August 29, 2025

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20001

Re: CMS-1828-P: Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies

Dear Administrator Oz,

The Council for Quality Respiratory Care (CQRC) appreciates the opportunity to provide comments on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; and Provider Enrollment provisions of the CY 2026 Home Health Prospective Payment System rate update proposed rule (Proposed Rule). The CQRC is a coalition of the nation's six leading supplemental oxygen and sleep therapy suppliers and manufacturing companies. Together we provide in-home patient services and respiratory equipment to more than 600,000 of the more than one million Medicare patients who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Similarly, we provide homecare services, equipment and supplies to more than one million Medicare patients with Obstructive Sleep Apnea (OSA).

The CQRC supports efforts to prevent fraud and abuse. We will continue to work with CMS to develop targeted approaches that include leveraging technology-based solutions that would help eliminate actual fraud and abuse while not unnecessarily burdening suppliers and reducing the level of care to Medicare beneficiaries. In addition, the CQRC has continuously supported the principles of the competitive bidding program (CBP) as well. We worked closely with the Trump Administration during its first term to develop policies that support a patient-centered approach to the program to better align the Medicare rates with market-based pricing. In this letter, we provide comments and recommendations related to achieving the Administration's goals in three areas: protecting patient access to quality care, reducing the cost of care, and preventing fraud and abuse. A brief summary of these comments and recommendations are below.

Summary of CBP Comments and Recommendations: As the Proposed Rule outlines, the challenge with Round 2021 centered on two policy choices that were inconsistent with the

recommendations of the DME community. The first was to allow for self-reported capacity in contrast to the CQRC recommendation to use a supplier's actual capacity. The second was to set demand at more than 100 percent despite the CQRC recommendation of setting demand at a small percentage below 100 percent to ensure a competitive market. We were pleased to read in the preamble of the Proposed Rule that CMS understands the critical nature of these two policy choices. We are concerned, however, that the proposed and untested 75th percentile methodology, when coupled with other changes to the bidding process, goes too far and will not achieve a balanced result of ensuring beneficiary access to quality DME products at a competitive sustainable cost. Therefore, we ask that CMS not finalize the proposed 75th percentile methodology with the other provisions of the Proposed Rule and instead work with stakeholders to identify and test the options with more current and realistic data to achieve an optimum result. This approach could include a pilot in a small number of states to avoid another nationwide CBP effort failing.

Summary of the Accreditation Recommendations. The CQRC continues to support efforts to reduce fraud and abuse in the Medicare program. We have worked tirelessly for the last decade with CMS and the Congress to adopt technology-based solutions that would streamline the documentation process and enhance CMS' efforts to eliminate fraud and abuse, particularly in the area of supplemental oxygen. While we appreciate the Agency's desire to strengthen the accreditation process, we are concerned that more frequent accreditation surveys will not achieve the goal of reducing fraud and abuse because accreditation organizations are designed to assess compliance with quality standards, not to police fraud and abuse. The proposal will not address false claims, a lack of medical necessity documentation, failure to provide services, or erroneous billing practices, which are the core challenges the Office of the Inspector General (OIG), Government Accountability Office (GAO), and others have identified in this area. Moreover, there are simply not enough resources for accreditation organizations to support annual review of the thousands of DMEPOS locations nationwide. The additional cost to suppliers, which our members have estimated to be greater than the amount suggested in the Regulatory Impact Analysis, will only drive up the cost of providing DME products at the same time CMS is trying to reduce Medicare expenditures to DME suppliers. Instead, we recommend that CMS maintain the three-year accreditation cycle for DME locations and adopt more targeted, technology-based solutions, such as the supplemental oxygen template clinical data elements that CMS has already developed but never required contractors to use for purposes of establishing medical necessity. We believe these types of technology-based solutions will be substantially more effective than an annual survey to make sure that suppliers adhere to the quality standards.

While CGM proposals are outside the scope of the CQRC's mission and this letter, we wanted to raise concerns about the proposal to apply CBP rates to products not being bid. From our experience with the inclusion of liquid oxygen in the supplemental oxygen product category, as well as previous experience when oxygen and CPAP/BiPAP devices were in a single category,

we caution CMS against assuming that CBP rates will easily transfer to other products. As we have seen with liquid oxygen, the result of getting this wrong can be devastating for patients.

I. Given concerns with the untested proposed 75th percentile methodology and changes to financial documentation requirements for the Medicare CBP, the CQRC would like to work with the Trump Administration to ensure that future CBP rounds address problems with the Round 2021 lead item methodology and protect patient access to prescribed DMEPOS equipment, supplies, and services.

Congress created the Medicare CBP to reset the Medicare rates for DMEPOS using market-based forces and to reduce incentives for bad actors to leverage gaps in program integrity that allowed for greater fraud and abuse. We caution CMS against overindexing on these goals in a way that will place beneficiary access at risk, allow bad actors to return to this area of health care, and increase overall Medicare expenditures.

A. Congress instructed CMS through the statute to reduce expenditures compared to pre-CBP spending and did not intend for a continued shifting of the comparator benchmark to require rates to be continuously lower than previous CBP rounds.

Congress enacted the CBP to reduce costs compared to the rates of the original DMEPOS fee schedule in place at the time the law was passed. Prior to implementation of CBP, fee schedule rates were "largely based on supplier charges from July 1986 through June 1987 (updated for inflation) and on information such as unadjusted list prices for products introduced after this period."[1] While one of the goals of the CBP included "lowering out-of-pocket costs and generating savings for the Medicare program," CMS historically noted it was also meant "to provide important benefits to Medicare beneficiaries and taxpayers."[2]

The Congress sought to achieve the goal of lower out-of-pocket costs and savings for Medicare using market-based prices as the comparator. The Congressional Research Service (CRS) captured the desire to leverage market-based forces to obtain the desired savings when it wrote, "investigations have shown that Medicare pays above-market prices for certain items of DME. Such overpayments may be due partly to the fee schedule mechanism of payment, which does not reflect market changes, such as new and less-expensive technologies, changes in

[1]MedPAC. "Payment Basics: DURABLE MEDICAL EQUIPMENT PAYMENT SYSTEM." (Oct 2024) available at https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_24_DME_FINAL_SEC.pdf (accessed Aug. 17, 2025).

