June 8, 2020

The Honorable Alex M. Azar, II  
Secretary  
The U.S. Department of Health and Human Services  
200 Independence Avenue, S. W.  
Washington, D. C. 20201

**RE: President’s FY 2021 Proposed Budget – DMEPOS Issues**

Dear Secretary Azar,

The American Association for Homecare (AAHomecare) submits this letter in Response to the Department of Health and Human Services’ [Fiscal Year 2021 President’s Budget in Brief](https://www.hhs.gov) that was published February 10, 2020. AAHomecare is the national organization representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members provide medical equipment and supplies for patients outside of the hospital setting to continue to improve the management of patients with acute and chronic conditions. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost-effective, safe and reliable home care products and services.

We identified 14 proposals within the Brief that would impact the DMEPOS industry and developed a response to each proposal. Below is a summary of our responses; our complete response follows.

**SUMMARY OF AAHOME CARE RESPONSES**

**Reform and expand durable medical equipment competitive bidding.**

**Response:** Due to the current COVID-19 Public Health Emergency, CMS should delay the implementation of the next round of the competitive bidding program. Furthermore, CMS should not conduct bidding in areas outside the 100 metropolitan areas that Congress originally authorized because it will accelerate the deterioration of access to needed equipment and supplies.

**Use retail price information for DME fee schedule rates.**
Response: Retail prices for DMEPOS do not reflect the services and requirements that suppliers provide under Medicare and therefore should not be a reference for Medicare’s DME fee schedule.

Eliminate the unnecessary requirement of a face-to-face encounter.
Response: AAHomecare supports this proposal and recommends that it be extended to removing the face-to-face requirements in Local Coverage Determinations.

Address excessive billing for durable medical equipment that requires refills or serial claims.
Response: AAHomecare is not in favor of this proposal. It is a duplicative effort and an additional expense to the Medicare program without added benefit.

Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation.
Response: AAHomecare supports this proposal.

Support coverage for innovative alternatives to DME for treatment and management of diabetes.
Response: Congress needs to take a more global approach to this concept and must consider not only pricing concerns, but coverage policies.

Change the Medicare Appeal Council’s standard of review.
Response: AAHomecare does not support this proposal. It is important that suppliers receive the full benefit of their appeals to the MAC.

Establish a post-adjudication user fee for the third level and the fourth level of appeals.
Response: AAHomecare does not support a filing fee. This would be duplicative punishment for suppliers who are already not paid for services rendered or had the payment recouped.

Expedite procedures for claims with no material fact in dispute.
Response: AAHomecare recommends a process where the supplier and OMHA agree on and sign an Agreed Statement of Facts upon which the ALJ will base its decision.

Increase the minimum amount in controversy required for an adjudication to the Administrative Law Judge to the Federal District Court amount in controversy requirement.
Response: AAHomecare has serious concerns about this proposal and does not support it.

Establish Magistrate Adjudication for claims with amount in controversy below new Administrative Law Judge amount in controversy threshold.
Response: AAHomecare is not in favor of this proposal. This proposal will steer most, if not all, DMEPOS appeals away from ALJs, denying them appropriate due process.

Limit appeals when no documentation is submitted.
Response: AAHomecare supports this proposal.

Remand appeals to the redetermination level with the introduction of new evidence.
Response: AAHomecare supports this proposal.

Require a good-faith attestation on all appeals.
Response: AAHomecare does not support this proposal. HHS should provide the additional resources needed to process appeals and address the issues that create the volumes of appeals.

AAHomecare’s complete responses to the proposals can be found on the following pages. We appreciate the opportunity to submit these comments. Please feel free to reach out if you would like any additional information.

Sincerely,

Tom Ryan
President & CEO
American Association for Homecare

Attachment: Impact of COVID-19 Supply Chain Disruptions and Increased Costs on DMEPOS Suppliers

CC: Deputy Secretary Eric Hargan
CC: Administrator Seema Verma
Reform and Expand Durable Medical Equipment Competitive Bidding. Under the Medicare Durable Medical Equipment (DME) competitive bidding program (CBP), DME suppliers can submit low bids during the competition to win a Medicare contract and get paid a higher price even though their low bid reduced prices for all other suppliers in the competition area. CMS uses prices from urban DME competitions to inform fee schedule prices in rural areas, thereby undervaluing true costs in rural areas and threatening access to care. Effective CY 2024, this proposal would change the way Medicare pays for DME under the CBP, from a single payment amount based on the maximum winning bid to the winning suppliers’ own bid amounts. As a result, Medicare payment to low bidders would be their low bid amount. It also would expand competitive bidding to additional geographic areas, including rural areas, and would add inhalation drugs to the CBP. This proposal would also remove the surety bid bond, which requires all suppliers to secure a surety bond for every competition. In the event that fewer than two suppliers submitted bids in a rural area, CMS would base prices on information from “similar” rural areas. ($7,730 billion in Medicare savings and $435 million in Medicaid savings over 10 years)

First and foremost, before responding to this proposal, AAHomecare requests that CMS consider the current COVID-19 Public Health Emergency (PHE) that has greatly impacted the HME industry and postpone the implementation of Round 2021 of the CBP.

Since the start of the COVID-19 PHE, CMS has made numerous policy changes designed to ensure patients can access necessary care. For beneficiaries with a medical need for home respiratory devices (such as non-invasive ventilator (NIV), oxygen, CPAP, RAD, nebulizer, etc.), CMS is not enforcing the clinical conditions for coverage, allowing patients with acute conditions to be treated at home instead of in hospitals. We appreciate CMS’ recognition that it is important to remove any unnecessary barriers to care during this pandemic. While CMS has openly recognized that the DMEPOS industry is struggling due to COVID-19, CMS has not postponed the implementation of Round 2021 of the Medicare DMEPOS CBP. Moving forward with the CBP will impede patient access given the current economic and care delivery landscape. We therefore urge CMS to delay Round 2021 of the CBP.

Serious Access Issues Will Occur: Previous rounds of the Medicare DME CBP demonstrate that it dramatically decreases the number of DMEPOS suppliers who can service beneficiaries in the competitive bidding areas (CBAs). CBAs are 100 of the most populous metropolitan areas, the same areas most impacted by COVID-19. CMS’ decision to remove NIVs from Round 2021 of the CBP will allow all qualified DME suppliers to continue to provide NIVs and related services in 2021; promoting beneficiary access to these critical items and services, particularly in cities most hard hit by the coronavirus. We commend CMS for this decision and ask CMS to recognize that access to other respiratory and DME items is as necessary as NIVs. We therefore urge CMS to delay Round 2021 until the later of: (1) 12 months after the end of the COVID-19 PHE, or (2) January 1, 2022.

During this PHE, our DME supplier members have experienced a dramatic increase in patients requiring home oxygen and other respiratory items and services, in the areas most impacted by the COVID-19 pandemic. Respiratory devices such as CPAP, RAD, and home oxygen are being prescribed for patients with the COVID-19 virus as well as for patients with acute and chronic conditions.

To assess the impact of the PHE on our members and their ability to serve beneficiaries, AAHomecare conducted a survey of member firms. Over 500 unique companies responded. The survey was designed to identify the ways that DME suppliers have adapted their operations in 2020 to accommodate supply chain disruption, as well as the magnitude of extra costs they have incurred as they respond to the COVID-19 PHE. Dobson DaVanzo & Associates
analyzed the survey results, and has presented that analysis in a May 13, 2020 report, “Impact of COVID-19 Supply Chain Disruptions and Increased Costs on DMEPOS Suppliers.”

