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ATTORNEY-CLIENT PRIVILEGE

Memo

Date:	May 5, 2017
To:	Tom Ryan, President AAHomecare
cc:	
From:	Thomas Barker, Partner Christian Springer, Policy Advisor
Regarding:	Legal Support for Reforms to the Competitive Bidding Program

On April 4, 2017, the American Association of Homecare (AAHomecare) met with top officials at the Center for Medicare & Medicaid Services (CMS) to discuss, among other things, the design of the competitive bidding program (in this memorandum "CBP" or "the bidding program") for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). From the perspective of AAHomecare members, there are multiple flaws in the design of the program. Attendees from CMS included CMS Administrator Seema Verma, Principal Deputy Administrator for Medicare Demetrios Kouzoukas, Counselor to the Secretary John Brooks, and Carla DiBlasio, Demetrios' deputy in CMS.

After learning about the perspective of AAHomecare members regarding the current design of the CB program, Ms. Verma requested our views concerning potential changes to the program and sought AAHomecare's specific proposals towards that end. In a previous letter to Secretary Price (Price Letter),[1] AAHomecare had set forth detailed reform proposals on six elements of the bidding program that could be implemented before the next round of bidding, slated for 2019. Some of these changes could be adopted through sub-regulatory guidance, while others would require notice-and-comment rulemaking. But notably, none would require legislation and could be implemented entirely through agency rulemaking or guidance.

[1] "Regulatory Reform Proposals for DMEPOS Competitive Bidding Program", dated March 23, 2017.

In light of the Price Letter's policy-oriented focus to reforming the bidding program, this memorandum establishes the *legal* basis for CMS to pursue each of the changes detailed in the Price Letter. Therefore, this memorandum should be read as a supplement to the Price Letter. Aside from providing legal support for the specific proposals outlined in the Price Letter, this memorandum also argues that, in the interim, CMS has the legal authority to extend the DMEPOS contracts currently in effect from January 1, 2019 to July 1, 2019. Doing so would provide more time for robust stakeholder input and minimize any potential disruption caused by the implementation of the proposals discussed herein.

I. BACKGROUND

A. Timing of The Various Rounds of Competitive Bidding

The CBP was established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[2] Although originally set to be phased in beginning in 2007, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)[3] made changes to the CBP and delayed its implementation until 2008. In 2009, CMS conducted the first round of bidding in 9 competitive bidding areas (CBAs), referred to as the "Round 1 Rebid". The Round 1 Rebid started January 1, 2011 and expired on December 31, 2013. Upon expiration of these contracts, the "Round 1 Recompete," also covering 9 CBAs, started on January 1, 2014 and expired on December 31, 2016. "Round 1 2017" contracts became effective January 1, 2017, and will expire on December 31, 2018. By law, CMS is required to re-compete the CBP once every three years.[4]

Meanwhile, CBP Round 2, which covered 100 CBAs, along with the National Mail-Order Program for diabetic testing supplies, started on July 1, 2013 and ended on June 30, 2016. "Round 2 Recompete," which covers 117 CBAs, became effective on July 1, 2016 and will also expire on December 31, 2018.[5]

On January 31, 2017, CMS announced its plan to consolidate all of the different rounds of CB into a single "Round 2019," which would cover 141 CBAs, to be effective from January 1, 2019 to December 31, 2021. However, shortly thereafter the January 31 announcement,

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[2] Medicare Prescription Drug, Improvement and Modernization Act (MMA), Pub. L. No. 108-173 (2003).

[3] Medicare Improvements for Patients and Providers Act (MIPPA), Pub. L. No. 110-275 (2008).

[4] § 1847(b)(3)(B).

[5] It is worth noting that January 1, 2016 also marked the beginning of the implementation of "adjusted fee schedules" for non-CBAs using information from CBAs. *See* § 1834(a) of the SSA. CMS included a transition policy in its final implementing regulation until July 1, 2016, and Congress extended the transition until December 31, 2016. *See* 21st Century Cures Act of 2016, Pub. L. 114-255 (Dec. 13, 2016). The adjusted fee schedules are now in full-effect, but they are largely being determined by the currently flawed bidding program, which is contributing to severe access issues for Medicare beneficiaries in rural areas.

