KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

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CMS Proposes to Change Definition of "Durable" for Medicare Durable Medical Equipment Coverage: Significant Implications for Manufacturers

On Friday, July 1, 2011, the Centers for Medicare and Medicaid Services (CMS) released a proposed rulemaking (hereinafter "Proposed Rule") that would have a significant impact on the categorical eligibility of certain types of durable medical equipment (DME) for Medicare coverage. *See* Proposed Rule. While the relevant provisions are intended to only apply prospectively for new products, the Proposed Rule would, if finalized, present serious problems for manufacturers of certain types of medical devices that do not have a minimum lifetime of three years. CMS is using the Proposed Rule to redefine the term "durable," presumably in an attempt to address legal vulnerabilities arising from several Medicare contractor determinations made earlier this year. The Proposed Rule will be published in the Federal Register on July 8, 2011. CMS will accept comments regarding the Proposed Rule until **August 30, 2011**.

Background

Since the inception of the DME benefit, manufacturers of medical devices have participated in an ad-hoc and uncertain process with CMS and local contractors to determine the length of time that medical "equipment must function in order to be considered 'durable.'" Under current regulations, for a product to become categorically eligible for coverage, the equipment must be "furnished by a supplier or a home health agency," able to "withstand repeated use," "primarily and customarily used to serve a medical purpose," "generally … not useful to an individual in the absence of an illness or injury," and "appropriate for use in the home." *See* 42 CFR 414.202. Notably, neither CMS regulations nor guidance documents define "minimum useful life." However, to date, CMS has generally not used this standard to make DME coverage determinations.

Over the past few months, CMS has been closely reviewing categories of DME to determine whether products in relevant categories meet the definition of durable. Through this review and CMS's conclusion that it needed additional guidance, the Agency has proposed adding a new sentence to the regulatory definition of DME. In addition to the previous criteria in the regulation, DME would have to have "an expected life of at least 3 years."

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Significantly, though, this requirement would only apply to "items classified as DME after" the effective date of the Final Rule.

Summary and Relevant Issues for Device and Drug Manufacturers

CMS's proposal to limit the category of DME that may be covered under the Medicare Program is sweeping in scope and quite controversial. First, it would establish a specific time component to the regulation that has not existed in the past. Arguably, the prospective universe of products that would meet the definition of "durable" would narrow significantly under CMS's Proposed Rule.

Second, the Agency's Proposed Rule creates groups of winners and losers without a rational basis. Existing technology and DME that meets the Agency's old definition of durability would presumably continue to be covered, but virtually identical products classified as DME or approved/cleared by the Food and Drug Administration (FDA) in the future would be excluded.

Third, the Proposed Rule leaves unresolved several ongoing disputes about certain products deemed not to have a long-enough reasonable useful life prior to the effective date of the Final Rule. Will CMS exclude additional devices as being non-durable prior to the Final Rule? Will the Agency overturn some of its recent DME decisions excluding from coverage certain devices with not long enough useful lives that lack strong bases in law?

Fourth, the Proposed Rule establishes a one-size-fits-all expected life standard, even though heretofore CMS had used varying standards for different DME categories. The Proposed Rule does not explain why it is creating one useful life standard rather than using different approaches in different contexts.

Fifth, CMS does not provide details about what it means when it limits the definition of DME to products "classified as DME" after the effective date of the Final Rule. How will CMS handle products that evolve, or improve their functionality? Will a new product that is placed within an existing DME billing and payment code be considered as "classified as DME" prior to the effective date of the Final Rule? In practical terms, how will the prospective-only application change the coding process?

In the Proposed Rule, the Agency emphasizes that "the 3-year minimum period of durability does not replace the RUL [reasonable useful life] standard established" under the DME payment rules. CMS indicates that "RUL rules are used to determine how often payment can be made for replacement items and is not a minimum lifetime requirement for determining whether an item is durable." *See* 42 U.S.C. 1395(m)(7)(C)(iii). According to CMS, the 3-year lifetime requirement is not necessarily "indicative of the typical or average lifespan of DME, which in many cases may last for much longer than 3 years."

The Proposed Rule does not explicitly modify the coverage rules for "attendant supplies" that are necessary for the use of DME. However, it does raise questions about how "multi-component" devices consisting of "durable and non-durable components" will be covered by Medicare. Specifically, CMS states that the "medically necessary function of the device" should be "durable" to ensure coverage and then asks for public comments on three different options for how categorical eligibility should be decided for multi-component devices. The three options on which CMS seeks comment are:

1. Apply the 3-year lifetime standard to the component(s) that perform the entire medically necessary function of the device.

2. Apply the 3-year lifetime standard to the component(s) that perform a vital part of the medically necessary function of the device.

3. Consider a device/system to be durable only if the cost of the durable component(s) over a period of time (for example, 5 years) makes up greater than 50 percent of the overall cost of the device/system over the same period.

CMS's Proposed Rule is certain to generate a great deal of controversy within many parts of the medical device community. Changing the definition of "durable" would impact medical device and pharmaceutical manufacturers alike; pharmaceutical manufacturers that make products administered through DME will want to evaluate carefully how their future DME products would be covered and what technology they may wish to rely upon. At a minimum, companies should consider submitting comments to CMS to outline their perspective regarding how the Proposed Rule should be modified.

CMS will accept comments regarding the Proposed Rule until **August 30, 2011**. King & Spalding possesses a great deal of experience representing medical device manufacturers and pharmaceutical manufacturers on Medicare coverage, coding, and payment issues. Attorneys on our FDA/Life Sciences and Health Care teams, as well as our National Appellate Practice, also possess extensive experience in challenging agency action in court. Our attorneys were intimately involved in the elimination of the least costly alternative policy and have represented clients on a number of high profile and precedent setting coverage, coding, and payment matters before the government. If you have any questions about the Proposed Rule, or if we can assist you in preparing comments, please contact us.