Supply Chain Issues are Dramatically Changing the Market: As a result of the public health and economic emergencies associated with COVID-19, DMEPOS suppliers have experienced supply chain interruptions such as sizeable delays and order cancellations in receiving equipment and supplies.¹ In addition, manufacturers and distributors have experienced cost increases due to the COVID-19 pandemic. In an effort to keep their employees safe, suppliers are incurring additional operating expenses such as providing IT equipment for staff to work remotely or obtaining additional vehicles to make DMEPOS deliveries.

Given the uncertainty COVID-19 has introduced to all aspects of healthcare delivery, it is important for CMS to recognize that the conditions under which the bids were constructed in 2019 no longer exist. Costs and availability of products are no longer predictable and bear no relationship to 2019 costs and availability. Further, important bidding program metrics of “expected supplier capacity” and “expected product demand,” which determine the eventual number of contractors, are no longer accurate due to the increased need for respiratory and related DME items due to the pandemic. The number of suppliers necessary to serve the increased number of respiratory beneficiaries, due to COVID-19, is significantly greater than what would have been required under 2017 and 2018 utilization estimates. Therefore, moving ahead with CB based on out-of-date market information has no economic justification. If the cost of goods rises, while at the same time the CBP payment rates are limited by both an earlier out-of-date price determination, the DMEPOS industry could face severe dislocation and Medicare beneficiaries will lose critical access to often life-saving DME items and services.

During this COVID-19 pandemic, DMEPOS suppliers are being financially harmed due to circumstances well beyond their control. Suppliers are no longer able to project either their costs, or the level and stability of revenue streams associated with delivering product to patients. Without the fundamental security that the supplier can acquire items at realistic and feasible costs, determining an accurate bid amount for a lead item in any of the product categories will not be possible going forward during the PHE. Factors like anticipated costs (both direct and indirect) for the lead and non-lead items, as well as anticipated utilization of the non-lead items, have risen since 2019, and the bids CMS contemplates using are no longer realistic or relevant. Furthermore, any policy that could restrict the availability of home respiratory therapies should be reconsidered in a marketplace disrupted by the virus spread.

The Dobson Davanzo report concludes that the survey data indicate an urgent need for CMS to postpone the 2021 Medicare CBP scheduled to begin January 1, 2021. This postponement will be even more essential if another COVID-19 peak arrives in the fall, as many models are currently forecasting.

Response to Proposal

- **The proposal to pay each winning bidder its own bid amount seems attractive at first, but would be confusing and unmanageable.** The challenge with paying each supplier at its own bid rate for all product categories and HCPCS is the overwhelming number of fee schedules that will need to be established in order for the MACs to be able to process claims. In addition, the proposal would be confusing to beneficiaries because different beneficiaries would have different copayment amounts, depending on which DME supplier they choose. In this era where pricing transparency and informing

¹ See Dobson, Davanzo & Associates, “Impact of COVID-19 Supply Chain Disruptions and Increased Costs on DMEPOS Suppliers,” (May 13, 2020)
beneficiaries of costs and copays, there would be no practical way for such a program to be established and implemented.

- Under the Medicare Modernization Act, Congress prohibited CMS from establishing CBPs in areas outside the current 100 highly populated metropolitan areas because Congress recognized that bidding was simply inappropriate in rural areas due to the limited number of suppliers and potential access issues. Congress understood that bidding requires a large number of participants to compete in the bid program, and a large enough number of contract suppliers to serve the population. In more rural areas, there are typically very few suppliers. For example, in South Dakota, there are 29 traditional DME suppliers to serve the entire state, an area of over 70,000 square miles. There are already demonstrated access issues in states such as North Dakota and there are simply not enough potential suppliers to participate in a bid program. Finally, auction experts agree that a rational bid program not only requires existing entities to participate in the bid program, but that the real competition comes from new entrants. In rural areas, there has been a sharp decline in DME suppliers over the last several years due to increased costs of serving these areas. It is highly unlikely that bidding in rural areas would attract enough new suppliers to provide the necessary competition.

- As a result of these extraordinary payment cuts in rural areas, beneficiaries in areas outside of CBAs have seen decisive drops in access to DMEPOS. Expanding CBP to these rural areas will only intensify access hurdles for beneficiaries living in these areas. Given the continued challenges of CBP and the special demographic and economics of areas outside CBAs, expanding CBP could exacerbate the access issues these beneficiaries face. We are very concerned about deteriorating access to DMEPOS in areas outside CBAs; expanding CBP to these areas will only aggravate access in rural areas.

- The Administration further proposes to use a reference price from other, “similar” rural areas if in a particular rural area there are fewer than two suppliers submitting bids. CMS should not pursue this arbitrary price setting exercise.

- The Administration proposes to eliminate the surety bid bond for bidding suppliers. For the same reasons AAIHomecare strongly supported Congress adding a surety bond requirement to the CBP, we continue to support the surety bid bond as a critical component of the CBP. It is normal and typical that bid programs require bidding parties to have a bid bond. Research shows that without a financial stake in the auction, via a bid bond, auctions are more likely to attract participants who simply want to drive the price down. This type of “gaming” was evident in the initial rounds of the bid program, before Congress mandated the bid surety bond, and led to unrealistically low bid rates.

Use Retail Price Information for DME Fee Schedule Rates. This proposal would allow CMS to annually update DME prices based on retail prices through rulemaking, without using the inherent reasonableness process. [$1.6 billion Medicare savings; $85 million in Medicaid savings over 10 years.]

Response

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2 Social Security Act (SSA), Section 1847(a)(1)
3 AAHomecare analysis based on data retrieved from PDAC.
AAHomecare strongly opposes using retail prices to annually update Medicare DME fee schedules because it is an "apples to oranges" comparison. Retail pricing does not include the many additional services/requirements that apply when providing the same item to beneficiaries, such as mandatory accreditation, claims submission, delivery, and beneficiary education, many of which are part of the Medicare DMEPOS Supplier Standards. It is important to understand that providing DME items and services to Medicare beneficiaries is much more costly than a simple cash transaction or a transaction with a typical managed care payer. Medicare documentation requirements, accreditation, audit costs and the various other compliance costs associated with being a Medicare supplier are simply non-existent when an individual purchases an item on the internet. CMS should therefore not use retail pricing, without any mark-up to account for the significant additional costs to serve Medicare beneficiaries, as data to establish pricing for new items. At a minimum, retail pricing should only be viewed as a wholesale/acquisition cost, and Medicare must add a percentage to reasonably incorporate the total delivered costs associated with providing the items and related services to beneficiaries.

Congress purposefully required CMS to engage in a series of analyses as part of the inherent reasonableness process, to ensure that the government could not engage in arbitrary price setting. The inherent reasonableness process requires the government to substantiate that price reductions are based on "valid and reliable" data. If CMS were to use "retail prices" to instead set DME payment amounts, there would be no assurance that those retail prices are fair and reasonable, or objectively represent the DME supplier’s total delivered costs.

Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for DME. Physicians must document a beneficiary’s face-to-face encounter with a physician or a non-physician practitioner as a condition for Medicare payment for a DME order. This proposal allows CMS flexibility in the enforcement of the face-to-face requirement, eliminating this overly burdensome requirement for most Medicare providers and beneficiaries. [No budget impact]

Response

AAHomecare supports the elimination of the face-to-face requirement, but notes that CMS has not enforced the Affordable Care Act’s (ACA) requirement for a face-to-face encounter as a condition for payment for certain DME items, despite CMS’ stated effective date of October 1, 2013. The most recent update on CMS’ website was on September 30, 2015, indicating, “CMS will not start actively enforcing or expect full compliance with the DME face-to-face requirements until further notice.”

While CMS may not be enforcing the ACA’s face-to-face encounter requirement, various Medicare local coverage determinations (LCDs) do require a clinical evaluation/faceto-face visit. Should this proposal come to fruition, it will not necessarily eliminate the face-to-face encounter requirements that reside in the LCDs. AAHomecare recommends expanding this proposal to also include removal of the face-to-face encounter that are included in the various DME LCDs. Meeting the face-to-face documentation requirement has been burdensome for the supplier community. Documentation in the medical record should be sufficient to support the medical need for ordered equipment and supplies.

Address Excessive Billing for DME that Require Refills on Serial Claims. By leveraging Medicare demonstration authority, this proposal tests whether using a benefits manager for serial DME claims results in lower improper
payments and reductions in inappropriate utilization. The benefits manager would be responsible for ensuring that beneficiaries were receiving the correct quantity of supplies or services for the appropriate period. [No budget impact]

Response

CMS currently requires DMEPOS suppliers to follow very stringent guidelines for replacing consumable and non-consumable supplies that ensure the beneficiary is in need of the refills. The current requirements are as follows.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between a supplier and the beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by a supplier or the beneficiary is not sufficient. The refill record must include:

- The beneficiary’s name or authorized representative, if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- For consumable supplies, i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.)—the supplier must assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies, i.e., those more durable items that are not used up but may need periodic replacement (e.g., positive airway pressure and respiratory assist devices’ supplies)—the supplier must assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. You must document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.7

The above instructions make it very clear that the supplier and the beneficiary concur on what they have and what the needs are. Current audit processes ensure that suppliers are following the CMS requirements for supplies.

In addition, CMS has issued stringent guidance on the time frames for beneficiary contact and the timing of shipping or delivering refill supply orders:

- For all DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use.
- For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined

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basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.8

The above instructions clearly outline the requirements for contacting beneficiaries, ensuring a need and the time frames for placing the order and delivery to the beneficiary.

CMS currently requires suppliers to document continued use as follows:

Continued use describes the ongoing utilization of supplies or a rented item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies.
- Supplier records documenting the request for refill/replacement of supplies in compliance with the REFILL DOCUMENTATION REQUIREMENTS section. This is deemed sufficient to document continued use for the base item, as well.
- Supplier records documenting beneficiary confirmation of continued use of a rental item.
- Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.9

The above instructions clearly outline the requirements for ensuring the equipment continues to be needed.

The concept of a benefit manager to serve as a ‘middle man’ between a supplier and a Medicare beneficiary would impact the ability to ensure access to needed equipment, accessories, and supplies. The current process of contact, documentation, order fulfillment, and shipping is tightly managed and to insert another point of contact would slow down the process and cause confusion and likely access issues for beneficiaries.

9 Noridian Healthcare Solutions, DME Jurisdiction D, Continued Use/Continued Need, accessed on 05/09/2018: https://med.noridianmedicare.com/web/jddme/topics/documentation/continued-need
In addition, on-going rentals for oxygen concentrators (E1390) alone average 592,113 patients per month based on Medicare claims allowed units for 2018. It is inconceivable that any number of benefit managers would be able to contact that many Medicare beneficiaries to ensure on-going rentals are needed.

If the concept of the benefit manager is to ensure suppliers are providing equipment and supplies as needed, it is a duplicative effort and an additional expense to the Medicare program. The current audit and oversight activities should be the mechanism with which suppliers are held accountable. The 2019 CERT improper payment rate, which identifies the root cause of insufficient documentation errors, shows that less than 19% of documentation issues were due to records of the supplier, the remaining 81% were due to prescriber records. We therefore recommend that CMS focus on prescriber patterns and processes is warranted.

Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation. Under current law, Medicare cannot hold a practitioner financially accountable for improperly documenting ordered items or services. This proposal would allow the Secretary to assess an administrative penalty on practitioners for ordering high-risk high-cost items or services without proper documentation, such as diagnosis or encounter data. The penalty would be $50 for Part B items/services and $100 for Part A services. [Budget neutral]

Response

AAHomecare supports this proposal. As noted above, the 2019 CERT improper payment rate, which identifies the root cause of insufficient documentation errors, shows that less than 19% of documentation issues for DME items were due to records of the supplier, the remaining 81% were due to prescriber records. The DME supplier has always been responsible for ensuring that the prescriber has sufficient medical record documentation to support the ordering of DME items, but has no leverage or ability to make sure the physician actually maintain adequate documentation. There is no financial or other incentive for practitioners to adequately document. We therefore support this proposal and urge CMS to ensure that it applies to the ordering of DMEPOS equipment and supplies.

Support Coverage for Innovative Alternatives to DME for Treatment and Management of Diabetes. Medicare DME coverage excludes non-durable alternatives to DME. This proposal would allow Medicare coverage for innovative non-durable medical equipment alternatives to treat and manage diabetes. Payment for these alternative items would be subject to competitive bidding and capped at the payment rate for their DME counterpart. [No budget impact]

Response

The current DME benefit requires an item to have a three year minimum lifetime requirement per CMS’ 2011 final rule. In its July 2017 report, “CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment,” the GAO reviewed a broader application of disposable devices that should be considered. AAHomecare provided comments to the GAO on the broadening of the

10 2018 Medicare claims data retrieved through FOIA request.
11 Centers for Medicare and Medicaid Services (2019). 2019 Medicare Fee-for-Service Supplemental Improper Payment Data
12 Id.
13 Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies. (76 Fed. Reg. 70227, November 10, 2011)CMS-1577-F)
definition of durable medical equipment to allow for manufacturers to innovate and develop disposal products that would meet the needs of patients and allow for Medicare coverage. Should Congress decide to expand the DMEPOS benefit to allow for coverage of disposable DME, it must include a broader spectrum of products beyond the treatment of diabetes.

With regard to Medicare payment for disposable medical equipment, applying current DME payment rates would be inappropriate. Current payment rates for new HCPCS codes are set via CMS’ gap filling methodology, a sorely outdated method to establish payment rates. The concept of pricing new innovative technology by deflating to 1986 pricing and then re-inflating based upon Medicare inflation updates since 1986 is nonsensical. There is no way to take new and developing technology and equate it to any of the current Medicare allowables that were developed for predecessor products that are substantively different than the new technology.

AAHomecare recognizes the need for innovation in the marketplace, however Congress needs to take a global approach to this concept and must consider not only pricing concerns, but also coverage policies.

**MEDICARE APPEALS PROCESS**

The Administration’s 2021 Budget proposal includes the following proposals to address the Medicare appeals process.

