American Association for Homecare

PROPOSED RULE SUMMARY

MEMORANDUM

Date: June 24, 2016

Subject: CY 2017 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive, Durable Medical Equipment, and DMEPOS Competitive Bidding Programs (CMS-1651-P)

Overview

On June 24, 2016, the Centers for Medicare and Medicaid Services (CMS) published the proposed rule titled, CY 2017 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive, Durable Medical Equipment, and DMEPOS Competitive Bidding Programs. This is an annual proposed rule that updates the bundled payment system for ESRD payment program and DMEPOS competitive bidding program. This summary includes proposed changes specifically related to the DMEPOS competitive bidding program. All the proposals and requests for comments by CMS are bullet pointed underneath each proposal topic.

Bid Surety Bond Requirement

PROPOSALS:

- Add a definition for "bidding entity" to mean the entity whose legal business name is identified in the "Form A: Business Organization Information" section of the bid.
- An entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA.
- The bond must be obtained from an authorized surety. An authorized surety is a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.
- A bid surety bond contains the following information:
    - (1) the name of the bidding entity as the principal/obligor;
    - (2) The name and National Association of Insurance Commissioners number of the authorized surety;
    - (3) CMS as the named obligee;
    - (4) The conditions of the bond as specified in this proposed rule at (h)(3);
    - (5) The CBA covered by the bond;
    - (6) The bond number;
    - (7) The date of issuance; and
    - (8) The bid bond value of $100,000.
- Bidding entities will be required to obtain bid surety bonds in an amount of $100,000 for each CBA in which they submit a bid.
    - This requirement is intended to ensure that bidding entities accept a contract offer(s) when their composite bid(s) is at or below the median composite bid rate used in the calculation of the single payment amounts.

- An entity's bid surety bond for that CBA will be forfeited and CMS will collect on it when:
    - (1) a bidding entity is offered a contract for any product category in a CBA,
    - (2) the entity's composite bid is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for the product category and CBA, and
    - (3) the entity does not accept the contract offer.
- When the bidding entity does not meet the forfeiture conditions, the bid bond liability will be returned within 90 days of the public announcement of the contract suppliers for the CBA.
- CMS will notify a bidding entity when it does not meet the bid forfeiture conditions and as a result CMS will not collect on the bid surety bond.
- Bidding entities that provide a falsified bid surety bond would be prohibited from participation in the current round of the CBP in which they submitted a bid and from bidding in the next round of the CBP.
    - Additionally, offending suppliers would be referred to the Office of Inspector General and Department of Justice for further investigation.
    - If CMS finds that a bidding entity has accepted a contract offer and then breached the contract in order to avoid bid surety bond forfeiture, the breach would result in a termination of the contract and preclusion from the next round of competition in the CBP.

REQUEST FOR COMMENT:

- CMS is considering whether a lower bid surety bond amount would be appropriate for a particular subset of suppliers, for example, small suppliers, and are specifically soliciting comments on whether to establish a lower bid surety bond amount for certain types of suppliers.

State Licensure Requirement

PROPOSAL:

- Revise 414.414(b)(3) to align with the language of the Act as revised by MACRA, to state that a contract will not be awarded to a bidding entity unless the entity meets applicable State licensure requirements.
    - This change does not reflect a change in policy as CMS already has a regulation in place to require suppliers to meet applicable State and local licensure requirements.

Procedure on Appeals Process for a Breach of Contract of DMEPOS Competitive Bidding Contract Action(s)

This rule also proposes to expand suppliers' appeal rights in the event of a breach of contract action by CMS. In particular, this rule proposes a revision to current regulations to provide that the appeals process is applicable to all breach of contract actions taken by CMS, rather than just for the termination of a competitive bidding contract. Therefore, the proposed revisions will expand to allow appeal rights for each breach of contract action.