[2]CMS. "Fact Sheet: MEDICARE ANNOUNCES TIMELINE FOR BIDDING AND BEGINS SUPPLIER EDUCATION CAMPAIGN FOR DURABLE MEDICAL EQUIPMENT (DMEPOS)" (Aug. 4, 2009) available at: https://www.cms.gov/newsroom/fact-sheets/medicare-announces-timeline-bidding-and-begins-supplier-education-campaign-durable-medical-equipment (accessed Aug. 17, 2025).

production or supplier costs, or variations in prices in comparable locations."[3] The GAO echoed this approach in its reports as well: "Both we [the GAO] and the HHS Office of Inspector General (OIG) have reported that Medicare and its beneficiaries have sometimes paid higher-than-market rates for various medical equipment and supply items."[4]

To achieve the goal of resetting the Medicare reimbursement rates for DMEPOS equipment, supplies, and services, Congress instructed CMS to establish CBP rounds with two important instructions related to savings. First, it required that "[t]he total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid."[5] The phrase "would otherwise be paid" is clearly in reference to the original (unadjusted) DMEPOS Fee Schedule rates. CMS has historically agreed with this interpretation, including during the first Trump Administration.

> 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.[6]

As this quotation from the CY 2017 Proposed Rule demonstrates, CMS recognized that rates would have to be able to fluctuate up and down to allow market forces, rather than the government, to determine the rates. Congress and CMS understood that relying on market forces to set rates is generally considered beneficial for the economy because it leads to a more efficient allocation of resources. Rates determined by the forces of supply and demand, rather than by the federal government, more accurately reflect the true cost of providing the equipment, supplies and services, benefiting the federal government and beneficiaries.

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[3]CRS. "Medicare Durable Medical Equipment: The Competitive Bidding Program" (Apr. 28, 2010).
[4]GAO. "Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid." (May 2012).
[5] 42 U.S.C. § 1395w-3(b)(2).
[6]CMS. "End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model." 81 *Fed. Reg.* 42802, 42863 (June 30, 2016)

Second, the Congress recognized that there would be a point at which the market worked and products should be removed from the CBP because no additional savings were available under real world circumstances. "The Secretary may exempt…items and services for which the application of competitive acquisition is not likely to result in significant savings."[7] The benchmark against which this question is asked is the original DMEPOS fee schedule that was in place when the Congress established the program. There is no language to suggest that the benchmark was to be reduced every bid cycle. In fact, the 2017 Proposed Rule indicates it would not be appropriate to use an adjusted fee schedule based on the most recent round of the CBP as the comparator. Doing so would create a race to the bottom. The plain reading of the statute supports this understanding by stating that Congress did not anticipate that savings would always be achievable for every item or service. When additional savings compared to the original fee schedule are no longer attainable, the Secretary should remove the products from the program because the market has worked.

As described in detail below, the CQRC is concerned that the proposed 75th percentile methodology does not permit CMS to leverage market forces to obtain the most efficient price that provides enough supply and protects beneficiary access. Given that the proposal creates barriers that distort market forces, the proposal would likely reduce rates in the short-term, lead to serious patient harm, and eventual increases in overall Medicare costs (*e.g.,* increased hospitalizations and emergency department visits) resulting from beneficiaries not being able to access the physician-prescribed devices. This concern is particularly acute given that there were known and well-publicized flaws in the previous bidding cycle's methodology (as is evidenced from Round I 2017 and Round 2 Recompete and the National Mail Order Recompete).[8] To avoid this harmful patient impact, we ask that CMS reinstate its saving benchmark as the original fee schedule and not try to ratchet savings down each bidding cycle by using the previous cycle's rates as the comparator.

B. While initial CBP rounds reduced rates to deter bad actors from engaging in fraud and abuse because of lower rates and increased supplier scrutiny, the proposed 75th percentile methodology with less stringent financial standards and supplier review will likely incentivize more fraud by unscrupulous actors.

While the CQRC agrees that historically the CBP may have deterred bad actors from engaging in fraud and abuse to drive "improper utilization,"[9] focusing on lowering rates alone

[7] 42 U.S.C. § 1935w-3(a)(3)(B).
[8] *See, e.g.,* Wayne Winegarden. "Reforming CMS' Competitive Bidding Process to Improve Quality and Sustainability." *Pacific Research Institute* (July 2018).
[9] CMS. "Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies." 90 *Fed. Reg.* 29108, 29250 (July 2, 2025) (Proposed Rule).

without maintaining strong financial documentation requirements and careful review will not permit the program to continue to act as a deterrent to fraud. In fact, if rates are below those supported by market forces, then it will be more likely that legitimate suppliers will leave the market entirely. It is important that future CBP rounds strike the right balance to encourage competition among healthy providers.

As the preamble states, "within the DMEPOS CBP, instances of waste, fraud, and abuse are less likely to occur for two reasons: lower payment amounts reduce the profit to be made from improper payments, and the reduction in number of suppliers and heightened scrutiny and monitoring of contract suppliers makes it more difficult for entities, particularly new entrants, intending to commit fraud to gain access to the program."[10] We acknowledge that initial rounds of the CBP were able to apply such principles to make the program less attractive to unscrupulous suppliers. A 2009 Government Accountability Office (GAO) report noted that in nearly two-thirds of the initial CBP price competitions, the number of suppliers decreased by at least 50 percent. The Miami competitive bidding area saw the largest decreases.[11] However, such reductions cannot be replicated year after year because they do not reflect the reality that costs have gone up for suppliers, and there are fewer suppliers participating. The CBP has already effectively reduced the number of individual DMEPOS suppliers by 23 percent from 113,154 in March 2008[12] to 87,800 in 2020.[13] It is important to remember that DMEPOS is an extremely broad category of products and a single supplier rarely fills prescriptions for a single device. In fact, the current total number of DMEPOS suppliers is nearly the same as the number of pharmacies in the United States filling prescriptions for drugs and biologicals. It is estimated that there are more than 88,000 pharmacies in the United States.[14]

Moreover, recent government investigations of DME fraud show that large, transnational criminal organizations are likely responsible for some of the most sophisticated and costly DME scams.[15] These schemes involve stealing Americans' identities, AI-generated consents,

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[10] *Id.*

[11] GAO. "CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program." (Nov. 2009).

[12] CMS. "Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards" 75 *Fed. Reg.* 52629 (Aug. 27, 2010).

[13] CMS. "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas" 86 *Fed. Reg.* 73860, 73870 (Dec. 28, 2021).

[14] Kimá Joy Taylor, Eva H. Allen, Taylor Nelson, and Sofia Hinojosa. "Guide to Equity in Pharmacy Services." *Urban Institute* (May 2024).

[15] Just this year, the Department of Justice charged 11 individuals—mostly foreign nationals from Russia and Eastern Europe—for orchestrating a $10.6 billion DME fraud scheme. The organization stole the personal information of over one million Americans and used dozens of sham U.S. medical supply companies to submit fraudulent Medicare claims for equipment that was not needed or not provided. Austin Littrell. "Biggest health care fraud crackdown in U.S. history targets $14.6B in alleged scams." *Medical Economics* (June 30, 2025) https://www.medicaleconomics.com/view/biggest-health-care-fraud-crackdown-in-u-s-history-targets-14-6b-in-

international money laundering, and fake U.S. companies. The Medicare rates matter little to such entities because they have no intention of providing equipment, supplies, or services. Thus, using CBP to reduce rates below market-based pricing will not deter them. However, strong financial documentation requirements and taking the time to review that documentation will keep fraudulent entities from being successful bidders. Eliminating the tax return extract, income statement, balance sheet, and statement of cash flow will make it easier for these fake companies to defraud the government. Moreover, it is critically important that bona fide bid assessments take place to confirm that suppliers can provide the equipment, supplies, and services at the amounts they are bidding. Even though these requirements are somewhat burdensome, legitimate suppliers embrace them as one of the multiple mechanisms needed to prevent unscrupulous entities from gaming the system, crowding out legitimate suppliers, and setting rates at levels that are not sustainable for legitimate entities.