**Change the Medicare Appeal Council’s Standard of Review.** Currently, when a party files a request for review of an Administrative Law Judge decision, the Medicare Appeals Council must review the decision de novo, from the beginning. This proposal would change the Council’s standard of review from a de-novo to an appellate-level standard of review. Changing the Departmental Appeals Board’s standard of review will increase adjudication capacity by up to 30 percent and further distinguish the Council’s role as an administrative appellate body. [No budget impact]

**Response**

AAHomecare is not in favor of changing the Medicare Appeal Council’s (“MAC”) standard of review from de-novo to appellate-level. It is relatively rare for a supplier to appeal an Administrative Law Judge (“ALJ”) decision to the MAC. A principal reason for this is the multi-year delay in receiving the ALJ decision. On those rare occasions when a supplier does appeal to the MAC, it is because the supplier has concluded that the prior appellate decisions are incorrect. The supplier has invested over three years in proceeding through the redetermination, reconsideration, and ALJ stages. By the time the supplier appeals to the MAC, the supplier has invested substantial time, money and effort into the appeal. Investing the additional time and resources to appeal to the MAC shows the importance of the appeal to the supplier. It is important that the supplier receive the full benefit of its appeal to the MAC. To accomplish this, the MAC needs to be able to review the complete appellate record, not just the ALJ decision.

**Establish a Post-Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals.** Currently, there are no administrative fees charged for filing a Medicare appeal, which has in some cases resulted in appellant’s often filing non-meritorious appeals. This proposal would establish a post-adjudication user fee for all Medicare appeals, other than beneficiary appeals, which are denied, or otherwise receive unfavorable disposition, by the Office of Medicare Hearings and Appeals and the Departmental Appeals Board. The user fee would support 10 percent of the administrative costs required to adjudicate appeals and encourage those appellants who frequently file to more carefully assess their appeals before filing. [No budget impact]
Response

AAHomecare is not in favor of a post-adjudication user fee. Suppliers file appeals because they believe the claim was denied in error. This would be duplicative punishment since the supplier is already not paid for services rendered or had the payment recouped and in some cases is paying interest charges. The current estimated wait time at the ALJ is 1,372 days, which means suppliers are waiting over three years to receive payment.\(^{15}\) In an effort to reduce the ALJ backlog, CMS developed two programs to reduce DME appeals: the QIC Telephone Demonstration and serial appeals initiative. As of Spring of last year, the QIC Telephone Demonstration was successful at overturning 64% of the claims and the serial appeals initiative overturned 75,000 claims.\(^{16,17}\) These numbers showcase that suppliers should not have had these claims denied in the first place. HHS should not be discouraging suppliers from appealing denied claims especially when there is strong evidence that support suppliers’ efforts.

It also appears that this proposal has the potential to disproportionately target the DMEPOS industry as the industry comprises approximately 50% of backlogged appeals, according to OMHA. DMEPOS appeals are the lowest dollar value and highest volume of all appeals. If Congress were to consider a post-adjudication user fee, it should consider a filing fee applied only to providers and suppliers of services that have the highest failure rate at the 3\(^{rd}\) and 4\(^{th}\) level of appeals.

Even in instances in which a supplier or provider receives an unfavorable outcome, the appellant may still disagree with that determination. The supplier/provider’s right to navigate through all levels of the administrative appeal process is outlined in 42 CFR Subpart I. At no point in time since this process was codified has there been a filing fee, either pre or post-adjudication. Only after the government failed to meet its obligations under the regulations (i.e., it takes over three years for an ALJ decision, as opposed to the required 90 days) has this been proposed for the sole purpose of dissuading suppliers/providers from exercising their appeal rights. It is widely recognized that CMS’s implementation of the Recovery Audit Contractor program led to the significant backlog of appeals, especially for DME. DME suppliers were subject to a significant increase in the volume of audits that they had to respond to. Responding to audits and denials and navigating the appeal process is already a considerable burden and is costly to the DME supplier. It is unfair to further punish a supplier for a backlog that was a direct result of actions taken by CMS. There is no incentive for suppliers to file frivolous appeals when they have to wait for years before an ALJ hearing is held. In contrast, the backlog itself is often seen as a disincentive for suppliers to file appeals because they prefer to not wait that long.

Lastly, because the post-adjudication user fee will be assessed only if the provider loses at the ALJ and MAC stages, the fee acts as a “penalty” for losing. It is costly and time-consuming for a supplier to appeal to the ALJ, and ultimately to the MAC. As previously mentioned, notwithstanding that the law requires ALJ decisions to be rendered within 90 days, because of CMS’s actions, it is taking over three years for ALJ decisions to occur. With very few exceptions, suppliers will not expend the time and money to pursue a frivolous appeal through the ALJ and MAC stages. If a supplier loses at the ALJ or MAC stage, it simply means that the ALJ/MAC disagrees with the supplier’s position. Such disagreement should not serve as the basis for a post-adjudication user fee that is, in reality, a penalty for pursuing the appeal.

\(^{15}\) Department of Health and Human Services, Office of Medicare Hearings and Appeals (OMHA), Average Processing Time By Fiscal Year, accessed on 05/29/20: [https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html](https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html)

\(^{16}\) Reported by C2C Innovative Solutions at Medtrade Spring 2018.

\(^{17}\) *Id.*
**Expedite Procedures for Claims with No Material Fact in Dispute.** Appellants have an option to bypass the Administrative Law Judge (ALJ) hearing at the third level of Medicare appeals by requesting expedited access to judicial review if specific conditions are met. This proposal would allow the Office of Medicare Hearings and Appeals to issue decisions on the record without holding a hearing if there is no material fact in dispute. These cases include appeals, for example, in which Medicare does not cover the cost of a particular drug or the ALJ cannot find in favor of an appellant due to binding limits on authority. This proposal would increase the efficiency of the Medicare appeals system and result in faster adjudications of pending appeals at the ALJ level of appeal. [No budget impact]

**Response**

AAHomecare is not opposed to this proposal. In order for the rights of the supplier and the Office of Medicare Hearing and Appeals (“OMHA”) to be preserved, AAHomecare recommends that the supplier and OMHA agree on and sign an Agreed Statement of Facts upon which the ALJ will base its decision.

**Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review.** The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal would increase the minimum amount in controversy required for adjudication of an appeal by an Administrative Law Judge to the Federal District Court amount in controversy requirement, which is $1,670 in calendar year 2020, and is updated annually. Appeals not reaching the minimum amount in controversy would be adjudicated by a Medicare magistrate. [No budget impact]

**Response**

AAHomecare is not in favor of increasing the minimum amount in controversy to the amount required for judicial review. Most DME claims fall under the judicial review threshold. For example, reimbursement policies require multiple claim submissions (e.g., once a month) for equipment rental and replacement of supplies. Each of these claims’ dollar amounts is small, but in the aggregate, they add up over a period of medical need. Raising the minimum amount in controversy will force most DME claims to a Medicare Magistrate. It is unlikely that Magistrates will have the depth of knowledge that ALJs have. This lack of knowledge will be detrimental to DME suppliers. Often, published medical coverage policy for DME is complicated and difficult to understand. This places Magistrates at a disadvantage which, in turn, places DME suppliers at a disadvantage.

Establishing a threshold of dollar value to determine whether an ALJ or a Magistrate will review an appeal does not take into account the complexity of the coverage criteria. Although a DMEPOS appeal may be a lower dollar amount, the complexity of the coverage criteria can make it more challenging for an ALJ or Magistrate to review. The determination of what is handled by a Magistrate should be determined by the complexity, not the dollar value.

