



Via email to secretary@hhs.gov

March 23, 2017

The Honorable Tom Price, MD
Secretary
The U.S. Department of Health and Human Services
200 Independence Avenue, S. W.
Washington, D. C. 20201

RE: Regulatory Reform Proposals for DMEPOS Competitive Bidding Program

Dear Secretary Price:

This is a follow-up to our letter submitted to you on February 28, to share with you reform recommendations on several issues related to Centers for Medicare and Medicaid's (CMS') DMEPOS competitive bidding program. The competitive bidding program's flawed design has caused enormous disruptions to suppliers and beneficiaries of DMEPOS, but we believe the Department of Health and Human Services (HHS) has an opportunity to correct some of the flaws before the next round of competitive bidding by issuing regulatory changes through the formal rulemaking process. In addition, some of these changes can be promulgated through CMS' sub-regulatory guidance. In this letter, we outline six reform proposals with an overview of the issue, rationale for the reform, and regulatory authority for the recommendation. **AAHomecare recommends CMS go through the formal rulemaking process to instate the proposed reforms in the next round of competitive bidding, slotted for 2019.** Although there are more problems we would like to discuss with you, we have identified six issues that can be fixed immediately by the Administration. In no particular order, below are the reform proposals that can be addressed immediately:

1. Use market clearing price to determine Single Payment Amount (SPA) for any item included in competitive bidding

RATIONALE: Using the median of bids distorted bid pricing because lowball bidders are guaranteed a contract. Adopting the clearing price as the SPA is fair to suppliers whose bids establish the cut off of the winning bids and blunts incentives for lowball bidding.

RECOMMENDED ACTION: Establish the SPA rate at the “Market Clearing Price,” the bid amount that is the cut off price for all winning bids (i.e., winning bids equal all bids at or below the clearing price).

2. Use historical claims data to determine supplier capacity

RATIONALE: CMS or contractor needs to improve its monitoring of contract suppliers’ ability (or willingness) to furnish all items in product categories and to assess the impact of contractors’ noncompliance on access for beneficiaries in the CBA.

RECOMMENDED ACTION: Revise 42 CFR § 414.414(e), 42 CFR 414.414(i), and 42 CFR § 414. 423 that would specify capacity requirements. CMS can make this change via sub-regulatory guidance.

3. Increase transparency of the competitive bidding program

RATIONALE: 42 CFR 414.414 establishes the framework CMS uses to select winning bidders, but does not articulate the standards CMS applies to arrive at those decisions. Suppliers have no assurance that CMS uses the same standards for each competition across CBAs or that CMS applies the same standards uniformly to all suppliers in the same bid pool.

RECOMMENDED ACTION: Revise 42 CFR §414.414 to explicitly articulate the standards/criteria CMS uses to select winning bidders. CMS can make this change via sub-regulatory guidance.

4. Reform competitive bidding product categories

RATIONALE: The current structure of competitive bidding product categories is too broad, resulting in low ball bidding by certain bidders which results in reducing beneficiary access to quality products and prohibiting specialty suppliers from participation.

RECOMMENDED ACTION: Reform competitive bidding product categories to enhance beneficiary access to quality goods and services. CMS can make this change via sub-regulatory guidance.

5. Apply uniform payment rules for transitioning DMEPOS competitive bidding beneficiaries

RATIONALE: Different rules apply for contract suppliers who accept beneficiaries from another contracted supplier as opposed to a non-contracted supplier. The burden is the same for the contracted supplier who is receiving a new beneficiary and there is no apparent rationale for the different rules.

RECOMMENDED ACTION: Revise the payment rules under §414.408 to allow contract suppliers that accept beneficiaries who change suppliers to receive additional rental payments whether the beneficiary is switching from a non-contracted supplier, or from another contract supplier.

6. Remove CMS’ authority to move forward with Continuous Positive Airway Pressure (CPAP) and Standard Power Mobility Devices (PMD) bundled payments

RATIONALE: Bundling creates the wrong incentives for suppliers who could establish formularies that diminish access for beneficiaries with specific individual needs and there is no authority that allows CMS to use competitive bidding to create new equipment categories like bundled bidding for CPAP or Standard PMDs.

