COALITION OF

Wound Care Manufacturers

September 4, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1590–P
P.O. Box 8013
Baltimore, MD 21244–8013

Submitted Electronically

RE: CMS-1590-P- Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (Including DME Face-to-Face Encounters) CY 2013

Dear Acting Administrator Tavenner**:**

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the proposed rule regarding DME Face to Face Encounters. The Coalition represents leading manufacturers of surgical dressings and other medical devices and supplies used by Medicare beneficiaries for the treatment of wounds. Many of our members manufacture Negative Pressure Wound Therapy (NPWT) as well as Pneumatic Compression Devices– which are subject to this proposed rule and therefore have a vested interest in this policy. We appreciate the opportunity to offer our comments and have divided them into both general and specific issues.

GENERAL COMMENTS

The proposal permits the Secretary to require as a condition for payment that a face-to-face encounter between a beneficiary and his/her physician or qualified practitioner precede an order for specified items of durable medical equipment (DME) (Specified Covered Items). The proposed rule would also greatly expand the number of DME items that would require a written order prior to delivery. Currently, providers must obtain a detailed written order prior to delivery for only a handful of items identified by CMS in

5225 Pooks Hill Rd. • Suite 1626 N
Bethesda, MD 20814
301 530 7846 T • 301 530 7946 F
marcia@nusgartconsulting.com
www.nusgartconsulting.com

the Program Integrity Manual. The proposed rule would extend this requirement to oxygen equipment, wheelchair accessories, hospital beds and accessories and any other Specified Covered Items as defined under the proposed rule and identified by CMS in the *Federal Register*. Providers will also be required to obtain documentation from the beneficiary's physician that a face-to-face encounter with the beneficiary occurred as condition of payment of Specified Covered Items – including Negative Pressure Wound Therapy.

We believe that beneficiaries and discharge planners would face significant delays in the initiation of service because DME providers would be precluded from delivering DME until they have received a qualifying order from the physician. Our comments address these concerns and include recommendations intended to help CMS develop and implement a final rule that is appropriately targeted and does not impose unnecessary and duplicative documentation requirements that can result in delayed service to beneficiaries.

Medicare policy has historically been to permit providers to dispense DME in response to a physician's verbal order for the item. Typically, the physician communicates the order directly to the provider who, in turn, initiates intake and assessment based on a written confirmation of the physician's verbal order, which is later ratified by the physician's signature and date. The communication between the supplier and the physician's office ensures that the order is accurately conveyed to the provider and promotes the timely delivery of services consistent with the beneficiary's medical need. Because providers may not bill Medicare for the item until they have a written order from the physician, the Medicare program is protected from any improper utilization or other abusive practices. This policy strikes a balance between CMS' need to ensure program integrity and a beneficiary's usually urgent need for the medical equipment. With the exception of a handful of specific items that require a written order prior to delivery to the beneficiary, CMS policy has recognized the value in permitting suppliers to begin servicing beneficiaries based on the physician's verbal order.

The proposed rule would disrupt this balance by requiring providers to have a written order prior to delivery for Specified Covered Items as defined under the proposed rule. Moreover, the written order must meet the criteria identified under the rule. If any of the required elements are missing or incomplete, the provider must return the order to the physician to get a qualifying order before he/she delivers the equipment in order to get paid. Providers would be required to obtain a written order prior to delivery for all of the Specified Covered Items identified in the proposed rule. Many of these items are DME items necessary to facilitate a beneficiary's transition from the hospital to the home. Should the proposed rule become final, it is fair to conclude that providers will be unable to meet discharge planners' expectation that equipment delivery occur within approximately two hours so patients can be discharged and sent home.

At a minimum, the requirement that providers obtain a written order prior to delivery of Specified Covered Items poses an inconvenience to hospitals and beneficiaries who

desire to go home. In some cases, the delay in discharging a beneficiary and the attendant costs could pose a hardship for beneficiaries. We believe that it is unnecessary for the Agency to impose a new hurdle for beneficiaries who need medical equipment, especially for DME items covered under a national or local coverage determination (NCD or LCD respectively) that already requires the beneficiary to have a face-to-face encounter with his or her physician. Designating these items as Specified Covered Items and requiring providers also to obtain a written order prior to delivery of the items does not give the Agency greater assurance than it currently has that the items are not procured through abuse or fraud.

The overwhelming majority of orders for DME are already made in an appropriate medical context. That is, DME is typically ordered as part of a beneficiary's routine medical care consistent with coverage determinations issued by CMS and its contractors. Consequently, it is unnecessary for CMS to create additional in-person evaluation or documentation requirements for many categories of DME. Moreover, when DME is ordered on discharge from an inpatient stay, it is likewise unnecessary for CMS to impose an additional face-to-face physician visit or documentation requirement because the beneficiary's need for equipment would have been evaluated during the stay.

Furthermore, as CMS implicitly acknowledges in the preamble to the proposed rule, the statute does not compel the Secretary to require a written order prior to delivery for all DME. Rather, the Secretary "is authorized" to require a written order prior to delivery for DME items that are "specified covered items." However, for any DME items the Secretary identifies as Specified Covered Items, she is obligated to require documentation by a physician that the order is based on a face-to-face encounter between the beneficiary and an authorized practitioner. The statute states that for any DME that the Secretary designates as a Specified Covered Item, she "shall" require that "such an order be written pursuant to the physician documenting that a physician, physician assistant, a nurse practitioner, or a clinical nurse specialist . . . has had a face-to-face encounter with the [beneficiary] . . ."

