963 F.Supp. 120 (1997)

Concetta DeSARIO, Betty Emerson, and Caroline Stevenson, Individually and on Behalf of all Others Similarly Situated

v.

Joyce A. THOMAS, Commissioner, Connecticut Department of Social Services, in her Official Capacity

v.

Donna SHALALA, Secretary, United States Department of Health and Human Services, in her Official Capacity.

No. 396cv646 (JBA).

United States District Court, D. Connecticut.

January 10, 1997.
Order Reconsidering Class Certification and Clarifying Injunction February 13, 1997.

123 *121 *122 *123 Shelley A. White, New Haven Legal Assistance, New Haven, CT, for plaintiffs Concetta DeSario and Betty Emerson.

124 *124 Sheldon V. Toubman, New Haven Legal Assistance, New Haven, CT, for intervenors-plaintiffs Caroline Stevenson and Howard Wolan.

Hugh Barber, Richard J. Lynch, Judith A. Merrill, Attorney General's Office, Health & Human Services, Hartford, CT, for defendant Joyce A. Thomas.

Lauren M. Nash, U.S. Attorney's Office, New Haven, CT, for third-party defendant HHS.

RULING ON PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION (DOCS. 3 & 68)

ARTERTON, District Judge.

This suit concerns the defendant's Medical Equipment, Devices and Supplies (MEDS) fee schedule. The plaintiffs, who receive benefits under the Medicaid program, have brought this action against Joyce Thomas, Commissioner of the Connecticut Department of Social Services (DSS), alleging that she has improperly administered Connecticut's Medicaid program, as it relates to the prior authorization procedure for payment of durable medical equipment (DME). Under the defendant's regulations, prior authorization for DME is required for all rentals regardless of cost, all replacement equipment, and any purchase item costing over $100. Connecticut Medical Assistance Provider Manual ("Conn. MAP Manual"), § 189.F.II.a. To obtain prior authorization, a vendor for DME submits a form along with a prescription from a physician to the Department of Income Maintenance for review. *Id.;* Conn.State.Agencies § 17-2-80.

In this suit, plaintiffs challenge the legality under the Medicaid Act and the Due Process Clause of the Fourteenth Amendment of two of the defendant's regulations. The two regulations are Conn. MAP Manual, § 189.E.II.a, which permits the defendant to deny coverage to Medicaid recipients for any items of durable medical equipment not listed on the defendant's MEDS fee schedule, and Conn. MAP Manual, § 189.E.III.a, which excludes specific pieces of durable medical equipment from coverage including air conditioners, air purifiers, and room humidifiers.

Plaintiffs filed their Complaint on April 11, 1996, together with a Motion for Preliminary Injunction and a Motion for Class Certification. Oral argument and an evidentiary hearing were held on April 24, 1996, and May 20, 1996.

Defendant Thomas has filed a Third-Party Complaint against Donna Shalala, Secretary of the Department of Health and Human Services, who also has filed a brief, which has been considered.

Intervenor Thomas Slekis moved for a preliminary injunction on December 13, 1996. Oral argument and an evidentiary hearing on the motion were held on December 30, 1996, and January 9, 1997. Meanwhile, the Court granted plaintiffs' Motion for Class Certification on January 7, 1997.

For the reasons set forth below, plaintiffs' Motion for Preliminary Injunction (Doc. 3) and intervenor Slekis's Motion for Preliminary Injunction (Doc. 68) are GRANTED.

I. BACKGROUND

The Medicaid program, enacted in 1965 as Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.,* is a joint state and federal medical assistance program that provides health care to specified categories of individuals and families who are financially and categorically eligible for these services. The State of Connecticut participates in the Medicaid program, *see* Conn.Gen.Stat. § 17-134 *et seq.* (authorizing the State of Connecticut to participate in the federal Medicaid program), and as a participating state must ensure that its state medical assistance plan complies with federal Medicaid law. *Wilder v. Virginia Hospital Ass'n,* 496 U.S. 498, 501, 110 S.Ct. 2510, 2513, 110 L.Ed.2d 455 (1990); *Bethphage Lutheran Service, Inc. v. Weicker,* 965 F.2d 1239, 1240 (2d Cir.1992); *Caldwell v. Blum,* 621 F.2d 491, 494 (2d Cir.1980).

Under the Medicaid Act, the defendant must provide services to adults with severe disabilities who are unable to work due to a medical condition or combination of conditions. 42 U.S.C. § 1396d(a). The Medicaid Act provides a list of federally reimbursable services that a state Medicaid plan must include, one of which is home health
125 services, *see* 42 U.S.C. § 1396a(a)(13)(B)-(C), and a *125 list of federally reimbursable services that a state Medicaid plan may include at its option, *see* 42 U.S.C. §§ 1396a(a)(1)-(17). The Medicaid Act also requires that a state plan for medical assistance must include "reasonable standards ... to the extent of medical assistance" in accordance with the objective of the Medicaid statute, 42 U.S.C. § 1396a(a)(17), and the defendant must provide "safeguards as may be necessary to assure that eligibility and services under the plan will be determined ... in a manner ... consistent with the best interests of the recipients." 42 U.S.C. § 1396a(a)(19).

The right of a recipient to health care under the Medicaid program is not limitless. The Supreme Court has stated:

> Medicaid programs do not guarantee that each recipient will receive the 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 ... That package of services has the general aim of assuring that individuals will receive necessary medical care, but the benefit provided remains the individual services offered 閳 not "adequate health care."

Alexander v. Choate, 469 U.S. 287, 303, 105 S.Ct. 712, 721, 83 L.Ed.2d 661 (1985). A state may place "appropriate limits on a [covered] service based on criteria such as medical necessity or utilization control." 42 C.F.R. § 440.230(d). If such limits are imposed, the service provided must be "sufficient in amount, duration, and scope to reasonably achieve its purpose." *Id.* at § 440.230(b). Moreover, the 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." *Id.* at § 440.230(c).

Among the services covered under the category of home health services are "medical supplies, equipment, and appliances suitable for use in the home." 42 C.F.R. § 440.70(b)(3). Federal law does not define the term "medical equipment"; however, any Medicaid item or service must be involved in "direct patient care" and be "for the express purpose of diagnosing, treating, or preventing ... illness, injury or other impairments to an individual's physical or mental health." *See* State Medicaid Manual § 4385.B. In the absence of binding federal interpretation of the term "medical equipment," states may employ reasonable definitions of the term which are consistent with the provisions of the Medicaid statute. *See* 42 U.S.C. § 1396a(a)(17).

The defendant has promulgated her own definition of durable medical equipment. Under Connecticut law, durable medical equipment is equipment which meets all of the following requirements:[1]

1. Can withstand repeated use

2. Is primarily and customarily used to serve a medical purpose

3. Generally is not useful to a person in the absence of an illness or injury

4. Excludes items that are disposable.

Conn. MAP Manual, § 189.E.B.

In furtherance of the administration of its Medicaid program, the defendant has developed the Medical Equipment, Devices and Supplies (MEDS) fee schedule, which comprises the exclusive list of items of durable medical equipment which the defendant will provide to Medicaid recipients. Under the defendant's regulations, Medicaid recipients must submit their requests for DME through an approved vendor, along with a physician's prescription. The defendant will only grant the required prior authorization for payment for equipment itemized on the MEDS list. Conn. MAP Manual, § 189.E.II.a.

At the May 20, 1996, evidentiary hearing, Elizabeth Geary, a Health Program Supervisor in the Medical Operations Division of the Department of Social Services,[2] testified that DSS developed a MEDS fee schedule
126 in 1993 and that a new fee schedule was scheduled to go into effect in June 1996. (May 20 Hearing, *126 Trans. at 103.) Between 1993 and June 1996, no items were added to or removed from the fee schedule. (Trans. at 204.) In addition, Ms. Geary stated that there is no regular procedure for periodically updating the fee schedule, and DSS has no formal procedure for securing input from Medicaid recipients or from other persons or agencies outside of DSS with respect to items to be included on the MEDS fee schedule. The items that the named plaintiffs have requested (the Simplicity ECU Series VII, air conditioner, air purifier, and room humidifier) are still not approved items on the defendant's current MEDS fee schedule. Moreover, air conditioners, air purifiers, and room humidifiers are explicitly excluded under the defendant's regulations. Conn. MAP Manual, § 189.E.III.a.

II. Claims and Relief Sought

Plaintiffs argue that defendant's exclusion of the durable medical equipment prescribed for them violates federal law in that it:

a) constitutes an unreasonable standard for determining eligibility for covered services which is inconsistent with the objectives of the Medicaid Act in violation of 42 U.S.C. § 1396a(a)(17);

b) violates the requirement that defendant provide Medicaid coverage for medically-necessary home health services, 42 C.F.R. §§ 440.70, 441.15, in sufficient amount, duration, and scope to reasonably achieve the purpose of such services, 42 C.F.R. § 440.230(b); and

c) is not an appropriate limitation on a covered service based on medical necessity. *See* 42 C.F.R. § 440.230(d).

