



Caring that Feels Right at Home

Via Electronic Submission

August 24, 2010

Donald Berwick, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule [CMS-1503-P] (75 Fed. Reg. 40039, July 13, 2010).

Dear Dr. Berwick:

The American Association for Homecare (AAHomecare) submits the following comments on the above captioned proposed rule.

AAHomecare is the only national association representing every line of medical equipment and services within the homecare community. The Association represents health care providers and manufacturers that serve the medical needs of Americans who require durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) such as oxygen equipment and therapy, sleep therapy technologies, mobility assistive technologies, diabetes therapy and other supplies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services, and supplies in their homes. Our membership reflects a cross-section of the homecare community, including national, regional, and local providers. With approximately 500 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value of quality health care services furnished to patients in their homes.

The proposed rule would make several changes to Medicare DMEPOS payment policy and the administration of the competitive bidding program (CBP) for DMEPOS items. Specifically, the proposed rule would:

- Adjust the formula for calculating the annual update for DMEPOS items;
- Eliminate the first-month purchase option for standard power wheelchairs;
- Modify payment policy for oxygen equipment for beneficiaries who relocate their residence outside the provider's service area;

- Eliminate transition payments for oxygen and capped rental equipment when beneficiaries change providers;
- Add an appeals process for contract providers terminated from CBP;
- Authorize the implementation of a national mail order competition for diabetes supplies; and
- Establish additional rules for diabetes supplies (50 percent rule and anti-switching rule.)

We discuss these issues in detail below.

I. COMMENTS

A. Payment Rules for Power Wheelchairs

Section 3136 of the Patient Protection and Affordable Care Act (ACA) of 2010 revised the payment methodology for power wheelchairs. Specifically, ACA modifies the methodology for establishing the monthly payment amount and eliminates the first-month purchase option for standard power wheelchairs effective January 1, 2011.

We are very concerned about the financial and administrative burdens along with policy-related issues that have not been considered following the elimination of the first-month purchase option. AAHomecare understands that Congress established this new payment policy and that CMS is required to implement the statute. However, we believe that it would be worthwhile to highlight our concerns with the policy in these comments.

For power wheelchairs furnished on or after January 1, 1991, section 1834(a)(7) of the Social Security Act (the Act), as amended by section 4152(c)(2) (D) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508), mandates that the provider of the power wheelchair offer the patient the option to purchase rather than rent the item. Since 1991, more than 95 percent of Medicare beneficiaries have exercised this lump sum purchase option for power wheelchairs. As such, we believe that the timelines, guidelines, and documentation requirements outlined in policy for accurate claims processing of power-driven wheelchairs is predicated on the management of lump sum payment and must be revised prior to implementation of these new payment requirements.

1. Short-Term Rental

As reflected in the requirements outlined in the Power Mobility Device (PMD) Local Coverage Determination (LCD), a PMD will be denied as not medically necessary if the underlying condition is reversible and the length of need is less than 3 months (e.g., following lower extremity surgery which limits ambulation). There is no precedent that precludes the short-term rental of other medically necessary durable medical equipment (DME) under the capped rental policy; therefore,

1. How will this policy limitation be revised to allow short term rentals (1 – 3 months) for a power wheelchair with the elimination of the first month purchase option for Group 1 and Group 2 standard power wheelchairs?
2. Under what circumstances, if any, will a short term (1 – 3 months) rental be precluded?

3. What documentation would be required if the physician prescribes a power wheelchair for short-term use (i.e., 2 months) and the beneficiary requires an additional 2 - 11 months of use?

2. Break in Service

By way of background, as reflected in the requirements outlined in the PMD LCD and Policy Article, all of the following is required at initial issue of a power wheelchair:

The treating physician must conduct a face-to-face examination of the patient before writing the order. Physicians shall document the examination in a detailed narrative note in their charts in the format that they use for other entries. The note must clearly indicate that a major reason for the visit was a mobility examination. A date stamp or equivalent must be used to document the date that the provider receives the report of the face-to-face examination. The written order that the provider must receive within 45 days after completion of the face-to-face examination must contain all of the following elements:

- Beneficiary's name
- Description of item ordered- This may be general - e.g., "power operated vehicle", "power wheelchair", or "power mobility device"- or may be more specific
- Date of the face-to-face examination
- Pertinent diagnoses/conditions that relate to the need for the POV or power wheelchair
- Length of need
- Physician's signature
- Date of physician signature