CMS announced that it is temporarily delaying moving forward with this proposal in order to "further [] review the program."[6]

In any event, both the "Round 1 2017" and "Round 2 Recompete" contracts are currently set to expire on December 31, 2018.

B. Underlying Statutes Implementing the Competitive Bidding Program

The provisions related to the operation of the CBP are located at § 1847 of the Social Security Act (SSA). The mechanism for determining the payment amounts under the bidding program are set forth at § 1834(a)(1) of the Act. As alluded to above, the CBP has been amended by Congress several times over the past 14 years. After being first established under the MMA of 2003,[7] in 2008 MIPPA delayed implementation of the CBP and made additional changes to the program.[8] The Patient Protection and Affordable Care Act (ACA) of 2010[9] further amended the program by expanding the scope of Round 2 and by requiring the use of CB information in non-CBAs.[10]

II. DISCUSSION

The following discussion is divided into two parts. The first argues that CMS has the statutory authority to extend the contracts under both "Round 1 2017" and "Round 2 Recompete" until July 1, 2019. The second part revisits the specific reform proposals outlined in the Price Letter and argues that CMS can pursue each of those proposals under its existing statutory authority.

A. CMS has the statutory authority to extend current contracts until July 1, 2019.

As discussed above, the Secretary is statutorily required to recompete contracts under the CBP "not less than once every 3 years."[11] In implementing regulations promulgated on April 10, 2007, CMS clarified that the length of contracts may be different depending on the circumstances, and that it would specify the length of those contracts in its Request for Bids (RFBs), so long as the length does not exceed 3 years.[12] Put differently, CMS has the statutory authority to set the length of its contracts under the CBP at any length up to 3 years.

In the instant case, neither the Round 1 2017 or Round 2 Recompete contracts currently stretch to the 3-year limitation, thereby offering CMS an opportunity to extend the contracts under both Rounds. Specifically, Round 1 2017 contracts currently have a term of two years, beginning January 1, 2017 to December 31, 2018. Round 2 Recompete contracts currently

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[6] "DMEPOS Competitive Bidding – Home", CMS.gov (last updated 3/10/17), available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html.
[7] § 302 of the MMA.
[8] § 154 of the MIPPA.
[9] Patient Protection and Affordable Care Act (ACA), Pub.. L. No. 111-148 (2010).
[10] *See id.* at § 6410.
[11] *See* § 1847(b)(3)(B) of the SSA; *see also* 42 C.F.R. § 414.422(b).
[12] *See* "Competitive Acquisition Program for DMEPOS," 72 Fed. Reg. 17992, 18049 (April 10, 2007).

have a term of two-and-a-half years, beginning July 1, 2016 to December 31, 2018. CMS could extend all of the contracts under both Rounds until July 1, 2019 by issuing notice-and-comment rulemaking and announcing its intent to extend the contracts.[13] Contractors who cannot or are unwilling to continue their obligations until the end of the new term could enter into a novation agreement with another party to continue performance. Alternatively, CMS can replace the contracted suppliers using a process akin to the one it employs for replacing terminated/suspended contracted suppliers.[14]

B. CMS has broad statutory authority to reform the CBP.

1. Under general principles of administrative law, CMS has extraordinary flexibility to change the direction of its regulatory policy.

One of the most settled principles of administrative law is that, generally speaking, agencies have broad flexibility to change the direction of their regulatory policy.[15] These changes may be the creation of new regulatory requirements, or the deregulation of the existing regime.[16] In either event, the procedural requirements of § 553 of the APA governs the *process* by which agencies may institute regulatory changes.[17] In short, regulations that were promulgated through notice-and-comment rulemaking generally require notice-and-comment rulemaking to be altered or discarded, while requirements issued through sub-regulatory guidance can be altered or discarded through sub-regulatory guidance.[18]

Importantly, regulatory changes are subjected to exactly the same level of review as any other agency action.[19] Just as with new rulemaking, an agency must provide a reasoned explanation for its action, but in the case where an action constitutes a change in policy, the reasoned explanation must display that the agency is *aware* it is changing its position.[20] However, the agency is not required to demonstrate to a court's satisfaction that its reasons for pursuing the new policy are *better* than the reasons for its old policy.[21] Notably, in instances where the new policy is predicated on factual findings that "contradict those which

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[13] We think that CMS would be required to adopt this policy through rulemaking rather than by issuing subregulatory guidance. Continuing the existing contracts would, in our view, constitute changing "a substantive legal standard governing … the eligibility of individuals, entities or organizations to furnish … services …under this title." Social Security Act § 1871(a)(2).

