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June 24, 2020

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Ave., S.W.  
Washington, D.C. 20201

**Re: Comments on CMS-5531-IFC, “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program”(85 Fed. Reg. 27550, May 8, 2020)**

Dear Administrator Verma:

I. Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services’ (CMS’) above captioned Interim Final Rule with Comment Period (5531-IFC/IFR). AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members are in patients’ homes every day and are uniquely qualified to be able to assist during the COVID-19 pandemic. Our comments focus on the IFR provisions impacting DMEPOS suppliers and their provision of care to beneficiaries during the COVID-19 public health emergency (PHE).

Overall, AAHomecare strongly supports the Agency’s decision to make significant accommodations and suspend certain Medicare requirements to facilitate the ability of DMEPOS suppliers to take care of an increased number of beneficiaries in their homes, avoiding hospitalizations and easing hospital overflow issues. While the relaxation of certain requirements is a positive and necessary step, there remain unanswered issues and ambiguities that require resolution to provide DMEPOS suppliers with reasonable assurance that the suspended application of certain rules will be upheld in the event of post-payment or other audits. Finally, we wish to thank the Agency for timely implementing the new fee schedules in non-rural, non-competitive bid areas, consistent with Congress’ directive in the Coronavirus Aid, Relief, and Economic Security Act.

## II. Non-Enforcement of Clinical Conditions for Coverage in NCDs, LCDs, and Policy Articles/Additional Clarification Needed

AAHomecare strongly supports CMS' decision to not enforce the clinical conditions for coverage across respiratory items to facilitate the ability of clinicians to prescribe the appropriate respiratory equipment and allow those beneficiaries to be treated at home, during this PHE. CMS made that announcement in its earlier IFR, stating, "we will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles) allowing for maximum flexibility for practitioners to care for their patients. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic."<sup>1</sup> In this statement, CMS affirmed that it will not be enforcing any of the numerous requirements embedded in the Medicare NCD, LCD and Policy Articles. For home oxygen, the NCD, LCD and Policy Articles include numerous requirements related to objective beneficiary blood gas measurements and testing criteria, physician documentation (including CMNs), and supplier documentation.<sup>2</sup> Since the issuance of 1744-IFC, AAHomecare has requested that the Agency to clarify the operational impact of the non-enforcement of these clinical conditions for coverage, to ensure that DME suppliers understand what types of medical need documentation is required for respiratory items during the PHE.

In this IFR (CMS-5531-IFC), the Agency provides additional information about what documentation will be needed once a physician prescribes a respiratory item. CMS states that there must still be documentation to meet the "reasonable and necessary" requirement to support the medical need for the respiratory item prescribed. This information, however, does not provide sufficient clarity since the existing "reasonable and necessary" criteria reside in the LCDs/NCDs, and those are the same LCDs/NCDs that are not being enforced during the PHE. CMS has repeated this language in its "[COVID-19 Frequently Asked Questions \(FAQ\) on Medicare Fee-for-Service \(FFS\) Billing.](#)"

In a third document, a FAQ titled, "[Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19,](#)" CMS addresses the same issue and explains with regard to NCDs and LCDs for respiratory related devices, that "CMS will not enforce clinical restrictions in certain NCDs and LCDs that otherwise restrict coverage of these devices and services for COVID-19 patients during the PHE. Clinicians will have more flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at the home but will need to continue to document those decisions in the medical record."<sup>3</sup> AAHomecare supports this clarification but strongly urges CMS to add the following language at the end of this FAQ answer to resolve remaining ambiguities:

**Documentation to support the "reasonable and necessary" requirement during the PHE should include a physician's standard written order (SWO) and documentation that the beneficiary has some type of respiratory-related acute or chronic condition. Additional testing, documentation or other requirements that reside in the Medicare NCDs, LCDs, and/or related Policy Articles are not required during the PHE. If the claim includes the KX and the CR modifiers along with the COVID-19 message in the narrative, then the "reasonable and necessary" requirement will be deemed to have been met/satisfied.**

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<sup>1</sup> 85 Fed. Reg. at 19230 (April 6, 2020) Section U.2

<sup>2</sup> See CMS Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 240.2, DME MAC LCD L33797, and Medicare Policy Articles A52514 and A55426.