Plaintiffs also argue that the denial of Medicaid coverage of the requested items constitutes a denial of Medicaid coverage based on the recipient's diagnosis, in violation of 42 C.F.R. § 440.220(c). Finally, plaintiffs contend that the automatic exclusion of Medicaid coverage for the plaintiffs' requested items through the defendant use of an exclusive fee schedule for DME constitutes an irrebuttable presumption that such equipment is not medically necessary, in violation of the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

The plaintiffs seek as relief an order barring the defendant from applying the exclusive MEDS fee schedule to their requests for approval of durable medical equipment and requiring the defendant to provide the medically necessary durable medical equipment for which they contend they are eligible.

III. PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION (Doc. 3)

The Court understands plaintiffs' Motion for Preliminary Injunction to apply just to the named plaintiffs, and not to the entire certified class. (*See* Mem. in Support of Pls.' Motion for Prelim. Inj., at 2.) Before addressing whether plaintiffs have met the requirements for a preliminary injunction, the defendant raises several issues which she claims act as a bar to this litigation.

A. Adequacy of Plaintiffs' Remedy at Law

First, although plaintiffs need not exhaust their administrative remedies, defendant argues that injunctive relief is inappropriate where the plaintiffs have an adequate remedy at law. *See, e.g., Potwora v. Dillon,* 386 F.2d 74 (2d Cir.1967); *Wallace v. Kern,* 520 F.2d 400, 407 (2d Cir.1975). Defendant argues that the State of Connecticut permits those aggrieved by a decision made by an administrative agency to appeal to the Connecticut state courts. *See* Conn.Gen.Stat. § 4-183. The court may reverse "the administrative findings, inferences, conclusions, or decisions [which] are (1) in violation of constitutional or statutory provision ... [or] (4) affected by other error of law." *Id.* at § 4-183(j). The Second Circuit recently found that this statutory scheme afforded plaintiff challenging the decision of the Medical Examining Board "an adequate means of addressing violations of federal law" that may have occurred during an administrative hearing. *Doe v. State of Conn., Dept. of Health Services,* 75 F.3d 81, 85 (2d Cir.1996).

In deciding whether this Court should refuse to assume jurisdiction of this matter, the Court applies the Younger
127 Doctrine, *see Younger v. Harris,* 401 U.S. 37, 91 S.Ct. 746, *127 27 L.Ed.2d 669 (1971), which has been applied to civil proceedings, *see Huffman v. Pursue, Ltd.,* 420 U.S. 592, 95 S.Ct. 1200, 43 L.Ed.2d 482 (1975), and to "state administrative proceedings, so long as the state court has a means of reviewing constitutional claims." *Cecos v. Jorling,* 895 F.2d 66, 70 (2d Cir.1990) (citing *Ohio Civil Rights Comm'n v. Dayton Christian Schools, Inc.,* 477 U.S. 619, 627-29, 106 S.Ct. 2718, 2722-24, 91 L.Ed.2d 512 (1986); *Middlesex County Ethics Committee v. Garden State Bar Ass'n,* 457 U.S. 423, 432-34, 102 S.Ct. 2515, 2521-22, 73 L.Ed.2d 116 (1982)). "To justify a refusal to assume jurisdiction on *Younger* grounds, a district court must answer three questions affirmatively: (1) is there an ongoing state proceeding; (2) is an important state interest implicated; (3) does the plaintiff have an avenue open for review of constitutional claims in the state court?" *Id.* (citing *Middlesex County Ethics Committee,* 457 U.S. at 432, 102 S.Ct. at 2521).

There is no record before the Court that any of the plaintiffs have appealed these decisions to state Superior Court under Conn.Gen.Stat. § 4-183. It is settled in this Circuit that "[a] federal court need not stay its jurisdictional hand where there is no state action pending at the time the federal suit is filed." *Cecos International,* 895 F.2d at 73. Because there were no state judicial or administrative proceedings pending at the time plaintiffs filed suit, defendant has failed to meet the first prong of the standard for abstention; thus, the Court declines to abstain from adjudicating this case. *See id.* at 70 (citations omitted) ("It is now black-letter law that abstention from the exercise of federal jurisdiction is the narrow exception, not the rule.").

B. Res Judicata Preclusion of Plaintiff's Claim

Defendant argues that the plaintiffs are bound by the adverse decisions of the administrative hearing officer, and that this suit is an attempt "to mount a collateral attack on those results." (Def.'s April 23 Memorandum, at 12.) Defendant argues that the doctrine of *res judicata,* or claim preclusion, provides:

> that a final judgment on the merits in one action bars subsequent relitigation of the same claim by the same parties and by those in privity with the parties ... That bar extends both to `issues actually decided in determining the claim asserted in the first action and [to] issues that could have been raised in the adjudication of that claim.'

Greenberg v. Board of Governors of Federal Reserve System, 968 F.2d 164 (2d Cir.1992) (quoting *N.L.R.B. v. United Technologies Corp.,* 706 F.2d 1254, 1259 (2d Cir.1983)). Defendant argues that under this doctrine, this Court cannot reexamine the factual and legal findings made by an administrative hearing officer, as well as those issue that the parties might have, but did not, assert in the administrative proceedings.

It is clear that federal courts are required by 28 U.S.C. § 1738 to give full faith and credit to state judgments and decisions by state administrative agencies that have been reviewed by state courts. However, there appears to be a dispute among the Circuits as to the preclusive effect of state administrative decisions unreviewed by state courts.

In *University of Tennessee v. Elliott,* 478 U.S. 788, 106 S.Ct. 3220, 92 L.Ed.2d 635 (1986), the Supreme Court held "that when a state agency `acting in a judicial capacity ... resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate,' ... federal courts must give the agency's fact finding the same preclusive effect to which it would be entitled in the State's courts." *Id.* at 799, 106 S.Ct. at 3226 (quoting *United States v. Utah Constr. & Mining Co.,* 384 U.S. 394, 422, 86 S.Ct. 1545, 1560, 16 L.Ed.2d 642 (1966)). The defendant argues that the Second Circuit has applied the same principle to findings of law as well and cites a statement in *Greenberg* in support: "Res judicata applies to judgments by courts and by administrative agencies acting in an adjudicative capacity." *Greenberg,* 968 F.2d at 164 (citing *United States v. Utah Constr. & Mining Co.,* 384 U.S. at 422, 86 S.Ct. at 1560). *See also Eilrich v. Remas,* 839 F.2d 630, 634 n. 2
128 (9th Cir.1988) (unreviewed agency determinations *128 of law and fact are entitled to preclusive effect).

This Court does not read *Greenberg* to apply to legal conclusions made by administrative hearing officers. First, the *Utah Mining* case which *Greenberg* cites as authority only concerned the preclusive effect of administrative fact finding, not legal determinations. Second, no case in this Circuit has cited *Greenberg* for the proposition asserted by the defendants, and no other Circuit besides the Ninth Circuit, *Eilrich v. Remas, supra,* has found that administrative decisions have a preclusive effect on courts regarding legal determinations. *See Edmundson v. Borough of Kennett Square,* 4 F.3d 186, 193 (3d Cir.1993); *Peery v. Brakke,* 826 F.2d 740, 746 (8th Cir.1987); *Gjellum v. City of Birmingham,* 829 F.2d 1056, 1064-65 & n. 21 (11th Cir.1987).

Finally under state law, hearing officers are staff employees of DSS and are not required to be attorneys. Conn.Gen.Stat. § 4-166 (1995). There is a "profound difference between the ability to resolve matters of credibility and fact ... and the ability to determine the more complex question[s]" of law under federal Medicaid law and the Constitution. *Edmundson,* 4 F.3d at 193; *See Schweiker v. Gray Panthers,* 453 U.S. 34, 43, 101 S.Ct. 2633, 2640, 69 L.Ed.2d 460 (1981) ("The Social Security Act is among the most intricate ever drafted by Congress."). Echoing the words of the Third Circuit, this Court "intimate[s] no disrespect" for the defendant's hearing officers "in stating that constitutional adjudication is not within [their] competence so as to bar a federal court from reexamining that legal issue." *Edmundson,* 4 F.3d at 192. An administrative agency is not the place to "finally decide issues that give pause even to federal courts despite [their] familiarity with that area of the law." *Id.*

For these reasons, the Court concludes that the plaintiffs' claims are not barred by the doctrine of res judicata.

