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September 4, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; Proposed Rules Centers for Medicare & Medicaid Services (CMS) 42 CFR Parts 410, 414, 415, 421, 423,425, 486, and 495 [CMS–1590–P] RIN 0938– AR11**[1]

Dear Acting Administrator Tavenner:

The American Association for Homecare (AAHomecare) submits comments on the above captioned proposed rule that implements §6407 of the Patient Protection and Affordable Care Act (ACA), which amends §1834(a)(13) of the Social Security Act.[2] Section 1834(a) as amended 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).[3] 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

[1] 77 Federal Register 4722 (Monday, July 30, 2012).
[2] 42 USC 1395m(13).
[3] 42 CFR § 410.38(g)(2), proposed.

written order prior to delivery for only a handful of items identified by CMS in the Program Integrity Manual (PIM).[4] 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.

AAHomecare represents durable medical equipment providers, manufacturers, and others in the homecare community that serve the medical needs of millions of Americans who require oxygen therapy, wheelchairs, medical supplies, inhalation drug therapy, and other medical equipment and services in their homes. AAHomecare members operate more than 3,000 homecare locations in all 50 states. In light of our members' expertise and experience, the Association is uniquely qualified to comment above captioned proposed rule.

Given the number and types of medical equipment and the many conditions for which it might be prescribed, AAHomecare is concerned that the proposed rule would create significant challenges and expense for CMS, beneficiaries, and DME providers alike. In particular, 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 face-to-face 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 and delays in discharges from in-patient facilities.

AAHomecare is confident that 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. We discuss these recommendations and others in more detail below.

I. COMMENTS

A. Expanding the Number of DME Items That Require a Written Order Prior to Delivery Is Unnecessary and Will Significantly Delay Service to Medicare Beneficiaries

1. Expanding the Number of DME Items That Require a Written Order Prior to Delivery Will Delay Services to Beneficiaries

[4] Program Integrity Manual (PIM), Internet Only Manuals (IOM), 100-8 Chapter 5, available at: http://cms.gov.

Longstanding Medicare policy has been to permit providers to furnish DME in response to a physician's verbal or written preliminary order for the item.[5] 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 preliminary order, which is later ratified by the physician's signature and date.[6] 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 or Certificate of Medical Necessity signed by the physician, the Medicare program is protected from any improper utilization or other abusive practices.[7]

This policy has served the Medicare program and beneficiaries well by striking a balance between CMS' need to ensure program integrity and a beneficiary's usually urgent medical need for the equipment. With the exception of a handful of specific items that require a written order prior to delivery to the beneficiary,[8] CMS policy has recognized the value in permitting providers to begin servicing beneficiaries based on the physician's preliminary order. Otherwise, beneficiaries in need of life-sustaining medical equipment such as oxygen would be required to wait for the equipment until the provider receives a written order from the physician.[9]

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, like oxygen and hospital beds, 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. More importantly, the discharge planner cannot safely discharge the beneficiary home without the equipment.

At a minimum, the requirement that providers obtain a written order prior to delivery of Specified Covered Items poses an inconvenience to inpatient facilities such as hospitals, skilled nursing and rehab facilities, 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. AAHomecare believes that it is

[5] Chapter 5, Medicare Program Integrity Manual (PIM), 100-8, available at: http://www.cms.gov.
[6] *Id*.
[7] *Id*. OIG Compliance Guidance for DMEPOS Suppliers, 64 Fed. Reg. 36368 (June 6, 1999).
[8] Chapter 5, Medicare Program Integrity Manual (PIM), 100-8.
[9] In 2004, CMS proposed requiring a written order for all DME prior to delivery to the beneficiary. In response to public comments, CMS did not finalize that proposal. CMS did, however, require a written order prior to delivery for power mobility devices. *See* Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles; 71 Fed. Reg. 17021 (April 5, 2006).

unnecessary for the Agency to create 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 any greater assurance than it currently has that the items are not procured through abuse or fraud.