Once the provider has determined the specific power mobility device that is appropriate for the patient based on the physician's order, the provider must prepare a written document (termed a detailed product description) that lists the wheelchair base and all options and accessories that will be separately billed. For the wheelchair base and each option/accessory, the provider must enter all of the following:

- HCPCS code
- Narrative description of the item
- Manufacturer name and model name/number
- Provider's charge
- Medicare fee schedule allowance

Prior to or at the time of delivery of a PWC, the provider must perform an on-site evaluation of the patient's home to verify that the patient can adequately maneuver the device that is provided considering physical layout, doorway width, doorway thresholds, and surfaces. Please note that this requirement is only applicable to power wheelchairs and no other rented DME.

This process is executed once for Medicare beneficiaries who exercise the option to purchase their power wheelchair in the first month, and providers submit a claim for lump sum payment from the Medicare trust fund, appending the KX modifier, indicating that these statutory requirements have been met. Currently there is no guidance in the LCD, policy article for power mobility devices, or in the Program Integrity Manual (PIM) with regard to the documentation requirements for monthly billing of power wheelchairs when there is a continuous need or when a break in service occurs.

For a beneficiary with a lifetime medical need –

1. What documentation will be required for a break in service ≤ 30 days, > 30 days but ≤ 60 days, and > 60 days with no change in condition?
 - a. What will constitute a continuation of the current rental period and an uninterrupted billing cycle?
 - b. What will constitute a continuation of the current rental period but require a new billing date in subsequent months?
 - c. What will constitute a new rental period starting at month 1?
 - d. Does the physician need to re-certify if there is no change in condition?
 - e. Under what circumstance are a new face-to-face examination, written order, and detailed product description required?
 - f. If the beneficiary returns home and the same model power wheelchair is provided post-discharge from a hospital (or skilled facility), or the original power wheelchair provided to the beneficiary was not picked up by the provider during the hospital stay, is a new home evaluation required?
 - g. If the beneficiary returns home but a different model power wheelchair with the same HCPCS code is provided post-discharge from a hospital (or skilled facility), is a new home evaluation required?

2. What documentation will be required for a break in service ≤ 30 days, > 30 days but ≤ 60 days, and > 60 days with a change in condition that does not meet the coverage criteria for a complex (K0835 or higher) rehab power wheelchair?
 - a. What will constitute a continuation of the current rental period and an uninterrupted billing cycle?
 - b. What will constitute a continuation of the current rental period but require a new billing date in subsequent months?
 - c. What will constitute a new rental period starting at month 1?
 - d. If this is considered a new rental period, will a new face-to-face examination, written order and detailed product description be required?
 - e. How is the physician to document the change in condition and communicate that information to the provider?
 - f. Assuming change in condition does not change the HCPCS code of the base-
 - i. If the beneficiary returns home and the same model power wheelchair is provided post-discharge from a hospital (or skilled facility), or the original power wheelchair provided to the beneficiary was not picked up by the provider during the hospital stay, is a new home evaluation required?

- ii. If the beneficiary returns home but a different model power wheelchair with the same HCPCS code is provided post discharge from a hospital (or skilled facility), will a new home evaluation be required?
- g. If the change in condition changes the HCPCS code of the base, will this constitute a new rental period starting at month 1?
 - i. K0823 to a K0822 with a skin protection cushion?
 - ii. K0823 to a K0825 (heavy duty)?

For beneficiary with a short-term (1-3 months) need –assuming short term rental will be permissible under the new requirements.

1. What documentation will be required for a break in service ≤ 30 days, > 30 days but ≤ 60 days, and > 60 days with no change in condition?
2. What documentation will be required for a break in service ≤ 30 days, > 30 days but ≤ 60 days, and > 60 days with a change in condition that does not meet the coverage criteria for a complex (K0835 or higher) rehab power wheelchair?

3. Claims Processing and Accuracy of Payment

ACA mandated the rental payment methodology for standard power wheelchairs, which is different from the payment methodology of power wheelchairs defined as “complex rehabilitative power-driven wheelchairs.”