C. Eleventh Amendment Bar

Finally, defendant maintains that the plaintiffs' Complaint should be construed as forcing compliance with state policies, and, thus, this case should be barred under the Eleventh Amendment. *See Pennhurst State School and Hospital v. Halderman,* 465 U.S. 89, 106, 104 S.Ct. 900, 911, 79 L.Ed.2d 67 (1984). A review of the Complaint indicates that the plaintiffs are not forcing the defendant to comply with her policies defining durable medical equipment, but, to the contrary, are challenging her policies which exclude coverage of certain durable medical equipment as violative of federal law. Thus, plaintiffs' claim for prospective relief is outside the strictures of the Eleventh Amendment. *See Mont v. Heintz,* 849 F.2d 704 (2d Cir.1988) (suit against state for failing to use state's true standard of need in calculating period of AFDC ineligibility was a claim for prospective relief seeking compliance with federal law and not barred by Eleventh Amendment).

D. Standards for Preliminary Injunction

The Court now turns to the merits of plaintiff's motion for preliminary injunction. "The issuance of a preliminary injunction is an extraordinary equitable remedy that should not be granted absent a clear showing the moving party has met its burden of proof." *Kraft General Foods, Inc. v. Allied Old English, Inc.,* 831 F.Supp. 123, 127 (S.D.N.Y.1993). *See* *Beech-Nut, Inc. v. Warner-Lambert Co.,* 480 F.2d 801, 803 (2d Cir. 1973).

The Second Circuit's standard for the issuance of a preliminary injunction is the following:

> "The party seeking the injunction must demonstrate (1) irreparable harm should the injunction not be granted, and (2) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits and a balance of hardships tipping decidedly toward the party seeking injunctive relief."

Shapiro v. Cadman Towers, Inc., 51 F.3d 328, 332 (2d Cir.1995) (quoting *Resolution Trust Corp. v. Elman,* 949 F.2d 624, 626 (2d Cir.1991)).

129 Although the moving party is usually required only to meet part (1) of the test and *129 either part (2)(a) or (2)(b), there are circumstances where the "serious questions" prong is not available. The Second Circuit recently affirmed the following exception to the standard:

> [W]here the moving party seeks to stay government action taken in the public interest pursuant to a statutory or regulatory scheme, the district court should not apply the less rigorous fair-grounds-for-litigation standard and should not grant the injunction unless the moving party establishes, along with irreparable injury, a likelihood that he will succeed on the merits of his claim.

Able, 44 F.3d at 130 (quoting *Plaza Health Laboratories, Inc. v. Perales,* 878 F.2d 577, 580 (2d Cir.1989)).

Defendant's actions pursuant to federal Medicaid law and the state Medicaid plan clearly qualify as being taken "pursuant to a statutory or regulatory scheme." *See id.* Thus, the applicable standard for determining if plaintiffs have met the requirements for a preliminary injunction is whether the plaintiffs have demonstrated the existence of irreparable harm if Defendant is not enjoined from her alleged illegal actions, *and* whether the plaintiffs have demonstrated their likelihood of success on the merits.

E. Irreparable Harm

In order to establish irreparable harm and meet the threshold requirement in a preliminary injunction, "the movant must demonstrate `an injury that is neither remote nor speculative, but actual and imminent' and that cannot be remedied by an award of monetary damages." *Shapiro,* 51 F.3d at 332 (quotation omitted).

Applying these standards, there is little question that Plaintiff DeSario is suffering an irreparable injury from defendant's refusal to provide her with a new environmental control system. The defendant's hearing officer made the following findings in his administrative decision:

> (1) "[t]he only way that [DeSario] is able to control her environment (i.e., reposition her bed, make and receive telephone calls, turn lights on and off, open her apartment door, control her heat and air conditioning, control her television) is with an environmental control unit";
>
> (2) Ms. DeSario presently "owns a donated, used environmental control unit that functions erratically and is unreliable";
>
> (3) because her current environmental unit is unable to perform this function, Ms. DeSario "is unable to reposition her bed when she has respiratory distress";
>
> (4) Ms. DeSario "now has to lie in bed with her left index finger on her telephone control button as she is unable to move her hand independently to push this button;"

(5) "[a]n environmental control unit can allow the applicant to remain in her home and can prevent her being placed in a long term care facility."

Notice of Decision Re: Concetta DeSario, March 28, 1996.

Plaintiff DeSario has clearly established that in the absence of injunctive relief she will be required to continue to sleep with her finger on a button so that she may be able to call for help and will not be able to relieve respiratory distress when no aid is available. Further, as the hearing officer found, Ms. DeSario is threatened with being institutionalized if she cannot receive a replacement environmental control unit. "The possibility that the plaintiff[] would be forced to enter [a] nursing home[] constitutes irreparable harm that cannot be prevented or fully rectified by a judgment later." *McMillan v. McCrimon,* 807 F.Supp. 475, 479 (C.D.Ill.1992).

Plaintiff Emerson submitted uncontradicted evidence from her physicians to establish that she will suffer irreparable harm if she does not receive an air purifier or air conditioner. Ms. Emerson's physician explained in his November 28, 1995, letter that:

> [a]ir conditioning and air purifications are both medically necessary for Ms. Emerson for the same reason: Her chemical sensitivity condition renders her highly susceptible to severe reactions to air-borne environmental toxins. Such reactions can only be prevented by the use of air conditioners and air purifiers which can remove these *130 toxins in the summer months and winter months, respectively.

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If Ms. Emerson does not receive the relief that she seeks, she will exacerbate an already seriously disabling condition, potentially activating severe systemic reactions including respiratory distress.

In addition, Plaintiff Caroline Stevenson has provided unrefuted evidence that her requested items are medically necessary. In a November 10, 1995, letter, Dr. Raymond P. Wong wrote that Ms. Stevenson was diagnosed with Environmental Illness/Multiple Chemical Sensitivities in 1984 and currently experiences respiratory, neurological, and allergy-like symptoms, muscle and joint pains, fatigue, weakness, digestive and absorption difficulties, and periodic depression. Dr. Wong stated that it is essential for Ms. Stevenson to control exposures to airborne molds, pollutants, scented products, pesticides, chemical cleaning agents, or smells from neighbors for which purpose he (Dr. Wong) prescribed, among other items, air purification equipment and a humidifier.

Based on the unrefuted medical evidence submitted, this Court finds that Ms. Stevenson will suffer irreparable harm from the described multiple symptomology should the injunction not be granted.

F. Likelihood of Success on the Merits

1. Defendant's exclusive use of its MEDS fee schedule in determining coverage of DME violates federal Medicaid law.

The first issue the Court will address is whether the defendant's use of an exclusive MEDS list, which defines the scope of coverage under the benefit category of durable medical equipment, is "sufficient in ... scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(a).

At the May 20, 1996, hearing, the defendant's witness Ms. Geary testified that DSS has made specific decisions to exclude certain environmental control systems, including humidifiers and air conditioners, but that she had no knowledge that the defendant ever had actually considered environmental control systems of the type requested for Ms. DeSario. (May 20 Hearing, Trans. at 108-109.) Further, she testified that the defendant's fair hearing officers have no authority to order Medicaid coverage for durable medical equipment which is not on the defendant's MEDS fee schedule or which is otherwise specifically excluded from Medicaid coverage by Conn. MAP Manual, § 189.E.III.a. (Trans. at 118-19.) She also stated that the defendant's policies provide no exceptions for non-covered items of durable medical equipment even where such equipment is the only medical service which can treat a particular medical condition. Finally, she testified that while the defendant is authorized

to waive application of her own regulations, she has never granted an administrative exception to provide Medicaid coverage for durable medical equipment not on the MEDS fee schedule. (Trans. at 123.)

The Court finds that the defendant's use of the MEDS fee schedule, in its present form, i.e., as an exclusive list, violates federal Medicaid law because it improperly limits the amount, duration, and scope of medically necessary durable medical equipment. The Court's decision is based on two factual findings. First, the defendant does 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." Second, 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.

The Court finds support for its conclusion in *Dodson v. Parham,* 427 F.Supp. 97 (N.D.Ga.1977), in which Medicaid recipients brought suit against the State of Georgia to prevent it from implementing use of an exclusive list of drugs for which Medicaid would reimburse pharmacists. The Court made findings of facts that many drugs not on the proposed list were necessary to provide health care services to Medicaid recipients. In order to
131 prescribe drugs not on the list, a physician was required to make a special *131 request, on the phone or in writing, to the state's Medicaid agency which would be reviewed by a doctor or pharmacy. Although the state projected that the determination of whether a drug not on the list would be approved within fifteen minutes when the request was made by telephone, or within two days when submitted in writing, the Court found that forty-five minutes and three to four working days was a more realistic calculation. Further, it was undisputed that the prior approval center would be open and available for requests only from 8:30 a.m. to 4:30 p.m. on weekdays. *Dodson,* 427 F.Supp. at 103.