2. Expanding the List of DME Items That Require a Written Order Prior to Delivery Is Unnecessary

Section 1834(a)(13) of the Social Security Act as amended by §6407 authorizes the Secretary to identify specified items of DME for which the provider must have a written order before delivering the item to the beneficiary. As CMS 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."[10] However, for any DME items the Secretary identifies as a Specified Covered Item, she is obligated to require documentation by a physician that the order was 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] . . .."[11]

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

[10] §1395m(13)(B)(i) states:

(B) Requirement of physician order

(i) In general

The Secretary ***is authorized*** to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1395cc(j) of this title or an eligible professional under section 1395w-4(k)(3)(B) of this title that is enrolled under section 1395cc(j) of this title has communicated to the supplier, before delivery of the item, a written order for the item. (Emphasis supplied).

[11] § 1395m (13) (B) (ii), states:

(ii) Requirement for face to face encounter

The Secretary ***shall require*** that such an order be written pursuant to the physician documenting that a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary. (Emphasis supplied).

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 timeframe 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. Beneficiaries and facilities stand to bear the burden of these new requirements as a result of disruption to delivery and continuity of care.

AAHomecare recommends that CMS exercise its discretion to exclude from the list of Specified Covered Items any DME covered under an NCD or LCD that requires a physician to see the beneficiary before ordering the item. These include oxygen and oxygen equipment and all ventilators including CPAPs and RADs. Additionally, any items necessary to ensure a safe discharge from an inpatient stay and preserve continuity of care, including wheelchairs, infusion pumps, hospital beds and accessories, glucose monitors, nebulizers, negative pressure wound therapy (NPWT), and ambulatory items, should also be excluded from the list of Specified Covered Items.

Moreover, because many of these items already require an in-person encounter between a physician and the beneficiary, requiring an additional face-to-encounter would be duplicative and would increase overall expenses to the system. Beneficiaries with chronic, progressive conditions may not see their physicians in the precise intervals contemplated under the proposed rule, forcing the beneficiary to make a return visit to the doctor. For some specialties such as pulmonology, our members report that beneficiaries face long waiting times for appointments. As we noted above, beneficiaries will bear the weight of the new documentation requirements with increased out-of-pocket costs and delays in the initiation of services.

Wheelchair accessories should also be removed from the Specified Covered Items list. As CMS states in the preamble, power mobility devices (PMD) already require a written order prior to delivery and are subject to an NCD and LCD that impose extensive medical necessity documentation requirements. Complex rehabilitative wheelchairs are also subject to extensive medical necessity assessment and documentation requirements. AAHomecare believes that, in light of the strict documentation standards in place for the base equipment, any program integrity benefits of requiring a face-to-face encounter and a written order prior to delivery for these wheelchairs and accessories are only marginal at best and do not outweigh the burden of documentation costs to physicians and DME providers or costs for delays in hospital discharges.

B. Documentation and Timing of the Face-to-Face Encounter Should Depend on Where the Encounter Occurred

1. Inpatient Stays

As we stated above, AAHomecare recommends that CMS exercise its discretion to limit the number of Specified Covered Items. Specifically, AAHomecare recommends that CMS exclude items like oxygen equipment, CPAPs, RADs, and other respiratory equipment for which an NCD or LCD requires a beneficiary be seen by a physician prior to the order. DME necessary to facilitate a safe discharge from an inpatient stay to the home and preserve continuity of care, including hospital beds and accessories, wheelchairs and accessories, implantable and external infusion pumps, glucose monitors, nebulizers, NPWT, and ambulatory items, should also be excluded items.