If CMS does ultimately increase the minimum amount in controversy to the amount required for judicial review, then AAHomecare strongly recommends that DME suppliers be allowed to aggregate small rental and/or recurring claims to be able to meet the higher dollar threshold.

**Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold.** The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal allows the Office of Medicare Hearings and Appeals to use Medicare magistrates for
appealed claims below the Federal District Court amount in controversy threshold, which is $1,670 in calendar year 2020 and updated annually. This policy enables Administrative Law Judges to focus on more complex and higher amount in controversy appeals, while ensuring that all appealed claims are adjudicated. [No budget impact]

Response

For the reasons explained in the preceding response, AAHomecare is not in favor of establishing Magistrate adjudication for claims with an amount in controversy threshold.

This proposal will steer most, if not all, DMEPOS appeals away from ALJs. As stated above, reimbursement for one monthly DMEPOS rental or purchase claim is very modest. These claims will be much smaller than those for inpatient stays, or in some cases, even a single physician office visit. Adopting an amount in controversy approach has the potential to deprive most DME suppliers the opportunity to appear before ALJs.

There are also important practical issues about how the Agency might implement this proposal. One important concern is the caliber of the experience and training that Magistrates will have. Medicare itself is a complex statutory scheme, rendered even more complicated by the breadth of the Secretary’s discretion and the discretionary authority he delegates to contractors to make decisions, including questions about whether items or service are “reasonable and necessary.” The DMEPOS benefit rules make up an especially intricate subset of Medicare program rules. AAHomecare is concerned that Magistrates will not have the knowledge base and skill set of ALJs.

If CMS does ultimately use Magistrates for appealed claims below the Federal District Court threshold amount, then AAHomecare strongly recommends that DME suppliers be allowed to aggregate small rental and/or recurring claims to be able to meet the higher dollar threshold.

Limit Appeals When No Documentation is Submitted. Currently, appellants may pursue Medicare appeals when they have not submitted any documentation. This proposal would limit the right of non-beneficiary appellants to appeal a redetermination of a claim that was denied because no documentation was submitted to support the items or services billed. This proposal would not apply to beneficiary appeals. Limiting the right to appeal when no documentation is submitted would incentivize providers and suppliers to submit documentation at the beginning of the appeals process so decisions can be made at the lowest, least costly level of appeal. [No budget impact]

Response

AAHomecare supports this proposal.

Remand Appeals to the Redetermination Level with the Introduction of New Evidence. Currently, a party can submit new evidence at the second level of appeals or later in the administrative appeals process, decreasing the efficiency of the Medicare appeals system and contributing to the backlog of pending appeals at the third and fourth levels of appeal. This proposal would permit the remand of an appeal to the first level of appeal when new documentary evidence is submitted into the administrative record at the second or later level of appeal. The proposal would permit exceptions if evidence was provided to the lower level adjudicator but erroneously omitted from the record, or if an adjudicator denied an appeal on a new and different basis than earlier determinations. This proposal would incentivize appellants to include all evidence early in the appeals
process and ensure the same record is reviewed and considered at subsequent levels of appeal. [No budget impact]

Response

AAHomecare supports this proposal. In so doing, AAHomecare suggests that Medicare guidelines make it clear that if an appeal is remanded to the redetermination stage, and if the claim is again denied at redetermination for whatever reason, then the supplier would maintain all appeal rights.

**Require a Good-Faith Attestation on All Appeals** Currently, there are no statutory requirements that appellants consider the merits of their appeal before filing. This proposal would require all appellants to include in their initial appeal filing an attestation that they are submitting their appeal under a good-faith belief that they are entitled to receive Medicare reimbursement. This proposal would also authorize the Secretary to sanction or impose civil monetary penalties on appellants who submit attestations that are found to be unreasonable or made in bad faith. [No budget impact]

Response

AAHomecare is not in favor of requiring a good faith attestation. If adopted, the requirement would effectively take away appeal rights in many instances. There are several concerns AAHomecare has, such as:

1. Will there be complementary language that punishes the CMS contractors for unreasonable/bad faith denials?
2. Will there be objective guidance on what constitutes an “unreasonable” or “bad faith” attestation?
3. Who makes the decision regarding whether an appeal is “unreasonable” or is filed in “bad faith?” It will likely be difficult to establish objective criteria.

By comparison, Federal Rule of Civil Procedure 11, which pertains to a lawsuit in federal court, says 18:

By presenting to the court a pleading...an attorney...certifies that to the best of the person’s knowledge, information, and belief, formed after an inquiry reasonable under the circumstances: (1) it is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; (2) the claims, defenses, and other legal contentions are warranted by existing law or by a non-frivolous argument for extending, modifying, or reversing existing law or for establishing new law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the denials of factual contentions are warranted on the evidence, or, if specifically so identified, are reasonably based on belief or a lack of information.

The Rule further states 19:

19 Id. at 11(c).
If, after notice and a reasonable opportunity to respond, the court determines that Rule 11(b) has been violated, the court may impose an appropriate sanction on any attorney...that violated the rule or is responsible for the violation.

In federal court, a determination of “bad faith” can only be made after the adverse parties argue to, and present evidence before, a federal judge or federal magistrate. The judge/magistrate will consider the evidence and apply it to the guidelines set out in Rule 11. Only after taking these steps might the judge/magistrate levy sanctions. And so, the question is this: If the attestation requirement is adopted for the administrative appeals process, will the same types of safeguards be given to providers?

Due to the administrative appeals process giving great deference to CMS and its contractors, and in light of the potential exposure to civil monetary penalties, if the proposed requirement goes into effect, many providers will elect not to pursue appeals. In addition, this may impact the access to care for Medicare beneficiaries because providers may decide not to provide services due to the cost and administrative burden such a change will have on providers.

In the DMEPOS industry, denials are often technical in nature, many being minor documentation errors even though the patient clearly needs the equipment and the medical records support the patient’s need for the equipment. In other instances, CMS contractors deny claims because the contractors assert that there is insufficient documentation showing medical necessity for the equipment. The determination of “medical necessity” is often subjective in the mind of the CMS contractor; because of this subjectivity, if a claim is decided because of “lack of medical necessity,” it is difficult for the DME supplier to prevail on appeal. In one case, a DME supplier appealed the denial of over 150 claims. On appeal, only a handful of the claims were allowed. Because this was an “extrapolated” audit (i.e., the CMS contractor extrapolated the percentage of claims denied to a much larger universe of claims), this supplier had no choice but to appeal. In this example, most of the patients medically needed the equipment but the physicians failed to sufficiently document the medical record to support the medical need. If the proposed requirement were in effect, as a result of the low success rate it would not be a stretch to see the government making an argument “after the fact” that the appeal was “unreasonable” and/or made in “bad faith.”

Further, in order to stop recoupments (arising out of post-payment audits) at the redetermination and reconsideration levels, the provider must file its appeal within 30 days at redetermination and then at approximately 45 days at reconsideration. If the proposed requirement is in effect, then providers will be required to weigh the effects of (i) filing an appeal early to avoid recoupment or (ii) filing an appeal later (resulting in recoupment) in order to build a case against a “bad faith” or “unreasonableness” assertion by the government. The certification requirement is an additional burden that will result in many providers being subjected to recoupment while they obtain additional documentation to reduce the risk of the government asserting an “unreasonableness” and/or “bad faith” claim against the provider.

