September 4, 1998

Dear State Medicaid Director:

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

As you know, the mandatory home health services benefit under the Medicaid program includes coverage of medical supplies, equipment, and appliances suitable for use in the home (42 C.F.R. § 440.70(b)(3)). A State may establish reasonable standards, consistent with the objectives of the Medicaid statute, for determining the extent of such coverage (42 U.S.C. § 1396(a)(17)) based on such criteria as medical necessity or utilization control (42 C.F.R. § 440.230(d)). In doing so, a State must ensure that the amount, duration, and scope of coverage are reasonably sufficient to achieve the purpose of the service (42 C.F.R. § 440.230(b)). Furthermore, a State may not impose arbitrary limitations on mandatory services, such as home health services, based solely on diagnosis, type of illness, or condition (42 C.F.R. § 440.230(c)).

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

In light of this interpretation of the applicable statute and regulations, a State will be in compliance with federal Medicaid requirements only if, with respect to an individual applicant's request for an item of ME, the following conditions are met:

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

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

HCFA's Regional Offices will be monitoring compliance with the statute and regulations that are the subject of this guidance. Any questions concerning this letter or the ME benefit may be referred to Mary Jean Duckett of my staff at (410) 786-3294.

Sincerely,

/s/
Sally K. Richardson
Director

cc:
All HCFA Regional Administrators
All HCFA Associate Regional Administrators for Medicaid and State Operations
Lee Partridge  American Health Services Association
Joy Wilson  National Conference of State Legislatures
be: HCFA Press Office CMSO Senior Staff