August 28, 2013

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201
Attn: CMS-1526-P

Submitted electronically at: http://www.regulations.gov

Re: Durable Medical Equipment Provisions in the Proposed Rule for Medicare Program; End-Stage Renal Disease Prospective Payment System

Dear Administrator Tavenner:

The Advanced Medical Technology Association (AdvaMed) submits the following comments regarding two provisions of CMS-1526-P, Clarification of the Definition of Routinely Purchased Durable Medical Equipment (DME) and Clarification of the 3-Year Minimum Lifetime Requirement (MLR) for DME.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Definition of Routinely Purchased DME

The Centers for Medicare & Medicaid Services (CMS) proposes to reclassify about 80 HCPCS codes from the “routinely purchased” DME category to the “capped rental” category of DME. The reclassified items are listed in Table 11 of the proposed rule. In the accompanying regulatory impact analysis, CMS notes that the three highest volume affected items would be ultrasonic bone growth stimulator (E0760), speech generating device (E2510), and tilt in space manual wheelchair (E1161). In making this proposal, CMS argues that the existing regulation, which specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987, does not support the continued categorization of the items listed in Table 11 as “routinely purchased.”

AdvaMed strongly opposes the proposed reclassification of the affected products. We believe the problem is continued reliance on a decades-old regulation that is based on an assessment of Medicare claims for a period more than 25 years ago. The fact that newer products are not
represented in such claims data is, of course, to be expected. Thus, what CMS should do is update its regulation to reflect the current medical technology marketplace in order to acknowledge that products that have come to market during the past 25 years (and those that may come to market into the future) may actually have equal standing to be considered “routinely purchased” as those that were routinely purchased by Medicare beneficiaries in 1986 and 1987. This would be a much more reasonable approach than the one being proposed, especially since some of the affected products have actually been recognized as “routinely purchased” for one or more decades.

Further, CMS’ proposed reclassification will, at least in some cases, have the effect of disadvantaging newer products compared to competitor products in use 25 years ago. For example, by proposing two different classifications for long bone growth stimulators, “routinely purchased” for older technologies and “capped rental” for newer technologies, CMS would create a non-level playing field and penalize manufacturers that have brought or will bring to market new technologies whose benefit to patients has been established by high quality clinical studies.

It is also important for CMS to understand that at least some of the affected products have been approved by the FDA for single patient use only, and thus are not appropriate for rental to multiple beneficiaries. We suspect that this was one of the factors that led to an earlier decision by CMS that these products should be considered “routinely purchased.” CMS’s new proposal would thus conflict with FDA approval decisions and previous Medicare contractor judgments.

In the proposed rule, CMS specifically solicited comments on the effective date(s) for reclassifying the affected items and proposed a three-phase implementation schedule, in recognition of the fact that some of the items are or may be included in the Round 2 and/or Round 1 Recompete phases of the Medicare DME, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program. CMS also invited comment on the alternative of adopting a January 1, 2014 effective date for all affected items paid under the fee schedule. Given our preceding comments, AdvaMed believes that instead of adopting any effective date for the proposed reclassification, CMS should maintain the current product classifications that have been recognized by Medicare and update its regulations to make them compatible with the judgments previously made by Medicare contractors and staff regarding the DME classification of post-1987 products.

CMS estimates that the proposed reclassification would produce Federal savings of $20 million per year for FYs 2014, 2015 and 2016, $30 million for FY 2017 and $40 million for FY 2018. This estimate is based on an assumption that the reclassified products would be rented an average of 8 months (the average rental period for all capped rental DME over the 2009 through 2011 period). The products in question have been routinely purchased historically because they are expected to be needed for a very long period of time. In developing any estimate of savings, CMS should not have assumed that each affected product might be rented for only relatively brief periods rather than simply relying on average rental data for products that have not been routinely purchased historically.

Further, the projected savings presume the same utilization of DME, and do not consider changes in care that may occur from the proposal, such as increased hospitalizations for surgery. With
respect to ultrasound bone growth stimulators, in January 2013 the United Kingdom’s National Institute for Health and Care Excellence issued guidance stating that this technology is cost saving compared with current management, through avoiding surgery. Small declines in DME spending could be offset by much larger increases in spending elsewhere. We do not, therefore, believe that the reclassification will result in the savings estimated by the agency, and will instead impose administrative burdens on beneficiaries and suppliers related to the rental process.