Adding more burdens to the appeal process will only dissuade suppliers from exercising their available appeal rights. Suppliers have already made a certification statement when enrolling in the Medicare program as well as each time a claim is filed. These are certifications for enrollment and claims submission are subject to Civil Money Penalties. The proposed additional burden is duplicative and punitive.

If the provider is unsuccessful at the reconsideration level, then it can appeal to an ALJ. Between the time of the reconsideration decision and the ALJ decision, the CMS contractor can recoup the denied claims. This might not be a severe burden to the supplier if the ALJ would render its decision within 90 days as is required by law. However, due to the significant backlog of ALJ appeals, it is taking ALJs three to four years to render decisions and
even after receiving an ALJ's favorable decision, a supplier must continue to wait for payment on the claim. This is a severe burden to suppliers. The solution to the appeal backlog is not discouraging appeals. Instead, HHS needs to provide the additional resources needed to process appeals. CMS has increased its audits without committing the additional resources to the appeal process. This is a flawed process that unfairly prejudices suppliers.
Impact of COVID-19 Supply Chain Disruptions and Increased Costs on DME Suppliers

A Survey of Companies
Impact of COVID-19 Supply Chain Disruptions and Increased Costs on DME Suppliers

A Survey of Companies

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Wednesday, May 13, 2020 — Final Report
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Executive Summary

On Friday, March 13, 2020, President Trump declared a national emergency due to the coronavirus disease (COVID-19). Hospitals, especially in major metropolitan areas, had been experiencing surges in the number of patients admitted to intensive care units with acute respiratory distress syndrome (ARDS). As the pandemic continues to ravage a nation still grappling with vast uncertainty over the characteristics and transmissibility of the virus, DMEPOS (durable medical equipment, prosthetics, orthotics, & supplies – DME for short) suppliers are facing mounting challenges in serving their patients, many of whom have become suddenly very ill, requiring respiratory support and other DME and related services.

At the same time, healthcare workers and DME suppliers are at considerable risk of contracting the virus through their daily work caring for patients. Patients with the virus who exhibit less severe symptoms are as a matter of practice encouraged to utilize home-based care. In many cases, having access to appropriate DME items (e.g., oxygen, ventilators, respiratory assist devices, CPAPs, and nebulizers) means that the patient can remain at home and avoid the risks of hospitalization. This is particularly important for those with COVID-19 who would receive appropriate care at home while freeing hospital beds for more severe cases, and for those with other respiratory ailments who would minimize their risk of exposure to the virus by receiving care in their homes.

As a result of the public health and economic emergencies associated with COVID-19, DMEPOS suppliers have experienced supply chain interruptions such as significant delays and order cancellations in receiving their equipment and supplies. In addition,
manufacturers and distributors have levied surcharges and passed along increases in their costs in response to the COVID-19 pandemic. Finally, in an effort to keep their employees safe, suppliers are incurring additional operating expenses such as utilizing personal protective equipment (PPE), providing IT equipment for staff to work remotely, or obtaining additional vehicles to make DMEPOS deliveries.

To understand the magnitude of these impacts upon their industry, AAHomecare fielded a survey of DMEPOS companies this April. Reflecting the urgency of the situation, over 500 unique companies responded within one week. The survey was designed to identify the ways that suppliers have adapted their operations in 2020 to accommodate supply chain disruption, as well as the magnitude of extra costs they incurred as they respond to the COVID-19 public health emergency. Open-ended responses were also collected which afforded respondents a way to provide detail on the various points concerning specific kinds of losses.

This report contains the quantitative findings from the survey as well as narrative answers that describe the changes COVID-19 has brought, such as the financial devastation from respondents having to close retail showrooms and stores. Both quantitative and qualitative responses indicate an urgent need for a postponement of the 2021 Medicare Competitive Bidding (CB) Program scheduled for implementation on January 1, 2021. This postponement will be even more essential if another COVID-19 peak arrives in the fall as many models are currently forecasting.

**COVID-19 has Upended Healthcare with Unprecedented Velocity**

Given the uncertainty COVID-19 has introduced to all aspects of healthcare delivery, it is important to recognize that the conditions under which the bids were constructed in 2019 no longer exist. Current costs and availability of products are no longer predictable and bear no relationship to 2019 costs and availability. Therefore, moving ahead with CB based on out-of-date market information has no economic justification. If the cost of goods sold rises, while at the same time the CB payments are limited by both an earlier out-of-date price determination as well as the consequences of the bidding process, the DMEPOS industry could face severe dislocation and Medicare beneficiaries will lose critical access to often life-saving DME. Suppliers are being financially harmed due to circumstances well beyond their control. They are no longer able to project either their costs, or the level and stability of revenue streams associated with delivering product to patients.

Concerning the challenge of staying in business, one respondent noted, “Lost business in
PAP therapy due to sleep lab closure, lost business in compression therapy due to elective surgery cancellations, and lost business in retail sales due to foot traffic decrease from the Stay at Home Order.”

Furthermore, without the fundamental security that the supplier can acquire items at realistic and feasible costs, determining an accurate bid amount for a lead item in any of the product categories will not be possible going forward, at least in the short term.

Factors like anticipated costs (both direct and indirect) for the lead and non-lead items, as well as historic and anticipated utilization of the non-lead items have changed significantly since 2019, and the bids CMS contemplates using are no longer realistic or relevant. Furthermore, any policy that could restrict the availability of home respiratory therapies should be reconsidered in a marketplace disrupted by the virus spread.

### CMS Policy Responses to Date

With temporary regulatory waivers and rule changes, CMS is attempting to equip the healthcare system with the “flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic.” For example, CMS said they were temporarily not enforcing the clinical conditions for coverage for respiratory DME items and waiving signature and proof of delivery requirements for DME. Another example is when DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, DME Medicare Administrative Contractors now have the flexibility to waive replacement requirements under Medicare such that the face-to-face requirement, a new physician’s order, and new medical necessity documentation are not required.¹ CMS is also waiving prior authorization and accreditation requirements for DME suppliers.

While CMS has openly recognized that the Industry is in turmoil due to COVID-19, CMS has not postponed the implementation of Competitive Bidding (CB) for 2021 based on pre-COVID-19 market signals. This policy of pushing ahead with CB appears to be counterproductive to patient care given the current economic and care delivery landscape, and the fact that the world has been irretrievably changed for the foreseeable future.

Summary of Key Findings

Quantitative findings are primarily in the areas of supply chain disruptions leading to delays and order cancellations, as well as increased costs from surcharges and price changes from manufacturers and distributors. In both areas, respondents were asked to quantify the length of time which the product was delayed, and the percentage increase in costs for each product category in which companies reported increases. Products include critical supplies for directly treating COVID-19 (such as respiratory assist devices and supplies, hospital beds, and PPE) and other product categories not directly relevant to treating COVID-19 patients, such as wheelchairs.

Findings on Delays and Supply Chain Interruptions

Across the sample of approximately 500 companies, respondents reported they were experiencing supply chain interruptions in each of fifteen product categories. Responses ranged from 96.9 percent of companies experiencing delays in receiving Personal Protective Equipment (PPE) to 21.2 percent experiencing delays in receiving Negative Pressure Wound Therapy Pumps/Supplies. See Exhibit 1.