[14] *See* 42 C.F.R. § 414.423.

[15] *See e.g. American Trucking Assns., Inc. v. Atchison, T. & S. F. R. Co.*, 387 U.S. 397, 416 (1967) ("[Regulatory] agencies do not establish rules of conduct to last forever.").

[16] *See e.g. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) ("[T]he forces of change do not always or necessarily point in the direction of deregulation.").

[17] *Id.* at 41 (holding that the same standards under § 553 of the APA apply to the rescission or modification of regulatory requirements).

[18] *See e.g., Perez v. Mortg. Bankers Ass'n*, 135 S.Ct. 1119, 1206 (2015) (holding that "agencies [must] use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance.").

[19] *See FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 514-15 (2009) ("We find no basis in the [APA] or in our opinions for a requirement that all agency change be subjected to more searching review.").

[20] *See id.* at 515.

[21] *Id.*

underlay [the agency's] prior policy", or where the prior policy has produced significant reliance interests, the agency must at the very least address the contradiction and/or reliance interests in its reasoned explanation.[22] Yet even in these instances, it is *ignoring* such matters that renders the agency action arbitrary and capricious, not the fact that the agency action contradicts its previous position.[23]

Thus, in pursuing regulatory changes, agencies must be able to demonstrate several things. The first is that the proposed agency action must be permissible under the statute. The second is that the agency must have good reasons for its proposed policy. The agency's reasons need not be demonstrably superior to the reasons of its old policy, but rather merely need to show:

> "[T]hat the reasons for the change, when viewed in light of the data available to it, and when informed by the experience and expertise of the agency, suffice to demonstrate that the new policy rests upon principles that are rational, neutral, and in accord with the agency's proper understanding of its authority."[24]

In the instant case, the reform proposals to the CBP included in the Price Letter may constitute conflicting changes to existing agency policy. However, as discussed above, the mere fact that a change may be contradictory to an earlier policy does not straightjacket CMS into continuing course with the existing bidding program. As long as CMS provides the public a reasoned explanation for its change in policy through the notice-and-comment rulemaking process, coupled with statutory support for its proposed regulatory action, CMS will comply with the requirements of the APA. Moreover, in cases where CMS pursues changes to sub-regulatory policy, the agency does not need to engage in notice-and-comment and can make changes unilaterally. Therefore, the legal arguments that follow must be considered in light of CMS' broad authority to pursue regulatory changes, and they are intended to supplement the policy-focused arguments advanced in the Price Letter.

2. <u>CMS has the statutory authority to use the market clearing price to determine the Single Payment Amount (SPA) for any item included in the bidding program</u>.[25]

The SPA is the amount that CMS determines is payable, based upon submitted bids, for each item or service in each CBP.[26] The statutory language does not prescribe a specific methodology that the Secretary must use to establish the SPAs, and instead broadly authorizes the Secretary to "determine a single payment amount for each item or service in each competitive acquisition area."[27] In the preamble to the implementing regulations, CMS acknowledged its broad authority to devise the methodology for determining SPAs when it stated that it "considered several different methodologies."[28] Ultimately, CMS concluded

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[22] *Id.* at 515-16.
[23] *Id.*
[24] *Id.* at 536 (Justice Kennedy's concurring opinion).
[25] *See* Price Letter, Reform Proposal 1.
[26] *See* § 1847(b)(5)(A) of the SSA. *See also id*. at § 1834(a)(1)(F)(i).
[27] *Id.*
[28] *See* 72 Fed. Reg. at 18044, *supra* n. 11.

that the SPA would be based on the median of the contract suppliers' bids.[29] CMS asserted that setting the SPA at the median of submitted bids "satisfies the statutory requirement that single payment amounts are to be based on bids submitted and accepted."[30]