Currently the GZ modifier must be used when physicians, practitioners, or providers want to indicate that they expect that Medicare will deny an item or service as not reasonable and necessary and they **have not** had an Advance Beneficiary Notice of Noncoverage (ABN) signed by the beneficiary. The GA modifier must be used when providers want to indicate that they expect that Medicare will deny an item or supply as not reasonable and necessary and they **do have on file** an ABN signed by the beneficiary.

The GK and GL modifiers are used when providers provide an upgrade – i.e., an item that goes beyond what is covered by Medicare. The descriptions of the modifiers are:

- GK - Reasonable and necessary item/service associated with a GA or GZ modifier
- GL - Medically unnecessary upgrade provided instead of non-upgraded item, no charge, no ABN.

If the beneficiary does not meet the coverage criteria specified in the medical policy for the item that is provided but does meet the criteria for a different type of device, the GK or GL modifier must be used. Providers decide which modifier to use depending on whether or not they want to collect the difference between the submitted charge for the upgraded item and the submitted charge for the item that meets coverage criteria from the beneficiary.

For Medicare payment purposes, power-driven wheelchairs are classified under various codes in the Healthcare Common Procedure Coding System (HCPCS) based on the level of performance

and functional characteristics of each power wheelchair that accommodate the specific needs of beneficiaries.

The DMEPOS Quality Standards mandate that providers ensure the beneficiary and/or caregiver(s) can use all equipment and item(s) provided safely and effectively in the settings of anticipated use. The provision of a complex rehabilitative power wheelchair may be prescribed, required, or requested to meet this mandate, and payment instructions must be provided for accuracy in claims processing prior to the implementation of Section 3136.

1. Will power wheelchairs coded K0830 and K0831 retain the option to purchase the chair in the first month?
 - a. Are there any scenarios (physician prescription, patient requested upgrade, no-charge upgrade) that change whether a beneficiary will retain the option to purchase a chair coded K0830 or K0831 or be required to rent it for 13 months?
 - b. Will an ABN be required under any of these circumstances?
 - c. What modifier(s) will CMS require be appended to the claim?
2. Will an upgrade from a Group 2 power wheelchair (K0822 – K0829) to a Group 3 power wheelchair base (K0848 – K0855) retain the option to purchase the chair in the first month?
 - a. Are there any scenarios (physician prescription, patient requested upgrade, no-charge upgrade) that change whether a beneficiary will retain the option to purchase a chair coded K0848 – K0855 or be required to rent it for 13 months?
 - b. Will an ABN be required under any of these circumstances?
 - c. What modifier(s) will CMS require be appended to the claim?

It is the opinion of our members that CMS should allow beneficiaries to upgrade to a purchased Group 3 power wheelchair if he/she wants or needs one and agrees to pay for it with a properly executed ABN.

4. Purchase Option in a Competitive Bid Area

ACA mandates that contract providers furnishing power wheelchairs in Competitive Bid Areas (CBAs), pursuant to contracts entered into prior to January 1, 2011 as part of Round 1 of the DMEPOS Competitive Bidding Program, will continue to be paid under the current regulations using 10 percent of the purchase price for months 1 through 3 and 7.5 percent for each of the remaining months and must continue to offer beneficiaries the purchase option for all power wheelchairs (PWC).

The proposed rule states that CMS is reevaluating whether or not changes to grandfathering rules are necessary. The Agency also believes that it is important to reevaluate the policy that restarts the 13-month capped rental period in situations where a beneficiary transitions from a noncontract provider to a contract provider at the beginning of a DMEPOS CBP effective with Round 2.

We believe these rules must be established for the management of Medicare beneficiaries affected by the Round 1 Rebid prior to implementation of a mandatory rental for standard power wheelchairs or the policy must be delayed until the start of Round 2.

For a beneficiary who lives outside a CBA and is renting a PWC from a non-contract provider at initial issue that moves into a CBA during the capped rental period-

1. Will the beneficiary be required to receive their power wheelchair from a contract provider?
 - a. Will the payment of the PWC to a contract provider begin at month 1 or pick up for the remainder of the rental cycle?
 - b. Will the beneficiary have the option to purchase the PWC from the contract provider?
 - c. How will denials for same and similar equipment on file be handled?
2. Will the beneficiary be required to continue renting from their non-contract provider?
 - a. Will the rental payment of the PWC be based on the fee schedule outside the CBA?
 - b. If the beneficiary moves out of the non-contract provider's service area during the rental period will the provider be required to repair, maintain and/or replace the beneficiary's PWC?
3. What documentation will be required if there is no break in service and the only change in billing is a change in address to a CBA zip code?

