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Dr. Donald Berwick, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-1850

September 9, 2011

RE: CMS-2348-P
Proposed Rule: Face to Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health

Dear Dr. Berwick:

The National Health Law Program (NHeLP) is a national public interest law firm working to advance access to quality health care and protect the legal rights of low income and underserved people, including people with disabilities. NHeLP serves legal services programs, disability advocates, community-based organizations, the private bar, providers and individuals working to preserve a health care safety net for the millions of uninsured or underinsured low-income people. NHeLP has long taken the position that Medicaid services should, to the greatest extent appropriate, be provided in home and community-based settings. Accordingly, we commend CMS for its proposed rule making clarifications about the home health service, 76 Fed. Reg. 41032 (July 12, 2011). We also offer a number of suggestions to strengthen the proposed regulations to ensure a robust benefit that serves the purposes for which it was created.

Codification of a generally applicable definition of medical supplies, equipment and appliances under the home health benefit.

In general, we support CMS's proposal to adopt a regulatory definition of medical supplies, equipment and appliances. We are, however, concerned that states may take it as a signal to make their policies for covering medical equipment, appliances and supplies more restrictive than they are at present policies. We therefore urge CMS to state in the preamble to the final rules that this is not the intention of adopting this definition.

We are also specifically concerned that the stated intent to "align" the definition with the Medicare program, 76 Fed. Reg. at 41034, will lead states to erroneously deny coverage of home health services because Medicare does not cover them. One of the primary purposes of the Medicaid program

is to "furnish . . . rehabilitation and other services to help such families and individuals attain or retain capability for independence and self care." 42 U.S.C. § 1396-1. Such services are critical to the lives of many Medicaid beneficiaries with significant disabilities who strive to remain in the community. There is no corresponding requirement in the Medicare Act.

We also recommend that CMS further clarify the proposed definition of medical equipment and appliances. The proposed language defining medical equipment as "reusable or removable" could be interpreted by states to allow exclusion of items that are custom made or customized, such as wheelchair components for the seating and positioning for individuals with the most severe orthopedic impairments. These items are presently and, for many years have been, routinely covered as items of medical equipment and have enabled individuals with the most severe disabilities to be integrated into the community. But, they often are not reusable and, in many cases, are not removable. We are unaware of any states that apply this "reusable" criterion to medical equipment, although some states, such as Connecticut, use the term "non-disposable" to differentiate medical equipment and appliances from medical supplies. We therefore urge the substitution of the term "reusable" with "non-disposable."

We also recommend that CMS clarify this definition to ensure that individuals with congenital conditions or developmental disabilities are not denied coverage of equipment or appliances because a state agency determines that they do not have an illness or injury. For example, an individual who was born with condition that inhibits his ability to speak should not be denied coverage of a speech-generating device because such a condition is not an illness or injury.

Accordingly, we recommend that the definition of medical equipment and appliances be revised as follows (our proposed language in italics):

> **§ 440.70(b)(3)(ii)** Equipment and appliances are defined as items that are primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of an illness or injury *or disabling condition*, can withstand repeated use, and *are non-disposable* or removable.

We commend CMS for its statement in the preamble to the proposed rules that "[i]tems that meet the criteria for coverage under the home health benefit must be covered as such. States will not be precluded from covering items through a Section 1915(c) HCBS waiver service, such as home modification, or through a Section 1915(i) State Plan option. However, the State must also offer those items as home health supplies, equipment and appliances." We recommend re-stating this text in the preamble to the final regulations and believe that such a statement would significantly benefit many Medicaid recipients. Several states have excluded equipment items that meet the definition of medical equipment and appliances by declaring them to be covered exclusively under a waiver. This text will make clear that states may not use such a rationale to deny coverage.