The court in *Dodson* found that Georgia's drug list did not provide prescription drugs to Medicaid benefits in sufficient amount, duration, and scope to comply with federal law. The Court held:

> the fatal flaws in the proposed program lie not so much in the drugs listed, but rather in the absence of what this court considers to be a medically sound and effective prior approval system.

Id. at 108. The court found that the proposed list was designed to be effective in only 90-95% of the medical problems a physician might encounter. *Id.* The approval mechanism for drugs not on the list was medically unsound because it did not contain emergency procedures which would allow physicians to obtain prior approval on week nights, weekends, or holidays, and because a doctor or pharmacy was not capable of making final approval decision for a drug that the "requesting physician in his experience has found to be medically necessary and indicated for a patient with whom he is intimately familiar." *Id.*

Unlike *Dodson,* where the state had some procedure, albeit not in compliance with federal law, to approve pharmaceuticals not on its list, *here* there exists no meaningful mechanism by which the defendant will timely consider a request for an item of durable medical equipment not already on its MEDS fee schedule. As attested to by the defendant's own witness, Ms. Geary, the defendant is authorized to make an administrative exception to the MEDS fee schedule only when a hearing officer makes a decision contrary to the department's decision, which would not occur if the hearing officers are required to use only the defendant's list in making their determinations. Ms. Geary posited that a recipient could make a direct request to the Commissioner but she has no recollection whether this has ever been done. (Trans. at 122-23.) Even if a recipient could have a direct request to the Commissioner for an administrative exception, recipients are not provided any notice of this additional avenue of DSS review, and, therefore, this procedural mechanism seems constitutionally defective. *See Goldberg v. Kelly,* 397 U.S. 254, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970).

While the Court has concluded that the defendant's *exclusive* use of its preapproved list for DME violates federal law as an unreasonable restriction on the amount, duration, and scope of a provided service, the Court does not find that the plaintiffs have established a likelihood of success that the use of a list is unlawful *per se.* The Medicaid Act "confers broad discretion on the States to adopt standards for determining the extent of medical assistance" offered in their Medicaid programs. *Beal v. Doe,* 432 U.S. 438, 444, 97 S.Ct. 2366, 2371, 53 L.Ed.2d 464 (1977). The Health Care Financing Administration of the Department of Health and Human Services provides

further interpretation on the authority of states to limit the amount, scope, and duration of covered medical equipment:

> States may place a money ceiling upon medical supplies and equipment based on a reasonable, fixed dollar amount per month or per year; or may require prior authorization for items costing more than a certain amount; or *may list those items for which it will reimburse:* or may require prior authorization for durable equipment.

HCFA Medical Assistance Manual, § 5.50.1-00 transmitted by SRS-AT-77-26 (MSA) (February 16, 1977) (emphasis added).

The Court must give considerable deference to an agency's interpretation of a statute that it administers, and may "not substitute its own reading unless the agency's interpretation is unreasonable." *Skandalis v. Rowe,* 14 F.3d 173, 178 (2d Cir.1994) (citing *Chemical Mfrs. Ass'n v. Natural Resources Defense Council, Inc.,* 470 U.S.
132 116, 125, 105 S.Ct. 1102, 1107-08, 84 L.Ed.2d 90 *132 (1985); and *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 844, 104 S.Ct. 2778, 2782-83, 81 L.Ed.2d 694 (1984)). "When an agency construes its own regulations, such deference is particularly appropriate ... and even more appropriate where, as here, we consider a small corner of a labrythine statute." *Id.* (referring to the Medicaid Act). The plaintiffs challenge the defendant's use of a list, but not the provision under HCFA Medical Assistance Manual, § 5.50.1-00, which permits states to utilize such lists. Because the use of a list is valid under federal regulations, this Court does not find that the plaintiffs have shown a likelihood success on the merits that the use of a non-exclusive list is an unlawful limitation on the amount, duration, and scope of services under 42 C.F.R. §§ 440.230 (b) and (d). The Court concludes merely that the plaintiffs will likely be successful in showing that plaintiff's process of reviewing requests for prior authorization for DME violates federal law insofar as it relies on an exclusive list for which there are no reasonably available procedures for seeking either modifications or exceptions.

2. Defendant's categorical exclusion of certain pieces of DME without considering medical necessity violates federal Medicaid law

Next, plaintiffs challenge the defendant's policy of excluding coverage for air conditioners, air purifiers, and room humidifiers under Conn. MAP Manual § 189.III.E.a as an impermissible limitation on the scope of services because it improperly restricts the provision of medically necessary services to Medicaid recipients in need of such DME. Federal law does not explicitly require that a state plan provide coverage of every piece of DME that a physician deems medically necessary. The opening section of the Medicaid Act provides that the purpose of the Act is for each state "to furnish (1) medical assistance on behalf of ... disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services."[3] 42 U.S.C. § 1396. The only statement from the United States Supreme Court regarding the provision of medical necessary services under Medicaid is this brief statement: "[S]erious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage." *Beal,* 432 U.S. at 444, 97 S.Ct. at 2371.

The Second Circuit has never addressed the issue of whether a state must provide all medically necessary services to Medicaid recipients. Courts throughout the country have split on this issue. *Compare Preterm, Inc. v. Dukakis,* 591 F.2d 121, 125 (1st Cir. 1979) (dictum in *Beal* does not require a state plan to provide all services
133 within a *133 mandatory category deemed medically necessary by a patient's physician); *Curtis v. Taylor,* 625 F.2d 645, 652 (5th Cir.1980) (state may limit services based on a judgment of degree of medical services so long as it does not discriminate based on medical condition) *with Dexter v. Kirschner,* 972 F.2d 1113, 1117 (9th Cir.1992) (participating states "must provide assistance to pay for *medically necessary* impatient hospital and physician's services for eligible persons"); *Weaver v. Reagen,* 886 F.2d 194, 198 (8th Cir.1989) (a state must provide "treatment that is deemed `medically necessary' in order to comport with the objectives of the Act.").

While courts have differed over whether a state must provide all medically necessary services under the Medicaid program, it is clear under the case law that the Medicaid Act requires a state to consider the medical necessity of an item at some point before denying coverage of the prescribed article of DME. In *Preterm, Inc. v.*

Dukakis, the First Circuit viewed the Medicaid Act as offering two possible opportunities to make this judgment regarding medical necessity:

> The first is the macro-decision by the legislature that only certain kinds of medical assistance are deemed sufficiently necessary to come under the coverage of its plan. The second is the micro-decision of the physician, that the condition of his patient warrants the administering of a type of medical assistance which the plan makes available.

591 F.2d at 125.

Under the Medicaid Act, a state may "reasonably exclude some procedures on the basis that they are never, or generally never, of sufficient medical necessity." *Hodgson v. Board of County Commissioners, County of Hennepin,* 614 F.2d 601, 607 (8th Cir.1980). However, the defendant has never stated in her briefs or through the testimony of Elizabeth Geary that air conditioners, air purifiers, and room humidifiers are never of sufficient medical necessity to treat certain medical conditions. Instead, the defendant has taken the position that the requested equipment are excluded from coverage under her definition of DME because the items are useful to individuals in the absence of illness or injury. (Def.'s June 6 Brief, at 5.)

Defendant argues that she has "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.'" *See Alexander v. Choate,* 469 U.S. at 303, 105 S.Ct. at 721 (citing 42 U.S.C. § 1396a(a)(19)). In *Alexander,* the Supreme Court upheld a 14-day limitation by the Tennessee Medicaid agency on the provision of inpatient hospital services. The plaintiffs alleged that the 14-day limitation would have a disproportionate effect on persons with disabilities, in violation of § 504 of the Rehabilitation Act of 1973, but the Court found that the limitation was neutral on its face because disabled and nondisabled persons had equal access to the benefit, and that the regulation did not deny persons with disabilities meaningful access to or exclude them from the particular package of Medicaid services Tennessee has chosen to provide. 469 U.S. at 309, 105 S.Ct. at 724.

Alexander is distinguishable from the instant case. In *Alexander,* all Medicaid recipients were treated the same by the Medicaid agency, in that they were entitled to 14 days of inpatient hospital care per year. The defendant's limitation of services in this case is not neutral on its face, as, for example, by placing a reasonable, fixed dollar amount on the durable medical equipment that a recipient may request per year, *see* HCFA Medical Assistance Manual, § 5.50.1-00. While the defendant may have proper grounds to categorically deny coverage of certain pieces of DME in all cases, the defendant may not categorically exclude a piece of DME without considering the medical necessity of an item either on a "macro" or "micro" level. *See Preterm,* 591 F.2d at 125. By never considering the "medical necessity" of air conditioners, air purifiers, and room humidifiers, the defendant has established an "irrebuttable presumption" that these pieces of DME can never be medically necessary. "This approach reflects inadequate solicitude for the applicant's diagnosed condition, the treatment prescribed by the
134 applicant's physicians, and the accumulated knowledge of *134 the medical community." *Pinneke v. Preisser,* 623 F.2d 546, 549 (8th Cir.1980) (striking down Iowa Medicaid policy of denying benefits for sex reassignment surgery). *See also Weaver v. Reagen,* 886 F.2d 194, 199 (8th Cir.1989) (Missouri Medicaid rule denying coverage of anti-viral drug AZT unless patients met certain criteria constituted an irrebuttable presumption that AZT can never be effective for persons with AIDS who did not meet the criteria).