To prevent fraud and abuse, we urge CMS to take the following steps:

1) Before adopting modifications to the CBP methodology, make sure the bid ceiling and SPA methodology support rates that are sustainable based on market forces.
2) Reinstate strong financial documentation requirements, assess suppliers against them as a first step in the bid evaluation process, and do not include any bidders in the array for setting the SPA that do not meet these requirements.
3) Adopt targeted, technology-based claims review policies, such as the supplemental oxygen template/clinical data elements for determining medical necessity.

II. The 75th percentile methodology does not reflect market-based pricing, jeopardizes patient access to physician-prescribed devices, and makes it easier for fraudulent entities, especially foreign actors, to conduct DMEPOS scams. We offer to work with CMS to consider and test other policy options in a smaller pilot program before implementing a new CBP round.

The CQRC supports the effort to address the capacity and demand flaws in lead item methodology used for Round 2021 that led to the reported variability in SPAs. Rather than considering multiple options for addressing these two very specific problems, the proposed revisions essentially seek to return rates to the median amounts. These amounts were not sustainable and resulted in many winning bidders never providing beneficiaries with the items and services for which they had contracted. Moreover, the proposed methodology does not

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alleged-scams (accessed August 23, 2025); *see also* AAPM&R. "DOJ Announces Massive Medicare DME Fraud Scheme." (Apr. 16, 2019) https://www.aapmr.org/members-publications/newsroom/member-news/2019/04/16/hpps-doj-announces-massive-medicare-dme-fraud-scheme (accessed Aug. 23, 2025) (The DOJ suspended payment privileges for 130 DME companies involved in a $1.7 billion fraud. This investigation revealed an international network using call centers in the Philippines and Latin America to market unnecessary medical braces to elderly U.S. beneficiaries. Kickbacks were paid to telemedicine companies that arranged for doctors to prescribe the equipment with little or no patient interaction).

include effective policies to ensure that the winning bidders will be able to meet beneficiary need. Servicing Medicare patients needs to be the overriding goal of the CBP effort.

First, CMS proposes to determine the number of winning bidders using data from previous rounds that is 10 years old for existing product categories. This change eliminates any effort to determine the likely current number of devices required to meet beneficiaries' needs in each CBA. While the calculation of the number of winning bidders is based on the number of suppliers that actually provided services in these most recent rounds, there is no indication that this utilization aligns with current beneficiary need. CMS seeks to address this problem by doubling the number of winning supplier contracts it will award. However, there is no evidence as to whether this increase will ensure that the number of contracts awarded will be enough or too many. While the policy may reduce the contracts awarded since the previous rounds, it does not actually allow CMS to determine the number of contracts that are needed in each CBA. Moreover, it may repeat the previous problem of awarding too many contracts.

Second, the proposed methodology would harm beneficiaries because it does not assess the ability of suppliers to actually provide equipment and services in a particular CBA when awarding contracts. Once the number of winning bidders is set, the policy does not ensure that the suppliers named as winning bidders and offered contracts will be able to provide any services individually or provide the necessary amount of devices and services required to meet all beneficiaries' needs in that CBA as a group. For example, if there are 20 bidders and CMS concludes that it will award only 10 contracts in that CBA, CMS will eliminate half of the bidders without assessing whether or not the 10 remaining bidders have sufficient capacity to meet expected demand. There is no safeguard to ensure that any winning bidder in a CBA has a track record of successfully supplying beneficiaries with the equipment, supplies, and services that they are prescribed in that area. This concern is particularly troubling given that the proposed methodology could result in no more than two suppliers in a CBA.

Third, the calculation of the SPA in the proposed 75th percentile methodology distorts the market in two critical ways that makes it less likely a sustainable rate will be achieved under the model. First, it uses the number of suppliers determined under the "sufficient supplier" policy to remove bidders at the higher end of the bid array without taking into account the historic/actual capacity of each supplier in the array. In the example above of 20 bidders in a CBA where CMS will award only 10 contracts, CMS eliminates the 10 bidders with the highest bid amounts, again without considering the ability of the bidders in the lower half of the array to actually provide beneficiaries with equipment, supplies, or services. This artificially lowers the final pivotal bid. Second, the proposed methodology would select the pivotal bid from the 10 lowest bids at the 75th percentile of this part of the array. Twenty-five percent of these bidders would be asked to accept bids at rates lower than what they attested was their "best price." Because bidders can decide not to accept the contract, it is possible that only the bottom 50 percent of bidders are awarded a contract. Clearly that is a race to the bottom that could put patient care at risk.

These three aspects of the proposed 75th percentile lead to essentially the same results that would be achieved if the flawed median methodology were reinstated. CMS is transparent about the goal in the preamble: the new proposed methodology was selected to ensure it is "more closely aligned to where the median of winning bid amounts would have fallen."[16] It does this by selecting the outcome (a median rate) and then applying complicated and less transparent policy steps to achieve that particular rate. These were the very results that raised serious concerns for Members of Congress, beneficiaries, physicians, patient advocates, economists, suppliers, and manufacturers in previous rounds.

As CMS notes in the preamble, the 75th percentile's new approach to achieving the median rate is an option that has never been attempted under the DMEPOS CBP. As a result, it will not only maintain many of the flaws of the previous median methodology, but will also likely have new ones. We do not think it is appropriate to apply these ideas without comparing the policies to other options that could resolve the problems encountered during Round 2021. (The CQRC shares some of these options below and we would welcome the chance to develop these or other options fully with the Administration). Moreover, it is important for CMS not to repeat the mistakes of the past by launching untested policy changes without first piloting them to ensure the correct balance among the goals of achieving savings, reducing fraud and abuse, and protecting beneficiary access. One major concern, which we have already noted, is that the bidders awarded contracts may not be able to meet beneficiary demand for these prescribed items. CMS acknowledges this potential in the preamble:

> However, there is no way to know for sure if the contract suppliers in the winning array under future competitions with this type of cap on the number of contracts awarded would have the capacity to furnish all of the items and services needed in the competition. Although larger suppliers should have economies of scale that would allow them to bid lower than smaller suppliers, it is possible that all large suppliers could be outbid by small suppliers that collectively do not have the capacity to meet demand for the items and service covered under their contracts.[17]

It is just a guess as to whether doubling the number of contracts for each CBA will address this potential situation. It seems particularly uncertain in areas where there are a small number of bidders.