Exhibit 1

Not able to acquire medical equipment and supplies (Oxygen and Oxygen related supplies) Ventilators, etc. on a timely manner therefore losing the sales.”
-Survey Respondent
Very concerning is the finding that 97 percent reported experiencing delays for PPE, 81 percent reported delays in receiving Oxygen, and 81 percent reported delays in receiving Ventilators. These product categories are the ones needed for treating COVID-19 patients, and these product categories had the widest reports of market failure. However, three other product categories are also important to treating COVID-19 patients, such as Hospital Beds, CPAPs/RADs, and Nebulizers. Nearly 60 percent of companies reported disruptions in receiving Hospital Beds. Approximately half of companies reported disruptions in receiving CPAP/RADs and Nebulizers, very likely due to the rapidly increasing number of COVID-19 patients.

Other product categories, such as Wheelchairs (all types), Support Surfaces, Enteral Nutrition, Walkers, Patient Lifts, Negative Pressure Wound Therapy, and Other Medical Supplies which are not used to directly treat individuals with COVID-19 infection also were subject to delays and cancellations. This disruption ranged from 49 percent of companies for Other Medical Supplies to 21 percent of companies for Negative Pressure Wound Therapy.

For the purposes of this report, we grouped these latter product categories together as they seem to be “collateral damage” from the extreme disruptions associated with the six product categories directly used to treat COVID-19 patients. Exhibit 2 shows how the two product groups differed as to the effect of the supply chain disruptions, with 70 percent of companies reporting disruption in product categories needed to directly care for COVID-19 patients vs. 30 percent of companies reporting on disruption to collateral product categories.

Exhibit 2

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“In demand items now cost more than what Medicare reimburses, shipping is more expensive, and vendors unable to price negotiate.”
Survey Respondent
In terms of the length of the delays in receiving products, delays were greater for product categories needed for directly treating COVID-19 patients, with 67 percent of companies reporting delays of 31 to 60 days and 74 percent reporting delays of over 61 days, and with 72 percent reporting no known timeframe or ETA. For other product categories (considered to be collateral to those directly used for COVID-19 patients), delays were shorter, with 33 percent of companies reporting delays of up to 30 days in receiving products, 26 percent reported 31 to 60 days delay, and only 28 percent reported that they had no known timeframe. The delays are consistent with those reported by mail order businesses like Amazon and its customers. Exhibit 3 contains these findings.

Exhibit 3

Findings on Incurring Increased Costs
Companies responded that they were incurring increased costs in all product categories. Responses ranged from 86 percent experiencing increased costs for PPE to 19 percent experiencing increased costs for Complex Rehab Technology Wheelchairs/Accessories. As with supply chain interruptions, the greatest number of respondents reported increased costs for PPE (86 percent), Oxygen (67 percent), Ventilators (48 percent) and other equipment directly used to treat COVID-19 patients. See Exhibit 4.
Exhibit 4

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Percent Answering Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal Protective Equipment</td>
<td>86%</td>
</tr>
<tr>
<td>Oxygen Equipment</td>
<td>67%</td>
</tr>
<tr>
<td>Ventilators (Invasive &amp; Non-Invasive)</td>
<td>48%</td>
</tr>
<tr>
<td>Hospital Beds</td>
<td>47%</td>
</tr>
<tr>
<td>Medical Supplies (ex. Ostomy, Urologicals)</td>
<td>35%</td>
</tr>
<tr>
<td>Nebulizers</td>
<td>32%</td>
</tr>
<tr>
<td>Support Surfaces</td>
<td>31%</td>
</tr>
<tr>
<td>CPAPs/RADs</td>
<td>29%</td>
</tr>
<tr>
<td>Manual Wheelchairs</td>
<td>25%</td>
</tr>
<tr>
<td>Negative Pressure Wound Therapy</td>
<td>24%</td>
</tr>
<tr>
<td>Enteral Nutrition</td>
<td>22%</td>
</tr>
<tr>
<td>Standard Power Wheelchairs</td>
<td>22%</td>
</tr>
<tr>
<td>Walkers</td>
<td>21%</td>
</tr>
<tr>
<td>Patient Lifts/Seat Lifts</td>
<td>21%</td>
</tr>
<tr>
<td>Complex Rehab Technology</td>
<td>19%</td>
</tr>
</tbody>
</table>

Exhibit 5 contains the percent of companies reporting increased costs by whether the product categories are directly used for COVID-19 patients or collateral to COVID-19. Just over half of companies reported cost increases for direct product categories whereas 25 percent of companies reported such increases for collateral product categories.

Exhibit 5

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Direct</th>
<th>Collateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>53%</td>
<td>75%</td>
</tr>
<tr>
<td>No</td>
<td>47%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Exhibit 6 contains the percentage increase that companies reported for the direct and collateral product categories. As can be seen in Exhibit 6, approximately 63 percent of products directly related to care of COVID-19 patients and approximately 38 percent of collateral products saw a price increase. There seems to be a positive correlation between
Executive Summary

the size of the price increase seen by a product and it being necessary to treat COVID-19. Seventeen percent of products directly related to treating COVID-19 patients saw an increase of greater than 30 percent whereas 1 percent for those products not directly used for COVID-19 saw an increase of this magnitude.

Exhibit 6

Companies Incurring Additional Operating Expenses

Survey respondents were asked about business activities that they had initiated due to COVID-19 and whether these activities had produced increased operational costs for them. Activities included procuring IT technology for staff to work remotely, additional PPE for staff and for customers engaging with staff, time spent cleaning and sanitizing facilities and vehicles, among others.

The survey contained the following open-ended question for respondents to discuss the specifics of their revenue losses and/or increased costs to do business:

In order to assess any additional operating expenses your business may have incurred as result of the COVID-19 pandemic, please indicate if any of the following business activities have resulted in increased costs (or lost business revenue) for your business?

Exhibit 7 contains the quantitative responses concerning the types of activities companies were engaged in to protect their staff and/or accommodate staff working from home during the pandemic. These results indicate uniform cost pressure across a wide variety of products and activities, each of which adds significant operating costs.

Exhibit 8 contains a sample of the qualitative responses which provide additional details of the activities and precautions the companies report taking every day to protect their staff members. It is important to read the story in company staff’s own words.
Executive Summary

Exhibit 7: Business Activities Implemented to Protect or Accommodate Staff Needs

Exhibit 8: Narrative Responses

“About 75% reduction in revenue. Massive increase in costs of doing business from policy updates, patient communications, curbside pick-up program, work from home programs, technology spending increases (zoom, telemed, etc.).”

“Increase time asking essential questions before delivery. Deciding on a daily basis how to accept referrals and carefully do set ups. Extensive cleaning before putting in vans and then cleaning vans and then cleaning equipment again to go back out. Multiple deliveries and pick-ups. Means multiple PPE, which is hard to come by. Using UV, ozone, alcohol to clean and sanitize.”

“We have split the workforce into two halves in order for us to keep working in the event we have a positive workforce case or exposure that will allow the other half to continue to work. We thought we were doing the right thing and applied for the Payroll Protection Program but since the money ran out, we are very scared we will not be able to continue our business in the next few months. Awful situation for us as we try to handle our current customers and new customers due to the COVID.”

“The delivery cost has increased by about 100%. Every delivery has to have the driver check in and disinfect as well as screen. It takes so much time to accomplish even a simple delivery or equipment check.”