RECOMMENDED ACTION: Repeal 42 CFR §414.409 which established bundled bidding programs for CPAP and standard power wheelchairs.

We have attached additional detail for each of these recommendations.

Our members are committed to providing quality health care services that improve the lives of patients living in their home setting. Resolving the issues highlighted in this letter are imperative to continuing to allow the DMEPOS industry to provide the quality services Medicare beneficiaries need. **AAHomecare recommends CMS go through the formal rulemaking process to instate the proposed reforms in the next round of competitive bidding, slotted for 2019, although in some instances noted above CMS can make the recommended change through sub-regulatory guidance.** In addition, CMS should emphasize that when State law requires a supplier to have a physical presence to be licensed in the State, the supplier must demonstrate when bidding that it has such a physical presence. We also recommend that for home respiratory therapies, CMS enforce the quality standard that requires a physical presence.

The current program is not sustainable as it stands. We believe the reforms highlighted in this letter will improve the credibility and sustainability of the competitive bidding program. We welcome the opportunity to have further conversations on the proposals.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Ryan". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Tom Ryan
President and CEO
American Association for Homecare

Reform Proposal 1:

Revise 42 CFR §414.402 to replace the definition of “pivotal bid” with:” Clearing Price is: the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.”

Revise 42 CFR §414.416(b) to establish SPAs at clearing prices [pivotal bid].

Situation and Problem:

42 CFR §404.4116(b) establishes SPAs at the median of all winning bids, *i.e.*, all bids at or below the clearing price.

CMS adopted this rule with no apparent justification except to achieve lower SPA prices.

The rule distorts bid pricing because lowball bidders are guaranteed a contract, but lowball bidders can be reasonably sure their reimbursement will be higher than their bids.

The rule places suppliers whose bids established the clearing price in the untenable position of having to accept bids that are significantly less than their estimated costs which presumably was their best bid offer.

Although bidders post a bid bond to guarantee they will accept a contract if their bid wins, the bond alone does not completely deter lowball bidding. Lowball bidders are almost certainly guaranteed a contract that pays more than their bids. This is a powerful incentive for low bidding; a contract award increases the value of suppliers’ businesses allowing them to sell their companies at a higher price than they would have if they had lost their bids.

Proposed Changes to Existing Policy:

Establish SPAs at the clearing price, the cut off bid that determines contract winners (*i.e.*, winning bids equal all bids at or below the clearing price).

Rationale:

This proposal incorporates the capacity provisions under the DMEPOS Market Pricing Program Act of 2013 (“MPP”).¹

Adopting the clearing price as the SPA is fair to bidders whose bids established the cut off price and blunts incentives for lowball bidding.

Using the clearing price to establish contract pricing is the standard for the overwhelming majority of auctions across all business and government sectors.

The proposed revision aligns with the goals of competitive bidding and ensures that the CB program remains sustainable and protects beneficiaries’ access to quality DMEPOS.

The proposed revision is consistent with Congress’ intent to use competition to establish Medicare pricing for DMEPOS in order to save program funds while maintaining beneficiaries’ access to quality items and services.

¹ H.R. 1717, available at: <https://congress.gov/>

Two hundred and forty-four (244) leading U.S. economists outside the DMEPOS industry analyzed the design of the competitive bidding program and voiced concerns about the incentives for lowball bidding that result from using the median of all winning bids instead of clearing prices to establish contract pricing.²

When the SPA equals the median of all winning bids, contract prices are roughly half of the clearing price, meaning half of all bidders are paid less than their bids, impairing the long-term viability of the program.

Establishing SPAs at the clearing price stabilizes the market in a CBA, assuring beneficiaries have better access to higher quality DMEPOS over the long-term

Evidence shows that fraud and abuse occurs when contract prices are at the median of the winning bids (selective fulfillment, non-fulfillment, etc.) because half of the "winners" lose money on every sale.³

² *Designed to Fail: The Medicare Auction for Durable Medical Equipment*, P Cramton, S Ellermeyer, B Katzman - Economic Inquiry, 53: 469-485 (2015).