CMS also recognizes that its modeling of the 75th percentile methodology may not be predictive of the impact of the new methodology either. "We acknowledge the simulation uses supplier bids from past competitions and does not reflect how suppliers

[16]CMS Proposed Rule, *supra* note 9 at 29243.
[17]*Id.* at 29243.

may actually bid in future competitions."[18] While CMS dismisses this concern based on its own belief, we are concerned that Round I 2017 and Round 2 Recompete results have led rates for some DMEPOS products, especially supplemental oxygen, to fall by 50 percent or more. It is difficult to imagine that with supply chain cost increases, the rise in labor costs, the tariff situation, and other factors not accounted for in the CPI-U, along with instability in the markets generally, that costs and bidding behavior from 2016 remains unchanged during the last 10 years.

In light of these concerns with the 75th percentile methodology, as well as those related to other aspects of the proposed changes to the CBP, we ask CMS not to finalize the proposed changes. The CQRC and other stakeholders are ready to work with the Administration to identify policies that would address its concerns with the previous methodology and those articulated by patients, advocates, physicians and other health care providers, suppliers, and manufacturers. It would then be possible to test such policies in a more limited way to ensure the policies achieve the desired goals before being launched in a new round.

A. CMS should avoid adopting a policy that creates a relatively arbitrary number of winning bidders and instead consider and test other options that address the problem of self-reporting capacity.

As noted above, the proposal to establish the number of contracts awarded in a CBA without taking into account supplier capacity or the overall needs of beneficiaries places patients at risk of not being able to access prescribed medical devices. It also creates significant potential for higher overall Medicare costs related to increased emergency department visits and hospitalizations. CMS has not released de-identified bid arrays from previous rounds of the CBP. The Proposed Rule also does not provide any data to support the conclusion that a smaller number of bidders provided the prescribed items and services to beneficiaries. It would be helpful to have this information to better understand the Agency's analysis. While we are pleased that CMS recognizes some previous winning bidders might not actually have provided beneficiaries with the contracted items and services, there is not enough data or evidence to support that doubling the number of calculated contracts from previous rounds will meet beneficiary needs. Before any policy like this one is applied nationwide, there needs to be more evaluation and testing.

The preamble expresses clear frustration with the self-reporting of capacity provided for certain product categories in Round 2021.[19] Without knowing more information, it is truly difficult to assess whether the bidders that estimated furnishing less than one percent of first year demand were new entrants that might have been legitimately estimating their actual first year capacity or were entities trying to game the system. CMS should have been able to assess

[18] *Id.* at 29245.
[19] *Id.* at 29241.

the veracity of these capacity estimates based on the financial documents provided as part of the bidding process. If CMS had adopted the stakeholder recommendation of applying actual capacity to existing suppliers, it could have weeded out those suppliers who likely were underestimating their capacity.

The preamble also questions why another percentage of bidders did not estimate being able to increase their capacity over historic levels.[20] In context, it is not necessarily surprising that many existing suppliers were unwilling to expand their business operations given the historic continued reimbursement cuts created by earlier rounds of the CBP. Again, the review of financial standards and bona fide bidding materials should have helped CMS assess the truthfulness of these estimates. If all suppliers had been held to actual capacity and the SPA set using the costs of those suppliers with historic actual capacity, CMS could have avoided the outlier problem that caused it to pause the last round of the CBP.

These two examples demonstrate that self-reported capacity is not a reliable way to assess supplier capacity. The CQRC had shared this concern previously with CMS and recommended an alternative to protect beneficiary access and hold bidders accountable for their actual capacity in a letter to the Administrator dated January 4, 2019, prior to the launch of Round 2021. These recommendations are only two of several that CMS should evaluate and potentially test before moving forward with the current proposed policy.

Another issue that arose from the Round 2021 effort relates to the previous policy of setting demand above 100 percent. CMS stated it chose this path to protect beneficiary access. However, using historic demand coupled with the grandfathering of existing suppliers would likely provide more than enough product to meet beneficiary needs. Setting demand at less than 100 percent would address the basic tenet of any bidding program that "the number of contracts awarded has to be limited to the degree that [bidders] face the risk of not being awarded a contract."[21] Thus, CMS should also consider setting demand at less than 100 percent to ensure a competitive bidding process.

Addressing the capacity and demand issues directly (as proposed here or as others might propose) should be one of the set of approaches CMS considers and tests before finalizing the Proposed Rule. The benefit of continuing to consider capacity and demand is that it provides transparent safeguards to protect patient access to prescribed medical devices while also maintaining the integrity of the bidding process. We encourage CMS to seek additional recommendations and engage in a meaningful dialogue with suppliers, manufacturers, patient advocates, physicians, and other health care providers to identify other potential ways to address the issue.

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[20] *Id.*
[21] *Id.*

B. Rather than set a limit on the number of contracts based on suppliers with claims in previous rounds, CMS should test other ways to ensure that the bidding process is truly competitive.

The process CMS sets forth for determining the number of contracts based on whether the product category is new or has been previously bid is difficult to assess because it is divorced from actual capacity and demand with the exception new product categories. For the reasons noted above, before finalizing this approach it should be compared to other ways to establish a competitive bidding process, such as no longer over-estimating demand or reducing demand for purposes of setting the SPA to a percentage less than 100 percent based not on a desired outcome of reaching the median bid amount for a lead item, but rather based on experience or testing to determine the most appropriate percentage. In addition, CMS should not create arbitrary ceilings on capacity as it did in previous rounds and instead hold bidders accountable for their actual capacity.

In response to the request for comments on estimating capacity in new CBAs, we agree that using the actual capacity of a supplier is appropriate. Self-reporting and self-estimation of future capacity are susceptible to gaming and will require additional resources for CMS to be more thorough in its evolution of the bidders' qualifications.

C. Another way to ensure competition is to pay winning bidders the amount they actually bid.

One way to ensure a truly competitive process would be to pay winning bidders at the amount they actually bid. Using a single rate incentivizes too many bidders to "low-ball" their bid amounts. These bidders understand that even if they bid an amount that is below the pivotal bid amount, the rate CMS will pay them will be higher than their bid. To remain in business, they are incentivized to skew the market. Given that CMS does not enforce a mandate to provide services once the contract is signed (as evidenced by statements in the preamble that fewer bidders billed Medicare than were awarded contracts), these entities distort market forces.