B. Application of Productivity Factors to the Covered Item Update

1. Section 3401 of ACA Is Based on Flawed Assumptions

Currently, DMEPOS fee schedules are updated annually by the Consumer Price Index for all urban consumers (CPI-U) for the last 12-month period ending the previous June. Under §3401 of ACA, the covered item update will be reduced by increases in productivity in private non-farm business (MFP) for the 10-year period ending with June of the previous year. This means that MFP payment reductions will occur automatically, by operation of law. The MFP reduction is effective for calendar year (CY) 2011 and subsequent years. CMS has selected a private consulting firm, HIS Global Insight (IGI) to project the MFP using proxy variables to replicate the productivity measure produced by the Bureau of Labor Statistics (BLS). Application of the MFP could result in an update of less than zero.

We understand that CMS has no choice but to implement §3401, but we are nonetheless compelled to highlight the flawed assumptions underlying §3401 as well as the long-term consequences of low payment rates and high operating costs for DMEPOS providers. Because the MFP measures the contributions to productivity of all sectors involved in production, Congress' decision to reduce DMEPOS reimbursement by the productivity gains in the broader economy, suggests that Congress intended for the Medicare program to share in these gains. This is a legitimate and worthy goal, but the indiscriminate application of the MFP to DMEPOS is fundamentally flawed.

The CMS Office of the Actuary recently issued a report that examines the consequences of automatically applying productivity measures to reduce payment rates for health care services.¹ The Alternative Trustees report examined trends in productivity to show how hard it is to sustain in labor-intensive service sectors. The report concludes that offsetting reimbursement to reflect productivity gains in the overall economy produces savings at first, but eventually, payment reductions become unsustainable, posing a threat to access unless Congress intervenes to increase rates. We believe that Congress may have unintentionally created a dynamic similar to the issues related to the sustainable growth rate for all providers who are subject to the MFP, which will require congressional action to preserve adequate payment rates.

There are also limits to whatever savings can be achieved by forcing providers to improve their efficiency and eliminate excess costs and waste from their operations.² These services are mostly delivered *via* direct personal encounters between a practitioner and a patient; and the timing and scope of the encounters depend on the practitioner's judgment and the patient's response to treatment. Because serving patients is labor intensive, providers are limited in their ability to improve their productivity and squeeze out excess costs. As providers reach these limits, there are likely to be serious access issues for beneficiaries.

For DMEPOS, CMS may see access problems sooner rather than later.³ The DMEPOS benefit has been subjected to successive cuts and payment freezes such that, over the last decade, oxygen reimbursement has been cut by more than 50 percent, reimbursement for power wheelchairs has been reduced nearly 37 percent, and reimbursement for other DMEPOS items was frozen from 2004 to 2009 then cut 9.5 percent in 2009.⁴ Higher operating expenses in the form of surety bonds and accreditation arrived in concert with the payment freezes and cuts. Today, providers are ramping up staff to meet the demands of CMS' new audit strategies.

2. CMS Should Reassess Its Policies to Reduce Providers' Operational Costs

The Alternative Trustees' Report is a reminder that there is a limit to how much CMS can realistically expect to save from programs like competitive bidding before payment rates become unsustainable. We understand that CMS lacks authority to modify §3401. CMS, however, can modify its policies to relieve some of the administrative burdens facing providers. CMS also has authority to ensure that bidding rules do not produce unsustainable payment rates. For example, CMS could take steps to reduce documentation burdens on providers, especially the new audit policies CMS adopted. CMS should also reconsider CBP rules that cap bids at the fee schedule amount for an item. Because ACA triggers cuts to the fee schedules automatically, capping bids at the current fee schedule amount for an item, establishes an unrealistically low threshold for bids. AAHomecare is already concerned that the payment rates for the Round 1 "rebid" are unrealistically low. The requirements of §3401 can only make the problem worse.

¹ Alternative Trustees' Report, CMS Office of the Actuary, August 5, 2010, available at: <http://www.CMS.gov>.

² *Id.* at 4.