³ See e.g., *The State of Expert Judgment Regarding Medicare's Competitive Bidding Program for Durable Medical Equipment*. The Moran Company (September 2016).

Reform Proposal 2:

Revise 42 CFR §414.414(e) to specify that bidders' capacity for furnishing product category items in a CBA equals their historical claims submission for the items.

Revise 42 CFR §414.414(e) to specify that inexperienced bidders in either the product category and/or competitive bidding area are not used to establish clearing price.

Revise 42 CFR §414.414(e) to include a new requirement for the CBIC or CMS to perform post award monitoring of contract suppliers to ensure they are furnishing product category items according to their contracts.

Revise 42 CFR §414.414(e) to specify that contract suppliers are in breach of contract if they do not furnish the items they agreed to furnish for three (3) consecutive quarters.

Revise 42 CFR §414.414(i) to make CMS recalculate SPAs for product category items when the Agency adds new contract suppliers to a CBA in order to meet beneficiaries' demand for the items.

Revise 42 CFR §414.423 to specify that CMS or CBIC will publish a quarterly list of contract suppliers who are under a CAP or whose contracts were terminated.

Situation and Problem:

CMS projects demand for product category items by looking at historical claims submission data for the items in a CBA and estimating how many beneficiaries will need the items over the contract term, then adjusting the estimates for seasonal fluctuations. Next, CMS asks bidders to project the number of items they can furnish during the term and compares bidders' self-reported capacity with their historical claims submission data for the items in the CBA.⁴ Bidders may also submit expansion plans explaining how they will ramp up capacity to meet new demand in the CBA.

CMS controls bidders' capacity projections in two ways. First, CMS caps bidders' capacity at 20% of the projected demand for product category items in the CBA. And second, CMS reserves the right to adjust bidders' self-reported capacity up or down based on its assessment of the bidder's financial ability to grow capacity.⁵ But CMS does not explain what factors it uses to make these adjustments. Because the Agency's capacity is an intrinsic component of the CB clearing price methodology, it is impossible to know whether CMS manipulates bidders' capacity in order to influence clearing prices. This lack of transparency relieves CMS of accountability for its' administration of the CB program.

CMS can add suppliers to a CBA if contract suppliers there cannot meet beneficiaries' demand for product category items, but the Agency does not recalculate SPAs for the items when it adds new contractors.

Proposed Changes to Existing Regulations:

CMS can make this change via sub-regulatory guidance. In addition, CMS should make the following regulatory changes.

Revise 42 CFR §414.414 (e)(1) and (2) to:

- State explicitly that a bidder's capacity to furnish product category items in a CBA equals his claims submission history for the items in the preceding 12 months.

⁴ *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*, 72 Fed. Reg. 17992 at 18039, (April 10, 2007).

⁵ *Id.* at 18037.

- Require CMS to give bidders their claims history and market share for product category items in a CB for the preceding 12 months.
- Inexperience bidders are not to be used to calculate the clearing price.
- Require CMS or the CBIC to engage in post-award monitoring to ensure contract suppliers furnish product category items according to their contracts, including the following:
 - a requirement to review contract suppliers' claims submission history quarterly;
 - a provision that contract suppliers who do not submit claims for the product category item(s) in their contracts breach the contract;
 - a stipulation that contract suppliers who are in breach for failing to furnish items according to their contracts may enter into a corrective action plan (CAP) under 42 CFR §414.423, and
 - a statement that CMS will terminate contract suppliers who do not agree to a CAP or who fail to meet the CAP's terms subject to their appeal rights under 42 CFR §414.423.

Revise 42 CFR §414.414(i) to:

Require CMS to recalculate SPAs for product category items when the Agency adds new contract suppliers to a CBA in order to meet beneficiaries' demand for the items.

Revise 42 CFR §414.423 to:

Require CMS or CBIC to publish a quarterly list of contract suppliers who are under a CAP or whose contracts were terminated.

Rationale:

This proposal incorporates the capacity provisions under the DMEPOS Market Pricing Program Act of 2013 ("MPP").⁶

Basing capacity on bidders' claim submission history prevents market distortions that occur when CMS "adjusts" bidders' capacity up or down.