The current proposal does not control for gaming on the lower end of the bid distribution. As seen in Round 2021 bidding, strategic low bidders distort any attempt to use all bids in the setting of an appropriate SPA. For example, in Table 38 of the Proposed Rule, CMS shows that in one market where the median bid was $83, a single bidder bid $41. This bid is implausibly low and demonstrates gaming on the part of this bidder, which most likely could not have delivered this particular supply more than 50 percent below the median bid and 78 percent below the pivotal bid for that market. This lack of attention to strategic bidding well below the cost of the product should also be addressed in order to land at a market-based price.

If CMS were to hold bidders to their bids and paid them based upon their bid amount, it would create an incentive for bidders to submit only reasonable bids and remove any incentive to attempt to game the bid process through low-ball bidding. It would also address fraud concerns since bidders would be held accountable for their submitted bid amounts and could not gain access to CBAs on the basis of implausibly low bid amounts. CMS could address low bidders in other ways, but the simplest solution of holding all bidders accountable may be the most elegant and generalizable way to achieve this goal with a rule that can apply equally well in large and small markets where there are many or few bidders. Other outlier-based methods may fail depending upon the exact number of total bids and number of strategic low bidders in each category and CBA.

We acknowledge that the statute indicates that the Secretary must "determine a **single** payment amount for each item or service in each competitive acquisition area"[22]; however, if CMS were serious about ensuring a truly competitive process it would work to redefine this term or use pilot authority to test this policy. This one change could result in substantial savings to the program.

D. The 75th percentile methodology should not be the only methodology considered for addressing flaws in previous rounds; any new methodology should be tested before it is implemented nationwide.

As noted above, the CQRC has serious concerns about the appropriateness of adopting the 75th percentile methodology. Given these overarching concerns, we do not support the proposal addressing how to calculate a pivotal bid amount when the 75th percentile falls between two bidders. We also echo our concerns about returning to the pure median methodology, as outlined in numerous letters, articulated by leading economic experts, and outlined in the Pacific Research Institute's analysis. While we do not reiterate them verbatim here, we urge CMS to take the time needed to work with suppliers, manufacturers, patient advocates, physicians, and health care professionals to identify more effective and sustainable approaches for future rounds of the CBP.

E. CMS should consider other options for addressing non-lead item products and not finalize the proposed ratios to established rates for non-lead items.

CMS proposes to "calculate the ratio based on the 2015 fee schedule amounts for each specific area rather than the average of the 2015 fee schedule amounts for all areas."[23] The preamble states that this policy seeks to eliminate the potential for "SPAs for non-lead items being higher than the fee schedule amount that would otherwise be paid because the 2015 fee schedule amounts for some areas are lower than the average of the 2015 fee schedule amounts

[22]42 C.F.R § 1395w-3(b)(5)(A).
[23]CMS Proposed Rule, *supra* note 9 at 29246.

for all areas."[24] At first glance, it might appear that use of the specific CBAs might be a more targeted approach. However, trying to use this "proxy" information as if it represented the actual relationship among these products will produce additional market distortions. The 2015 fee schedule is the only information CMS has on the cost relationship among the lead item and non-lead item products. It does not represent an exact calculation of those relationships. Nor does it represent current market-based pricing. The community has previously aligned around using the unadjusted 2015 Fee Schedule for calculating the non-lead item ratios at the national level because doing so recognizes that the ratios are not an exact science.

If CMS wished to ensure greater accuracy among the ratios, it could test other models. For example, it could collect cost data from suppliers and manufacturers to develop more current ratios. It could also develop a new methodology in which bidders bid on all HCPCS codes in a product category. While the previous composite bid methodology was deeply flawed and distorted the market, these data could be used to establish non-lead item ratios as well. In brief, there are many other ways to construct non-lead item ratios that CMS has not considered.

Even maintaining the current non-lead item ratio policy based on the fee schedule amount for all areas presents challenges. These ratios were set using data from 2015. There has not been a systematic review of this 10-year-old data to determine whether the ratios need to be updated. The interaction between lead item pricing ratios and the restrictive bid ceiling needs to be addressed to ensure that the next round of competitive bidding does not produce distorted results.

F. The CQRC agrees that the SPA should be updated by the CPI-U during years two and three of a competitive bidding cycle, but the updated rates should not be capped; instead the updates should be applied as annual updates are applied in other Medicare payment systems.

The CQRC agrees that it would be more appropriate and result in more accurate and efficient bidding if CMS were to provide the certainty and confidence that the CPI-U would be used to update SPAs in years two and three of each bid window. We appreciate that CMS recognizes that the COVID-19 Public Health Emergency (PHE), supply chain disruptions, and recent years' higher-than-normal inflation have increased the cost of providing services.

However, we do not agree that the final SPAs updated by the CPI-U should be capped at an arbitrary amount as proposed. No other Medicare program has its overall payment rates capped in such a manner. Annual updates (whether from proxies like the CPI-U or market-basket increases) are applied to the payment rates without being subject to such an arbitrary cap. One concern is that a significant market disruption could result in inflation that drives rates above the cap. Using the CPI-U would protect Medicare from that situation happening frequently, but

[24] *Id.*

still be nimble enough to respond to market forces. As noted above, this very narrow interpretation is not consistent with Congressional intent as evidenced from the plain reading of other parts of the statute and the legislative history.

G. While the CQRC appreciates the transparency of defining the conditions under which CMS would not award contracts, we are concerned that the Proposed Rule is arbitrary and untested and will likely lead to beneficiary harm.

CMS proposes to codify that "a contract would not be awarded for a competition if the SPA for the lead item would be greater than the lesser of 110 percent of the adjusted fee schedule amount for the lead item, if applicable, or 100 percent of the unadjusted fee schedule amount for the lead item."[25] While we support having a clear standard, the specific proposed standard raises concern. CMS establishes 10 percent above the adjusted fee schedule based on its view that the reduction in utilization from previous rounds of CBP is due to fraud. However, it does not consider whether the reduction was also due to rates being too low to support patient access, as is clearly the case with supplemental oxygen products. As we saw after the COVID-19 pandemic, there were periods when inflation exceeded 10 percent. We urge CMS to work with the community to identify an appropriate standard by considering alternatives that take into account all of the data without making utilization or other assumptions.

H. The proposed bid ceiling amount does not reflect market-based pricing and is likely to result in market inefficiencies and access problems for beneficiaries.

As noted earlier in this letter, the CQRC is deeply troubled that the Proposed Rule would adopt a bid ceiling at an amount that is below the best information available on current market-based prices for the equipment, supplies, and services provided. Specifically, the proposal would use the "lesser of the most recent SPA for the item, adjusted by an inflation factor, plus 10 percent or the unadjusted fee schedule amount for the item". The proposed bid ceiling would not allow the program to remain nimble to respond to market forces. The 10 percent option to allow the rate to be higher than the current SPA is an arbitrary percentage that does not appear to have been developed through any type of analysis of the market-based pricing for equipment, supplies, and services or recent changes in market forces, such as supply chain and labor increases. Moreover, it assumes SPAs calculated for urban areas would be sufficient for rural and non-CBA/non-rural areas, which they are not.