Adding new items of DME to list of items that require a written order prior to delivery will delay beneficiaries' access to medically necessary medical equipment, delay hospital discharges, and increase the administrative burden for physicians and DME providers. Physicians, in particular, will face new pressure from DME providers and hospitals to complete a written order that meets Medicare requirements in a much shorter time frame than they do now. For busy physician offices, this added burden will not be easily offset by the payment amount proposed under the rule. Importantly, any additional program integrity benefits will be marginal at best and will not outweigh the overall costs of imposing new documentation burdens on physicians and DME providers that will ultimately impact beneficiaries and hospitals in the delivery and continuity of care.

SPECIFIC COMMENTS

FACE-TO-FACE ENCOUNTER WITHIN 90 DAYS OF THE WRITTEN ORDER IS TOO RESTRICTIVE

The requirement for a face-to-face encounter represents a significant practice change for both physicians and beneficiaries. For beneficiaries with multiple conditions that may require Specified Covered Items, extra required visits to the MD can represent a significant burden in terms of transportation, physical demand, and financial obligation. Physicians and other practitioners are currently burdened with overbooked practices and extensive documentation requirements. As a result, DME suppliers already have difficulty in obtaining required documentation for ordered medical equipment from physician offices. The proposed timeline for the encounter to occur within 90 days prior to the written order will increase the burden for both beneficiaries and physicians. Also, many Medicare patients have chronic conditions for which they see their doctor every 4-6 months, at which time the various chronic conditions are evaluated and potential treatment courses are implemented. During the treatment course, if more conservative approaches fail, the need for a Specified Covered Item may arise, which may well be beyond 90 days from the visit where the condition requiring treatment was initially discussed. Expanding the timeframe for visits before the written order to 6 months as contemplated by the ACA allows the beneficiary and physician more flexibility.

The face-to-face encounter should not be allowed to occur after the written order and delivery of the Specified Covered Item. Neither the beneficiary nor the physician has much impetus to follow through with the encounter once the equipment is delivered, and the supplier is then unable to bill Medicare. If the face-to-face encounter is a condition of payment for a Specified Covered Item, then the encounter should occur before the supplier takes the financial risk of placing the equipment.

DELAY EFFECTIVE DATE OF FINAL RULE TO ALLOW FOR ADEQUATE TRAINING/NOTIFICATION OF PHYSICIANS AND BENEFICIARIES

The effective date of the final rule should be delayed at least until mid 2013 and perhaps later, to allow for the extensive training and notification of both physicians and beneficiaries. This is a significant change for physicians to incorporate into practice; getting physician documentation for DME is already a challenge for both suppliers and beneficiaries. We understand that CMS plans for extensive education on this issue however we are concerned that the time remaining in 2012 is inadequate to provide the robust training needed to ensure understanding of and compliance with this new rule. Delaying implementation of the rule until at least July 2013 allows adequate time for notification and training of physicians and beneficiaries.

PHYSICIANS MUST BE HELD RESPONSIBLE FOR COMPLYING WITH THE FACE-TO-FACE ENCOUNTER REQUIREMENT AND ASSOCIATED DOCUMENTATION

Medical suppliers of Medicare-covered equipment with extensive documentation requirements (such as detailed in a LCD or NCD) are already often challenged in obtaining required documentation from prescribing physicians. The face-to-face encounter requirement adds another level of complexity for all stakeholders. Physicians seem unaware of or unconcerned that the DME supplier cannot be paid by Medicare for equipment provided unless the physician's documentation meets requirements. To avoid jeopardizing Medicare beneficiary access to needed equipment, CMS must clearly communicate that the physician who signs off on the order for a Specified Covered Item is responsible for ensuring that the face-to-face encounter requirement is met and for submitting the required documentation directly to the DME supplier. The DME supplier should not be responsible for scheduling face- to-face visits to ensure the requirement is met. Physicians who are continually noncompliant with the rule should be subject to corrective action.

LOW COST ACCESSORIES SHOULD NOT BE PART OF THE FINAL RULE'S LIST OF SPECIFIED COVERED ITEMS

Finally, the current proposed list of Specified Covered Items includes equipment that have a fee schedule well below $1000, including accessories to the primary equipment. As an example, HCPCS code E0669 (half leg garment to be used with pneumatic compression device) payment rate is between $167 and $196. These types of items are accessories to the primary equipment (including E0651 and E0652). Similarly E0651 utilizes accessories as well. To require a separate face-to-face encounter to document need for an accessory for primary equipment already vetted in a previous face-to –face encounter and currently in the possession of the beneficiary seems unduly burdensome. We would suggest that these types of low cost accessories (including HCPCS E0655 – E0673) be removed from the final list as the cost of the face-to-face encounter outweighs any potential benefit to the Medicare program.

COALITION'S RECOMMENDATIONS

The Coalition recommends the following:

1. CMS exercise its discretion to exclude from the list of Specified Covered Items any items necessary to ensure a safe discharge from an inpatient stay and

continuity of care. These include the following: wheelchairs, implantable and external infusion pumps, hospital beds and accessories, glucose monitors, nebulizers, negative pressure wound therapy (NPWT), pneumatic compression devices (and associated low cost accessories as noted above) and ambulatory items as well as accessories for primary equipment already vetted in a previous face-to-face encounter.

2. CMS should delay implementation of the rule until at least July 2013 to allow adequate time for notification and training of physicians and beneficiaries.

CONCLUSION

The Coalition appreciates the opportunity to provide our comments on this very important provision in the physician fee schedule proposed rule. The Coalition believes that physicians and Medicare beneficiaries should have timely access to DME- in which we believe this proposed rule would greatly impact. If you need further information or have any questions, please do not hesitate to contact me.

Sincerely,

Karen S Ravitz, JD
Senior Policy Advisory