<sup>3</sup> See CMS FAQ, "[Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19.](#)"

## A. Grandfathering Issues

As noted above, we strongly support CMS' suspension of the enforcement of the clinical conditions of coverage for respiratory and certain other DME items. We believe that CMS intended to continue to cover and pay for beneficiaries with initial dates of service during the PHE, but whose medical need continues beyond the PHE, based upon the physician's determination of medical need. Home oxygen equipment is paid on a monthly rental basis. We recommend that CMS clarify that all beneficiaries with an initial date of service during the PHE will continue to be covered under the medical review criteria in effect during the PHE, throughout that beneficiary's period of medical need, as determined by the physician. In addition, any beneficiary on home oxygen therapy whose 3 and/or 12-month recertification occurs during the PHE, should be deemed to have met the medical necessity requirements in place during the PHE.

There are three groups of beneficiaries with claims for home oxygen therapy during the PHE:

1. Beneficiaries whose initial date of service is during the PHE and whose medical need (as determined by the prescribing practitioner), continues beyond the expiration of the PHE: Claims for the entire period of medical need should be evaluated based upon the requirements in place during the PHE and be covered and paid as long as medical necessity remains per the physician's order.
2. Beneficiaries on oxygen therapy whose initial date of service was prior to March 1, 2020, but whose 3 month or 12 month recertification occurs during the PHE: Claims for dates of service during the PHE through the end of medical need should be evaluated based upon the requirements in place during the PHE.
3. Beneficiaries whose initial date of service for oxygen or CPAP was within 3 months prior to March 1, 2020: Claims for these beneficiaries should be evaluated based on the medical necessity requirements in effect during the PHE, because DME suppliers are having a difficult time obtaining medical documentation from the prescriber during the PHE.

*Recommended CMS Guidance for Oxygen, CPAP, RAD, Nebulizer and Non-Invasive Ventilators:* AAHomecare recommends that CMS provide the following clarification in its FAQ, "[COVID-19 FAQ on Medicare Fee-for-Service Billing](#)," in the section titled "National Coverage Determinations":

### **Question:**

**With the suspension of the enforcement of the clinical indications for respiratory DME items, will Medicare cover and pay for claims for beneficiaries who began service on respiratory items (e.g., oxygen, RADs, CPAP, nebulizers and non-invasive ventilators) during the PHE, but whose medical needs continue beyond the PHE? Will rental claims for dates of service after the PHE for these items be evaluated based upon the medical need requirements in place during the PHE?**

### **Answer:**

- All claims for home oxygen therapy for beneficiaries whose initial date of service is during the PHE, or whose 3 or 12 month recertification occurs during the PHE, will be evaluated based upon the "reasonable and necessary" requirements in place during the PHE.
- Claims for home oxygen therapy for beneficiaries whose initial date of service was within 3 months prior to the PHE will be evaluated based upon the "reasonable and necessary" requirements in place during the PHE.

- **All claims for RAD, CPAP, nebulizers and NIV and related supplies/medications for beneficiaries whose initial date of service is within three months prior to the PHE (or for CPAP beneficiaries who failed their initial trial but want to keep their CPAP) should be evaluated based upon the medical necessity requirements in place during the PHE.**

#### B. CPAP Initial and Repeat Sleep Study

The Medicare NCD and LCD for CPAP equipment and supplies requires beneficiaries to undergo a sleep study and meet certain objective requirements associated with that sleep study.<sup>4</sup> With the non-enforcement of the Medicare NCD and LCD for CPAP, sleep studies and repeat sleep studies are not required if a physician prescribes PAP therapy. **We recommend that CMS provide clarification in a FAQ that if a physician orders a CPAP for a beneficiary during the PHE, and there is some evidence of the beneficiary having a respiratory condition, then an initial sleep study is not required, and the claim would be deemed to meet the “reasonable and necessary” requirement. Similarly, if the beneficiary fails the initial 3 month compliance requirement, and the beneficiary is not able to obtain a repeat sleep test (because, for example, the sleep lab is closed), then that repeat sleep study is not necessary, and subsequent claims for CPAP claims will be deemed to meet the “reasonable and necessary” requirement.**