For example, for oxygen concentrators, the new bid ceiling is below the pivotal bid from Round 2021 in 60 percent of the CBAs, according to an analysis by Health Management Associates (HMA). This arbitrary cap has the potential to lead to access issues in many CBAs.

[25] *Id.* at 29250.

While CMS was concerned about the high bids with low capacity estimates in Round 2021, the median of publicly released SPAs in the oxygen product category showed that the majority of legitimate bids would have resulted in a SPA that was 27.7 percent higher than the previous SPAs. This median increase is more likely to reflect market-based pricing given the policies CMS implemented for the lead-item methodology. The amount of the percentage is not surprising given the following facts:

- First, bidders knew that these rates would not only apply in CBAs but also rural areas, so they had to bid higher than previous CBP rounds to account for the application of these rates outside of the densely populated CBAs.

- Second, there were well-documented patient access issues related to supplemental oxygen based on patient complaints and CMS claims data.[26]

- Third, suppliers provided evidence to CMS that pricing in CBAs, non-CBA/non-rural areas, and rural areas were below the cost to provide the therapy.

Together, these data support that bids under Round 2021 would have been higher to align with market forces.

Price ceilings have never been associated with free markets in classical economics. In other industries, they have been known to lead to shortages or other inefficient market behavior. The proposed bid ceiling is set so low that it is unclear whether markets could meet the stated demand at the ceiling price. As the preamble states, if implemented the impact of the bid ceiling would be a race to the bottom and endanger beneficiaries.

> Bidding entities would be educated that they would not be allowed to enter bids that are higher than these proposed limits. The SPAs going from one round to the next would not be able to exceed the 10 percent increase in payments that, as discussed previously, we believe would still allow contracts to be awarded in accordance [with the statute].[27]

Given the previous Round 2021 design flaws regarding self-reported capacity and over-inflated demand that produced an unusable round of bidding – at considerable cost to the industry and taxpayers – CMS should carefully consider and test whether its process is sufficient to produce pricing that clears all market demand and ensures access to care.

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[26]Jacobs SS, Lindell KO, Collins EG, Garvey CM, Hernandez C, McLaughlin S, Schneidman AM, Meek PM. Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy. Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey. Ann Am Thorac Soc. 2018 Jan;15(1):24-32. doi: 10.1513/AnnalsATS.201703-209OC. PMID: 29048941.
[27]CMS Proposed Rule, *supra* note 9 at 29250.

I. The proposed "streamlining" of the financial document requirements will make it easier for bad actors and unscrupulous foreign entities to commit fraud and abuse against the Medicare program.

A central concept of a successful CBP is that the winning bidders are legitimate organizations that have the capacity to provide the appropriate prescribed devices and services to Medicare beneficiaries. By reducing the financial documentation requirements to a business credit report with a numerical credit score or rating (or a business credit report showing no data or insufficient information to generate a credit score and a personal credit report with a numerical credit score or rating from the bidding entity's Authorized Official or Delegated Official listed in CMS' PECOS), CMS is eliminating its best opportunity to eliminate fraudulent suppliers from the program. Truncating the process both in terms of documentation and the review period will make it much easier for foreign entities, which public reports demonstrate have targeted the Medicare DMEPOS program, to gain a strong foothold into the program.

While not perfect, the current financial documentation requirements and careful review process help to weed out illegitimate suppliers prior to contracts being awarded. As noted elsewhere in this letter, additional steps, including paying bidders at their bid amount, could strengthen this process.

Moreover, these financial documents are critically important to assessing a bidding entity's capacity. While CMS may not have acted on its concerns about self-reported capacity by removing bidders from the Round 2021 competition, the financial documentation appears to have allowed it to assess the veracity of the self-reported capacity based on the comments included in the preamble to the Proposed Rule. As we have noted elsewhere in this letter, taking into account a bidder's capacity is essential to ensuring beneficiary access to the devices in each product category. As a corollary, it is also important that CMS maintain the current detailed documentation requirements and review process to assess capacity as well.

CMS also seeks to allow for an attestation-only process for determining the small supplier threshold. Given the discussion about CMS' concerns regarding self-reporting of capacity, it is surprising that CMS proposes self-reporting for gross revenues. We urge CMS to retain the financial documentation requirements currently in place to assess suppliers' gross revenues.

Therefore, the CQRC requests that CMS retain the current financial documentation requirements and not finalize the proposed modifications.

J. The CQRC supports several of the other proposed modifications to the DMEPOS CBP.

The CQRC supports the following proposed modifications to the process:

- Streamlining the evaluation and notification processes by informing bidding entities if a covered document was missing by the close of the bid window. Each bidding entity would receive a notification stating if: (1) a covered document(s) was missing by the close of the bid window; or (2) no covered document(s) was missing by the close of the bid window.

- Codifying the way CMS currently addresses non-qualifying surety bonds. If CMS determines that a bid surety bond requirement is not met, the bidder would be notified by CMS and would be provided with an opportunity to correct the deficiency on the bid surety bond via a bid surety bond rider.

- Allowing Medicare payment to Indian Health Services (IHS) or Tribally operated facilities and suppliers that furnish competitively bid items and services to AI/AN Medicare beneficiaries who reside in a CBA so that the AI/AN Medicare beneficiaries can retain the benefits described previously when receiving DMEPOS items and services from a Tribal supplier.

- Unilaterally terminating or modifying every DMEPOS CBP supplier contract impacted by a PHE if the following conditions are met: (1) the Secretary of HHS declares a PHE; (2) CMS determines the PHE has created an access concern for beneficiaries receiving items and services under the DMEPOS CBP in certain CBAs or defined area(s) within CBAs; (3) CMS determines that awarding additional CBP contracts, per 42 CFR 414.414(i), would not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude those specific areas from the DMEPOS CBP would alleviate access concerns.

K. The proposed changes to the CBP focused on only one set of options and has not fully considered other policy alternatives that would be less likely to create barriers to beneficiary access or that would better address fraud and abuse, while setting rates closer to market-based pricing.

The Proposed Rule states that CMS considered three possible methods for calculating the SPA. These three methods were to set the payment amount at the median price (50th percentile), the 75th percentile, and the market clearing price (100th percentile). Unfortunately, this approach leads to a result where the only alternatives to the proposed 75th percentile are both policies which previously failed to meet the needs of the program. The median was used during initial rounds but eventually discarded as inadequate due to misaligned incentives for low-ball bidding and other market distortions. By contrast, the 100th percentile bidding methodology was proven unworkable, as predicted by the CQRC, due to the extreme outliers in

certain CBAs which would have set the SPA far above previous prices resulting from outlier high bidders due to the self-reported capacity and over-estimated demand set by CMS.