In sum, AdvaMed urges CMS to withdraw the proposed reclassification of certain DME products.

3-Year Minimum Lifetime Requirement (MLR) for DME

On November 10, 2011, CMS issued a final rule in which it revised the definition of DME at §414.200 by adding a 3-year MLR effective January 1, 2012, that must be met by an item or device in order to be considered durable for the purpose of classifying an item under the Medicare benefit category for DME. At that time, CMS noted that the 3-year durability requirement would only apply to new products, and, to the extent that a modified product is not a new product, the 3-year MLR would not be applicable.

In the latest proposed rule, CMS provides limited additional guidance regarding this matter. More specifically, CMS notes that if a “grandfathered” DME product is modified (upgraded, refined, reengineered, etc.) after January 1, 2012, the item would still be classified as DME as a grandfathered item unless the modified product now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012. CMS provides the following as a specific example: equipment covered prior to January 1, 2012, and described by code X, has a life of at least 2 years and that item is modified after January 1, 2012 such that it no longer lasts 2 years; such modification would render the item “new” and it would be subject to the 3-year MLR.

AdvaMed believes that the grandfathering policy should be applied in a way that would allow continued Medicare coverage of “modified” products as DME even though they may continue to have an expected life of less than 3 years (as was historically the case before the products were modified). However, AdvaMed has concluded that the additional guidance in the proposed rule is inadequate and results in continuing uncertainty for manufacturers, suppliers and beneficiaries. We are further concerned that CMS might end up applying shortsighted, “line drawing” policies that would have the effect of discouraging manufacturer innovation with respect to product types long covered by Medicare as DME. Below we elaborate on our concerns.

First, CMS’ proposed clarification leaves unanswered some key questions regarding which products will continue to fall within the grandfathering provision. As such, it does not ensure that the three-year MLR will promote the innovation of existing technologies, which provide tremendous value to the Medicare program by improving the health of Medicare beneficiaries and lowering costs. Although CMS suggests that a “modified” product would include a product that has been “upgraded, refined, reengineered, etc.,” it does not provide further details regarding the extent of changes that could be made to an existing DME product such that it would still be subject to the grandfathering provision. In other words, the proposed rule does not provide
clarity on what is a completely “new” product that would never be subject to the grandfathering provision, and what would be considered a “modified” product that would be subject to the grandfathering provision provided that the modifications did not result in a reduced minimum lifetime of the product.

In AdvaMed’s August 26, 2011 comment letter on the original proposed rule for establishing a 3-year MLR, we raised many of the same issues enumerated above that remain unresolved in the new proposed rule. At that time, we recommended that CMS convene a study panel to allow stakeholders to collaborate with the agency in finding answers to these questions and to avoid a “one-size fits all” approach that fails to recognize the wide and complex array of DME products covered by the 3-year MLR.

We again urge that CMS convene this study panel to examine at a minimum the following central questions:

- Must a “modified” item fall within the same HCPCS code and/or DME product category as a grandfathered item in order for it to also fall within the grandfathering provision?
- Would a premarket approval (PMA) product approved after January 1, 2012 that is similar in structure and function to grandfathered products be considered a “modified” version of the grandfathered products? Is a newly-cleared 510(k) product considered to be a “modified” version of a predicate device?
- What modifications can be made to a grandfathered product (including products with disposable components) that would result in more efficient and effective medical treatments (and thereby improve the health of Medicare beneficiaries) but reduce the minimum lifetime of the product.

AdvaMed believes that, even with the agency’s proposed clarification to the grandfathering provision of the 3-year MLR, manufacturers will not be allowed to introduce technological advancements to their products without the threat of losing Medicare coverage. As a result, manufacturers will be discouraged from investing in medical innovation. AdvaMed recommends that CMS, in its continued implementation of the 3-year MLR, instead promote policies that create incentives for manufacturers to make innovative modifications to medical technologies that will improve the health of Medicare beneficiaries and thereby lower costs to the Medicare program.

We would be pleased to answer any questions regarding these comments. Please contact me at rprice@advamed.org or (202) 434-7227.

Sincerely,

Richard Price
Senior Vice President,
Payment and Health Care Delivery Policy