#### III. Clarification to CMS COVID-19 FAQ on Medicare FFS Billing - Oxygen

We appreciate CMS’ various guidance documents to clarify issues, and recommend that CMS clarify an issue that is included in CMS’ [“COVID-19 Frequently Asked Questions \(FAQ\) on Medicare Fee-for-Service \(FFS\) Billing”](#) in the “Oxygen” Section (p. 113 of 6/19/20 version). Additional language (below in **bold**) is necessary because there may be continuing rental claims for oxygen that go beyond the PHE, but if the physician prescribed the oxygen during the PHE, then the criteria in place during the PHE should last as long as the physician determines medical need for that beneficiary. We therefore recommend that CMS clarify the last sentence to read: “At the conclusion of the PHE for the COVID-19 pandemic, we will return to enforcement of these clinical indications for coverage, **for beneficiaries with an initial date of service after the PHE has ended.**”

#### IV. Telehealth Issues and Recommendations for Post-PHE

AAHomecare strongly supports CMS’ expansion of telehealth services to facilitate access to care while minimizing in-person encounters during this COVID-19 pandemic. Telehealth is an efficient way for practitioners and beneficiaries to communicate and can often effectively replace in-person visits, with no concomitant disadvantages.

AAHomecare strongly supports the ability of beneficiaries and physicians to conduct virtual services (e.g., telehealth, e-visits, and virtual check-ins), both during the PHE and beyond, in lieu of certain in-office visits. Virtual services allow the beneficiary and physician to appropriately communicate about ongoing needs, and in many situations, eliminate the need for an in-person (face-to-face encounter) visit to the doctor’s office. During the PHE this promotes social distancing, keeping both the beneficiary and health care practitioner safer. While we understand that Congress must make some statutory changes in order for CMS to make permanent changes to the ability of providers to engage in expanded telehealth activity,

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<sup>4</sup> See Medicare Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)

we wanted to explain how telehealth and other virtual services can be an efficient and effective way for physicians and beneficiaries to communicate about ongoing needs for certain DME items.

We recommend that virtual services that are allowed during the PHE also be allowed on a permanent basis after the PHE. We recommend, however, that virtual services be reserved for physicians and other prescribers with an established beneficiary relationship.

Virtual services can effectively be used for situations where the physician has an ongoing relationship with the beneficiary, has already prescribed the medically necessary DMEPOS item, and the physician needs to check in with the beneficiary to ensure continued medical need, or a need for additional supplies. In the DME realm, there are many areas where the beneficiary is required to re-visit the physician to ensure continuing medical need and to obtain a prescription for refills of supplies. There are also policies that require an in-person visit if the beneficiary chooses to switch items within a particular LCD. We believe the purpose of these types of in-person office visits can be more efficiently accomplished via virtual services and urge CMS to allow for these after the PHE has ended.

We believe the following are examples of when in-person visit requirements can be effectively and efficiently performed instead through a virtual service, with the decision to conduct a virtual service in lieu of the in-person visit be the prescriber's choice:

- CPAP and RAD
  - Beneficiary has been prescribed CPAP, and a virtual service should be allowed to meet the 12-week trial requirement.
  - Beneficiary is on CPAP therapy. A virtual service should be allowed for purposes of the physician documenting the beneficiary's ongoing need for supplies to be used with CPAP.
- Oxygen
  - Beneficiary has been prescribed home oxygen therapy. The beneficiary and physician should be able to conduct a virtual service for the original oxygen prescription, recertification at 3 months and at 12 months, and any.
- Power Mobility Devices and Manual Wheelchairs
  - Virtual services can be used to authorize for continued medical need and repairs.
- Medical Supplies such as Ostomy and Urological Supplies
  - Virtual services can be used to authorize continued medical need.
- Continuous Glucose Monitors (CGMs) and Diabetic Testing Supplies
  - Virtual services can be used for the initial set up and to authorize continued medical need.

