December 20, 2013

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
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Washington, DC 20201

Jonathan Blum, Deputy Administrator and Director
Centers for Medicare & Medicaid Services
Department of Health & Human Services
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Melanie Combs-Dyer, Acting Director for Provider Compliance Group
Centers for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Blvd.
Mail stop: C3-09-27
Baltimore, MD 21244

Re: Implementation of the Face-to-Face Encounter Requirements for Durable Medical Equipment

Dear Ms. Tavenner, Mr. Blum and Ms. Combs-Dyer,

The Advanced Medical Technology Association (AdvaMed) would like to raise a concern over the methods in which states are implementing the face-to-face requirement for certain items of durable medical equipment (DME) covered under the Medicaid program and how that compares to CMS’s delay of the requirement for Medicare. 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 produce the majority of the health care technology purchased annually in the United States and a significant share of that purchased annually around the world.

AdvaMed has supported provisions in the Affordable Care Act (ACA) (Section 6407) requiring that a physician or other specified non-physician practitioner have a documented face-to-face encounter with Medicare and Medicaid beneficiaries and conduct an evaluation of the patient to determine their need for certain items of DME. These in-person evaluations are essential for
ensuring that patients receive the items and equipment most appropriate for their medical conditions. They are also important for preserving the integrity of the Medicare and Medicaid equipment benefits.

Our September 4, 2012 comment letter to CMS on the proposed rule for implementing the face-to-face encounter requirement for Medicare covered DME made these points, and also argued that regulations should not create onerous burdens for providers. In that letter, we recommended that CMS consider a number of changes to the proposed rule for implementing the requirement and CMS incorporated several of our recommendations into the final rule. Among the changes we recommended at that time was a delay in the effective date of the final regulations for the face-to-face requirement for Medicare DME from January 1, 2013 to July 1, 2013, or such later date as found reasonable to provide adequate education to patients and providers about the new requirements. CMS has delayed the effective date of the final rules for the requirement two additional times, indicating this past September that it expects to enforce the DME face-to-face requirement at a date to be announced sometime in calendar year 2014.

AdvaMed was pleased to note in a proposed rule published in the Federal Register July 12, 2011, for implementing the ACA’s comparable face-to-face requirement that must apply to medical supplies, equipment, and appliances covered by Medicaid that CMS intended to maximize consistency with the Medicare program’s requirement in order to reduce administrative burden on the provider community. In this regard, CMS was following a provision in ACA that directed the Secretary to apply the face-to-face encounter requirement for Medicaid in the same manner and to the same extent as the requirements established for Medicare DME. The July 12, 2011 Medicaid rule proposed to apply the same requirements to Medicaid-covered medical supplies, equipment, and appliances as it would use for Medicare-covered DME. This rule has not yet been finalized.

AdvaMed has learned that in the absence of a final Medicaid rule for face-to-face encounters as well as the absence of an effective date for the Medicare rule, some States have moved ahead to establish their own face-to-face requirements. We have learned that three States have done so—Georgia, Kentucky, and Nevada—and that each of these States has established timelines and periodicity schedules for face-to-face encounters different from each other and different from the final rule that would apply to Medicare-covered DME.

Our concern with this development is the administrative burden it can create for practitioners and suppliers when CMS’s goal was to reduce this burden by maximizing consistency across Medicare and Medicaid. If States continue to establish their own face-to-face encounter rules that are different from the federal rules, practitioners could have two different sets of rules that would apply to the same item of DME. Suppliers providing DME in multiple states would have to worry about several sets of practitioner face-to-face encounter rules applying to their products. This is unnecessarily confusing and burdensome.

AdvaMed believes that sufficient time has passed for providers and patients to be educated about the new face-to-face encounter requirements. We urge CMS to announce a specific enforcement date for the Medicare requirements and also to finalize a rule that makes the Medicaid’s program’s face-to-face encounter requirements consistent with Medicare. In the interim, we also
urge CMS to encourage states to delay implementation until the Medicare implementation date is determined.

We thank you for considering these comments. Please contact Richard Price, Senior Vice President, Payment and Health Care Delivery Policy, at 202-434-7227, if you require assistance or have questions.

Sincerely,

/s/
Don May
Executive Vice President
Payment and Health Care Delivery Policy