CMS and CBIC need to improve their monitoring of contract suppliers' ability (or willingness) to furnish all of the items in any product categories they agreed to furnish in their contracts and to assess the impact of contractors' breach of contract on access to product category items for beneficiaries in the CBA.

To ensure CMS' accountability for running the CB program and facilitate HHS' oversight of how CMS administers CB, the Agency must promulgate regulations that clearly define the standards it applies to evaluate bidders' eligibility, capacity, bid acceptance and contract awards.

⁶ H.R. 1717, available at: <https://congress.gov/>

Reform Proposal 3:

Revise 42 CFR §414.408 to apply uniform payment rules for contract suppliers who accept beneficiaries from another supplier.

Situation and Problem:

42 CFR §414.408 establishes the payment rules for suppliers in CBAs and determines reimbursement for contract suppliers when beneficiaries change suppliers.

The rules allow for additional monthly rental payments to contract suppliers who accept beneficiaries from grandfathered suppliers or ones who move from an area outside a CBA to a CBA.

Contract suppliers who accept a beneficiary from a grandfathered supplier, or one who moves from a non-CBA to a CBA, can restart the 13-month contract for rental equipment at the applicable SPA for the item in the CBA.

Contract suppliers who accept a beneficiary on oxygen from a grandfathered supplier, or one who moves from a non-CBA to a CBA receive up to 36 monthly rental payments, or at least 10 monthly payments, whichever is greater, at the applicable SPA amount for oxygen in the CBA.

Contract suppliers who accept beneficiaries from another contract supplier do not receive additional rental payments.

There is no apparent rationale for the distinction the rule makes between beneficiaries switching to a contract supplier from a grandfathered supplier, or one moving from a non-CBA to a CBA, and those switching from contract suppliers. The burden to the contract supplier of receiving beneficiaries whose equipment or oxygen is at or near the end of the rental period is the same whether the beneficiary is switching from a contract or grandfathered supplier, or is moving from a non-CBA to a CBA.

Proposed Changes to Existing Policy:

CMS can make this change via sub-regulatory guidance.

Revise the payment rules under §414.408 to allow contract suppliers that accept beneficiaries who change suppliers to receive additional rental payments whether the beneficiary is switching from a grandfathered supplier, another contract supplier or is moving from an area outside a CBA to a CBA.

Rationale:

The burden to the contract supplier of receiving beneficiaries whose equipment or oxygen is at or near the end of the rental period is the same whether the beneficiary is switching from a contract or grandfathered supplier, or moving to a CBA from a non-CBA.

Reform Proposal 4:

Narrow the definition of “product category” under 42 CFR 414.402 to specify that a product category “consists of DMEPOS items that treat the same condition as identified in NCDs or LCDs.”

Situation and Problem:

Currently, CMS creates broad categories by combining several medical policies into loosely related groups of items identified by their HCPCS codes. These broad product categories result in several problems, including the following:

- Creating an uneven playing field and barriers to entry for smaller niche suppliers who do not offer every product line in the category (*e.g.*, many suppliers furnish CPAPs and RADs, but not oxygen). CB rules require contract suppliers to furnish every HCPCS code in the product category, so suppliers who furnish only one product line, like CPAPs and RADs, but not oxygen, cannot bid. But narrowing product categories to the HCPCS reflected in individual medical policies, would allow suppliers to bid on only one product line, increasing competition and beneficiary choice of contract suppliers.
- Encouraging low ball bidding by bidders who intend to furnish only one product line for specific segment(s) of the product category, but who have no intention of furnishing any of the others. Currently, product categories encompass multiple medical policies, including DMEPOS items that are only loosely related. For example, the product categories combine: oxygen with CPAP; hospital beds with support surfaces with seat lift chairs; and standard manual wheelchairs with standard power wheelchairs. Bidders can bid low on the items they do not intend to furnish, but higher on the ones they will. This results in two negative effects. First, the product category methodology distorts SPAs by skewing bids on individual items downward. And second, for some product lines in the CBA there will not be enough contract suppliers to meet beneficiaries’ demand.
- Masking the potential savings that would result from competitively bidding items in a product category by driving SPAs downward as described above, causing CMS to make inaccurate decisions about what items should be subject to bidding.
- Reducing both competition for some product categories and beneficiaries’ choice of contract suppliers because niche suppliers cannot participate in the bidding.