Generally, DME ordered for discharge from an inpatient stay will fall into one of the categories above and should not be a Specified Covered Item. However, to the extent a Specified Covered Item is ordered for discharge from an inpatient stay, we recommend that CMS treat evidence that the order was the result of the stay as adequate documentation that a face-to-face encounter occurred. Under these circumstances, the beneficiary's need for the DME would have been assessed during the stay and requiring additional document of the encounter would be duplicative and of little additional value. Further, a beneficiary may have been followed by hospitalists or other professionals who are qualified to evaluate a beneficiary for equipment within their scope of practice under state law. Consequently, when an assessment occurs during an inpatient stay, the clinician's evaluation, which is affirmed by the physician order, should be sufficient documentation of a face-to-face encounter.[12]

2. Timing

Requiring a face-to-face encounter to occur in the 90 days before the physician or practitioner orders the Specified Covered Item would generally be adequate. However, most beneficiaries who receive Specified Covered Items have chronic or progressive conditions for which they may see a physician only one or twice a year. DME providers should be able to rely on a documented face-face-face encounter that occurred up to six-months from the date of order if the encounter was for the condition or related to the condition that gives rise to the need for DME. Further, because Specified Covered Items require both a written order prior to delivery and documentation of a face-to-face encounter, it would be logically impossible for the written order to be the result of a face-to-face encounter if the encounter has not occurred at the time the order is written. Moreover, it is not reasonable to expect providers to furnish the item without documentation that the in-person encounter took place. Once a beneficiary has received the Specified Covered Item, he or she has little incentive to see the doctor. The provider, meanwhile, will not be paid for the item unless he/she has obtained a signed Advance Beneficiary Notice of Noncoverage (ABN) from the beneficiary.

CMS should not impose a physician visit requirement for prescription renewals, supplies used with the device, and repairs or replacement of equipment, as Congress' interest in ensuring the physician has

[12] AAHomecare understands that §1834(a) limits the practitioners who may perform the face-to-face encounter. We note, however, that beneficiaries under a home health plan of care are, by definition, homebound and cannot leave the home to see a physician. For Specified Covered Items ordered during a home health episode, CMS should accept documentation of the face-to-face encounter for home health if the item ordered is related to the reason necessitating the home health care.

evaluated the patient's need for a Specified Covered Item has already been met with the initial face-to-face evaluation conducted at the time the device or item was initially prescribed.

3. Documentation and Communication of the Face-to-Face Encounter

The in-person visit should be recorded in the patient's medical record. Moreover, it should be sufficient for the fact of the visit to be recorded as long as the beneficiary otherwise meets all the qualifying criteria for the Specified Covered Item that is ordered. Because each Specified Covered Item will have different qualifying criteria, it is not feasible to have one form that applies to each one. When the encounter is performed by someone other than physician, DME providers should receive a copy of the medical record documenting the encounter. AAHomecare sees little value in having a form that documents only that the encounter occurred if the DME provider will also be required to produce medical record documentation to support the assessment performed during the encounter. Consequently, AAHomecare recommends that CMS adopt either option 2 or 3, which would require the physician to initial or sign the portion of the medical record that documents that the face-to-face encounter occurred.

AAHomecare would also like to emphasize that the Association is committed to working with CMS to develop standardized documentation elements applicable to specific DME items. A standardized form that documents the elements CMS and its contractors require for coverage of a DME item should be recognized by CMS as part of the beneficiary's medical record and should establish the beneficiary's medical need for the item. Without this type of form, CMS is unlikely to see a meaningful reduction in the DMEPOS error rate because contractors have free rein to make *ad hoc* changes to coverage or documentation policies or to impose their own interpretive gloss on policies, often retroactively. AAHomecare would like to work with CMS to move forward on this issue.

Both the medical record documenting the encounter and the written order should be communicated to the DME provider in writing prior to the delivery of the Specified Covered Item. The written order and the documentation of the face-to-face encounter should be communicated to the DME provider from the physician practice ordering the Specified Covered Item.

C. CMS Should Hold Physicians Accountable for Documenting the Face-to-Face Encounter

AAHomecare agrees that CMS should compensate physicians for their time in documenting the face-to-face encounter. However, we question whether the proposed $15.00 payment amount will be adequate. For Specified Covered Items, the physician must provide a written order prior to delivery in addition to documentation of the encounter. We also recommend that that CMS compensate physicians for complying with all documentation requirements proposed under the rule, not just for documenting the encounter performed by another practitioner. Under the proposed rule, physicians will be required to communicate a written order and other documentation as well as provide more extensive documentation in a much shorter timeframe than they have been required to do in the past.