Plaintiffs have offered sufficient medical evidence that their requested DME may be medically necessary to treat their conditions. By not considering any evidence regarding the "medical necessity" of air conditioners, air purifiers, and room humidifiers, defendant appears to have ignored the possible necessity that some Medicaid recipients might have for these items "that might be merely palliative for others." *Jeneski v. Myers,* 163 Cal.App.3d 18, 209 Cal.Rptr. 178, 189 (2d Dist.1984). Thus, Conn. MAP Manual § 189.III.a. improperly denies plaintiffs "meaningful access" to a mandatory package of Medicaid services, *See Alexander v. Choate,* 469 U.S. at 309, 105 S.Ct. at 724, leading this Court to find that this policy is not "reasonable" and "consistent with the objectives of Title XIX." *See Preterm,* 591 F.2d at 125 (citing *Beal v. Doe,* 432 U.S. at 441, 97 S.Ct. at 2369).

In other cases, courts have ordered a state Medicaid agency to fund "medically necessary" services, particularly where the medical evidence supports a finding that it is the only known treatment. *See Pinneke, supra; Weaver, supra.* While the record in this case at this stage does not permit the Court to make similar determination of the

medical necessity of the requested items or the availability of other alternatives, where the defendant has offered no evidence that she has even considered the medical necessity of these items, the policy appears violative of federal law.

3. Plaintiffs have not shown a likelihood of success that the defendant denied coverage of DME due to diagnosis, type of illness, or condition.

Under federal law, a state Medicaid agency may use medical need as a criterion in determining whether to approve a requested item of DME for a recipient, although a state "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." 42 C.F.R. § 440.230(c). *See* *Hern v. Beye,* 57 F.3d 906 (10th Cir.1995) (state cannot deny Medicaid funding for qualified women who are victims of rape or incest); *Hope Medical Group for Women v. Edwards,* 63 F.3d 418 (5th Cir.1995), *cert. denied,* ___ U.S. ___, 116 S.Ct. 1319, 134 L.Ed.2d 471 (1996) (state cannot limit abortion funding to those cases where mother's life is at stake). Plaintiffs argue that defendant's denial of Medicaid coverage for an environmental control unit which is used almost exclusively by persons who are quadriplegic and for a humidifier for persons with Medical Chemical Sensitivity, while providing humidifiers for certain other medical conditions, constitutes a denial of Medicaid coverage based on the recipient's diagnosis. *See* 42 C.F.R. § 440.220(c).

In *Visser v. Taylor,* 756 F.Supp. 501 (D.Kan.1990), relied on by the plaintiffs, the state denied coverage for an FDA-approved drug Clozaril, which is used to treat schizophrenia. The court held that based on the evidence in the case, the state acted arbitrarily, capriciously, and in contravention of the Social Security Act in denying coverage on the basis of the recipient's diagnosis, type of illness, and mental condition. Similarly, in *Allen v. Mansour,* 681 F.Supp. 1232 (E.D.Mich.1986), the court held that the state could not deny funding for a liver transplant for a Medicaid recipient suffering from alcoholic cirrhosis who had not documented a two-year period of abstinence because liver transplant surgery was medically necessary and the only available procedure to resolve recipient's liver disease. *See* *Ledet v. Fischer,* 638 F.Supp. 1288 (M.D.La.1986) (state cannot limit eyeglasses services only to postcataract surgery patients).

Based on the record in this case to date, plaintiffs have not shown a likelihood of success on the merits that the
135 defendant's denial of Ms. DeSario's environmental control unit and Ms. Stevenson's room humidifier *135
constitutes an impermissible restriction based on medical condition. As for Ms. DeSario, the plaintiffs do not argue that the defendant has an explicit policy of refusing coverage of equipment necessitated by persons with quadriplegia, but instead that the defendant does not include coverage for *any* type of environmental control system. Because the defendant has never considered whether the Simplicity ECU, Series VII meets the definition of the defendant's definition of durable medical equipment, and simply denied coverage because it was not on the MEDS fee schedule, the Court finds that it is premature to consider if that denial could be said to be based on her medical condition.

With respect to room humidifiers, defendant's witness Elizabeth Geary testified that DSS provides Medicaid coverage for oxygen humidifiers, which are humidifiers which attach to oxygen therapy equipment used by persons with respiratory conditions, but not for room humidifiers. Plaintiffs argue that oxygen humidifiers and room humidifiers are both "humidifiers" in that they both inject moisture into the air breathed by recipients and the distinction in coverage constitutes a denial based on a medical condition. The Court disagrees. An oxygen humidifier is used in the administration of a high level of oxygen through a mask or a nasal cannula, and generally has no use to a person in the absence of an illness or injury. (May 10 Hearing, Trans. at 123-124.) Based on the record presented in this case to this point, this Court finds that oxygen and room humidifiers cannot be equated as serving a similar purpose; thus, plaintiffs have not demonstrated their likelihood of success on this claim.

IV. THOMAS SLEKIS'S MOTION FOR PRELIMINARY INJUNCTION (DOC. 68)

Although the Court has determined that plaintiffs DeSario, Emerson, and Stevenson are entitled to preliminary relief, the unique circumstances of intervenor Slekis require separate analysis. Specifically, Mr. Slekis alleges that, unlike the other named plaintiffs, he is already in possession of the DME for which he seeks state payment; though indigent, he is personally liable for the accrued rental fees for the equipment; the vendor of the DME has indicated that it will repossess the equipment if rental fees continue to be unpaid; and loss of the DME may swiftly result in serious aggravation of his medical condition. In light of these allegations and the evidence presented at the December 30 hearing, the Court ordered the defendant to provide payment for Mr. Slekis's DME during the period of time up to and including the continuation of the hearing on January 9.

A. Facts

Based on the evidence presented at the December 30 and January 9 hearings, the following facts are found to be established for purposes of Mr. Slekis's Motion for Preliminary Injunction. Mr. Slekis, a forty-year-old man, has been a paraplegic since an automobile accident in 1979. He receives approximately $600 per month in disability payments, as well as health care benefits through Medicaid.

As a result of his confinement to wheelchairs and beds, Mr. Slekis is susceptible to skin breakdowns, for which he has been subject to many episodes of hospitalization and surgery. Specifically, Mr. Slekis has suffered recurrent problems with decubiti (bed sores) in such areas as his hips, buttocks, and feet. In order to address these decubiti, Dr. Richard Kostecki has performed approximately fifteen to twenty flap surgeries on Mr. Slekis since 1985. This procedure involves cleaning out the sore, shifting nearby tissue into the resulting hole, and closing the skin on top. Hospitalization generally lasts ten days to two weeks, after which time the patient must continue to exercise care with his wound in order to prevent it from reopening. Because a patient only has a limited quantity of tissue near a given decubitus, flap surgeries may not be performed indefinitely to address recurring problems. Dr. Kostecki testified that Mr. Slekis may be able to undergo only one or two more flap procedures in the region of his buttocks. Once a patient has exhausted his ability to benefit from flap procedures in a given area of his body, 136 progressively *136 more complicated surgical procedures become necessary to address decubiti, including the grisly "fillet" procedure, in which a leg is sacrificed in order to provide tissue to fill in the wound. If not treated, a decubitus presents a significant risk of infection, which may lead to permanent impairment or death.

Mr. Slekis was most recently hospitalized in October 1996, during which time he underwent both a flap procedure and the amputation of his lower left leg. The amputation was performed in order to address a sore on Mr. Slekis's left foot that never closed properly and that showed signs of dangerous deterioration. The sore was originally caused by a burn wound; however, Dr. Kostecki testified that the ongoing problems with the wound were the result of repeated trauma, much of which was likely related to the difficulties that Mr. Slekis, as a paraplegic, experiences when he transports himself from bed to wheelchair and back again. In this process of moving himself, Mr. Slekis's skin may be compromised not just by banging parts of his body against the hard surfaces of the wheelchair, but also by the simple act of dragging his body across the surface of his bed.

