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**The National**

**Assistive Technology Advocacy Project**

*Project of Neighborhood Legal Services, Inc 237 Main Street • Suite 400 • Buffalo NY • 14203*

(716) 847-0650 • (716) 847-0227 FAX • (716) 847-1322 TDD • [www.nls.org](http://www.nls.org)

## **Exclusive Lists: Frequently Asked Questions**

By Diana M. Straube, Staff Attorney  
National Assistive Technology Advocacy Project  
716-847-0655, extension 220, [dstraube@nls.org](mailto:dstraube@nls.org)

### **What Is an “Exclusive List” in the Context of Medicaid Funding of Durable Medical Equipment (DME)?**

An “exclusive list” is a list of items the state Medicaid agency conclusively considers to be durable medical equipment (DME). In order for the list to be considered an “exclusive list,” the state Medicaid agency must insist that only items on the list are covered as DME and deny all requests for items not on the list, even when the items are shown to be medically necessary in individual cases.

### **May the State Medicaid Agency Maintain an “Exclusive List”?**

According to the policy letter issued by the Center for Medicare and Medicaid Services (CMS), dated September 4, 1998 (as described below), a state Medicaid agency may maintain a list of DME for convenience purposes, but may not use that list to deny Medicaid funding for a medically necessary item that otherwise fits within the state’s definition of DME.

### **What is the Legal Authority for Claiming That State Medicaid Agencies May Not Maintain “Exclusive Lists”?**

There are several provisions within the federal Medicaid Act and its implementing regulations that disallow “exclusive lists.” States that participate in the Medicaid program must have state Medicaid plans that include reasonable standards for determining the extent of medical assistance under the plan, consistent with the objectives of the Medicaid Act. 42 U.S.C. § 1396a(a)(17)(A). The reasonable standards provision requires states to provide medically necessary services sufficient in amount, duration, and scope to reasonably achieve their purpose, 42 C.F.R. § 440.230(b), and prohibits the placement of arbitrary limits on the provision of DME based solely on diagnosis, type of illness, or condition of the recipient. 42 C.F.R. § 440.230(c).

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The National Assistive Technology Advocacy Project is funded through a grant received from the Rehabilitation Service Administration, U.S. Department of Education, to the Rehabilitation Engineering Society of North America (RESNA) (with a subcontract to Neighborhood Legal Services, Inc.) under contract number H224B050003. The opinions expressed herein do not necessarily reflect the position of the U.S. Department of Education, and no official endorsement by the U.S. Department of Education of the opinions expressed herein should be inferred.

Further, state Medicaid agencies must ensure that medical services are equal in amount, duration, and scope for all categorically-needy recipients, 42 U.S.C. § 1396a(a)(10)(B), 42 C.F.R. § 440.240(b)(1). This is often referred to as the “comparability” requirement.

### **What Does the CMS Policy Letter Say about “Exclusive Lists”?**

First, it might be helpful to know the context in which CMS issued the policy letter. The plaintiffs in a Second Circuit case called *DeSario v. Thomas*, 139 F.3d 80 (1998), sued after the Connecticut Medicaid agency limited coverage of DME to those items that appeared on the agency’s fee schedule, and denied coverage for items not on the fee schedule, even when the items appeared to meet the state’s definition of DME. The Second Circuit approved Connecticut’s use of a DME fee schedule to make coverage determinations, holding that state Medicaid agencies are not required to provide every medically necessary item that falls within the state’s definition of DME.

In response to the DeSario decision, the Health Care Financing Administration, now CMS, wrote the September 4, 1998 policy letter as “interpretive guidance” for state Medicaid directors.<sup>1</sup> The CMS letter declares that while states may develop and use pre-approved lists such as a fee schedule, for administrative convenience, states violate the reasonable standards and amount, duration, and scope provisions of the federal act if they do not have reasonable and meaningful procedures for requesting items of DME that do not appear on the fee schedule or pre-approved list. CMS stated that with regard to an individual’s request for an item of DME, federal law requires that:

- States have a process that is timely and “employs reasonable and specific criteria” for making coverage determinations for individual items of DME. The criteria must be “sufficiently specific” so that recipients can determine whether an item has been “arbitrarily excluded from coverage based solely on diagnosis, type of illness, or condition”;
- States make their processes and criteria, and pre-approved lists, available to Medicaid recipients and the public;
- States inform Medicaid recipients of their right to a fair hearing to challenge the legality of an adverse coverage determination.

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<sup>1</sup> The CMS letter begins, “[w]e have received a number of inquiries regarding coverage of medical equipment (ME) under the Medicaid program in light of the ruling of the United States Court of Appeals for the Second Circuit in DeSario v. Thomas.”

According to the letter, pre-approved lists should be regarded as evolving documents subject to periodic amendment in order to keep pace with available technology.

The *DeSario* decision was appealed to the Supreme Court. Reported as *Slekis v. Thomas*, 525 U.S. 1098 (1999), the Supreme Court remanded the matter to the Second Circuit, for “further consideration in light of the interpretive guidance issued by the Health Care Financing Administration on September 4, 1998.”