“There is no way to put a $ on the amount of stress that is caused from owning a small HME in a rural area (that CMS classifies otherwise), being quarantined at home with family members with Coronavirus and still making sure oxygen/respiratory patients are properly taken care of. I would not attempt to walk into the office so my sister (co-owner) would FaceTime me to ensure patients were given the correct supplies. She’s an accountant and knows nothing respiratory so it was challenging. Ex-employees stepped up and helped in several occasions. I feel the time spent for each patient has doubled because I’m now following up with each to evaluate and go over anything they didn’t understand remotely. I have no time to get charts finished to bill because I’m now back to working 14 hours a day to just handle the new setups and meeting patient needs.”
Detailed Study Findings

Quantitative findings in this chapter are organized into two categories: 1) the presence and magnitude of supply chain disruptions, and 2) increased product costs from surcharges and higher prices from manufacturers and distributors.

In this chapter of the report, we present the survey findings for each product category concerning supply chain interruptions and increased costs.

**Personal Protective Equipment (PPE)**
Nearly all companies reported supply chain interruptions (97 percent) in receiving PPE, with almost 35 percent experiencing a delay of up to 60 days and 46 percent reporting that they have no known timeframe or ETA for receiving their orders.

In terms of increased costs, 86 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on PPE. Of those, approximately 44 percent of companies reported experiencing increased costs of over 30 percent.

**Respiratory Equipment**

**OXYGEN**
Approximately 81 percent of companies reported supply chain interruptions in receiving Oxygen equipment, with 32 percent experiencing a 30-60-day delay in receiving product. Approximately 25 percent reported that they had no known timeframe or ETA for receiving their product.

In terms of increased costs, 67 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on oxygen equipment. Of those, approximately 56 percent of companies reported experiencing increased costs of up to 20 percent.
VENTILATORS
Approximately 81 percent of companies reported supply chain interruptions in receiving Ventilators, with 27 percent reporting up to 60 days delay and 53 percent reporting they had no known timeframe or ETA for receiving product.

In terms of increased costs, 48 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on ventilators. Of those reporting increases, approximately 34 percent of companies reported experiencing increased costs of up to 20 percent.

NEBULIZERS
Approximately 49 percent of companies reported supply chain interruptions in receiving Nebulizers, with 65 percent experiencing up to 60 days delay in receiving product.

In terms of increased costs, 32 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on Nebulizers. Of those reporting increases, approximately 37 percent of companies reported experiencing increased costs of up to 20 percent.

CPAPS/RADS
Approximately 53 percent of companies reported supply chain interruptions in receiving CPAPs/RADs. Of those reporting a delay, approximately 62 percent reported experiencing up to a 60 day delay in receiving product.

In terms of increased costs, 29 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on CPAPs/RADs. Of those, approximately 32 percent of companies reported experiencing increased costs of up to 20 percent.

Hospital Beds
Approximately 59 percent of companies reported supply chain interruptions in receiving hospital beds. Of those, approximately 64 percent reported experiencing up to 60 days delay in receiving product.

In terms of increased costs, nearly approximately 47 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on hospital beds. Of those, approximately 49 percent of companies reported experiencing increased costs of up to 20 percent.
Detailed Study Findings

**Support Surfaces**
Approximately 31 percent of companies reported supply chain interruptions in receiving support surfaces. Of those, 65 percent reported experiencing up to 60 days delay in receiving product.

In terms of increased costs, 31 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on support surfaces. Although 58 percent reported no change, approximately 35 percent of companies reported experiencing increased costs of up to 20 percent.

**Enteral Nutrition**
Approximately 27 percent of companies reported supply chain interruptions in receiving enteral nutrition, with 62 percent experiencing up to 60 days delay in receiving product.

In terms of increased costs, 22 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on enteral nutrition. Of those, approximately 29 percent of companies reported experiencing increased costs of up to 20 percent.

**Negative Pressure Wound Therapy Pumps and Supplies**
Approximately 21 percent of companies reported supply chain interruptions in receiving negative pressure wound therapy pumps and supplies. Of those reporting a delay, nearly 38 percent reported delays of up to 30 days, and 29 percent reported that they had no known timeframe or ETA for receiving product.

In terms of increased costs, 24 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on negative pressure wound therapy pumps and supplies. Of those, approximately 23 percent of companies reported experiencing increased costs of up to 10 percent.

**Patient Lifts/Seat Lifts**
Approximately 22 percent of companies reported supply chain interruptions in receiving patient lifts/seat lifts. Of those, 50 percent reported a 30-day delay in receiving product, and nearly 20 percent reported no known timeframe or ETA.

In terms of increased costs, 21 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on patient lifts/seat lifts.
Wheelchairs

MANUAL WHEELCHAIRS
Approximately 30 percent of companies reported supply chain interruptions in receiving manual wheelchairs. Of those, 74 percent experiencing up to 60 days delay in receiving product.

In terms of increased costs, 25 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on manual wheelchairs. Of those, approximately 31 percent of companies reported experiencing increased costs of up to 20 percent.

STANDARD POWER WHEELCHAIRS
Approximately 26 percent of companies reported supply chain interruptions in receiving standard power wheelchairs, with 49 percent experiencing a 30 day delay in receiving product.

In terms of increased costs, 22 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on manual wheelchairs. Of those, approximately 23 percent of companies reported experiencing increased costs of up to 10 percent.

COMPLEX REHAB TECHNOLOGY WHEELCHAIRS
Approximately 36 percent of companies reported supply chain interruptions in receiving complex rehab technology wheelchairs, with 64 percent experiencing up to a 60 day delay in receiving product.

In terms of increased costs, 19 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on complex rehab technology wheelchairs. Of those, approximately 22 percent of companies reported experiencing increased costs of up to 20 percent.

Walkers
Approximately 24 percent of companies reported supply chain interruptions in receiving walkers, with approximately 54 percent experiencing a 30 day delay in receiving product.

In terms of increased costs, 21 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on walkers. Of those, approximately 28 percent of companies reported experiencing increased costs of up to 20 percent.

Medical Supplies
Approximately 49 percent of companies reported supply chain interruptions in receiving medical supplies, with 66 percent experiencing up to a 60 day delay in receiving product.
In terms of increased costs, 35 percent of companies reported that manufacturers and distributors had increased costs or levied surcharges on medical supplies. Of those, approximately 34 percent of companies reported experiencing increased costs of up to 20 percent.

**Conclusion**

In conclusion, we find it to be somewhat anomalous that CMS is making many concessions to accommodate COVID-19 market disruptions, but it contemplates implementing payments based on outdated market data embedded in CB based pricing. CB bids are no longer relevant because: 1) costs and product availability have changed, 2) cost of doing business has changed, 3) historic demand for which they base capacity on is not relevant.

Recent events have demonstrated the extreme fragility of the healthcare delivery system. Fundamentally, the CB Program is designed to limit the number of contracted suppliers available to meet projected demand. Capacity was based on historic demand, which does not account for the changes in health care demand due to the pandemic.

There has been a 36% reduction in suppliers since CB began. Currently, CB is on pause nationwide, allowing any willing and eligible DME supplier to provide equipment, services, and supplies. Restricting access to the number of companies available to meet the country’s needs during a public health emergency could have catastrophic consequences. Furthermore, there are still significant unknowns about the longer-term ongoing medical needs of those affected by the virus as preliminary research points to issues with the lungs, heart, and brain. Maximizing capacity is critical to ensure that we have the infrastructure needed to support these individuals.