On October 30, 1996, following the most recent hospitalization, Dr. Kostecki prescribed a RIK mattress for Mr. Slekis. This product, demonstrated to the Court by Nancy Lansing at the December 30 hearing, consists of a mattress filled with an oil-based liquid and covered with exceptionally loose-fitting sheets. In his October 30 letter, Dr. Kostecki particularly noted the benefits of such a mattress with respect to the problem of "shearing," which occurs when pressure is placed on the skin by horizontal movement across a bed or other hard surface. Dr. Kostecki stated that "the vast majority" of Mr. Slekis's breakdowns were related to shearing injury, and concluded, "It is my belief that multiple future hospital admissions could be prevented by the use of a mattress such as the RIK mattress." (Slekis Hearing, Pl. Ex. 7.)

On October 31, 1996, a DME vendor, Connecticut Rehab and Medical Products, Inc. ("Connecticut Rehab"), submitted to defendant a request for prior authorization for a RIK mattress for Mr. Slekis under the Medicaid program. The mattress was requested under the appropriate code for a RIK mattress in the Medicare system (E1399). On the same day, a RIK mattress was delivered to Mr. Slekis. Since delivery of the mattress, Mr. Slekis has experienced no new skin breakdowns, although an older sore has become inflamed. Indeed, at the January 9 hearing, Dr. Kostecki testified, based on his examination of Mr. Slekis the previous day, that Mr. Slekis's skin was in better shape than it had been for years. Dr. Kostecki noted, for instance, that a sore on Mr. Slekis's remaining heel, which has presented recurring problems, had not reopened. Dr. Kostecki was not aware of any explanation for the improvement in Mr. Slekis's condition other than the use of the RIK mattress.

In response to Connecticut Rehab's Request for Prior Authorization, the defendant issued a Request for Information on December 18, 1996. (Pl.'s Ex. 1.) This "Request" reads as follows:

> E1399 is not a valid Medicaid code. Please utilize the variety of available procedure codes (see 6/1/96 fee schedule) for an appropriate code. There are codes for products that are less expensive and would be beneficial to meet the client's medical need. Please resubmit with the available code you select.

Although defendant has suggested that this is not a final denial of authorization for a RIK mattress, Mr. Slekis has shown that no other Medicaid codes would be applicable to the mattress, particularly in that the mattress is neither motorized nor filled with air or water. Accordingly, the Court concludes that, though denominated a "request for information," the defendant's response was effectively a denial of prior authorization for the RIK mattress.

B. Irreparable Harm

The irreparable harm to which Mr. Slekis would be subject upon the loss of his RIK mattress is readily apparent. Dr. Kostecki and Ms. Lansing, a nurse specializing in wound care, testified that the process of skin breakdown
137 may begin within a few hours of a *137 patient's contact with an inappropriate surface. Mr. Slekis likewise testified that red blemishes, an indication of compromised circulation to a particular skin area, appear on his skin within a few hours of being in the wrong position or unwittingly in contact with a hard surface. The medical testimony further established that Mr. Slekis is more prone to skin breakdown than many paraplegics due to his numerous flap surgeries, his prior history of skin breakdown, and his regular transfers from bed to wheelchair and back again. Moreover, Mr. Slekis's condition is further compromised by the recent amputation: stump areas are particularly prone to breakdown due to the tendency of amputees to place weight on the stump while in bed, driving the stump down into the mattress and subjecting it to substantial friction and pressure.

Mr. Slekis's own record of repeated and lengthy hospitalizations demonstrates the severity of the harm that may result from skin breakdown. Continued aggravation of Mr. Slekis's condition may result in the need for additional operations, which will likely be of an increasingly serious and debilitating character. Defendant has suggested that Mr. Slekis may alleviate his problem simply by spending more time in his bed and less in his wheelchair; however, the loss of independence that would be result if Mr. Slekis were forced by his skin condition to remain bedridden or institutionalized clearly amounts to a substantial harm in its own right.

The harms at stake plainly fall into the category of "irreparable." As will be discussed further below, Dr. Kostecki's testimony established that the RIK mattress would be uniquely efficacious in preventing these harms; therefore, the Court concludes that the irreparable harm prong is satisfied.

C. Likelihood of Success on the Merits

As set forth above, plaintiffs have shown a likelihood of success on the merits of their claim that defendant's exclusive reliance on the MEDS list when evaluating requests for prior authorization violates federal law. Therefore, the analysis would need go no further if Mr. Slekis were merely requesting a redetermination of his request in a manner that comported with federal law. However, Mr. Slekis also seeks preliminary relief that will

permit him to keep his RIK mattress during the pendency of his renewed request. In short, Mr. Slekis asks the Court to stand in for the appropriate state agency and render a decision on the merits of his request for authorization.

Defendant opposes this effort by arguing that Mr. Slekis has shown neither a medical necessity for the RIK mattress nor that other devices on the MEDS list could not meet his medical needs as well as the RIK product. The Court is unpersuaded by either contention. Dr. Kostecki testified that Mr. Slekis's history of skin breakdown has been substantially caused by the shearing effect of the various bed surfaces previously used by Mr. Slekis. While the testimony established that Mr. Slekis's decubiti in the buttocks area are also a product of pressure caused by sitting in a wheelchair, Dr. Kostecki opined that as much as forty percent of the problem was attributable to shearing, and that, in fact, shearing due to movement across bed surfaces likely initiated the process of decubitus formation by causing "cracks" in the scar tissue arising from prior flap procedures. In any event, whatever the source of the decubiti in the buttocks area, the Court notes that Mr. Slekis has been subject to skin breakdown on other parts of his body and that Mr. Slekis's stump presents a significant new risk in this regard. In sum, the Court finds, based on the present record, that Mr. Slekis has established a medical need for a bedding surface that significantly reduces shearing and vertical pressure, which are the forces causing bed sores.

Defendant suggests that Mr. Slekis may exacerbate his skin condition by such bad habits as improper diet, lack of exercise, and consumption of alcohol, as well as his refusal to cooperate with a visiting nurse. There is no dispute that Dr. Kostecki's treatment of Mr. Slekis has not addressed all conceivable risk factors. Moreover, in some respects, Mr. Slekis appears less than a model patient (although the testimony indicates that Mr. Slekis
138 does knowledgeably and assiduously check his skin condition on a regular basis, Dr. Kostecki trusts Mr. Slekis's
*138 ability to evaluate his own progress after surgery, and Mr. Slekis is aware of the proper techniques for getting into his wheelchair). However, the Court does not see why "medical necessity" should be measured by reference to the model patient. In any event, the weight of the risk factors beyond Mr. Slekis's control, such as his history of flap surgeries and his amputation, lead the Court to conclude, based on the present record, that Mr. Slekis would have a medical necessity for a special bed surface regardless of whether other risk factors were more fully addressed. Finally, the Court is troubled by the defendant's suggestion that Mr. Slekis just needs to spend more time in bed. While the testimony established that Mr. Slekis's condition may be aggravated both by sitting in a wheelchair and by the process of transporting himself from bed to wheelchair and back again, the Court finds Mr. Slekis's quest for independence admirable and clearly consistent with the purposes of the Medicaid statute, which is intended to help beneficiaries "attain or retain capability for independence or self-care." *See* *Skubel v. Sullivan,* 925 F.Supp. 930, 941 (D.Conn.1996) (Burns, J.) (quoting 42 U.S.C. § 1396). The Court is of the opinion that "medical necessity" must also be determined by reference to this goal of independence, which is reflected in defendant's own definition of "medical necessity" in other contexts.[4] (Mem. of Supp. Authorities in Support of Slekis Motion, Ex. A.)

Is the RIK mattress capable of meeting this medical need? In closing argument, defendant's counsel called the mattress an "exotic" device and attempted to characterize it as untested. The testimony suggests that the RIK mattress has not been subjected to independent, scientific study with appropriate control groups. Moreover, the Court is disinclined to grant significant probative weight either to the RIK marketing materials admitted into evidence or to much of the self-serving testimony of Ms. Lansing, who is employed by a distributor of RIK products. However, the Court cannot conclude that the mattress is "exotic" or of undemonstrated efficacy. Both Dr. Kostecki and Dr. Deutsch, defendant's medical consultant, stated that independent clinical tests of specific medical products are rare, especially with respect to a product that is as new as the RIK mattress and with respect to the use of a product in the home health care context; therefore, the Court accords little weight to the lack of such studies in the record. The testimony clearly establishes that the product is covered by many private and public health care payers, including Medicare, the Connecticut Department of Mental Retardation, and Massachusetts's Medicaid program. The testimony of Dr. Kostecki, Ms. Lansing, and even Dr. Deutsch demonstrates that the RIK mattress is currently used by several hospitals and other health care providers in Connecticut. Finally, the efficacy of the RIK mattress is shown by its positive effects on Mr. Slekis's condition over the past two months, which even Dr. Deutsch characterized as a "significant finding." Thus, the Court finds that Mr. Slekis will likely succeed in showing that the RIK mattress meets his medical needs.