PROPOSALS:

- Expand the appeals process for suppliers who have been sent a notice of a breach of contract stating that CMS intends to take one or more of the actions as a result of the breach.
    - CMS will make separate decisions for each breach of contract action after reviewing the hearing officer's recommendation.
    - Remove the breach of contract actions of (1) requiring a contract supplier to submit a corrective action plan; and (2) revoking the supplier number of the contract supplier.
        - Remove the supplier number revocation action because the DMEPOS CBP does not have the authority to revoke a DMEPOS supplier's Medicare billing number.
    - Revise to state that CMS will specify in the notice of breach of contract which actions they are taking as a result of the breach of contract.
    - Remove the requirement that the breach of contract notice to the supplier be delivered by certified mail to allow CMS the flexibility to use other secure methods for notifying suppliers.
    - Add language to specify that the effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless a timely hearing request has been filed or a corrective action plan (CAP) has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.
    - Subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant. CMS retains the option to offer the supplier an opportunity to submit another CAP, if CMS deems appropriate, in situations where CMS has already accepted a prior CAP.
    - In the event the supplier fails to timely request a hearing, the breach of contract action(s) specified in the notice of breach of contract will take effect 45 days from the date of the notice of breach of contract. Scheduling notice must be sent to all parties, not just the supplier.
    - CMS will make separate decisions for each recommendation when the hearing officer issues multiple recommendations.
    - The notice of CMS' decision will be sent to the supplier and the hearing officer and will indicate whether any breach of contract actions included in the notice of breach of contract still apply and will be effectuated, and will indicate the effective date of the breach of contract action, if applicable.
    - A supplier who is precluded will not be allowed to participate in a specific round of the CBP, which will be identified in the original notice of breach of contract.
    - If CMS decides to impose other remedies, the details of the remedies will be included in the notice of breach of contract.

Methodology for Adjusting DMEPOS Fee Schedule Amounts for Similar Items with Different Features using Information from Competitive Bidding Programs

CMS examined instances within the HCPCS where there are multiple codes for an item (for example, a walker) that are distinguished by the addition of features (for example, folding walker versus rigid walker or wheels versus no wheels) which may experience price inversions. The review included all groupings of similar items with different features within each of the product categories. The items affected included transcutaneous electrical nerve stimulation (TENS) devices, walkers, hospital beds, power wheelchairs, group 2 support surfaces (mattresses and overlays), enteral infusion pumps, and seat lift mechanisms.

As shown in Table 12 below, under the 2015 DMEPOS fee schedule, Medicare pays more for walkers with wheels than walkers without wheels. The same is true for walkers that fold as compared to walkers that do not fold. Walkers that are rigid and do not fold are very rarely used and have extremely low utilization, and a walker that folds and has wheels is used much more frequently than a walker that folds but does not have wheels.

TABLE 12 –Average of 2015 DMEPOS Fee Schedule Amounts for Purchase of Walkers

Code	Item	Average 2015 Fee Schedule Amount[1]	2014 Allowed Services
E0130	Rigid Walker without Wheels	$64.97	59
E0135	Folding Walker without Wheels	$78.97	5,053
E0141	Rigid Walker with Wheels	$107.89	455
E0143	Folding Walker with Wheels	$111.69	95,939

[1] Average of 2015 fee schedule amounts for all areas

Under the DMEPOS CBP, because the folding walker without wheels (E0135) is used more frequently than the rigid walker without wheels (E0130), code E0135 receives a higher weight than code E0130. In addition, under the 2015 fee schedule, Medicare pays more for code E0135 than code E0130. A supplier's bid for each item in the product category is multiplied by the weight assigned to the item, and the sum of these calculations equals the supplier's composite bid. Contracts are offered to eligible suppliers with the lowest composite bids. Therefore, the higher the weight for an item in a product category, the more the bid for that item will affect the supplier's composite bid and chances of being offered a contract for that product category.

The first price inversion involves a rigid walker without wheels (E0130). A rigid walker without wheels has lower fee schedule amounts on average and a lower weight than a folding walker without wheels (E0135), yet under competitive bidding, it has a greater SPA than the folding walker. The second price inversion involves a rigid walker with wheels (E0141), which has lower fee schedule amounts on average and a lower weight than a folding walker with wheels (E0143), but has a greater SPA than the folding walker with wheels under competitive bidding. The third price inversion involves a rigid walker without wheels (E0130), which has a greater SPA than a folding walker with wheels despite having lower fee schedule amounts on average and a lower weight than the folding walker with wheels (E0143).