### **Have Other Courts Referred to the CMS Policy Letter?**

Several significant cases decided since the CMS letter was issued have referred to it. For example, when Missouri attempted to substantially reduce the number of items of DME covered by Medicaid for most categorically-needy Medicaid recipients (the full range of DME would be available only to Medicaid recipients who were blind, pregnant, or under the age of 21), the Eighth Circuit in *Lankford v. Sherman*, 451 F.3d 496 (2006), held that “a state's failure to provide Medicaid coverage for non-experimental, medically-necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid.” In so ruling, the court gave considerable deference to the opinion of CMS, as set forth in the State Medicaid Director letter, that in order to be consistent with the reasonable-standards requirement and the objectives of Medicaid, a state Medicaid agency must have a meaningful procedure for requesting non-covered items. 451 F.3d 496 at 511-512.

In another case, *Bell v. Agency for Health Care Admin.*, 768 So.2d 1203 (1<sup>st</sup> Dist Fla, 2000), a Florida rule incorporated an exclusive list of items of DME that were available to adult Medicaid recipients. The adult plaintiff had an insulin pump and needed insulin pump supplies, which the Medicaid agency claimed were not available through the Medicaid program. Although agency administrators in individual cases could apparently “override” its computer to provide DME not on the list, Medicaid recipients were not advised as to the procedure for requesting such items.

Deferring to the interpretive guidance in the CMS letter, the court held that the Florida rule violated federal principles set forth in the CMS letter because the rule did not articulate the process for seeking items not on the list, did not employ reasonable and specific criteria for coverage of certain DME, and did not inform beneficiaries of their right to a fair hearing to challenge an adverse determination. 768 So.2d at 1204.<sup>2</sup>

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<sup>2</sup> See also *T.L. v. Colorado Dept. of Health Care Policy and Financing*, 42 P.3d 63 (Co. 2001) (citing the CMS policy letter and *Slekis v. Thomas*, the court concluded that, by expressly excluding coverage of hot tubs or jacuzzis under all circumstances and without regard to medical necessity, the state violated federal law) and *William T. ex rel. Gigi T. v. Taylor*, 465 F. Supp. 2d 1267 (N.D.Ga. 2000) (finding that the September 4, 1998 policy letter reflects a reasonable interpretation of the law, the court deferred to it in holding that Georgia may not categorically deny coverage for augmentative communication devices). In contrast, see *Rodriguez v. City of New York*, 197 F.3d 611 (2<sup>nd</sup> Cir. 1999) (court held that state's refusal to fund safety-monitoring as personal care services did not violate Medicaid Act.)

## **Is the State Medicaid Director Letter Accessible?**

The letter is currently available on the CMS web site, [www.cms.hhs.gov](http://www.cms.hhs.gov). The letter can be found in the Medicaid section by following the links for “State Medicaid Director Letters,” then selecting the date “09/04/98” with the subject title, “Medical Coverage.” The letter can also be obtained by contacting the author at the National Assistive Technology Advocacy Project, 716-847-0655, extension 220, or [dstraube@nls.org](mailto:dstraube@nls.org).

## **Can a State Medicaid Agency Violate the Ban on “Exclusive Lists” Even If it Does Not Use Pre-approved Lists or Fee Schedules?**

Yes. “Exclusive lists” can have many forms and a state Medicaid agency may violate the ban without having a pre-approved list or fee schedule. Federal law requires that Medicaid recipients be provided a meaningful procedure for requesting an item of DME, and the opportunity to challenge denial of an item. These requirements are meaningful only if Medicaid recipients are *informed* about procedures for requesting items the agency claims are not covered, and of their right to challenge a coverage determination at a fair hearing.

State Medicaid staff may impede the prior authorization process by verbally informing equipment vendors or therapists that it would be a waste of time to submit a prior authorization request for a certain item because it is never covered by Medicaid, or by rejecting or otherwise refusing to process prior authorization requests. In addition to violating the prohibition against “exclusive lists,” such action of the part of the agency deprives the Medicaid recipient of the opportunity to challenge the agency’s claims of non-coverage through an administrative fair hearing.

## **What If a State Medicaid Agency Follows Medicare Criteria?**

Medicare and Medicaid are entirely different programs, with different mandates. The purpose of the Federal Medicaid Statute is to help individuals “attain or retain capacity for independence or self-care.” 42 U.S.C. § 1396. Medicare has no comparable statement of purpose. Further, Medicare does not have provisions comparable to the “reasonable standards” and “amount, duration, and scope” provisions of the federal Medicaid Act.