³ It is worth noting that the CPI-U is itself an output measure (compared to a market basket which measures input costs), raising a legitimate question about whether an MFP adjustment should even be applied to Medicare payment for DMEPOS.

⁴ The Medicare Modernization Act of 2003 (MMA) changed the payment formula for respiratory medications used with DME from the drugs average wholesale price (AWP) to the manufacture's average sale price for the drug plus a six percent (%) mark-up (ASP+ 6%).

3. Greater Transparency with Respect to Calculating MFP

The proposed rule does not describe the factors CMS considered in selecting the private consulting firm that will calculate the MFP or the process CMS used to retain the consultant. CMS also failed to provide its rationale for using a private firm to calculate the MFP when other government sources might be available. We request that CMS publish this information and publish a more detailed explanation of the consultant's methodology.

4. Providers' Operational Requirements

Finally, providers need to plan and program billing systems to include new DMEPOS payment amounts before they are effective January 1, 2011. We request that CMS give providers at least 90 days advance notice of the 2011 DMEPOS fee schedules.

C. Oxygen Provisions

CMS proposes to modify the rules that apply when a beneficiary on oxygen relocates outside the provider's service area. Under 42 USC §1395m, Medicare pays a monthly rental fee for oxygen and "caps" payment after the 36th month. Providers who furnish oxygen during the 36-month rental period continue servicing the oxygen equipment for the duration of the beneficiary's period of medical need for the remainder of the equipment's useful.⁵ CMS has interpreted §1395m to mean that after oxygen payments cap, the provider furnishing the oxygen *must* fully service the beneficiary either directly or under arrangements for an additional 24 months. Even if the beneficiary moves or travels away from the provider's service area, the provider servicing the beneficiary when the equipment caps must continue do so, or contract with a provider who can. CMS has established this interpretation through implementing regulations and program instructions.⁶

The same rule does not apply in situations where the beneficiary relocates outside the provider's service area before reaching the 36 month cap. Consistent with the statutory language, a beneficiary who moves away from the provider's service area can select a new provider of his choice.⁷ CMS' proposal would require providers to continue servicing beneficiaries if they relocate after only 18 months on service.

The revisions CMS is proposing are contrary to the explicit language of §1395m and are beyond the Agency's authority to implement. AAHomecare believes that CMS is aware that it lacks authority to require providers to continue servicing beneficiaries after they have been on service

⁵ ii) **Payments and rules after rental cap**

After the 36th continuous month during which payment is made for the equipment under this paragraph--

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

42 U.S.C.A. § 1395m (emphasis supplied).

⁶ See, e.g., Travel Oxygen, May 7, 2009 available at: <http://www.medicarenhic.com>.

⁷ 42 CFR 414. 226

for only 18 months, but the Agency justifies the proposal on the need to protect beneficiaries who relocate near the end of the rental period. According to CMS, these beneficiaries cannot find providers who are willing to take them on because they are near the payment cap. However, as is evident from the preamble, CMS understands that §1395m applies only after the equipment caps – after 36 rental payments – and not before. The preamble states:

[W]e finalized §414.226(g)(1) which, in accordance with section 1834(a)(5)(F)(ii)(I) of the Act, requires the supplier that furnishes oxygen equipment during the 36-month rental period to continue furnishing the oxygen equipment after the 36-month rental period. . . . As we noted when finalizing this rule, section 1834(a)(5)(F)(ii)(I) does not provide any exceptions to this requirement.

75 FR 40040, 40220 -40221 (emphasis supplied).

Subsequent attempts to amend §1395m support the conclusion that only Congress can restrict a beneficiary from switching to a new provider before the 36 month cap. On November 27, 2009, U.S. House of Representatives passed H.R. 3962, the Affordable Health Care for America Act. Section 1147 (b) of the bill would have amended §1395m to require oxygen providers to continue servicing beneficiaries who relocate after having been on service for only 27 of the 36 months in the rental period.⁸ If Congress believed that CMS could impose this requirement through regulation, it would not have bothered with a bill to amend §1395m. Importantly, Congress did not include §1147 (b) in ACA. The only logical conclusion we can draw from the legislative history of ACA is that Congress determined that it was unnecessary to revise §1395m.