TABLE 13 – Round 2 (2016) Price Inversions for Purchase of Walkers

Code	Item	2015 Fee[1]	Avg SPA[2]
E0130	Rigid Walker without Wheels	$64.97	$47.23
E0135	Folding Walker without Wheels	$78.97	$43.05
E0141	Rigid Walker with Wheels	$107.89	$75.03
E0143	Folding Walker with Wheels	$111.69	$45.92

1 Average of 2015 fee schedule amounts for all areas

2 Average of Round 2 2016 SPAs

If the items with additional features are more expensive and are also utilized more than the items without the features, a price inversion can result in a CBA due to the item weights and how they factor into the composite bids, as described above.

CMS considers 2 methodologies to adjust for price inversion.

Method 1: Limits the SPA for the code without the feature to the SPA for the code with the feature before the SPA is used to adjust the fee schedule amounts for the item. For example, the 2016 SPA for E0130 (Rigid Walker without Wheels) in Akron, OH is higher than E0135 (Folding Walker without Wheels) even though E0135 has more functions than E0130. Under method 1, the SPA for E0130 will be brought down to E0135.

TABLE 14 – Adjustment of 2016 SPAs for Purchase of Walkers for Akron, OH to Eliminate Price Inversions with Method 1

Code	Item	2015 Fee[1]	2016 SPA	Adjusted Amount[2]
E0130	Rigid Walker without Wheels	$64.97	$50.85	$44.88
E0135	Folding Walker without Wheels	$78.97	$44.88	n/a
E0141	Rigid Walker with Wheels	$107.89	$84.82	$48.62
E0143	Folding Walker with Wheels	$111.69	$48.62	n/a

1 Average of 2015 fee schedule amounts for all areas

2 The SPA would be adjusted to this amount before making adjustments to the fee schedule

If method 1 is finalized, CMS would indicate that additional price inversions involving additional sets of two items to which this rule would be applied would be identified in a table in the preamble of the final rule. An example of such a table is provided below in Table 15 using codes for walkers, seat lift mechanisms, and TENS devices:

TABLE 15 –Additional Price Inversions Subject to 42 CFR §414.210(g)(6)

Item	Code Without Feature(s)	Code With Feature(s)	Feature(s)	Adjustment
Walker	E0130	E0135	Folding	E0130 SPA adjusted not to exceed (NTE) SPA for E0135
Walker	E0141	E0143	Folding	E0141 SPA adjusted NTE SPA for E0143
Walker	E0130	E0143	Folding, Wheels	E0130 SPA adjusted NTE SPA for E0143
Walker	E0135	E0143	Wheels	E0135 SPA adjusted NTE SPA for E0143
Seat Lift	E0629	E0627[1]	Powered	E0629 SPA adjusted NTE SPA for E0627
Seat Lift	E0629	E0628[1]	Powered	E0629 SPA adjusted NTE SPA for E0628
TENS	E0720	E0730	Two Additional Leads	E0720 SPA adjusted NTE SPA for E0730

[1] Codes E0627 and E0628 both describe powered electric seat lift mechanisms. Code E0627 describes powered seat lift mechanisms incorporated into non-covered seat lift chairs.

Method 2: The second methodology CMS considered and is proposing would limit the SPAs in situations where price inversions occur so that the SPAs for all of the similar items, both with and without certain features, are limited to the weighted average of the SPAs for the items based on the item weights assigned under competitive bidding. This approach would factor in the supplier bids for the lower volume and higher volume items. This would establish one payment for similar types of items that incorporates the volume and weights for items furnished prior to the unbalanced bidding and resulting price inversions. To illustrate how method 2 would work, the 2016 SPAs for codes E0130, E0135, E0141, and E0143 for the Vancouver, WA CBA, and the amounts they would be adjusted to before applying the fee schedule adjustment methodologies using the weights from Round 2 Recompete are listed in Table 16 below.