Proposed Changes to Existing Policy:

CMS can make this change via sub-regulatory guidance.

- Distinct Competitive Bidding Product Categories: Products / HCPCS codes included in a competitive bidding product categories should be designed to address a specific need. Recommend that the product categories be as follows:
 - Oxygen, Oxygen Equipment and Related Supplies and Accessories
 - Continuous Positive Airway Pressure (CPAP) Devices, Respiratory Assist Devices (RADs) and Related Supplies and Accessories
 - Nebulizers, and Related supplies
 - Enteral Nutrients, Equipment and Supplies
 - Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories
 - Transcutaneous Electronic Nerve Stimulation (TENS) Devices and Supplies

- Hospital Beds, Equipment and Related Supplies and Accessories
 - Support Surfaces, Group 1 and 2 and Related Supplies and Accessories
 - Commode Chairs and Related Supplies and Accessories
 - Patient Lifts and Related Supplies and Accessories
 - Seat lift mechanisms
 - Walkers and related accessories and supplies
 - Standard Power Wheelchairs, Scooters, and Related Accessories
 - Standard Manual Wheelchairs, and Related Accessories
- Perform a Rigorous Product Category Analysis: Creating a rigorous analytical tool and using it to decide whether to include a medical policy (and all the DMEPOS items within its scope) in CB as a product category, will yield more accurate bidding decisions for CMS. (See Appendix 1)
 - Perform a Rigorous HCPCS Code Analysis: Creating a rigorous analytical tool and using it to decide to decide whether to include individual items identified by their HCPCS code product categories subject to CB will yield more accurate bidding decisions for CMS. (See Appendix 2).
 - Freeze Medicare Coverage and Payment Rules: Holding changes to medical policies to the end of the contract term (*i.e.*, the end of a bidding round in a CBA) protects beneficiaries' access to quality DMEPOS and choice of suppliers. Bidders project their costs for furnishing DMEPOS in a product category over the contract term on assumptions they make according to rules in place when they submit bids. These rules include requirements in: medical policies, the program integrity manual, and the claims processing manual among others (*i.e.*, changes in coding, coverage, payment and/or compliance requirements). Changes to these rules typically increase contract suppliers' cost of doing business in the CBA, jeopardizing their financial viability and by extension, access and quality for beneficiaries.

Rationale:

Limiting product categories to include only DMEPOS items within the scope of individual NCDs or LCDs:

- Discourages low ball bidding compared to the broad product categories that CMS uses today, (*i.e.*, Respiratory Equipment and Related Supplies and Accessories, General Home Equipment and Related Supplies and Accessories, and Standard Mobility Equipment and Related Accessories). These broad product categories create barriers to bidding/entry for suppliers who specialize in only one type of product in the category (*e.g.*, CPAP/RAD supplier does not provide oxygen) and encourage suppliers who do not plan to furnish **every** item in the broad category to submit very low bids on product category items they do not intend to furnish. There is precedent for this approach. In Round 2 Recompete CMS removed nebulizers from the Respiratory Equipment product category and TENS from the General Home Equipment product category.
- Levels the playing for all bidders by allowing suppliers to bid only on the product lines they furnish.
- Furthers an accurate assessment of the costs savings to Medicare of competitively bidding items in a product category by avoiding distortions that result from bidding on product categories that combine multiple medical policies. CMS' use of broad product categories based on multiple medical policies not only encourages low ball bidding, the low-ball bids also distort the true costs savings to Medicare of bidding the product category. This, in turn, adversely affects CMS' ability to make accurate determinations about whether to bid a product category.
- Protects beneficiaries' access to quality DMEPOS items and maximizes competition and savings for the program. Because CMS requires contract suppliers to furnish every HCPCS in a product category, the current

policy favors suppliers that carry the broadest assortment of DMEPOS items and services to the detriment of niche suppliers that specialize in a single line of service.

Product Category/HCPCS Code Analysis:

- Adopt a well-defined and rigorous methodology for deciding which product categories are suitable for bidding. The methodology must consider both potential Medicare savings **and** the impact that bidding items in the product category will have on beneficiaries' care and access.