As to whether other bed surfaces may be equally suitable to Mr. Slekis's needs, the defendant argues that Mr. Slekis's needs may be met by a low air loss mattress with pump, which was added to defendant's MEDS fee schedule in June 1996, under code E0277. This product is a type of mattress with a motorized air pump that may be placed on top of a mattress or bed frame. Dr. Kostecki concedes that Mr. Slekis has had success during his hospitalizations with low air loss bed systems, and that such a product might be adequate to meet his medical needs. Dr. Deutsch testified that his review of the literature indicates that the bed system product has been the subject of favorable clinical studies. However, in the Court's view, this evidence of the efficacy of the low air loss bed system in hospital use is not probative of the efficacy of E0277 in home use. The state did not demonstrate
139 the equivalence of the listed mattress product and the bed system. First, a motorized bed *139 surface is vulnerable to power outages when in use in a residence, which does not have the backup generator capabilities of a hospital. In the event of a power outage, the mattresses will deflate in no more than an hour, which presents a grave risk to Mr. Slekis in light of the speed with which decubiti may form. Indeed, Mr. Slekis testified that he tried a different sort of motorized air mattress at home in the 1980's and suffered several times from skin blemishes as a result of deflation caused by power outages during the night. (Dec. 30 Hearing, Trans. at 46.) Mr. Slekis indicated that his residence has suffered an additional power outage since his last hospitalization, although he was not harmed because the RIK mattress is not motorized. Furthermore, the low air loss mattress may be subject to additional shortcomings that are not applicable to the full bed system, which is the specific product with which Mr. Slekis has had success in the past and to which the cited clinical studies seem to pertain. If simply placed on top of a normal bed, the E0277 mattress will be impossibly high for a paraplegic to mount, as Ms. Geary conceded in her testimony on January 9, unless an additional purchase of a height-adjustable bed is contemplated. Additionally, Ms. Geary had no information as to whether the E0277 product possessed the same sort of anti-shear covering that is one of the critical features that helps the bed system (and the RIK mattress) to address Mr. Slekis's medical needs. Indeed, Ms. Lansing's testimony, though self-serving, indicated that the RIK mattress's special, loose covering, which was demonstrated to the Court, rendered the RIK product uniquely well-suited for patients particularly vulnerable to shearing problems. Dr. Kostecki's personal observations with the RIK mattress in light of his knowledge of how shear affects vulnerable skin confirms that the RIK mattress possesses special properties in this regard. In sum, the Court concludes that Mr. Slekis has demonstrated a likelihood of success in showing both a medical need for the RIK mattress and that Group II support surfaces have not been shown to adequately meet his medical needs.

Defendant raises a final argument that merits comment: defendant contends that, even if the RIK mattress is medically necessary for Mr. Slekis, the state is not obligated to meet the medical needs of each individual Medicaid recipient, but only of the Medicaid population as a whole. As noted above in connection with plaintiffs' Motion for Preliminary Injunction, the Court finds there to be a division of authority as to whether state Medicaid programs must provide all medically necessary services for each and every recipient. The Court declines to take a position on this issue, but, as set forth above, concludes that state programs must at least assess and take account of medical needs at some level of the process, whether in establishing coverage policies or in deciding individual requests for services. Based on the present record, the Court cannot conclude other than that defendant has been remiss in her obligations in this regard.

The inadequacies in the preparation and implementation of the MEDS fee schedule have already been discussed above. The Court further notes that the evidence presented in connection with Mr. Slekis's motion amply demonstrates the problems with defendant's methods of handling coverage for DME. Before June 1996, defendant did not cover in any form the low air loss technology that her counsel has touted so much in this litigation. In connection with the June list revision, Ms. Geary, one of four individuals responsible for the changes, could not recall obtaining input from a single physician with respect to surface support devices[5] this, despite the fact that Dr. Deutsch, defendant's medical consultant, has an office in the very same building as Ms. Geary. When asked why defendant chose to place the low air loss mattress on the fee schedule, as opposed to the whole bed system, Ms. Geary indicated that she felt the products were functionally comparable, yet cross
140 examination revealed that her knowledge of the products was limited, and, indeed, that she had never even seen *140 them except in pictures. The Court is concerned that a continuing lack of attention to the medical needs of the Medicaid population may also be demonstrated by the fact, made clear in defendant's closing argument, that defendant has made no provision whatsoever for providing Group II support surfaces on a durational basis no

matter how compromised a patient's skin 🔲 which will meet the twin objectives of long-term cost-reduction and independence-retention by preventing medical deterioration; i.e., it is clear that defendant declines to provide support surfaces for preventive purposes, even when skin breakdown seems virtually inevitable, and instead insists that beneficiaries wait until Stage 3 or 4 decubiti have formed, although such advanced ulcers require expensive and debilitating surgical treatment. This does not seem an "appropriate limit on a covered service based on criteria such as medical necessity or utilization control"; nor does it appear that the provision of DME in this regard is "sufficient in ... duration ... to reasonably achieve its purpose." *See* 42 C.F.R. § 440.230(b) & (d).

While the defendant may or may not be generally obliged to meet the medical needs of each individual patient, the Court concludes that, where it has been demonstrated that the defendant has not accounted for the medical needs of the Medicaid population as a whole with respect to providing appropriate support surfaces for recipients in their homes, the Court may properly order preliminary relief that is designed to prevent irreparable harm by fully meeting the demonstrated medical needs of a particular Medicaid beneficiary. Otherwise, defendant could wholly disregard medical needs and avoid its obligations to employ "reasonable standards," to assure that the Medicaid program is operated in "the best interests of the recipients," and to provide services sufficient "to reasonably achieve" the purposes of the program. *See* 42 U.S.C. § 1396a(a)(17) & (19); 42 C.F.R. § 440.230(b).

V. RELIEF

A. Plaintiffs DeSario, Emerson, and Stevenson

For the reasons stated above, the Court finds that the plaintiffs have demonstrated a likelihood of success on the merits that Conn. MAP Manual § 189.E.II.a and § 189.E.III. is inconsistent with the objectives of the Medicaid Act to furnish medical assistance to disabled individuals whose income and revenues are insufficient to pay for medically necessary services. 42 U.S.C. § 1396a(a)(a)(17)(A). The Court declines to find that the plaintiffs have shown a likelihood of success on their claim that defendant's policies improperly deny coverage based on "diagnosis, type of illness or condition." *See* 42 C.F.R. § 440.230(c). Because of the resolution of these issues, the Court need not address the other contentions raised by the parties.

In furtherance of the Court's finding, the following preliminary relief is ordered on behalf of plaintiffs DeSario, Emerson, and Stevenson:

> (1) The defendant is enjoined from using Conn. MAP Manual § 189.E.II.a and § 189.E.III.a as the exclusive determinant of plaintiffs' preauthorization requests for durable medical equipment.
>
> (2) Plaintiffs shall be permitted to resubmit their requests for prior authorization of DME based on a recent physician's prescription and/or report reflecting the medical necessity for the requested item. Such requests must be acted upon by the defendant within seven (7) working days after receipt, and may not be denied solely on the grounds that the requested DME is or is not listed in Conn. MAP Manual § 189.E.II.a or § 189.E.III.a. If defendant denies any of the plaintiffs' requests for prior authorization, the plaintiffs may appeal the defendant's decision through the defendant's fair hearing procedures which shall also reflect defendant's discontinuation of the currently constituted MEDS list as dispositive for such appeals of denials of prior approvals. Plaintiffs may thereafter appeal adverse fair hearing decisions to state court pursuant to Conn. Gen Stat. § 4-183.

B. Thomas Slekis

141 As set forth above, the Court finds that Mr. Slekis has shown irreparable harm if he *141 loses his RIK mattress and likelihood of success in demonstrating that he would be entitled to retain the mattress at state expense pursuant to an assessment of his medical needs and the adequacy of alternatives. Accordingly, the following preliminary relief is ordered:

(1) The defendant shall reconsider Mr. Slekis's request for prior authorization within seven (7) working days of this order. In determining whether to grant prior authorization for the RIK mattress, the defendant may not rely solely on the MEDS fee schedule, but must take into consideration its assessment of Mr. Slekis's medical needs and the adequacy of alternative devices to meet those needs.

(2) During the pendency of Mr. Slekis's request for prior authorization, including any fair hearing or appeals process, the defendant shall pay the charges necessary for Mr. Slekis to retain the RIK mattress. If defendant's determination and any subsequent appeals ultimately prove adverse to Mr. Slekis, defendant shall continue to make the requisite payments for the RIK mattress until some alternative product deemed by defendant to meet Mr. Slekis's medical needs is provided to him.

