



HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

January 26, 2016

The Honorable Orrin Hatch
Chairman
Senate Finance Committee
Room 219 Senate Dirksen Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
Room 219 Senate Dirksen Building
Washington, D.C. 20510

The Honorable Johnny Isakson
Room 131 Senate Russell Building
Washington, D.C. 20510

The Honorable Mark R. Warner
Room 475 Senate Russell Building
Washington, D.C. 20510

Dear Chairman Hatch, Ranking Member Wyden and Senators Isakson and Warner:

Pursuant to the Senate Finance Committee's release of the Chronic Care Working Group (CCWG) Options Document, we are pleased to submit comments from the Health Industry Distributors Association (HIDA). We applaud your bipartisan efforts in examining the Medicare fee-for-service program, especially with the goal of better serving beneficiaries suffering from chronic medical conditions.

HIDA's members deliver life-saving healthcare products to approximately 295,000 points of care including over 210,000 physician offices, 6,500 hospitals, 44,000 nursing home and extended care facilities, and 33,500 medical facilities in the nation and are committed to promoting safety and savings throughout the healthcare supply chain.

Medical products distributors offer the nation's providers on-demand access to over 200,000 medical products essential for patient care. Providers value this "one-stop shopping" resource, as it helps them manage supply costs and focus time and resources on patient care. Most products sold by a medical products distributor are sold to a healthcare provider. As such, virtually every patient procedure is supported in some way by products supplied by a distributor.

We encourage the CCWG to include enteral nutrition therapy (tube feeding) as part of its review. Tube feeding is critically important for maintaining nutrition and hydration levels for specific disease states such as renal failure, diabetes and chronic pulmonary disease. As part of this effort, we recommend:

- The removal of the enteral nutrition therapy product category from Medicare's competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) due to the acuity level of the patients receiving nutritional support;
- The adoption of a verification process to ensure winning contract suppliers have adequate product offerings for all enteral formulas, equipment and supplies subject to competitive acquisition; and



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- Passage of the DME Access and Stabilization Act (s. 2312), legislation to protect access to essential home medical equipment products for seniors, as well as individuals with significant disabilities and chronic conditions, who reside in rural communities around the country.

Removal of Enteral Nutrition Therapy from Medicare's Competitive Bidding Program

HIDA has long supported efforts that are consistent with the Centers for Medicare & Medicaid Services' (CMS) original position that enteral nutrition is not a well-suited product category for a competitive acquisition program. In CMS' 2004 report to Congress, the agency recommended that the enteral product category be excluded from future rounds of competitive bidding. The product category was removed from the first round of the demonstration program because of the complexities involved with the SNF provider setting and the acuity level of patients requiring enteral nutrition therapy. Subsequent rounds of the demonstration project retained only product categories overwhelmingly used in private homes. Given CMS's initial recommendation and the fact that the SNF setting was not the intended target of competitive bidding, we question why the agency chose to include enteral nutrition therapy in both the first and second rounds of the program. Therefore, the enteral nutrition therapy product category should be removed from future rounds of the program, as it was never successfully tested during the initial demonstration projects.

Guaranteed Access to Enteral Formulas

Apart from removing the enteral nutrition therapy product category from the competitive bidding program, HIDA recommends that CMS adopt a verification process to ensure winning contract suppliers have adequate product offerings for all enteral formulas, equipment and supplies subject to competitive acquisition.

For a Medicare beneficiary to qualify for enteral nutrition therapy reimbursement, they must have a diagnosis that directly contributes to the non-functioning of part of the gastrointestinal tract (i.e., patients who cannot swallow and/or digest and absorb adequate nutrition). The diagnosis must cause a permanent non-function to the gastrointestinal tract and require a feeding tube to provide life-sustaining nutrients. There are a variety of clinical conditions or disease states that can cause functional impairment of the gastrointestinal tract, including muscular paralysis, cognitive neurologic disorders, and anatomic impairments. To meet the needs of a diverse patient population and various healthcare needs, a wide range of enteral nutrition formulas exists. There are standard formulas and more specialized formulas designed for patients with specific conditions, such as renal failure, gastrointestinal disease, hyperglycemia/diabetes, liver failure, acute and chronic pulmonary disease, and wound healing.