In the course of defending its adoption of determining the SPA by reference to the median of the submitted bids, CMS stated its belief that the methodology "represent[s] a reasonable payment amount and does not favor large or small suppliers, and [] this approach is more equitable than other approaches suggested…."[31] With respect to its statutory authority to consider other methodologies, CMS remarked that § 1847(b)(5)(A) requires that payment be made based on "submitted and accepted bids", which would prohibit it from basing the SPA only on the highest or lowest bids, as some commenters suggested.[32] CMS also observed that the same statutory language would not allow it to pay the lower of either a supplier's bids or the SPA because "a single payment amount…does not lend itself to an interpretation that would allow us to pay the lesser of the two amounts."[33]

In the instance case, the proposal detailed in the Price Letter is squarely within CMS' statutory authority to adopt. Specifically, setting the SPA at the "clearing price" (i.e. pivotal bid)[34] continues to adhere to the statutory requirement that payment be based on "bids submitted and accepted" because the clearing price (pivotal bid), by definition, *includes all bids that were submitted and accepted*. Put differently, CMS would be using precisely the same process as it currently does, but instead of using the median of the range of bids to set the SPA (an extra step), it uses the *actual* intersecting point between access and price.[35] Therefore, establishing the SPA at the pivotal bid is well within CMS's broad statutory authority to determine the SPA, as the agency itself explained its authority.

3. <u>CMS should repeal bundled bidding programs for continuous positive air pressure (CPAP) and standard power wheelchairs because the payment policy is beyond CMS' statutory authority</u>.[36]

On November 6, 2014, CMS finalized a bundled bidding program for CPAP and standard power wheel chairs that provides for continuous monthly rental payments.[37] In the preamble of the implementing regulation, CMS acknowledged that it was not implementing any particular statutory provision, but rather was exercising its "broad authority under section 1847 [of the SSA] to establish payment rules for the CBP."[38] CMS asserted that the general payment rules for the CBP is governed by § 1847(b), which, according to CMS, "mandates payments based on bids submitted and accepted by Medicare for the competitively priced

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[29] *Id.*
[30] *Id.* at 18045.
[31] *Id.* at 18046.
[32] *Id.* at 18047.
[33] *Id.*
[34] *See* 42 C.F.R. § 414.402.
[35] *See infra* at 7-9 for more discussion on how CMS establishes the pivotal bid.
[36] *See* Price Letter, Reform Proposal #6.
[37] *See* 42 C.F.R. § 414.409(a).
[38] *See* "ESRD PPS, Quality Incentive Program, and DMEPOS," 79 Fed. Reg. 66120, 66235 (Nov. 6, 2014).

items and services."[39] Based on this language, CMS concluded that it has "discretion" to determine whether items and services are paid for on a purchase or a rental basis, so long as the total payments to contract suppliers are expected to be less than they would be otherwise.[40] However, CMS overreached its statutory authority when it adopted bundled payments for CPAP and standard power wheelchairs for at least three reasons.

First, CMS lacks statutory authority to implement bundled payments because Congress did not intend to cede to the Secretary its control over the payment rules for DME under the six carefully structured equipment classes at § 1834(a)(2)-(7) of the SSA. The payment parameters for these six classes were meticulously defined by Congress, which tied reimbursement for the equipment to the type of equipment, the likely duration of a beneficiary's medical need, and the cost to Medicare of paying for it. Both the payment amount and rules regarding payment methodology under each of these classes is explicitly set forth in statute.[41] In enacting the bidding program under § 1847, Congress did not repeal the equipment classes at § 1834(a), indicating its intention that the bidding program establish only the payment amount for a particular item of DME, and not the rules regarding payment methodology.

Importantly, CPAP and standard power wheelchairs belong to one of these equipment categories,[42] which means that even though their payment amounts may be changed, they cannot be bundled because that would be interfering with the rules regarding payment methodology. In other words, bundled payments change the methodology of payment from a pre-determined duration (rental cap) to a continuously recurring duration, which is beyond CMS' statutory authority to change under the bidding program; the agency is only authorized to establish the *payment amount* as the SPA derived from competitive bidding.[43]

Second, CMS cannot bundle payment for CPAP and standard power wheelchairs because § 1847 of the SSA explicitly requires that SPAs be established for *each* item or service in each CBA.[44] Although CMS based its bundled payment policy on the statutory mandate that payments be made on "bids submitted and accepted under this section for such items and services,"[45] the agency omitted the subsequent sentence clarifying that the SPAs must be calculated for *each* item or service. The complete provision states:

> (5) Payment
> (A) In general

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[39] *Id.*
[40] *Id.*
[41] *See* generally § 1834(a) of the SSA.
[42] *See* § 1834(a)(7) of the SSA.
[43] *See* § 1847(a)(5)(F) of the SSA.
[44] *See* § 1847(b)(5)(A) of the SSA ("Payment under this part for competitively priced items and services described in subsection (a)(2) of this section shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.").
[45] *See* 79 Fed. Reg. at 66235.