Unlike the Medicaid program, the Medicare program may use lists of covered and non-covered items of DME. In fact, a list of non-covered items can be found on the website of NHIC, Inc., ([http://www.medicarenhic.com/cpt\\_agree.shtml](http://www.medicarenhic.com/cpt_agree.shtml)), the Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) for Jurisdiction A (which includes Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont) by clicking on “All Medical Review” on the left-hand side of the home page. A review of the list shows that the DME MAC for Jurisdiction A does not approve funding for such items as standing frame systems, one position; bath/shower chairs; and multiple types of hearing aids. A state Medicaid agency that maintained such a list and conclusively denied funding for any of these items (assuming they fit within the state’s definition of

DME), without regard to medical necessity, would be violating the “reasonable standards” and “amount, duration and scope” provisions of the federal Medicaid statute.

### **May a State Medicaid Agency Create an “Exclusive List” by Use of Reimbursement Rates?**

Yes. For example, if reimbursement rates are so low that certain customized or custom-made items would never be provided, the state Medicaid agency has effectively denied coverage of those items simply by virtue of having an insufficient reimbursement rate. In *Esteban v. Cook*, 77 F. Supp. 2d 1256 (S.D. Fla 1999), the plaintiffs challenged an absolute limitation of \$582 on the coverage of wheelchairs, claiming that the cap was unreasonable and violated Medicaid’s requirement that services be sufficient in amount, duration and scope to achieve their purpose. The insufficient reimbursement rate effectively prevented Medicaid recipients from obtaining power wheelchairs, since no vendor could afford to provide them at such a low reimbursement rate.

Referencing the CMS State Medicaid Director letter, the court held that in order to comply with federal Medicaid law, a state must: employ reasonable and specific criteria by which an individual item of DME will be judged for coverage; make its processes and criteria, as well as its list of pre-approved items, available to the public; and inform recipients of their right to a fair hearing to determine whether an adverse decision is contrary to federal law. (77 F. Supp. 2d 1256, at 1260).

### **What If a State Medicaid Agency Uses Criteria Not Included in its Definition of Durable Medical Equipment?**

Although state Medicaid agencies may “place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures,” 42 C.F.R. § 440.230(b), having criteria other than medical necessity, not included in its definition of durable medical equipment, may create an “exclusive list.”<sup>3</sup>

### **Are There Other Examples of How State Medicaid Agencies May Create an “Exclusionary List” by Employing Criteria Not Included in the Definition of Durable Medical Equipment?**

There are a number of examples of how state Medicaid agencies may create an “exclusionary list” by employing criteria not included in the definition of durable medical equipment, including the following:

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<sup>3</sup> Several courts, however, have interpreted 42 C.F.R. § 440.230(b) to mean that agencies may use criteria other than “medical necessity” and “utilization control procedures” to limit coverage. See *Casillas v. Daines*, 580 F. Supp. 2d 235 (S.D. N.Y. 2008), *Semerzakis v. Commissioner of Social Services*, 274 Conn. 1, 873 A.2d 911 (Conn. 2005) (using an orthodontic assessment called the Salzmann Assessment to determine the medical necessity of orthodontic treatment in individual cases was an appropriate utilization control procedure).

- If a state Medicaid agency insists that it only covers items approved by the Food and Drug Administration (FDA), the agency may refuse to fund medically necessary items that do not require FDA “approval” but otherwise meet the state’s definition of DME.

The Food and Drug Administration regulates the marketing of medical devices to assure they are safe and effective. There are three regulatory classes of medical devices and placement within these classes is based on the degree of control necessary to assure the devices are safe and effective. Not all items of DME require FDA “approval” in order to be marketed. Some devices, such as those in Class I, require pre-market notification rather than pre-market approval. According to the FDA website, 47 percent of medical devices fall into Class I and 95 percent of these devices are exempt from the regulatory process. (See <http://www.fda.gov/cdrh/consumer/geninfo.html>).

At least four New York fair hearing decisions involving a type of adult crib have rejected the notion that an item must be FDA approved in order to be covered under Medicaid. In *Matter of Zoe*, FH # 4919369L, the Administrative Law Judge noted that, “[t]he definition of durable medical equipment does not mandate that same be FDA approved. While medical registration may be a factor, absence of such FDA approval is not dispositive of the issue.”(at 7)<sup>4</sup>

- Rhode Island Medicaid provided binaural hearing aids only to individuals 21 years of age and under; individuals over 21 years of age who have been utilizing two hearing aids and now require replacement of the hearing aids; individuals who are gainfully employed or are likely to become employed if the hearing problem is corrected; or visually impaired individuals. In *Jasset v. Rhode Island Dept. of Human Services*, Not Reported in A.2d, 2006 WL 2169891 (R.I. Super. 2006), the agency conceded these criteria were unrelated to medical necessity. The court therefore found the policy regarding binaural hearing aids to be arbitrary and capricious and in violation of Medicaid standards. (2006 WL 2169891, at 5).

**Date of Last Update: February 2009**

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<sup>4</sup> See also *Matter of Joseph*, FH # 4827393R at 7, *Matter of Naomi*, FH # 5104116N at 6, and *Matter of Mathew*, FH # 5105965Y at 4. All four decisions are available from the National Assistive Technology Advocacy Project.