In addition to these LCD-specific recommendations, there are several other types of in-person visit requirements where DME suppliers are required to visit the beneficiary home in advance of providing the item. The objectives of these in-person visits can often be accomplished just as well via telephone. While not technically telehealth, we recommend that CMS allow DME suppliers to conduct the required home assessment via telephone, in lieu of requiring an in-person visit when the beneficiary has switched to Medicare fee for service from a commercial payor. We have the same recommendation for beneficiaries who have reached the 60-month reasonable useful lifetime for oxygen. In both of these instances, the DME supplier is required to ensure that the equipment remains in good working order. An additional visit

that is triggered by the payor switch or reaching the 60-month cap may not be necessary. Given the DME supplier's ongoing obligation to ensure that equipment remains in good working order, the DME supplier should be able determine the appropriate time to conduct that equipment check.

V. Physician Orders for Power Mobility Devices; Objective Measures

CMS has suspended for the duration of the PHE all face-to-face encounters. The Medicare LCD for power mobility devices, however, requires the prescriber to assess the beneficiary through certain objective measures and document those to qualify the beneficiary for coverage of the PMD. **AAHomecare requests that CMS provide written clarification in a FAQ that the physician does not need to have an in-person meeting with the beneficiary, but can utilize his/her clinical judgement and review of the patient and his/her medical records to meet this requirement, for the duration of the PHE. We further recommend that this only be permitted for physicians with a pre-existing relationship with the beneficiary, to ensure that the physician is familiar with the beneficiary's condition.**

VI. Outstanding Issues/Clarification Needed

A. Beneficiary Signatures Issues

In CMS' "DMEPOS: CMS Flexibilities to Fight COVID-19," CMS states<sup>5</sup>:

Signature Requirements: CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.

In this guidance document, CMS acknowledges that there are multiple signature requirements related to the provision of DMEPOS. Proof of delivery is one requirement, but there are additional documents, such as Assignment of Benefits forms, payment authorizations, purchase option letters for power mobility devices, change of payer attestation, etc. Under normal Medicare policy, the beneficiary/representative must sign all of these documents and return them to the DME supplier. At this point, the DME MACs have been educating the DME supplier community that this signature waiver applies only to proof of delivery and does not apply to other documents that require a beneficiary signature. It makes little sense to require in-person signatures for some documents, and not for others. We believe CMS intended the signature waiver to apply to all beneficiary signature requirements, not just the proof of delivery document. We therefore request that CMS clarify and instruct the DME MACs that the signature waiver applies to all required beneficiary signatures.

**We recommend that CMS revise the above FAQ as follows:**

Signature Requirements: CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19. **All beneficiary signature requirements related to the provision of DME are waived during the PHE.**

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<sup>5</sup> See CMS FAQ, "[DMEPOS: CMS Flexibilities to Fight COVID-19](#)"

## B. Face-to-Face Encounter Issues

AAHomecare supports CMS' decision in the 1744-IFC to waive all face-to-face encounters, explicit or implied, for the duration of the PHE, to minimize in-person contact. CMS states: "...to the extent that an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications, or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic."<sup>6</sup> The waiver of the face-to-face encounters in the provision of DME is important during this pandemic, as there are many instances in which the DME supplier is required to have in-person encounters with the beneficiary in his/her home. There are also numerous requirements for the beneficiary to return to the prescribing physician for an in-person visit, often for the physician to certify continuing medical need, or the need for additional supplies to use with the prescribed DME. While we believe that CMS intended to waive all of these in-person encounters during the PHE under the IFR, we urge CMS to issue the following more detailed clarifications in a FAQ regarding appropriate alternatives for in-person encounters during the PHE.