Freeze Medicare coverage and payment rules for the term of a bidding round:

- DME suppliers develop their bids based on the rules in effect at the time of bidding. Changes to the codes, rules or requirements (coding, coverage, compliance and payment policies) will directly affect the viability of suppliers' bids. So, changes to those codes, rules or requirements need to trigger a new round of bidding to reflect the change unless CMS holds the changes until the end of the bidding round. There is precedence for exempting CB contracts signed prior to implementation of a change in payment policy from applying to CB. Standard power wheelchairs in the round 1 rebid were bid as a purchase item and remained eligible to be paid as a purchase for the full term of CB contracts in the round 1 rebid CBAs.

Appendix 1

Select appropriate medical policies for competitive bidding. In evaluating medical policies for potential competitive bidding, we would suggest that following factors be considered:

- Total allowed expenditures.
- Total number of suppliers furnishing products for the specific medical policy within a competitive bid area (CBA) to ensure that there is adequate access to the products within the CBA.
- Level of service associated with the products included in the medical policy. This is necessary to be specified in the bid requirements to ensure that services are provided and that their costs are represented in the bids submitted.
- Complexity of the product selection decision tree beyond that represented by the specific HCPCS codes and descriptors. For example, does the HCPCS code include products in a variety of shapes, sizes, materials, configurations, technologies, etc.?
- Therapeutic nature of the products included in the medical policy. For example, a report published by the Agency for Healthcare Research and Quality (AHRQ) in April, 2006 indicates that there has been a 63% increase in hospitalizations associated with wounds between 1993 and 2003. Further, it suggests that the average cost to treat these patients is \$37,800. What would be the impact if competitively bidding reduced access to products designed to prevent skin breakdown or treat skin breakdown? The risk of costs must be considered when shifted to other sectors of healthcare if quality and/or access are reduced as a result of competitive bidding.

The following is an illustration of how this methodology could be applied in evaluating a medical policy for inclusion in competitive bidding:

Question	Points
1. What was the total annual expenditure by Medicare Part B for this medical policy in YYYY? (If < \$50M = 0 pts, < \$100M = 5 pts, \$100 to 250M = 10 pts, \$250 to 500M = 15 pts, > \$500M = 20 pts)	
2. What is the ratio of suppliers furnishing products from the medical policy to the number of beneficiaries requiring such products within the defined MSA? (If X then 20 pts, Y then 10 pts, Z then 0 pts.)	
3. Do the products associated with the medical policy commonly require unique, "individualized" set-up and / or adjustment? (Never = 20, moderate = 10, considerable = 0)	
4. For products within the medical policy, are there additional considerations required beyond what is defined by the HCPCS codes themselves? For example, shape, size, materials, and physical configuration? (None = 20, moderate = 10, considerable = 0)	
5. Are the products defined by the medical policy intended to prevent or treat a condition which, left unchecked could result in other costs to the Medicare program through a hospital / LTC admission and length of stay? (no = 20, yes = 0)	
Total Score (out of 100 possible):	

Scoring could then be used to establish a minimum threshold for bidding and to compare the benefits of bidding one category of product versus another. Using such a methodology on a medical policy basis within an identified CBA would provide the greatest likelihood for achieving savings while protecting care and access. Question one would address potential savings. Question two would address access. Questions three and four would address the needs for skilled delivery/quality and service. Question five would consider the potential impact to the Medicare system as a whole considering the potential for additional medical complications and expenses that could result from poor product and service performance.