Finally, we suggest that CMS make clear in the preamble to the final regulation that medical supplies, equipment and appliances are a separate stand-alone home health service, and that it is not necessary for individuals to meet the requirements for other types of home health services in order to gain access to these items. Specifically, states cannot require that individuals qualify for

skilled nursing or therapy services in order to receive medical equipment, supplies or appliances, nor can they require a 60 day plan of care. Nor may they impose additional state restrictions that are not part of the federal requirements for supplies, equipment and appliances such as requiring that they be limited to services for temporary recovery from specific incidents, be limited to non-routine supplies necessary to the delivery of a participant's nursing care and described in the plan of care, or any other state requirement that is not a federal requirement for receiving equipment and supplies.

Clarification that home health services cannot be restricted to individuals who are homebound or to services furnished in the home.

We commend CMS for codifying the requirement, recognized in *Skubel v. Fuoroli,* 113 F.3d 330 (2d Cir. 1997), that states may not limit coverage of home health services to those provided in the home. States have continued to impose such a limitation, notwithstanding the *Skubel* holding. This proposed language will make it clear to all states that such a limitation violates Medicaid law.

CMS has previously emphasized, in Olmstead Update No. 3, that such restrictions violate Medicaid regulatory requirements and are inconsistent with the Americans with Disabilities Act's community integration mandate. *See* Dear State Medicaid Director (July 25, 2000). As CMS has stated, such a rule is contrary to the principle that people with disabilities can and do live in the community and that Medicaid policies should advance, not interfere with, the goal of community integration. Even so, states continue to violate this requirement. Notably, Missouri imposed an explicit homebound requirement on access to home health care, which both CMS and the Eighth Circuit noted was inconsistent with CMS's directive that homebound requirements are prohibited. *Lankford v. Sherman*, 451 F.3d 496, 512-13 (8th Cir. 2006) (citing Letter from James G. Scott, Associate Regional Administrator for Medicaid and Children's Health, to Gary Sherman, Director of the Missouri Department of Social Services (Nov. 21, 2005)). Codifying this requirement will make it clear to states that such policies are illegal and help eliminate the need for Medicaid enrollees to resort to federal court to ensure that the state Medicaid agency complies with the law.

We believe, however, that the proposed regulatory language captures only part of CMS' intention, stated in the preamble, to prohibit homebound requirements. There is no explicit language in proposed § 440.70(c) that prohibits state from restricting coverage of home health services to individuals who are homebound. We therefore urge CMS to specify in the regulation itself that states may not limit coverage of home health services will to individuals who are homebound or physically incapable of leaving their home. As CMS has stated, and the Eighth Circuit recognized, states cannot require that an individual require skilled nursing services or be physically incapable of leaving the home as a condition of receipt of home health services. *See Lankford,* 451 F.3d at 512-513 (citing Letter from James G. Scott to Gary Sherman 2 (Nov. 21, 2005) (stating that Missouri may not institute a homebound requirement or mandate that recipients receive skilled nursing services to receive home health services)). Yet, some states continue to restrict coverage of home health to such individuals.

Accordingly, we suggest that CMS revise its proposed language as follows (our proposed language in italics):

> § 440.70(c)(1) Nothing in this section should be read to prohibit a recipient from receiving home health services in any non-institutional setting in which normal life activities take place *or to permit a state to require that an individual be homebound or unable to leave his home in order to receive home health services.*

Exclusive lists or irrebuttable presumptions in determining coverage of items of medical equipment.

We commend CMS for reemphasizing in the preamble that states may not use lists or presumptions in limiting coverage of items under the home health benefit unless states have a reasonable process for requesting exceptions to such lists or presumptions that are based upon specific criteria. 76 Fed. Reg. at 41034. CMS made this rule clear in its September 4, 1998 Dear State Medicaid Director Letter responding to the Second Circuit's decision in *DeSario v. Thomas,* 139 F.3d 80 (1998), *vacated,* 525 U.S. 1098 (1999) (DeSario letter). It is necessary to reaffirm this rule because many states have failed to adhere to it. Advocates have identified and communicated to CMS numerous examples of states that have exclusive lists, categorically exclude "non-covered" items, and establish presumptions that certain items may never be covered, regardless of whether they otherwise fit a state's definition of medical supplies, equipment or appliances.

