On June 24th, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule (CMS-1651-P) that would revise payment rates and policies related to the competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Comments on the proposed rule are due by August 23, 2016. As explained in more detail below, CMS proposes the following changes to the DMEPOS competitive bidding program:

- Revise the limits on bids for individual items for future competitions so that they are based on the otherwise applicable unadjusted fee schedule amounts.

- Establish an alternative to the current bidding methodology for product categories that include two or more similar items with different features, and where previous competitions resulted in price inversions. This new bidding method would apply to enteral pumps.

- Revise and expand its methodology for adjusting DMEPOS fee schedule amounts for similar items with different features using information from competitive bidding programs.

- Require a bidding entity to obtain a $100,000 bid surety bond for each competitive bidding area (CBA) in which it submits a bid.
• Establish an appeals process for suppliers who receive a breach of contract notice from CMS.

• Codify in the regulations the statutory requirement that a contract will not be awarded to a bidding entity unless the entity satisfies applicable state licensure requirements.

In addition, CMS is soliciting feedback on the accessibility of DME for people dually eligible for Medicare and Medicaid, as well as potential regulatory or legislative reforms that could address Medicare and Medicaid DME program misalignments. Interestingly, this request for information appears to be limited to DME, and does not reference other DMEPOS items.

**Bid Limits for Individual Items under the DMEPOS Competitive Bidding Program**

CMS proposes to revise the limits on bids for individual items for future competitions (including re-competes) so that they are based on the fee schedule amounts that would have applied if adjustments had not been made based on information from competitive bidding programs. CMS specifies in the preamble to the proposed rule that “the bid limits for enteral nutrients, equipment, and supplies (enteral nutrition) would be based on the 2015 fee schedule amounts established in accordance with section 1842(s)(1) of the Act, prior to application of section 1842(s)(3), but updated for subsequent years based on the factors provided as section 1842(s)(1)(B)(ii) of the Act. In other words, the bid limits would be based on fee schedule amounts established in accordance with section 1842(s)(1), without applying the adjustments authorized by section 1842(s)(3)(B) of the Act.”

CMS acknowledges that to continue using the adjusted fee schedule amounts as bid limits for future competitions would not allow SPAs to fluctuate up or down to reflect the cost of furnishing items and services over time. When awarding contracts in future rounds of the competitive bidding program, CMS intends to consider total payments to suppliers by accounting for several factors (i.e., bid limits, the number of entities that can submit claims for payment, beneficiary access, payments to suppliers on an assignment-related basis, and beneficiary cost sharing limitations (20 percent of the SPA)). As we indicated in a previous communication, this is a far more favorable provision for industry stakeholders than the bidding limits provisions in the competitive bidding bills currently pending in Congress (S. 2736, H.R. 5210).

**Bidding Methodology and Single Payment Amounts**
for Certain Groupings of Similar Items with Different Features

CMS proposes an alternative approach to the current bidding methodology for situations where a product category includes a grouping of two or more similar items with different features, and where previous competitions resulted in “price inversions.” CMS proposes to define price inversion as:

Any situation where the following occurs: One item (HCPCS code) in a grouping of similar items (e.g., walkers, enteral infusion pumps, or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (e.g., wheels, alarm, or Group 2 performance); the average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and, following a competition, the SPA for the code with the feature is lower than the SPA for the code without that feature.

Under CMS’ proposal, a supplier would bid to furnish an entire grouping of similar items with different features. Rather than submitting bids for each individual HCPCS code for each item, a supplier would make one bid that would account for the cost of furnishing all similar items. CMS would designate a “lead item,” which initially would be the item in the grouping of codes with the highest total nationwide allowed services for calendar year 2012. CMS proposes using allowed services from CY 2012 to identify the lead item for the first time this bidding method is used since the price inversions began with the Round 2 competitions and contracts that began on July 1, 2013. CMS wants to ensure that the effects of price inversions do not impact the utilization of the various items used to identify the lead item. However, for subsequent competitions, the lead item would be identified as the code with the highest total nationwide allowed services for the most recent and complete calendar year that precedes the competition.

The supplier’s bid for the lead item would be used as the basis to calculate the SPAs for the similar items within that grouping. CMS would automatically calculate the SPA for any similar item in the grouping based on the ratio of the average of the similar item’s fee schedule amounts for all areas nationwide in 2015, to the average of the lead item’s fee schedule amounts for all areas nationwide in 2015.
CMS proposes to announce which items would be subject to this bidding method at the start of each competition in each CBA where the bidding method is used. The groupings of items that initially would be subject to this policy include:

- Enteral pumps (HCPCS codes B9000 and B9002)
- Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373).
- Seat lift mechanisms (HCPCS codes E0627, E0628, and E0629).
- TENS devices (HCPCS codes E0720 and E0730).