Appendix 2

Selecting specific HCPCS codes for competitive bidding from medical policies chosen for bidding. In evaluating HCPCS codes for potential competitive bidding we would suggest that following factors be considered:

Question	Points
A) What was the total annual expenditure by Medicare Part B for this HCPCS code in YYYY? (If < \$XXM = 0 pts, If ≥ \$XXM but < \$YYM = 5 pts, If ≥ \$YYM but < \$ZZM = 10 pts, If ≥ \$ZZM but < \$\$\$M = 15 pts, If ≥ \$\$\$M = 20 pts)	
B) Do the products associated with the HCPCS code commonly require unique, "individualized" set-up and / or adjustment? (Never = 20, moderate = 10, considerable = 0)	
C) Are there additional decisions required beyond what is defined by the HCPCS codes itself in selecting the product for the individual? For example, shape, size, materials, and physical configuration? (None = 20, moderate = 10, considerable = 0)	
D) Would replacement of the specific manufacturer, make and model product the beneficiary is currently using with another product assigned to the same code have a potentially detrimental impact on the individual's health? Does the code include multiple technologies? (Yes = 0, No = 20)	
E) Are the products defined by the HCPCS code intended to address a specific condition via prevention or treatment? (Yes = 0, No = 20)	
Total Score (out of 100 possible):	

Scoring could then be used to establish a minimum threshold for bidding a HCPCS code within a defined medical policy. Once again, using such a methodology would certainly provide the greatest likelihood for achieving savings while protecting care and access. Question “A” would address potential savings. Questions “B, C and D” would address the needs for skilled delivery / quality service. Questions “D and E” would consider the potential impact to the Medicare system as a whole, evaluating the potential for additional medical complications and expenses that could result from a lack of access to specific products and services.

Reform Proposal 5:

Revise 42 CFR §414.414 to explicitly articulate the standards CMS uses to select winning bidders and establish clearing prices.

Situation Problem:

42 CFR §414.414 establishes the framework CMS uses to select winning bidders, but does not articulate the standards CMS applies to arrive at those decisions.

Suppliers have no assurance that CMS uses the same standards for each competition across CBAs or that CMS applies the same standards uniformly to all suppliers in the same bid pool. Suppliers who win or lose do not understand the reasons for the outcome. More importantly, CMS can escape public accountability for how it administers the CB program.

Much of the bid submission “rules” are in sub regulatory “guidance” documents published on the Agency’s or CBIC contractor’s website. These bulletins and FAQs are not regulations, but they are nonetheless binding on bidders even though they are subject to change without notice.

Although these website bulletins and FAQs establish or change “a substantive legal standard” that the Secretary must publish by regulation, CMS adopts these rules without giving suppliers, beneficiaries or referral sources advance notice of the requirements and an opportunity to comment on them.⁷

Using the Agency’s or the CBIC website to publish bulletins or FAQs that establish the requirements bidders *must* follow to remain the bid pool and win contracts results in the haphazard dissemination of rules and is inconsistent with due process.

Among the most troubling:

- 42 C.F.R. §414.414(d)(1) requires suppliers to prove they meet minimum financial standards to receive a contract award. The RFB identifies the **documents** bidders must submit to establish their financial viability. But the Agency reserves the right to require different documents in other bidding rounds.⁸ Crucially, CMS has never articulated the financial **standards** the Agency uses to assess a bidder’s financial capacity which, in turn, determines whether CMS will accept his bid. Suppliers have lost contracts for not meeting financial “standards,” but do not know what standards they “failed.” They cannot challenge CMS’ decision and do not know what they have to “fix” in order to win a contract in the next bidding round. The result is that CMS lacks public accountability for how it decides whether to accept a supplier’s bid.
- 42 C.F.R. §414.416(b)(1) establishes SPAs at the median of all winning bids, *i.e.*, all bids at or below the clearing price. But unlike what is the standard protocol for auctions across all government and business sectors, CMS does not publish even redacted bids. There is no mechanism to check the fairness and accuracy of CMS’ supplier selection and contract awards decisions. Again, CMS avoids public accountability for how it evaluates bids and selects winning bidders.

⁷ 42 USC 1395hh, states, in part:

No rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation[.]

⁸ *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*, 72 Fed. Reg. 17992 at 18037, (April 10, 2007).