A particular concern of CMS' choice of SPA setting methodology is its lack of attention to capacity considerations. Traditional auctions accept bids until all capacity is fulfilled. By contrast, a 75th percentile methodology ensures that 25 percent of bidders are required to provide supplies below their bid amount or exit the market. If bidders in the top 25 percent of the array refuse to participate at the SPA, that CBA would be at risk of failing to deliver the needed capacity, creating shortages for beneficiaries in that area. Importantly, these top 25 percent of bidders may represent far more than 25 percent of total capacity because the proposed methodology weighs all bids equally. Given the lack of accountability for low bid amounts, the highly restrictive bid ceiling, and the failure to consider capacity when setting the SPA, there is extreme risk that one or more CBAs will fail to procure the needed capacity to ensure beneficiary access to care.

If CMS wishes to address the failure of Round 2021 with a new methodology, it should focus on methods to remove outlier bids while setting the SPA as close to the market clearing price as possible to ensure beneficiary access to care. There are many alternative options available to achieve market-based pricing. It is unclear why CMS did not consider other, more nuanced approaches before settling on the proposed 75th percentile. A sample of possible alternative methodologies includes:

- A SPA set at the 95th or 90th percentile would come closer to the market clearing price while ensuring a single outlier high bidder is less likely to drive the final SPA.

- A SPA set at the lesser of the 100th percentile or the 75th percentile + 5% (or 10%) could allow CMS to choose the market clearing price whenever no outliers are present while capping the outlier amounts relative to the 75th percentile.

- CMS could set the SPA at the 75th or 90th or 95th percentile after removing "outlier" bids or clusters of bids which are significantly different than contiguous bids in the array.
    - In particular, CMS should want to exclude low strategic bids below cost as non-relevant to the setting of the SPA.

- CMS could set the SPA at the 75th or 90th or 95th percentile after considering capacity. That is, rather than weighting all bids equally, CMS could instead weight bids by capacity so that it ensures that the final SPA captures a significant portion of the overall capacity needed to serve the market.

While the CQRC does not yet recommend these options yet, we wanted to share them as examples of alternative methods that could be considered. The most promising options

should then be tested before beneficiaries are placed at risk or there is another unsuccessful CBP round.

As part of this process of considering other policies to address these issues, the CQRC asks that CMS keep in mind the following principles:

- The process should be market-based, allowing for rates to fluctuate up or down based on the unadjusted fee schedule. It is unreasonable to assume costs (and therefore prices) have continued and will continue to decline since the inception of the CBP in 2008.

- Clear financial documentation requirements should be maintained with a careful review by CMS and its contractors to ensure that bidders' bids are legitimate (which would help address unrealistically high and low bids) and that these suppliers can and will actually provide the products and services in the CBA.

- The bidding process should require bidders to bid line-item prices in each category, given that the current and proposed ratios used to calculate non-lead item rates do not reflect the actual cost relationship among products. This truth can be seen most readily in product categories with inversions between the actual equipment and supplies.

- The SPA calculation should not be calculated before each financial documentation, quality compliance, capacity, and bona fide bid amounts are assessed so that the bid amounts arrayed reflect legitimate, qualified suppliers.

- Bidders at or below the pivotal bid should be paid the amount they bid, just as commercial insurers negotiate specific rates with individual suppliers.

- The Remote Item Delivery (RID) option being proposed should not be permitted where there is a rental asset in place. There cannot be a separation of the rental unit and the supply items. This would interfere with patient care, creates confusion for the patient, and lacks accountability for the suppliers.

L. Summary: CMS should not finalize the proposed modifications to the DMEPOS CBP. Instead, we ask that CMS work with the community to identify other options for addressing its concerns and meeting the needs of beneficiaries. CMS should test these options before any modifications are implemented nationwide to avoid another failed CBP round.

The CQRC does not oppose restarting the CBP for certain product categories. We also agree that the anomalies in Round 2021 need to be addressed before a new round launches. However, the proposed 75th percentile methodology seems designed to reinstate the outcomes of the median methodology that have been discredited. The proposed methodology contains other flaws as well that will likely harm beneficiaries and lead to increased Medicare costs related to emergency department visits, hospitalizations, and other expensive health care services. Moreover, the proposals may have the unintended consequence of making it easier for bad actors, especially foreign entities, to engage in fraudulent and abusive behavior. To avoid such outcomes, we encourage CMS not to finalize the proposed changes to the DMEPOS CBP. Instead, we ask that CMS work with the CQRC and other stakeholders to address the Administration's cost containment goals in a manner that is balanced and protects beneficiary access to medically prescribed devices, supplies, and services.

III. If CMS were to move forward with a new round of CBP in the near future, CMS should remove supplemental oxygen from future rounds to lock in savings already achieved and support legislative reforms to restore access to liquid oxygen and respiratory therapy services.

Congress created the Medicare CBP to reset the Medicare rates for DMEPOS using market-based forces. As noted in Section I.A., the original fee schedule rates were based on supplier charges from one year in the mid-1980s and other information such as unadjusted list prices.[28] In addition to seeking to lower costs for beneficiaries and the program, Congress sought "to provide important benefits to Medicare beneficiaries."[29] CMS recognized that Congress wanted to maintain access for beneficiaries. To achieve the goal of lower out-of-pocket costs and savings for Medicare, the Congress turned to a market-based pricing policy. As quoted in Section I.A., both CRS and the GAO reports demonstrated the intent of Congress to use the CBP to set rates at market-based prices.[30]

Relying on market-based prices as the "gold standard" for efficiency and accessibility, Congress instructed CMS to establish CBP rounds with two important instructions related to savings that support this market-based pricing approach. First, "[t]he total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts

[28]MedPAC, *supra* note 1.
[29]CMS Fact Sheet, *supra* note 2
[30]CRS, *supra* note 3; GAO, *supra* note 3.

that would otherwise be paid."[31] Clearly, the Congress wanted to reduced Medicare spending that was occurring when it authorized the CBP. However, it did not require a continued ratchetting down of rates evidenced by its decision to allow for items and services to be removed from the program over time. "The Secretary may exempt…items and services for which the application of competitive acquisition is not likely to result in significant savings."[32]

While savings are a central goal of the program as evidenced in the statute, the critical question is what benchmark Congress intended CMS to use. That benchmark is the original DMEPOS fee schedule which was what was in place when the Congress established the program. There is no language to suggest that the benchmark was to be reduced every bid cycle. Doing so would create a race to the bottom. The second provision supports this understanding by clearly stating that the Congress did not anticipate that savings would always be achievable for every item or service. When additional savings compared to the original fee schedule are no longer attainable, the Secretary should remove the products from the program.