TABLE 16 – Adjustment of 2016 SPAs for Purchase of Walkers for Vancouver, WA to Eliminate Price Inversions Method 2

Code	Item	2015 Fee[1]	2016 SPA	Round 2 Recompete Item Weight	Adjusted Amount[2]
E0130	Rigid Walker without Wheels	$64.97	$51.62	0.1%	$45.53
E0135	Folding Walker without Wheels	$78.97	$47.65	4.8%	$45.53
E0141	Rigid Walker with Wheels	$107.89	$81.62	0.5%	$45.53
E0143	Folding Walker with Wheels	$111.69	$45.22	94.6%	$45.53

[1] Average of 2015 fee schedule amounts for all areas

[2] The SPA would be adjusted to this amount before making adjustments to the fee schedule

This weighted average SPA would be used to adjust the fee schedule amounts for these four codes rather than simply limiting the SPAs for E0135 and E0143 in Table 16 above. This method uses item weights in a product category to adjust the SPA before making adjustments to the fee schedule amount. Under proposed method 2, these three price inversions would be addressed so that the SPAs for all of the similar items described by codes E0130, E0135, E0141, and E0143 in this CBA would be adjusted to the weighted average of the SPAs for these codes for similar items in this CBA.

Although CMS believes that both method 1 and method 2 would correct inverted SPAs, method 1 simply limits the amount paid for the item without a feature(s) to the item with the feature(s), while method 2 factors in the SPAs for all of the items. CMS is proposing to use method 2 because it takes into account the supplier bids for all of the similar items into account in establishing the payment amounts used to adjust fees; and therefore, factors in contemporary information relative to bids and supplier information for various items with different features and costs.

PROPOSALS:

- Adopt a definition of price inversion as any situation where the following occurs:
    - (a) one item in a product category includes a feature that another, similar item in the same product category does not have (for example, wheels, an alarm, or Group 2 performance);
    - (b) the average of the 2015 fee schedule amounts for the code with the feature is higher than the average of the 2015 fee schedule amounts for the code without the feature; and
    - (c) the SPA for the item with the feature is lower than the SPA for the item without that feature.
- In situations where price inversions occur under a CBP, the SPAs for the items would be adjusted before applying the fee schedule adjustment methodologies.
- The adjustments to the SPAs would be made using method 2 described above.
- Use method 2 to adjust the SPAs for all of the similar items where price inversions have occurred, both with and without certain features, so that they are limited to the weighted average of the SPAs for the items in the product category in the CBA before applying the fee schedule adjustment methodologies.
- Apply this rule to price inversions as defined in this proposed rule for the groupings of similar items listed in the Table 18 below.
- Add a definition of “total nationwide allowed services”, to mean 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.
- Define the weight for each code in a grouping of similar items for purposes of calculating the weighted average as the proportion of the total nationwide allowed services for the code for claims with dates of service in calendar year 2012 relative to the total nationwide allowed services for each of the other codes in the grouping of similar items for claims with dates of service in calendar year 2012.

- Use data from calendar year 2012 because this is the most recent calendar year that includes data for items furnished before implementation of Round 2 of the CBP and the beginning of the price inversions. The weights reflect the frequency that covered items in a grouping of similar items were furnished in calendar year 2012 on a national basis relative to other items in the grouping.
- To avoid the aforementioned price inversions in situations where CMS finds that a product category includes a grouping of two or more similar items with different features, CMS would utilize an alternative to the current bidding methodology. Under this alternative bidding methodology, CMS will designate one item as the lead item for the grouping for bidding purposes. The item in the grouping with the highest allowed services during a specified base period will be considered the lead item of the grouping.
- the lead item bidding method only applies to a subset of similar items with different features identified in this rule, as opposed to an entire product category.
- CMS would automatically calculate the SPAs 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.
- Use the fee schedule amounts for 2015 for the purpose of determining the relative difference in fee schedule payments for similar items.
- The supplier would be educated at the time of bidding that the SPAs for the other similar items would be based on its bid for the lead item, and the supplier is therefore submitting bids for all of these items when bidding on the lead item.
- Namely all codes for walkers, hospital beds, and standard power wheelchairs would be subject to this proposed rule and not just those codes for walkers, hospital beds, and standard power wheelchairs where price inversions have already occurred.
- To identify the lead item, CMS proposes using allowed services from calendar year 2012 for the first time this bidding method is used for specific items in specific CBAs.
- Once this bidding method has been used in all competitions for an item the lead item would be identified for future competitions based on allowed services for the items at the time the subsequent competitions take place rather than the allowed services from calendar year 2012.

REQUEST FOR COMMENTS:

- CMS is soliciting comments on both method 2, which they are proposing, and method 1, which they are considering.