> Payment under this part for competitively priced items and services described in subsection (a)(2) of this section shall be based on bids submitted and accepted under this section for such items and services. **Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area**.[46] (emphasis added)

Currently, CMS distinguishes different items based on their unique Healthcare Common Procedure Coding System (HCPCS) codes, and services based on their Current Procedural Terminology (CPT) codes. When CMS bundles payment for CPAP and standard power chairs, it establishes a single payment amount that folds into several *different* items and services, all distinguishable by their unique HCPCS and CPT codes. Based on the statutory provision identified above, and contrary to CMS' assertion in the 2014 Final Rule, the agency does not have unbridled discretion to combine multiple items and services into a single payment amount as it has done with CPAP and standard power wheelchairs. CMS is statutorily obligated under the bidding program to determine single payment amounts *for each* item and service, just as the agency asserted in prior rulemaking implementing the bidding program:

> "Section 1847(b)(5)(A) of the Act requires that the Secretary determine a single payment amount *for each* item in each CBA based on the bids submitted and accepted for that item…single payment amounts for individual items in the product category *must* be determined."[47]

Third, § 1847 does not authorize CMS to expand the categories of items and services to include maintenance and repair. Congress was clear that it viewed maintenance and repair as distinct from items and services that were included in the CBP. Specifically, "items and services" are defined as:

> "Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs).[48]

Conspicuously missing from this definition is any reference to services, particularly those related to maintenance and repair. Moreover, in the subsequent subparagraph, Congress again indicates its view that maintenance and repair is distinct from items and services when it created special rules for payment to grandfathered suppliers for servicing and replacement

[46] § 1847(b)(5)(A) of the SSA.
[47] *See* 72 Fed. Reg. at 18044-45.
[48] *See* § 1847(a)(2)(A) of the SSA.

of certain equipment.[49] In short, Congress never authorized CMS to consider maintenance and repair as factors to be considered for payment under the bidding program, and therefore CMS overreached when it unilaterally implemented bundled payments for CPAP and standard power wheelchairs.

4. CMS has the statutory authority to explicitly articulate the standards/criteria the agency uses to determine suppliers' qualifications to receive contract awards.[50]

Although CMS outlines the process it uses to select winning bids in regulations, it does not articulate the standards it uses to arrive at those decisions.[51] Most relevant information is published on CMS' website or its contractor's website as FAQs and/or bulletins, but even then the process that CMS uses to arrive at its decision is left shrouded in mystery. Among some of the more troubling elements that are not publicized have to do with minimum financial standards,[52] CMS' selection of evaluation and selection of bids,[53] and CMS' evaluation of supplier capacity.[54] There is no statutory requirement that CMS maintain this information as non-public, and CMS never addressed its rationale for keeping this information non-public. Therefore, CMS could easily pursue notice-and-comment rulemaking and clearly articulate, in the regulatory text itself, the standards/criteria the agency uses to determine suppliers' qualifications to receive contract awards. This would make CMS accountable for its administration of the program and would facilitate oversight of CMS' administration of the CBP by the Department of Health and Human Services (HHS).

5. CMS has the statutory authority to make specific changes to the regulations governing the agency's evaluation of bids, selection of new suppliers after bidding, and breach of contract policies.[55]

As described above, CMS outlines the general process it uses to evaluate bids submitted for items within a product category at 42 C.F.R. § 414.414(e). The statutory basis underlying this procedure is located at § 1847(b)(4)(A) of the SSA, which authorizes the Secretary to limit the number of contractors in a CBP to the number necessary to furnish items to meet projected demand for covered items and services under the contract, and to base contract awards on suppliers' capacity to meet those projected needs. Specifically, the provision reads:

> (A) In general.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected

[49] *See* § 1847(a)(4) of the SSA (specifically singling out "appropriate servicing and replacement").
[50] *See* Price Letter, Reform Proposal #5.
[51] 42 C.F.R. § 414.414.
[52] *See* 42 C.F.R. § 414.414(d)(1).
[53] *See* 42 C.F.R. § 414.416(b)(1).
[54] *See* 42 C.F.R. § 414.414(e)(2).
[55] *See* Price Letter, Reform Proposal #2

> demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.[56]

CMS interpreted this provision to require that it first determine the expected demand for an item in a CBA by using historical claims submission data, and then, second, that it estimate supplier capacity based on the supplier's historical record of providing DMEPOS in a given CBA and its self-reported ability to provide future DMEPOS in a given CBA.[57] Therefore, any change to the current regulatory requirements under this statutory provision must adhere to these two principles.

In the instant case, all of the proposed changes to the regulations at 42 C.F.R. § 414.414(e) comply with these two principles set forth in the underlying statute.[58] The proposals to revise § 414.414(i) and § 414.423 are also within CMS' statutory authority to adopt.

With respect to § 414.414(e), CMS can specify that bidder's capacity for furnishing product category items in a CBA equals their historical claims submission for the items because it would be consistent with the statute. First, CMS would still be projecting demand for an item through historical claims submission data, as required by statute. Second, CMS would be taking into account the ability of suppliers to furnish the necessary items in very much the same way it is currently doing so now, which it developed in adherence to the statute. The primary difference would be that the *regulatory text* would now explicitly state that calculation for determining a supplier's capacity is their claims submission history for those items in the preceding 12 months.[59]

Moreover, CMS can exclude inexperienced bidders from its calculation of the pivotal bid.[60] This would be within CMS' statutory authority because currently, CMS already makes adjustments to a supplier's projected capacity for the purposes of finalizing the pivotal bid depending on whether the agency is convinced that the supplier is viably representing their projected capacity.[61] By excluding inexperienced bidders from the calculation of the pivotal bid, CMS is simply recognizing that there is no reliable information to determine whether an inexperienced supplier's projected capacity calculations are actually realistic, viable and worth including for the purposes of calculating the pivotal bid. And to be clear, excluding the bids from the calculation of the pivotal bid would not prevent these suppliers from being awarded contracts, for they may still have composite bids that are at or below the pivotal bid for that product category. It merely protects other bidders' payment amounts from unjustifiably aggressive and inexperienced bidders.

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[56] *See* § 1847(b)(4)(A) of the SSA.
[57] *See* 72 Fed. Reg. at 18039-40.
[58] *See* Price Letter, Reform Proposal #2.
[59] Currently, the regulatory text is vague. *See* 42 C.F.R. § 414.414(e).
[60] *See* 42 C.F.R. § 414.414(e)(5).
[61] *See* 72 Fed. Reg. at 18039.

Additionally, CMS can create a new requirement that would require the Competitive Bidding Implementation Contractor (CBIC) or CMS to perform post award monitoring of contract suppliers to ensure they are furnishing product category items according to their contracts. CMS has the statutory authority to do this under § 1847(b)(8) of the SSA.

Turning to § 414.414(i), CMS can specify it will recalculate SPAs for product category items whenever the agency adds new contract suppliers to a CBA in order to meet beneficiaries' demand for items. As discussed previously, CMS has wide latitude to determine the SPA. And although in the implementing regulations CMS expressed concern that launching another round of CB to replace terminated or suspended suppliers would compound already existing access problems to DMEPOS, recalculating the SPAs is not the same thing as re-launching a new round of bidding. Specifically, CMS would simply need to substitute the terminated/suspended supplier's composite bid from the lowest-to-highest array with that of the new supplier and re-set the SPA. After all, the new supplier had already participated in the initial round of CB.

Finally, CMS can revise § 414.423 to specify that CMS or CBIC will publish a quarterly list of contract suppliers who are under a corrective action plan (CAP) or whose contracts were terminated. The statutory language does not instruct CMS with any specifics on how to deal with breaching parties, suggesting that CMS has wide latitude to establish its preferred policies. Considering the extent to which CMS has already crafted policies regarding breaching parties, it would be consistent for the agency to introduce a publication requirement among these requirements as well.