Under this new methodology, the following represents the lead item bidding for enteral pumps and relative difference in fees:

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Features</th>
<th>Allowed Services for 2012</th>
<th>Average of 2015 Rental Fees</th>
<th>Fee Relative to Lead Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>B9002</td>
<td>Pump with alarm</td>
<td>265,890</td>
<td>$121.70</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>(lead item)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B9000</td>
<td>Pump without alarm</td>
<td>935</td>
<td>$115.47</td>
<td>0.95</td>
</tr>
</tbody>
</table>

Methodology for Adjusting DMEPOS Fee Schedule Amounts for Similar Items with Different Features Using Information from Competitive Bidding Programs
In a CY 2015 final rule, CMS adopted a methodology to address “unbalanced bidding” for certain situations where bidding for similar but different enteral pumps and standard power wheelchairs resulted in single payment amounts (SPAs) for higher utilized items with additional features (i.e., an enteral pump with an alarm or a Group 2 power wheelchair) being less than the SPAs for lower utilized items without those features (i.e., an enteral infusion pump without an alarm or Group 1 power wheelchair). Specifically, the current regulations limit the SPA for items without additional features (i.e., enteral pumps without an alarm) to the SPA for items with the additional features (i.e., enteral infusion pumps with an alarm) prior to using these SPAs to adjust fee schedule amounts. Thus, enteral pumps already were subject to a rule intended to address unbalanced bidding.

CMS proposes to expand and revise its methodology to address instances where a price inversion occurs under a competitive bidding program following the competition for a grouping of similar items. Before applying the fee schedule adjustment methodologies, CMS proposes that the SPAs for each item in the grouping of similar items in the CBA would be adjusted to equal the weighted average of the SPAs for the items in the grouping of similar items in the CBA. The weight for each item (HCPCS) code to be used in calculating the weighted average would be “equal to the proportion of total nationwide allowed services furnished in calendar year 2012 for the item (HCPCS) code in the grouping of similar items, relative to the total nationwide allowed services furnished in calendar year 2012 for each of the other items (HCPCS codes) in the grouping of similar items.” The “total nationwide allowed services” would include “the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services.”

The groupings of items that would be subject to this policy include:

- Enteral infusion pumps (HCPCS codes B9000 and B9002)
- Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373).
- Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823).
• Seat lift mechanisms (HCPCS codes E0627, E0628, and E0629).
• TENS devices (HCPCS codes E0720 and E0730).
• Walkers (HCPCS codes E0130, E0135, E0141, and E0143).

CMS considered expanding the method currently utilized for enteral infusion pumps and standard power wheelchairs, but ultimately decided that this method was insufficient since it “simply limits the amount paid for the item without a feature(s) to the item with the feature(s).” In contrast, the alternative proposed methodology “factors in the SPAs for all of the items.”

**Bid Surety Bond**

The Medicare Access and CHIP Reauthorization Act of 2015 mandated that with respect to competitive bidding rounds beginning not earlier than January 1, 2017 and not later than January 1, 2019, CMS must require each bidding entity to submit a surety bond in the range of $50,000 to $100,000 for each CBA in which the entity submits a bid. CMS was provided the discretion to determine the amount and form of the surety bond. CMS proposes that a bidding entity would be required to obtain a $100,000 bid surety bond for each CBA in which it submits a bid. The bid surety bond would need to be obtained from an authorized surety on the Department of the Treasury’s Listing of Certified Companies. CMS suggests that the $100,000 amount would provide assurance that bidding entities submit substantiated bids, and believes that such surety bonds would contribute to an increase in the contract acceptance rate. However, CMS is soliciting comments on whether a lower bid surety bond amount would be appropriate for a particular subset of suppliers (i.e., small suppliers).

CMS proposes conditions for forfeiture of the bid surety bond and return of bond liability. If a bidding entity is offered a contract for a product category in a CBA, the entity’s composite bid is at or below the median composite bid rate for all bidding entities included in the calculation of the SPAs for the product category and CBA, and the entity does not accept the contract offer, the entity’s surety bond for the CBA will be forfeited and CMS will collect on it. If a bidding entity does not satisfy the bid surety bond forfeiture conditions, the bid surety bond liability will be returned to the bidding entity within 90 days of the public announcement of the contract suppliers for the CBA.

CMS proposes that an entity may be prohibited from participating in the current round of the competitive bidding program and from bidding in the next round if it
provides a falsified bid surety bond. In addition, such suppliers would be referred to the Office of Inspector General and the Department of Justice for additional investigation. If a bidding entity accepts a contract offer and subsequently breaches the contract to avoid forfeiture of the bid surety bond, the entity’s contract would be terminated and the entity would be prohibited from participating in the competitive bidding program.

Appeals Process for a Breach of Contract Action(s)

Currently, CMS has instituted an appeals process only for suppliers whose contracts are terminated. The rule proposes to establish an appeals process for suppliers who have received a breach of contract notice from CMS indicating that CMS intends to: (1) suspend the contract; (2) terminate the contract; (3) preclude the supplier from participating in the competitive bidding program; or (4) avail itself to other remedies allowed by law.

State Licensure

The proposed rule codifies in the regulations the statutory requirement that a contract will not be awarded to a bidding entity unless the entity satisfies applicable state licensure requirements. CMS notes that this is not a change in policy since the CMS previously required contract suppliers to meet state and local licensure requirements.