We are sympathetic to the plight of beneficiaries facing access issues as a consequence of the current oxygen reimbursement policy. As an association, we believe we have made a conscientious effort to head off these problems and remain willing to work toward resolving them. However, the proposal CMS is advancing will not resolve the access issues facing beneficiaries; it just changes the timing of the problem. The only way to protect beneficiaries is to address the financial disincentives that limit access to oxygen in the first place.

In the short term, CMS could address these access issues by revisiting its decision to apply the same rules to oxygen and oxygen equipment without distinguishing between the two. Congress

⁸ Section 1147 of the bill stated:

(b) Ensuring Supply of Oxygen Equipment -

(1) IN GENERAL- Section 1834(a)(5)(F) of the Social Security Act (42 U.S.C. 1395m(a)(5)(F)) is amended--

(A) in clause (ii), by striking 'After the' and inserting 'Except as provided in clause (iii), after the'; and

(B) by adding at the end the following new clause:

'(iii) CONTINUATION OF SUPPLY- In the case of a supplier furnishing such equipment to an individual under this subsection as of the 27th month of the 36 months described in clause (i), the supplier furnishing such equipment as of such month shall continue to furnish such equipment to such individual (either directly or through arrangements with other suppliers of such equipment) during any subsequent period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary, regardless of the location of the individual, unless another supplier has accepted responsibility for continuing to furnish such equipment during the remainder of such period.'

clearly intended for the payment cap to apply to oxygen *equipment*, but they did not cap payment for oxygen *contents* for as long as oxygen remains medically necessary. After the 36th rental payment, when payment for the equipment caps, “the supplier furnishing the *equipment* . . . shall continue to furnish such *equipment* during any period of medical need . . .” § 1395m (5)(F)(i)(I). A separate provision, § 1395m (5)(F)(ii)(II), authorizes the Secretary to continue to pay for oxygen “for the period of medical need.”

Instead of limiting beneficiaries to the oxygen provider that their local provider chooses for them after having been on service for only 18 months, CMS should acknowledge that, after 36 months, the provider furnishing the “capped” equipment must continue to furnish the equipment to the beneficiary, either directly or under arrangements with a local provider he/she retains. Because there is no “cap” on oxygen contents, however, the beneficiary can select any provider at the new location to deliver contents.

1. More than 10 Months of Payment Needed to Ensure Access to New Oxygen Technology Prices

Under the final rule on competitive bidding, contract providers in a CBA who accept oxygen beneficiaries transitioning from a non-contract provider will receive payment for at least 10 months before the transfer of ownership requirement would apply.

In contrast, in the same rule, CMS will ensure that contract providers receive a minimum of 13 months payment for providing a capped rental item to a beneficiary who transfers from a non-contract provider. Thirteen months is the maximum amount a provider could receive under the Medicare fee-for-service program. CMS will therefore “make whole” contract providers who provide capped rental payments, but will only compensate contract providers providing oxygen items at 28 percent of what a provider in the fee-for- service program would receive.

In the underlying competitive bidding final rule, CMS states that this 10-month payment level would compensate the provider’s costs in providing oxygen concentrators. CMS does not, however, address the significantly higher up-front costs of new oxygen technology. Unless contract providers can be assured the financial base to provide new technology, beneficiary access will cease. Therefore, with respect to new technology (e.g., oxygen generating portable equipment, or OGPE), CMS needs to ensure that contract providers receive a minimum of 36 months of payment. This would be consistent with CMS’ payment rule for capped rental, which provides a full 13 months of payment to contract providers who are required to serve beneficiaries after the initial month of medical need has begun.

C. Competitive Bidding Issues

1. Transition Payments for Beneficiaries Who Switch to a Contract Provider

CMS is proposing to modify the one CBP policy that protects beneficiaries in a way that is fair to contract and non-contract providers. Appropriately, beneficiaries are free to change providers at anytime during the contract period. Currently, if a beneficiary using rental or oxygen equipment switches to a contract provider from a non-contract provider, Medicare will make additional

rental payments to the provider. For beneficiaries on oxygen more than 27 months, the provider receives 10 more payments. If a beneficiary switches providers before he has title to rental equipment, Medicare makes an additional 13 payments to the new provider.

This policy protects beneficiaries in two ways. It preserves whatever freedom they have to choose a provider and it ensures continuity of care for beneficiaries caught in the transition to the program. Losing bidders can decide whether or not to “grandfather” their patients without disrupting their care. Finally, the policy compensates contract providers who assume the care of these beneficiaries even though they will generate less revenue over the contract term.