### 1. Home Oxygen, Five-Year Payment Cycle

After a beneficiary has been on home oxygen for 60 months, the DME supplier is required to perform an in-person assessment of the equipment and replace it in order to begin another billing cycle.<sup>7</sup> During this PHE, to avoid in-person encounters, the DME supplier can assess over the phone if the equipment is in good working condition. If the DME supplier determines that the equipment is in good working condition, the DME supplier should not be required to replace the equipment in order to re-start the 36-month billing cycle, for the duration of the PHE. If the equipment does require replacement, then the DME supplier would do so. The DME supplier is responsible for ensuring that the equipment remains in good working order. **We recommend that CMS provide clarification in a FAQ that replacement of oxygen equipment is not necessary at month 60, if the DME supplier has determined through a telephone assessment that the equipment is in good working order, and that the DME supplier can then begin to bill for the next 36-month rental payment cycle.**

### 2. Home Assessment/Wheelchairs

Under the Medicare LCDs for manual and power wheelchairs, the DME supplier is required to conduct an assessment of the beneficiary's home in order to ensure that the home provides adequate access for the beneficiary to use the wheelchair in the home.<sup>8</sup> Since CMS has waived face-to-face encounters, actual and implied, this type of face-to-face encounter between a DME supplier and a beneficiary and his/her family is waived as well. On May 14, 2020, the DME MACs issued a joint article confirming that these in-person encounters are waived during the PHE. **We recommend, however, that CMS (or the DME MACs) provide additional clarification that DME suppliers can instead fulfill this requirement through a telephone conversation (or via video or in person, if feasible) with the beneficiary and/or his/her caregiver.**

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<sup>6</sup> 85 Fed. Reg. at 19266.

<sup>7</sup> Medicare payment rules for home oxygen include 36 months of rental payment, followed by 24 months of no monthly rental payments, payment during those 24 months is limited to a small maintenance and servicing payment, once every six months. See 42 C.F.R. §414.226

<sup>8</sup> See Medicare Local Coverage Determination (LCD): Power Mobility Devices (L33789)

### 3. NPWT Issues

The Medicare LCD for negative pressure wound therapy (NPWT) requires clinicians to measure wounds monthly to document progressive wound healing.<sup>9</sup> Under normal circumstances, these wound assessments are conducted by professional clinicians in the patient's home, doctor's office, or wound care clinic. These assessments are in-person encounters that CMS has waived during the PHE, and therefore should not be required for patients undergoing NPWT during the PHE. This is important for patient care during the PHE because if the DME supplier cannot obtain evidence of wound improvement from a clinician during the PHE, then the supplier would be required to have the beneficiary return the NPWT device and discontinue their NPWT treatment, resulting in serious negative results for a vulnerable population suffering from difficult wounds. We therefore urge CMS to clarify in a FAQ that the LCD's clinical indication requiring wound improvement over subsequent months of NPWT will be waived during the PHE, if the DME supplier is not able to obtain this information from the clinician.

#### C. Recommendations to Modify Certain Additional Policies During the PHE

##### 1. Hospital Beds

AAHomecare recommends that CMS suspend the enforcement of the clinical conditions for coverage for hospital beds, as CMS has done for respiratory DME items, for the duration of the PHE. During this pandemic, DME suppliers are providing home oxygen therapy to beneficiaries with acute conditions, who otherwise would be taken care of in the hospital. These beneficiaries with home oxygen therapy needs typically also have a medical need for a hospital bed in their home. Our members experience during the PHE confirms that physicians often prescribe a hospital bed when prescribing home oxygen therapy. Therefore, CMS should suspend the enforcement of the clinical conditions for coverage for hospital beds, for beneficiaries who are also prescribed home oxygen therapy. **We recommend that CMS provide clarification in a FAQ that for the duration of the PHE, that the clinical conditions for coverage of hospital beds will be suspended. Information to support the reasonable and necessary requirement should include medical record documentation that the physician has prescribed the hospital bed, and that the beneficiary has some type of respiratory-related condition. Additional documentation or other requirements that reside in the Medicare NCDs, LCDs, and/or related Policy Articles are not required.**

##### 2. Wound Care/Surgical Dressings – Refills and Documentation of Continued Medical Need

During this COVID-19 pandemic, DME suppliers who provide wound care supplies to beneficiaries on an ongoing basis are finding it difficult to connect with the prescribing physician to obtain the appropriate documentation for continued medical need, as required by the Medicare LCD and other Medicare sub-regulatory documents for surgical dressings.<sup>10</sup> For example, physicians are required on a monthly basis to update in the beneficiary's medial record the beneficiary's continuing medical need, based upon a monthly evaluation of the beneficiary's wound(s). To accommodate beneficiaries with a medical need for refills of surgical dressings during the PHE, we urge CMS to allow for some modification/relaxation of

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<sup>9</sup> See Medicare LCD L33821

<sup>10</sup> Medicare LCD L33831, Medicare Policy Article A54563



the documentation requirements for the provision of refills of surgical dressings/wound care items.