Also, as previously mentioned, states have categorically excluded certain items from coverage as medical equipment even though they meet the definition of medical equipment. For example, states exclude specific wheelchair components such as standing features, regardless of a recipient's medical need for such equipment. Some states have declared that speech-generating devices may only be covered under the optional speech-language pathology service category, which the state does not cover, and not under the mandatory home health benefit, despite the fact that they also meet the definition of medical equipment. States have denied coverage of any item that is physically attached to floors, walls, or ceilings (such as patient lifts), regardless of whether they fit the state's definition of medical equipment on the grounds that they are "home modifications" coverable only under a waiver. Coverage limitations such as these are contrary to Medicaid law and need to end.

Because of the extensive record of some states' failure to comply with this requirement, we are asking CMS to codify this rule. We agree, however, with CMS's statement that the principles set forth in the DeSario letter are not specific to home health medical equipment. 76 Fed. Reg. at 41034. In fact, as reflected in the many court decisions over several decades, the statutory and regulatory basis for the prohibition on exclusive lists set forth in the DeSario letter applies equally to all other Medicaid benefit categories, whether mandatory or optional. We therefore agree that it would be problematic to codify this rule solely in the context of home health medical equipment because it would suggest that the same principle does not apply to other services.

Accordingly, we propose that CMS amend 42 C.F.R. § 440.230, which governs amount, duration, and scope for all covered services. We propose that the current subsection (d) be renumbered as subsection (e). New subsection (d) and (f) should be added. The regulation would then read as follows (new proposed language in italics):

§ 440.230 Sufficiency of amount, duration, and scope.

(a) The plan must specify the amount, duration, and scope of each service that it provides for –

(1) The categorically needy; and
(2) Each covered group of medically needy.

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.

(d) *The agency may not have exclusive lists of covered services, lists of excluded items or services, or irrebuttable presumptions against coverage of particular services or items or categories thereof.*

(e) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.

(f) *The agency must provide a process for requesting items or services not specifically listed as covered that: (1)is timely; (2) employs reasonable criteria that are sufficiently specific to enable an individual to show that a particular service or item meets the definition of one or more covered benefits categories; and (3) provides for written notice to the recipient of the right to notice and hearing under part 431 to determine whether an adverse coverage decision is contrary to law.*

Face to face encounters

The proposed rule implements the requirement in Section 6047 of the Affordable Care Act (ACA) that health care practitioners document a face-to-face encounter with an individual before certifying that home health services are necessary. CMS has proposed that such an encounter must take place within the 90 days prior to or within 30 days after the start of services. 76 Fed. Reg. at 41038 (proposed § 440.70(f)(1)).

We believe that this time frame is appropriate for authorization of most types of home health services, but does not allow for sufficient time for more complicated medical equipment that requires evaluation by a physical or occupational therapist. In practice, a physician may see a patient and determine that there is a general need for a wheelchair. But, it is then necessary to refer the patient to a clinic or other facility for an evaluation, fitting, and other adjustments.

This can take more than 90 days, particularly because scheduling multiple appointments in that time frame will be a challenge given the busy schedules of clinics and providers. In addition, the necessity for providers to complete paperwork will add additional delays. Even though an additional face-to-face encounter may take place in the 30 days after the physician certifies necessity, requiring an additional doctor visit is not consistent with the ACA's goals of increasing efficiency and reducing costs. Accordingly, we recommend that the requisite time frame be extended to six months for medical equipment and appliances.

Thank you for your attention to these comments and please do not hesitate to contact Sarah Somers, at (919) 968-6308 ext. 102 or somers@healthlaw.org if you have questions.

Sincerely,

/s/
Emily Spitzer
Executive Director