- 42 C.F.R. §414.414(e)(2) requires CMS to ensure sufficient supplier capacity to meet beneficiaries’ demand for product categories items in a CBA. CMS projects demand by looking at historical claims submission for the items in the CBA and estimating how many beneficiaries will need an item over the contract term then adjusts for seasonal fluctuations. Next, CMS asks bidders to estimate their capacity to furnish the items and compares bidders’ self-reported capacity to their historical claims submission for the items.⁹ If a bidder’s estimate requires an expansion, CMS evaluates his expansion plan to see if it satisfies an “expansion threshold score.”¹⁰
- CMS also controls capacity by capping a bidder’s capacity at 20% of the market for the product category and stipulating that it may “adjust” a bidder’s capacity up or down depending on its evaluation of the bidder’s financial ability to meet increased demand.¹¹ But CMS has never disclosed its capacity projection analysis, supplier expansion threshold scores, or how it determines whether to adjust a bidder’s estimate of his capacity. Because CMS’ decisions about capacity are at the heart of the clearing price methodology, it is impossible to know whether CMS manipulates bidders’ capacity to influence clearing prices. Once again, this means CMS has no accountability for its administration of the CB program.

Proposed Changes to Existing Policy:

Clearly articulate the standards/criteria CMS uses to determine suppliers’ qualification to receive contract awards, especially the following:

- §414.414(d)(1): Financial Standards
- §414.416: Redacted Submitted Bids to Confirm the Clearing Price and SPA Price
- §414.41(e)(2) & §414.414(h)(2): Capacity Estimates and Threshold Capacity Scores

Rationale:

The proposed revisions would make CMS accountable for its administration of the program, especially its decisions on bidder eligibility, bid acceptance and contract awards and would facilitate oversight of CMS’ administration of the CB program by the Department of Health and Human Services.

⁹ 72 Fed. Reg. 17992 at 18039, (April 10, 2007).

¹⁰ *CBIC Review of Supplier Capacity and Expansion Plans Fact Sheet*, available at: <http://dmecompetitivebid.com/palmetto/cbicrd1recompete.nsf/DocsCat/8WSJ9K0402>

¹¹ *Id.* at 18039.

Reform Proposal 6:

Repeal 42 CFR §414.409, establishing bundled bidding programs for CPAP and standard power wheelchairs because the rule exceeds CMS' authority to engage in competitive bidding (CB).

Repeal 42 CFR §414.412(a)(4) because CMS' decision to cap bids for bundled CPAP items at the 1993 fee schedule rate is arbitrary and capricious.

Situation and Problem:

42 USC § 1395-w-3, the enabling statute for CB, does not give CMS authority to change the equipment categories set forth in §1395m, the general payment authority for DMEPOS.

CMS has significant latitude to engage in CB programs, but the Agency must nonetheless operate within the framework Congress created under §§1395m and 1395w-3. That framework directs the Agency to use CB to establish payment amounts for DMEPOS in CBAs, and to pay for DMEPOS consistent with the equipment categories under §1395m.

Congress did not repeal §1395m or relieve CMS from complying with its mandates when it enacted §1395w-3. Instead, Congress chose to leave the equipment categories in place and use CB programs only to establish new payment amounts for DMEPOS in CBAs.

There is no authority that allows CMS to use CB to create new equipment categories like bundled bidding for CPAP or standard power wheelchairs.

Assuming, but not conceding that CMS could engage in bundled bidding for CPAP, CMS' decision to cap bids for CPAP bundles at the 1993 fee schedule rate is arbitrary and capricious.

CMS' exemption from judicial or administrative review for its administration of CB programs applies only when CMS is acting under the scope of its statutory CB authority.

42 CFR §414.409 exceeds the scope of CMS authority under §§1395m and 1395w-3. The rule is invalid, does not authorize CMS to engage in bundled bidding programs and is procedurally vulnerable in a judicial challenge.

Proposed Changes to Existing Policy:

Repeal §414.409 because the rule is beyond the scope of CMS' statutory CB authority and procedurally vulnerable in a judicial challenge.

Repeal 42 CFR §414.412(a)(4) because the rule lacks any factual foundation, exceeds CMS' statutory CB authority and is arbitrary and capricious.

Rationale:

The rule exceeds the Agency's CB authority under §§1395w-3 and 1395m.

Bundling creates the wrong incentives for suppliers who could establish formularies that diminish access for beneficiaries with specific individual needs.

There is no consensus for what is in a baseline bundle, so evaluating bids would be arbitrary at best.

Bundling works a disservice for beneficiaries who would have a lifetime of copays compared to having copays for only 13 months as they do now.