That is the case with supplemental oxygen, which is why we ask CMS to remove it from the CBP. Under the CBP, the rates for supplemental oxygen have fallen by nearly 50 percent from the original fee schedule payment amount (as updated annually by CPI-U). Based on the data CMS shared after Round 2021,[33] the SPAs increased, but only one CBA saw a SPA at the bid ceiling. The remaining 129 were below the bid ceiling. It is worth nothing that one challenge with Round 2021 that often goes unmentioned is that bidders were told their bids had to cover rural costs as well because CMS planned to apply the final SPAs to the non-CBA areas in addition to the CBAs. As a result, bidders had to account for the higher costs in the non-CBA/non-rural and rural areas in this round.

The mode of the percent difference between the pivotal bid amount and the former CBA SPAs (adjusted fee schedule amount) was 27.7 percent. This means that bidders in most CBAs bid roughly 28 percent higher than the previous SPA amount. Larger suppliers had shared data with CMS prior to Round 2021 showing that those SPAs were below costs in CBAs by 5 percent, non-CBA, non-rural areas below their cost by 11 percent, and more than 22 percent below cost in rural areas prior to 2018 bidding program. Given supply chain costs increases attributed to the pandemic, the data provide a legitimate rationale to support the conclusion that when market forces were allowed to work, the bids would increase in response to these market forces.

Well-documented problems with patient access are another indicator that bidding supplemental oxygen in future rounds is "not likely" to provide additional savings. Despite the preamble suggesting CMS has seen no patient impact in its monitoring program, physicians and

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[31] 42 U.S.C. § 1395w-3(b)(2).
[32] *Id.* at § 1935w-3(a)(3)(B).
[33] CMS. "Pivotal Bid Summary" (Jan. 15, 2021) available at: https://dmecompetitivebid.com/cbic/cbicr2021.nsf/DID/NHD3ABSCXD (accessed Aug. 17, 2025).

CMS' own claims data tell a much different story. The American Thoracic Society (ATS) published that patients are unable to access liquid oxygen and patients relying upon other modalities of supplemental oxygen also experience access issues.[34] CMS' own claims data shows a 126 percent reduction in claims for portable liquid oxygen and a 136 percent reduction in claims for stationary liquid oxygen when there has been no new treatment option available and an actual increase in the conditions for which physicians prescribe liquid oxygen. From 2017 to 2025, the CMS claims files show that the number of Medicare beneficiaries accessing portable liquid oxygen fell from 13,157 to 2,989 patients. During the same time period, the number of Medicare beneficiaries accessing stationary liquid oxygen equipment fell from 8,464 to 1,620 patients.[35] The reason for this decline is not due entirely to beneficiaries' enrollment in MA plans (which is about 50 percent nationwide). Nor is it due entirely to eliminating fraud and abuse, which CMS estimates, without any basis, in the Proposed Rule to be 10-20 percent. This change reflects a real patient barrier to accessing liquid oxygen due to the CBP taking rates below market-based prices.

Trying to squeeze out additional savings from supplemental oxygen at this time would be a pyrrhic victory for CMS. Clinical literature shows that supplemental oxygen reduces overall Medicare spending by reducing emergency room visits, hospitalizations, and other costly services.[36] If CMS were to further push down the reimbursement rates for supplemental oxygen, the access issues beneficiaries have already experienced would likely increase. As a result, CMS would end up spending more money on treating these patients in more expensive settings and for additional entirely preventable complications.

In light of the fact that the Congress authorized CMS to remove items and services from the CBP when savings could no longer be achieved, we ask that supplemental oxygen be removed from future rounds of the CBP. Moreover, given the serious access problems that already exist for liquid oxygen, CMS should establish a new rate based upon a cost data collection program because bundling liquid with the other oxygen modalities has substantially distorted the current rate. Simply freezing rates for liquid oxygen at the current level will not provide sufficient resources to reconstruct the infrastructure necessary to provide liquid oxygen.

IV. CQRC supports reducing fraud and abuse and urges CMS to adopt more effective policies than the proposed annual accreditation surveys.

The CQRC agrees with CMS that it is important to police fraud and abuse. Unfortunately, the proposal to require costly and time-intensive annual accreditation surveying will not be

[34]Jacobs, *supra* note 26.
[35]HMA. "Analysis of CMS Claims for Stationary and Portable Supplemental Oxygen." (2025).
[36]*See, e.g.,* Sami R, Savari MA, Mansourian M, Ghazavi R, Meamar R. Effect of Long-Term Oxygen Therapy on Reducing Rehospitalization of Patients with Chronic Obstructive Pulmonary Disease: A Systematic Review and Meta-Analysis. Pulm Ther. 2023 Jun;9(2):255-270. doi: 10.1007/s41030-023-00221-3. Epub 2023 Apr 24. PMID: 37093408; PMCID: PMC10203089.

justified by the anticipated additional benefit of reducing fraud and abuse. Accreditation organizations simply are not designed to police fraud and abuse. Their job is to assess whether suppliers meet the CMS quality standards. These standards focus on business and product-specific service requirements. They do not assess claims or interaction with patients to be able to determine if there has been fraud.

Increasing accreditation to an annual requirement will only increase the cost of providing services without providing meaningful reduction in fraud and abuse. We understand the accreditation organizations do not have the resources to expand these surveys from once every three years to annually. Trying to force such a dramatic increase in workload could jeopardize the accuracy and integrity of all surveys. Virtually all other providers, including hospitals, are surveyed once every three years. There is no indication that suppliers are not meeting the quality standards in a greater proportion than these other providers. We do realize that the OIG and others believe DMEPOS generally is more susceptible to fraud and abuse than other providers. The solution to that perceived problem is to leverage technology to support a more effective and accurate review of claims. For example, the CQRC continues to recommend that CMS require contractors to adopt the supplemental oxygen template clinical data elements in lieu of using medical record notes for purposes of establishing medical necessity. CMS has already developed this template but never required contractors to use it. We believe these types of technology-based solutions will be substantially more effective than an annual evaluation to make sure that suppliers adhere to the quality standards.

V. Conclusion

We thank CMS for providing the CQRC with the opportunity to provide comments on the Proposed Rule. While we cannot support it being finalized as drafted, we are committed to working with CMS to address the challenges in the current bidding methodology to support future rounds for the CBP. We also would like to work with CMS to address the failure of the CBP to support beneficiaries requiring supplemental oxygen by removing it from the CBP and establishing new rates to support liquid oxygen. Finally, we again urge CMS to act to address fraud and abuse by adopting the technology-based solution of an electronic supplemental oxygen template. We look forward to future conversations. Please reach out to our executive director, Kathy Lester, if you have any questions about our comments.

Sincerely,
Robin Menchan
Chair, Council for Quality Respiratory Care

Attachments:

- Pacific Research Institute. “Reforming CMS’ Competitive Bidding Process to Improve Quality and Sustainability.” (July 2018).
- CQRC. “Letter to CMS Administrator Seema Verma” 2019 capacity letter