits some portion of the Medicaid population of the state. The state would have to demonstrate that the physician’s decision to prescribe the DME or service goes against “clinically accepted standards of medical practice” and is not in the best interest of the recipient. Additionally, the cost of the item and whether a more useful or “just as good” DME or service exists should be considered but are less of an important consideration than the physician’s opinion that the recipient needs the DME or service. Furthermore, the benefit of the DME or service should be considered in the context that it may cost less in the long run than alternative services or DME that are covered. Therefore, cost consequences would have to greatly outweigh the patient’s needs for coverage to be denied when the physician has prescribed it, and it meets clinically accepted standards of medical practice. It follows that these considerations would only have to slightly outweigh cost considerations for coverage to be permitted.

CONCLUSION

Physician’s expertise and clinical practices have long been used as benchmarks for what good medical care is. “[F]or more than 200 years, the courts in malpractice cases have turned to clinical practices for evidence of when and under what circumstances medical care should be considered medically necessary . . . .” As health care costs have risen, however, states have become blinded by financial concerns and have thus found it more useful to base decisions on fiscal policy rather than on a physician’s standard of what is beneficial for the patient. These concerns are real and need to be addressed, but more important is the health of individual Medicaid recipients. Our country may not have a constitutionally recognized right to health care, but it does have an understanding of human dignity and basic human rights. From these beliefs stems the need to at least ensure that poor disabled persons such as Slekis and DeSario have the means of showing why they need to have certain DME or services covered by Medicaid and this includes employing their physicians’ medical expertise in coverage decisions.

255. See, e.g., DeSario, 963 F. Supp. at 129 (stating that the environmental control unit that plaintiff DeSario wanted would allow her to stay in her home rather than having to go to a long-term care facility).

256. See Slater v. Baker and Stapleton, 95 Eng. Rep. 860, 862 (King’s Bench 1767) (stating that “the usage and the law of surgeons . . . [and] the rule of the profession” is the correct standard of review for determining liability of a surgeon in malpractice suits).