6. CMS has the statutory authority to apply uniform payment rules for contract suppliers who accept beneficiaries from another supplier.[62]

Under current policy, contract suppliers who accept beneficiaries from another contract supplier do *not* receive additional rental payments.[63] This is in contrast to contract suppliers who accept a beneficiary from a grandfathered supplier, or a beneficiary who moves from a non-CBA to a CBA.[64] Contract suppliers under these circumstances can either restart the 13-month contract for rental equipment, or in the case of oxygen equipment, receive the greater of up to 36 monthly rental payments, or at least 10 monthly payments.[65] According to CMS, this distinction is attributable to the fact that the underlying statutory provision only authorizes the agency to make the aforementioned rental adjustments to grandfathered rental items and oxygen equipment rental items only.[66]

Even if that interpretation of the statute were correct, it does not preclude CMS from making the same adjustment to rental payments for contract suppliers who receive beneficiaries from other contract suppliers. There is independent statutory authority for CMS to pursue this policy. Specifically, § 1834(a)(7)(A)(i)(I) states:

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[62] *See* Price Letter, Reform Proposal #3.
[63] *See* 42 C.F.R. § 414.408(h)(3)(ii).
[64] *See id.* at § 414.408(h)(3)(i) and § 414.408(h)(8)(i)(2)(i).
[65] *Id.*
[66] *See* 72 Fed. Reg. at 18002; *see also* § 1847(a)(4) of the SSA.

> (I) In general.—Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (**but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months**) (emphasis added).

Given that the statutory language provides the Secretary with the flexibility to determine what constitutes "continuous use" for the purposes of meeting the 13 month cap on payment, CMS could interpret "continuous use" to *reset* whenever the beneficiary switches contract suppliers. In this way, CMS could, while acting within its statutory authority, ensure the new contract supplier will receive the full 13 months of rental payments for having accepted a beneficiary from a different contract supplier.

7. CMS has the statutory authority to narrow the definition of "product category" to DMEPOS items that treat the same condition as identified in national coverage determinations (NCDs) and local coverage determination (LCDs).[67]

Product categories refers to the grouping of related items that treat a similar medical condition and are included in the CBP.[68] Product categories are important because they determine the composite bid that suppliers receive, which in turn determines whether they are awarded a contract or not. Currently, product categories are defined in each Request for Bids and are often extraordinarily broad and combine several medical policies into loosely related groups of items identified by their HCPCS codes. According to CMS, grouping items in such a way to form product categories "will allow Medicare beneficiaries to receive all of their related products from one supplier, which will minimize disruption to the beneficiary."[69] Importantly, CMS asserted that it has the authority to "choose to establish different product categories from one CBA to another, as well as in different rounds of CB in the same CBA."[70] Indeed, the statute does not use the term "product category" at all, and further, it gives CMS the explicit authority to exempt certain items unlikely to result in significant savings.[71] Therefore CMS has near complete discretion to determine what items will constitute a product category.

In view of CMS' wide latitude in determining product categories, there is no legal impediment to adopting a definition of a product category based on items that treat the same condition as identified in NCDs and LCDs. CMS could easily adopt this policy through sub-regulatory guidance, specifically through the RFBs it issues at the beginning of a bidding round. But if CMS were to adopt this this definition formally as part of the regulatory text at 42 C.F.R. § 414.402, the agency should proceed through notice-and-comment rulemaking to

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[67] *See* Price Letter, Reform Proposal #4.
[68] *See* 12 C.F.R. § 414.402.
[69] 72 Fed. Reg. at 18029.
[70] *Id.*
[71] *See* § 1874(a)(3)(B) of the SSA.

comply with the requirements of the APA. In either event, CMS would be acting in accordance with its statutory authority under the CBP.

III. CONCLUSION

CMS has broad statutory authority to develop and implement the CBP originally mandated by Congress in the MMA and later amended by subsequent legislation. It is undeniable that there is room for improvement of the existing bidding program in light of the challenges being experienced by many DMPEOS suppliers and Medicare beneficiaries under the program. The reform proposals presented in the Price Letter do not only offer comprehensive policy solutions to the CBP's ongoing challenges, but they are also legally sound and within CMS' statutory authority. Long-standing principles of administrative law provide firm legal support for CMS' ability to change critical features of the CBP program. Therefore, CMS should extend the current contracts under both Rounds to July 1, 2019, while using the interim period to institute the proposed changes through notice-and-comment rulemaking and sub-regulatory guidance where appropriate.