TABLE 18 – Groupings of Similar Items

Grouping of Similar Items	HCPCS Codes[1]
Enteral Infusion Pumps	B9000, B9002
Hospital Beds	E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, E0304
Mattresses and Overlays	E0277, E0371, E0372, E0373
Power Wheelchairs	K0813, K0814, K0815, K0816, K0820, K0821, K0822, K0823
Seat Lift Mechanisms	E0627, E0628, E0629
TENS Devices	E0720, E0730
Walkers	E0130, E0135, E0141, E0143

[1] The descriptions for each HCPCS code are available at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html

Bid Limits for Individual Items under the DMEPOS Competitive Bidding Program

If the fee schedule amounts are adjusted as new SPAs are implemented under the CBPs, and these fee schedule amounts and subsequent adjusted fee schedule amounts continue to serve as the bid limits under the programs, the SPAs under the programs can only be lower under future competitions because the bidders cannot exceed the bid limits in the CBP. To continue using the adjusted fee schedule amounts as the bid limits for future competitions does not allow SPAs to fluctuate up or down as the cost of furnishing items and services goes up or down over time.

CMS is proposing this change because the Agency believes the general purpose of the DMEPOS CBP is to establish reasonable payment amounts for DMEPOS items and services based on competitions among suppliers for furnishing these items and services, with bids from suppliers being based in part on the suppliers' costs of furnishing the items and services at that point in time. CMS believes the intent of the program is to replace unreasonably high fee schedule amounts for DMEPOS items and services with lower, more reasonable amounts as a result of the competitive bidding.

PROPOSALS:

- Specify that the bids submitted for each individual item of DMEPOS other than drugs cannot exceed the fee schedule amounts established in accordance with sections 1834(a), 1834(h), or 1842(s) of the Act for DME, off- the-shelf (OTS) orthotics, and enteral nutrition, respectively, as if adjustments to these amounts based on information from CBPs had not been made.
    - Specifically, the bid limits for DME would be based on the 2015 fee schedule amounts.
- With respect to the alternative bidding rules proposed above, when evaluating bids for a grouping of similar items in a product category submitted in the form of a single bid for the

highest volume item in the grouping, or lead item, CMS proposes to use the weighted average fee schedule amounts for the grouping of similar items in order to establish the bid limit for the purpose of implementing this proposed provision.

- Use total nationwide allowed services for all areas for the individual items, initially from calendar year 2012, to weight the fee schedule amount for each item for the purpose of determining a bid limit for the lead item based on the weighted average fee schedule amounts for the entire grouping of similar items.

Access to Care Issues for DME

REQUEST FOR INFORMATION:

CMS seeks to examine how overlapping but differing coverage standards for DME under Medicare and Medicaid may affect access to care for beneficiaries and administrative processes for providers and suppliers. CMS seeks to obtain additional information to help target efforts to promote timely access to DME benefits for people dually eligible for Medicare and Medicaid.

Please provide comments on the scope of the following issues related to DME access for dual eligible beneficiaries:

- Obstacles to timely receipt of needed DME and repairs due to conflicting program requirements;
- Challenges or opportunities faced by Medicaid beneficiaries who newly qualify for Medicare, including challenges related to new and preexisting items, repairs, and providers;
- The percentage of Medicare competitive bidding contractors in the state which accept Medicaid;
- The role of prior authorization policies under either program and whether these policies offer suppliers sufficient advance notice regarding coverage;
- Impacts on beneficiaries from delayed access to needed equipment and repairs;
- If access problems are more pronounced for certain categories of equipment, the categories of DME for which the access problems arise the most frequently or are most difficult to resolve;
- Challenges faced by suppliers in meeting different supporting documentation and submission requirements, and
- Other prevalent access challenges due to DME program misalignments. We also invite feedback regarding potential regulatory or legislative reforms to address DME program misalignments including:
- State Medicaid program policies that promote coordination of benefits and afford beneficiaries full access to benefits;
- Strategies to promote access to timely, effective repairs, including from suppliers who that did not originally furnish the equipment;
- Policies to address challenges faced when beneficiaries transition from Medicaid-only to dual eligible status; and

- Other ways to promote timely DME access for dual eligible beneficiaries, without introducing new program integrity risks or increasing total expenditures in either Medicare or Medicaid.

Please include specific examples when possible while avoiding the transmission of protected information. Please also include a point of contact who can provide additional information upon request.