Currently, under Medicare's competitive bidding program for DMEPOS, there is no mechanism in place to ensure that a beneficiary will have access to a full suite of standard and specialized formulas from the CMS contracted supplier in their respective metropolitan statistical area (MSA) and rural area/non-MSA. The current competitive bidding program has created a

situation where an enteral beneficiary not only has restricted access qualified healthcare suppliers in the Medicare program, but also has restricted access to the prescribed enteral products needed for nutritional support. Given this fact, HIDA recommends that CMS adopt a verification process to ensure winning contract suppliers have adequate product offerings for all enteral formulas, equipment and supplies subject to competitive acquisition

Passage of the DME Access and Stabilization Act

HIDA strongly support the enactment of S.2312, The DME Access and Stabilization Act, to help minimize the impact on enteral nutrition suppliers servicing providers and beneficiaries in non-competitive bid areas (non-CBAs). The legislation provides much-needed relief from proposed Medicare reimbursement cuts affecting home medical equipment suppliers who face unique challenges and increased expense associated with serving patients in less-densely populated areas nationwide.

HIDA is opposed to the application of competitive bidding pricing in non-MSAs (i.e., rural, low population density areas). Medicare's competitive bidding program was clearly intended for large metropolitan areas and is poised to impede patient access to DMEPOS services and supplies now that the program's pricing structure is being implemented in rural and frontier areas nationwide per the Affordable Care Act (ACA). The payment structure established by CMS for suppliers servicing non-MSAs does not represent the true cost associated with providing goods and services to these areas (e.g., rural suppliers have to drive further to service less Medicare beneficiaries). Regional suppliers who generally service patients and providers in these areas will have great difficulty competing on prices with those suppliers who service urban areas. The significant reduction in reimbursement these suppliers face as of January 1, 2016, will lead to reduced access, service and choice for Medicare beneficiaries. There are limited companies that currently service rural patients and providers.

To help minimize the impact on enteral nutrition suppliers servicing providers and beneficiaries in these areas HIDA encourages the passage of S. 2312, either as a stand-alone bill or as part of the chronic care legislative package. S 2313 will require CMS to make adjustments to the payment structure finalized for applying competitive bidding-derived pricing to non-CBAs. Key components of the legislation will:

- Apply a 30% positive adjustment to rural single payment amounts (SPA) (calculated on a national basis) for suppliers in non-bid, "rural" areas as defined by CMS.
- Apply a 20% positive adjustment to regional single payment amount (RSPA) for suppliers in all other non-bid areas.
- Provide a two year phase-in period for bidding derived pricing for non-bid areas.
- Set the ceiling for future bidding rounds of the competitive bidding program at the unadjusted fee schedule rates in effect on January 1, 2015, instead of CMS' proposal to set a bid ceiling at the previous bid amount rates.

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- Instruct CMS to revisit pricing adjustments for non-bid areas that takes into account travel distance, clearing price and other associated costs furnishing this equipment for prices that will be in effect on January 1, 2019.
- Effective January 1, 2020, new Medicaid allowable caps will be applied to the federal portion of reimbursement that mirrors the Medicare rates.

Thank you for reviewing our concerns and considering our comments. We appreciate the opportunity to suggest important modifications specific to the Medicare Part B fee-for-service program that should be adopted as CMS moves forward with implementing the DMEPOS competitive bidding expansion provisions included in the ACA. These modifications will ensure that patients and providers have uninterrupted access to life-sustaining medical products as the competitive bidding program expands nationwide.

We look forward to working with you and your staff on policy changes protecting essential enteral nutrition therapy formulas, equipment and supplies and other DMEPOS for seniors, as well as individuals with significant disabilities and chronic conditions, who reside in rural communities around the country.

Please contact me at rouse@HIDA.org, or (703) 838-6125 with any questions you have regarding the competitive bidding program's impact on HIDA's membership or the role of medical products distributors in the healthcare supply chain.

Sincerely,



Linda Rouse O'Neill
Vice President, Government Affairs
Health Industry Distributors Association