Specifically, AAHomecare recommends that:

- DME suppliers be allowed to use pre-existing medical record documentation, from previous orders, to provide the beneficiary with a re-supply of wound care supplies;
- DME suppliers be allowed to accept verbal orders for treatment/product changes; and
- if a beneficiary contacts the supplier for a refill order, allow the DME supplier to follow up with the prescriber/health care practitioner to obtain responses to medical need questions via telephone, and allow the DME supplier to document those responses in the supplier's patient record.

Further, AAHomecare supports the recommendations of the Alliance of Woundcare Stakeholders, which has submitted detailed recommendations to CMS.<sup>11</sup> These recommendations request that CMS allow a waiver of the definition of "qualifying wound," waiver of the requirement of certain elements of the wound evaluation, relief from certain documentation requirements for continued need and refill of supplies, waiver of the practitioner's signature requirement on the Standard Written Order, allowing a signature attestation instead, and leniency on the potential overlap of Part A and Part B benefits.

#### VII. Conclude TPEs and Post-PHE Audits

CMS has suspended pre-payment medical reviewed conducted by Medicare Administrative Contractors (MACs) under the Targeted Probe and Educate program (TPE) for the duration of the PHE.<sup>12</sup> It appears that CMS expects the MACs to resume those same TPEs at the end of the PHE. AAHomecare recommends that instead of resuming TPEs that were in process as of the beginning of the PHE, CMS should cancel those TPEs. At the end of the PHE, CMS should instruct the MACs to begin new TPEs based on new data analysis. We make this recommendation because it is likely that the PHE will continue for some time, and resuming the TPEs will make less sense given the many waivers that have been put in place that affect the documentation suppliers will be able to produce.

With respect to audits conducted after the PHE has ended, on claims submitted with dates of service during the PHE, AAHomecare recommends that CMS clarify that any audits be focused on ensuring that medical record documentation is consistent with the requirements in place during the PHE. In addition, AAHomecare urges that post-PHE audits place a priority on claims where there is a reasonable suspicion of fraud.

#### VIII. Suspension of Accreditation for Newly Enrolling DMEPOS Suppliers

AAHomecare disagrees with CMS' decision to not require accreditation for newly enrolling DMEPOS suppliers. CMS has announced this in its FAQ titled, "[Durable Medical Equipment, Prosthetics, Orthotics and Supplies: CMS Flexibilities to Fight COVID-19](#)." CMS is also waiving certain screening requirements for DMEPOS supplier applications and expending new applications from providers. In the absence of a demonstrated access issue to DME suppliers, we do not support these relaxations because we believe they may have the unintended effect of promoting potentially fraudulent and abusive behavior by new

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<sup>11</sup> See [Alliance of Woundcare Stakeholders Letter to Secretary Alex Azar dated April 6, 2020](#)

<sup>12</sup> See [CMS COVID-19 Provider Burden Relief FAQ \(April 2020\)](#)

entrants. Instead, we recommend that CMS allow the accreditation organizations to use their judgement regarding the relaxation of their standards during this PHE.

IX. Support Removal of NIV from Competitive Bidding; Urge CMS to Delay 2021 Competitive Bid Program

AAHomecare supports CMS' decision to remove non-invasive ventilators (NIVs) from the 2021 competitive bidding program. For the same reasons that CMS made this decision, CMS should delay the entire Round 2021 DME competitive bidding program.

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 NIVs, oxygen, CPAPs, RADs, nebulizers, etc.), CMS will not enforce 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 competitive bidding program. Moving forward with the competitive bidding program will impede patient access given the current economic and care delivery landscape. We therefore urge CMS to delay Round 2021 of the competitive bidding program.