VI. CONCLUSION

For the foregoing reasons and under the foregoing conditions, plaintiffs' Motion for Preliminary Injunction (Doc. 3) and intervenor Slekis's Motion for Preliminary Injunction (Doc. 68) are GRANTED. This order shall remain in effect until further order of the Court.

IT IS SO ORDERED.

RULING ON PENDING MOTIONS [docs. 56, 58, 83, 86]

Defendant's Motion to Reargue (Doc. 83)

The Court construes defendant's motion as a motion to reconsider the Court's ruling on class certification (Doc. 72) and the Court's ruling on the motions for preliminary injunction by plaintiffs DeSario, Emerson, Stevenson, and Slekis (Doc. 74). As to the ruling on class certification, defendant's motion is GRANTED. In light of the colloquy with counsel on January 28, 1997, and the agreement between the parties as to the appropriateness of modifying the class definition, the two certified subclasses will be defined as follows. The first class, to be known as the "DeSario" subclass will consist of:

> All Connecticut Medicaid recipients who have been, or who in the future will be, denied Medicaid coverage for equipment which they allege to be durable medical equipment on the basis that such equipment is not included on the Connecticut Department of Social Services' fee schedule list for such equipment.

The second subclass, which will be referred to as the "Emerson" subclass, will consist of:

> All Connecticut Medicaid recipients who have been, or who in the future will be, denied Medicaid coverage for equipment which they allege to be durable medical equipment on the basis that such equipment is not included on the Connecticut Department of Social Services' fee schedule list for such equipment, because such equipment is identified by the Department as being specifically excluded from coverage.

The remainder of defendant's motion, which concerns the Court's ruling on the motions for preliminary injunction, is DENIED. Defendant first contends that the Court made no findings with respect to the adequacy of the MEDS fee schedule in meeting the needs of the Medicaid population as a whole. However, the Court specifically stated that it need not, and at present would not, rule on the legal question of what burden of proof plaintiffs have on this element because the Court concluded that plaintiffs have made an ample showing in this regard for purposes of the preliminary injunction motions. As set forth in the Court's ruling, defendant appears to have no procedures for regularly or systematically updating the MEDS fee schedule to take into account new products and new medical research; the fee schedule seems to be developed and maintained with minimal input from physicians with

relevant areas of specialization; defendant' uses its fee schedule as the dispositive determinant for all requests
142 for prior authorization, regardless of Medicaid beneficiaries' *142 individual medical necessities; and, with respect to support surfaces specifically, defendant makes no provision for long-term care of patients with severely compromised skin, taking little account of the statutorily-mandated requirement to promote the independence and self-sufficiency of Medicaid beneficiaries. In light of these findings, the Court has little difficulty concluding that plaintiffs have demonstrated a likelihood of success in showing the inadequacy of the MEDS fee schedule with respect to the medical needs of the Medicaid population as a whole, should it be plaintiffs' burden of making such a showing at a trial on the merits (or whether this element should be viewed as defendant's affirmative defense to plaintiff's claims of failure to meet their individual needs).

Next, defendant argues that the Court may not order payment of the cost of plaintiff Slekis's RIK mattress without a determination that Mr. Slekis is eligible for such coverage. Defendant quotes the Supreme Court's decision in *Lavine v. Milne* that "nothing in the Constitution requires that benefits be initiated prior to the determination of an applicant's qualifications at an adjudicatory hearing." 424 U.S. 577, 586, 96 S.Ct. 1010, 1016, 47 L.Ed.2d 249 (1976). However, the Court has both conducted an adjudicatory hearing in connection with Mr. Slekis's motion for preliminary injunction and made a determination of Mr. Slekis's coverage for purposes of the requested emergency relief. Accordingly, the Court finds no merit in defendant's argument.

Lastly, defendant requests a clarification as to the Court's ruling with respect to plaintiffs' burden of proof. However, for the reasons set forth above, the Court need not fully delineate plaintiffs' burden at this time and will give the parties full opportunity for briefing on this issue before any classwide relief is considered. The Court concludes that plaintiffs have satisfied all of the requirements that defendant argues to be applicable.

For the foregoing reasons, defendant's motion is GRANTED in part and DENIED in part.

Plaintiffs' Motion for Clarification (Doc. 86)

Plaintiffs move to clarify the Court's preliminary injunction in light of defendant's redetermination of intervenor Slekis's request for prior authorization, purportedly in compliance with the preliminary injunctive relief ordered. The Court's order plainly contemplated that defendant would take into account Mr. Slekis's medical condition, the appropriateness of the RIK mattress as a device to meet Mr. Slekis's medical needs, and the ability of other items on the MEDS fee schedule to meet his needs. However, the Court did not contemplate that defendant would impose on Mr. Slekis a burden that it has never imposed on any other applicant: the burden to demonstrate 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 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."

The Court has already detailed the shortcomings of the MEDS fee schedule above and in the ruling on the motions for preliminary injunction. The Court further notes that defendant has conceded that it does not provide support surfaces for preventive purposes, a policy that is also apparent from defendant's medical guidelines; therefore, the Court regards it as 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. By requiring any additional showing to this, the Court can discern no intent on the part of defendant other than to require Mr. Slekis to provide detailed statistical data about the support surface needs of the Medicaid population, data which defendant itself apparently does not possess and did not use in preparing the MEDS fee schedule. (See Testimony of Dr. Deutsch, January 9, 1997, Trans. at 511-12.) Imposing such a requirement on an applicant who is seeking an item of DME not on the MEDS fee schedule operates virtually to restore the MEDS fee schedule as
143 a dispositive criterion in evaluating requests for prior authorization. *143 This is plainly prohibited by the Court's preliminary injunction.

For the foregoing reasons, the Court GRANTS plaintiffs' motion for clarification, and holds that defendant may not require those plaintiffs who receive redeterminations of their requests for prior authorization pursuant to the preliminary injunction, to demonstrate that medical equipment covered by the department is inadequate with respect to the Medicaid population as a whole.

Motions by Howard Wolan to Intervene and for Preliminary Injunction (Docs. 56 & 58)

Pursuant to, and subject to the terms of, the stipulation of the parties dated February 10, 1997, Howard Wolan's motion to intervene (Doc. 58) is GRANTED. The clerk is directed to docket intervenor Wolan's complaint. In light of the February 10 stipulation, Mr. Wolan's motion for preliminary injunction (Doc. 56) is DENIED without prejudice as moot.

IT IS SO ORDERED.

[1] The defendant's definition of DME parallels the federal government's definition of DME under the Medicare program. *See* 42 C.F.R. § 440.170.

[2] Ms. Geary, a pharmacist by training, heads the defendant's department that reviews requests for prior authorization of medical equipment devices and supplies.

[3] The Medicaid Act does not define "medically necessary." The Supreme Court in *Doe v. Bolton,* 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973) provided some indication of the meaning of this term when it struck down portions of a Georgia law as unduly burdening the constitutional right of privacy outlined in *Roe v. Wade,* but upheld a portion of the statute banning abortions that an attending physician determined to be unnecessary. The Court held,

Whether ... an `abortion is necessary' is a professional judgment that ... may be exercised in the light of all `factors
 physical, emotional, psychological, familial, and the women's age
 relevant to the well being of the patient.' All these factors may relate to health. This allows the attending physician the room he needs to make his best medical judgment.

Doe v. Bolton, 410 U.S. at 192, 93 S.Ct. at 747-48.

In *Beal v. Doe,* the respondents sued the State of Pennsylvania over its Medicaid plan which limited funding for medically necessary abortions only if continuation of the pregnancy threatened the mother's life or if the infant would be born disabled, or if the pregnancy was the result of rape or incest. *Id.* The Supreme Court held that because the respondents did not comply with the statute by obtaining a physician's testament on the necessity of the abortion, the abortions sought were purely elective and not fundable under the "medically necessary" requirement. In ruling, the *Beal* Court did not define "medically necessary" but referred to the *Bolton* definition of "medically necessary" in a footnote: "We were informed during oral argument that the Pennsylvania definition of medical necessity is broad enough to encompass the factors specified in *Bolton." Beal,* 432 U.S. at 442 n. 3, 97 S.Ct. at 2370 n. 3.

Thus under *Bolton* and *Beal,* the Supreme Court appears to define "medically necessary" as a professional judgment made by a physician considering the physical, emotional, psychological, and familial factors relevant to the well-being of the patient.

[4] The Court notes that the need for defendant to take into account a recipient's efforts to retain independence in making her coverage decisions is also of profound importance in the case of plaintiff DeSario.

[5]
During his closing argument on January 9, defendant's counsel criticized plaintiff for asking the Court to render a coverage decision based on the testimony of a single physician (Dr. Kostecki). Counsel stated, "That is not how government decisions are made." Apparently, counsel was correct.