AAHomecare believes that it is imperative for CMS to ensure that physicians have an adequate incentive to furnish the written order and documentation of the encounter to the DME provider promptly. Equally important, CMS must hold physicians accountable for documenting the face-to-face encounter in a manner that complies with CMS documentation standards. Physicians should understand that they too are responsible when CMS or its contractors determine that the documentation is inadequate to support payment for the Specified Covered Item. Physicians who repeatedly furnish a DME provider with noncompliant documentation should face sanctions. Finally, CMS should commit to an aggressive education campaign targeting physicians at least six months before the rule's effective date.

II. CMS MUST HAVE STANDARDS FOR TERMINATING NON-RANDOM PREPAYMENT COMPLEX MEDICAL REVIEW

AAHomecare understands that CMS is no longer mandated to provide an end date for providers under non-random prepayment complex medical review. We recommend that the Agency exercise its discretion to implement standards that contractors must follow when they place providers on non-random complex prepayment medical review. Prepayment review cuts a provider's cash flow, affecting its ability to furnish services to beneficiaries. A provider that is placed on prepayment review for an extended period may be forced to close its business. In fact, AAHomecare is aware of providers that closed as a result of contractors' aggressive prepayment audit strategies.

Without some reasonable limitation on contractors' ability to place a provider on prepayment review, AAHomecare is concerned that will act as if they have *carte blanche* to place providers on prepayment review indefinitely. Providers also have a right to know what benchmarks they must meet to be removed from prepayment review. Our members' recent experience with prepayment audits confirms that contractors do not or cannot articulate the thresholds they must meet to be taken off prepayment review. Moreover, without standards, contractors will vary in what they require to remove a provider from the requirement of complex prepayment medical review.

III. CONCLUSION

To reiterate, adding new items of DME to the 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 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 and furnish documentation of the in-person encounter in a very short timeframe. 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. These burdens would threaten the timely delivery and continuity of care for beneficiaries and increase costs to hospitals and other in-patient facilities that need to discharge Medicare beneficiaries promptly.

Consequently, AAHomecare recommends that CMS exercise its discretion to exclude from the list of Specified Covered items:

- DME covered under an NCD or LCD that requires that a physician see the beneficiary before ordering the item. These include oxygen and oxygen equipment and all ventilators including CPAPs and RADs;
- DME necessary to ensure a safe discharge from an inpatient stay and continuity of care including wheelchairs, infusion pumps, hospital beds and accessories, glucose monitors, nebulizers, NPWT, and ambulatory items;
- Wheelchair accessories; and,
- DME ordered for discharge from an inpatient stay because the beneficiary's need for the DME would have been assessed during the stay.

CMS also should not permit the face-to-face encounter to occur after the item is ordered because Specified Covered Items require both a written order prior to delivery and documentation that the order was the result of a face-to-face encounter. Further, we see little value in having a form that documents only that the face-to-face encounter occurred if the DME provider will also be required to produce medical record documentation of the encounter. Consequently, we recommend that CMS adopt either option 2 or 3, which would require the physician to initial or sign the portion of the medical record that documents that the face-to-face encounter occurred. The medical records documenting the encounter should be communicated to the DME provider prior to the delivery of the Specified Covered Item along with the written order.

Finally, AAHomecare recommends that CMS compensate physicians for documenting the face-to-face encounter and communicating the documentation and the written order to the DME provider. Importantly, this compensation must be sufficient to ensure that the physician complies with the rule. Physicians, moreover, should be held accountable for failing to furnish the DME provider with documentation that meets CMS standards.

AAHomecare appreciates the opportunity to submit these comments. Please feel free to contact me if you have any questions about the issues we raised above.

Sincerely,

Walter J. Gorski
Vice President of Government Affairs