Serious Access Issues Will Occur: Previous rounds of the Medicare DME competitive bidding program demonstrate that it dramatically decreases the number of DMEPOS suppliers who can service beneficiaries in the competitive bid 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 competitive bidding program 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 within a few weeks. 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 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 their equipment and supplies<sup>13</sup>. In addition,

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<sup>13</sup> See Dobson, Davanzo & Associates, "Impact of COVID-19 Supply Chain Disruptions and Increased Costs on DMEPOS Suppliers," (May 13, 2020)

manufacturers and distributors have experienced costs 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 increase in 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 more 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 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. DMEPOS providers are being financially harmed due to circumstances well beyond their control. Providers are no longer able to project either their costs, or the level and stability of revenue streams associated with delivering product to patients.

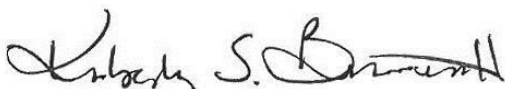
Furthermore, without the fundamental security that the supplier can acquire items at realistic and feasible costs, determining an accurate bid amount for a lead item in any of the product categories will not be possible going forward during the PHE. Factors like anticipated costs (both direct and indirect) for the lead and non-lead items, as well as historic and anticipated utilization of the non-lead items often have risen 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.

The Dobson report concludes that the survey data indicate an urgent need for a postponement of the 2021 Medicare competitive bidding program 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.

X. Conclusion

AAHomecare appreciates the opportunity to provide these comments. Please contact us with any questions, or if you would like additional information.

Sincerely,



Kimberley S. Brummett, MBA  
Vice President for Regulatory Affairs

# Impact of COVID-19 Supply Chain Disruptions and Increased Costs on DME Suppliers

*A Survey of Companies*



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# 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 faced with mounting challenges in serving their patients, many of whom have become suddenly very ill, requiring respiratory support and other DME and related services.

**A one-year delay of CB 2021 would help ensure that there are no unnecessary or inappropriate barriers to patients being able to access home respiratory products, hospital beds, and other needed supplies and home medical equipment due to COVID-19 market dislocation.**

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,

# Executive Summary

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

***“We have had a significant decline in patient contact lines of business - example, CPAP setups have nearly completely stopped because we do not have adequate PPE to protect ourselves and the patient while conducting a CPAP setup. We are also experiencing business losses for non-hospice type DME because patients are not going to the doctor to get things like walkers, CPAPs, wheelchairs, etc. due to local quarantines in effect. This also creates payroll issues because I have less business, but don't want to lay off workers - so I'm trying to keep staff employed, with significant declines in business. I need the staff for when we start to loosen restrictions on patient contact/social distancing.” -***  
*Survey respondent*



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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.”

***“Operating supplies for oxygen have doubled in cost AND have been either on allocation or orders are rejected by manufacturers. We have had to spend considerable time and expense finding new or alternative suppliers and evaluating product quality and availability.”***

*Survey respondent*

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.<sup>1</sup> 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.

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<sup>1</sup> <https://www.cms.gov/files/document/covid-dme.pdf>