CMS proposes to eliminate these transition payments to save Medicare beneficiaries and the program the expense of making the additional payments and copayments to the contract provider. CMS is misguided. Every one of the rationales the Agency advances to justify the policy is fundamentally flawed. We concede that the proposal will save money, but in the context of the overall program, these savings are small. CMS acknowledges this point in the preamble, noting that in its experience so far, the number of beneficiaries who switch providers is small. For this small group of patients, CMS believes that the financial burden of the additional copays can be a hardship.

In justifying the proposal, CMS states that the current policy pre-dates amendments to oxygen reimbursement under §144(b) of the Medicare Improvements for Patients and Providers Act (MIPPA). Section 144(b) repealed the requirement for beneficiaries to own their oxygen equipment at the end of the 36-month rental period. The Agency believes that at least for oxygen, the fact that providers retain ownership of the equipment adequately compensates contract providers who accept beneficiaries who transfer.

This rationale incorrectly assumes that equipment acquisition costs are the only expense providers incur in furnishing oxygen to Medicare beneficiaries. As AAHomecare has stated in past comments, the acquisition costs for oxygen equipment are only a fraction (28 percent) of the administrative and operational costs that providers incur for servicing Medicare beneficiaries. Additional costs include, among others, personnel costs for patient education and monitoring and operational costs for quality monitoring and regulatory compliance.

This rationale also assumes that beneficiaries who switch to a contract provider will bring oxygen equipment with them. This assumption is incorrect because, as CMS points out in the preamble, providers retain title to the equipment. Contract providers must furnish oxygen equipment to beneficiaries who change providers during the 36-month rental period. Similarly, beneficiaries who switch to a contract provider before they own their rental equipment will need to obtain equipment from the new provider. Without the transition payments, these contract providers will not be fully reimbursed for the equipment and services *they are required to furnish* when they initiate service to these patients.

The proposed policy is even harder to apply to rented standard power wheelchairs. The losing bidder who furnished the product to a beneficiary who switches would lose any payments remaining in the rental period. In other words, they will not receive full compensation for a device that they purchased and fitted to meet the beneficiary’s needs and which may not be

suitable to rent again. Meanwhile, the contract provider accepting the patient must provide him/her with equipment for which he/she will also not be fully reimbursed.

Although the proposal would save money for Medicare and beneficiaries, it risks whatever freedom of choice beneficiaries might have under CBP. It is also fundamentally unfair to contract providers, and in the case of standard power wheelchairs, to non-contract providers as well. Importantly, CMS' proposal inappropriately shifts the administrative costs of CBP to contract providers *who have no choice but to accept* beneficiaries who request their services. If beneficiaries are unable to afford additional copays, the contract provider can waive them after making a determination of the beneficiary's legitimate financial need. AAHomecare recommends that CMS withdraw this proposal.

2. National Mail Order DMEPOS CBP for Diabetic Testing Strips

The proposed rule includes a framework for a national CBP for diabetic testing strips. CMS cites data that shows that almost 62 percent of Medicare beneficiaries obtain their test strips by mail, giving rise to potential savings from a national bidding program for these products. CMS also recognizes that beneficiaries need access to test strips through local pharmacies to accommodate a beneficiary's preference to consult with a pharmacist, or the need for an emergency "refill" of supplies.

AAHomecare urges CMS not to move forward with the broad expansion of national CBP for mail order diabetes testing supplies until it has a chance to review and evaluate the mail order program that is part of the Round 1 Rebid process. As CMS has no experience with the product category or delivery mechanism in the competitive bidding context, we believe that it is critically important that CMS use Round 1 as a learning experience.

We cannot underestimate the dramatic impact of the issues that CMS is considering for the diabetes marketplace. We would appreciate the opportunity to work with the Agency as it sorts through the complicated issues related to this benefit category.

Definitions Related to Diabetic Supplies

We believe that CMS must be aware of all facets of the diabetic testing supplies marketplace before making policy changes that will significantly change this marketplace. Providers have an economic necessity to serve Medicare beneficiaries with products that can be furnished at the CBP price point. The Round 1 single payment amounts simply cannot support the products and services that are used by Medicare beneficiaries today.

Given these price points, the only logical conclusion that can be reached is that Medicare beneficiaries who receive supplies through mail order will either be required to switch products or utilize the retail channel. Both have effects on the Medicare program in that CMS will not realize anticipated savings. If beneficiaries are required to switch diabetic testing products, they may not control their diabetes, which may lead to other co-morbidities.

A mail order item is one that is delivered to the beneficiary's home "regardless of the method of delivery" and would apply to any DMEPOS item delivered to a patient's home. Because the vast majority of DMEPOS is delivered by the provider either directly or under arrangements, the definition does not distinguish between supply items like test strips that can be safely furnished by mail or common carrier and medical equipment that is delivered and set up in the beneficiary's home.

Similarly, the definition of a non-mail order item turns on whether the beneficiary obtains the item in person from a local retail establishment. Again, we note that this definition does not distinguish among the different categories of DMEPOS. There are many kinds of DMEPOS items that can be purchased from brick and mortar retail establishments, and the proposed definition would apply to all of them. CMS should revise this definition to capture items that can be appropriately furnished via mail order and those that cannot. If it is CMS' intent to retain these broad definitions, we request that the Agency clarify the scope of any future national mail order CBP for DMEPOS.

CMS also needs to clarify the standards that mail order providers will be required to meet.

50 Percent Rule

AAHomecare recommends that CMS issue proposed guidance for comment that outlines the methodology the Agency will employ for calculating the 50 percent threshold of the Medicare diabetic testing supply product availability. In addition, CMS should consult with industry experts to determine whether the methodology ultimately used provides results consistent with what is available to Medicare beneficiaries today.

We recommend, as part of the data collection, that CMS conduct a confidential survey to gather accurate mail order market share data for the Medicare-aged population. The survey should also ask all the respondents to identify the brands and products they have furnished by mail order. This is an important first step because market share data for mail order and retail medical supply establishments are not the same.

For example, even though IMS Health is the world's leading provider of market intelligence to the pharmaceutical and healthcare sectors, the data may not be useful in the context of CBP because it encompasses all age demographics, including pediatrics and managed care, not just the Medicare-aged population. Product selection for the Medicare-aged population may vary widely from that of younger populations. In addition, not all manufacturers report sales via IMS, and most DME providers do not report to IMS at all. So, while the IMS database is large, there is no uniform source of market share data that could accurately predict what mail order products Medicare patients with diabetes use most often. Further, claims data has limited utility for establishing the 50 percent benchmark because although claims include HCPCS code descriptors, they do not identify specific brand names for mail order supplies.

Anti-Switching Rule

Given published Round 1 reimbursement rates and the cost of acquisition for all types of diabetic testing strips furnished by DME providers today, beneficiaries will need to be moved onto new products for the economic viability of the providers (acquisition cost of most products is above reimbursement rate). The key issue from our perspective is how will both “switching” and “influencing” be defined.

Moreover, how will this rule be monitored and managed? Will providers have to offer all brands, or will they be able to refer to other contracted bidders? If a manufacturer runs an advertisement for a product and the beneficiary calls the distributor who provides it, how does that relate to the definition of influencing and switching products? CMS must consider that new, more advanced technological products may improve beneficiary outcomes and the incidence of diabetes in the Medicare population.

3. Competitive Bidding Boundaries for the Largest MSAs

AAHomecare generally agrees with CMS’ proposal to subdivide the three largest MSAs into distinct CBAs.

Our recommendation is that CMS draw boundary lines along the main travel arteries within the MSAs. Using zip codes or county boundaries may be unworkable across a large MSA if the travel arteries do not correspond to the physical boundary lines for counties and zip codes.

4. Appeals Terminated Contract Providers

Finally, AAHomecare supports the appeals process for terminated contract providers. Including an appeals process under CBP protects contract providers from arbitrary or mistaken decisions by CMS or its contractors and preserves the continuity of care for the beneficiaries they are serving.

II. CONCLUSION

In closing, we respectfully request that CMS adopt the recommendations we made in these comments. AAHomecare appreciates the opportunity to submit these comments. Our staff is available to discuss these issues in greater detail with you at your convenience. Please feel free to contact Mr. Walter Gorski, AAHomecare’s Vice President for Government Relations, at 703-535-1894.

Sincerely,



Tyler J. Wilson
President
American Association for Homecare