# Executive Summary

## 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.

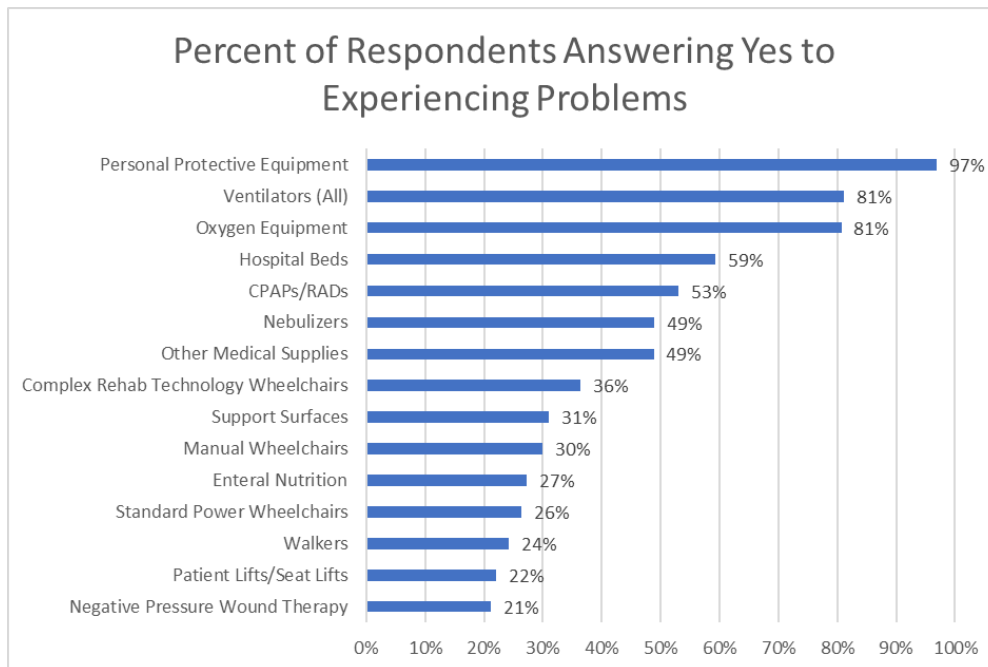
*“Not able to acquire medical equipment and supplies (Oxygen and Oxygen related supplies) Ventilators, etc. on a timely manner therefore losing the sales.”*

*-Survey Respondent*

## 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



# Executive Summary

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.

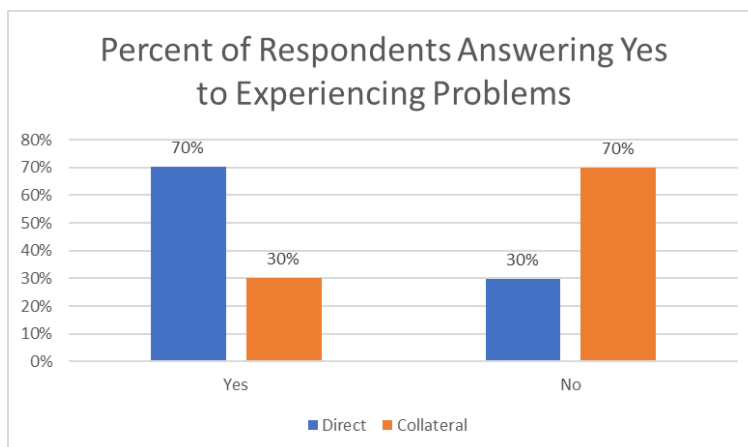
*“In demand items now cost more than what Medicare reimburses, shipping is more expensive, and vendors unable to price negotiate.”*

*Survey Respondent*

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.

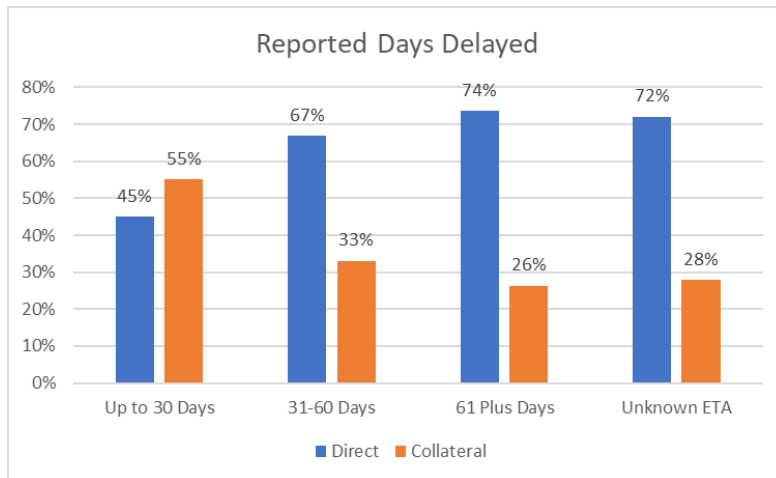
**Exhibit 2**



# Executive Summary

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.

# Executive Summary

## Exhibit 4

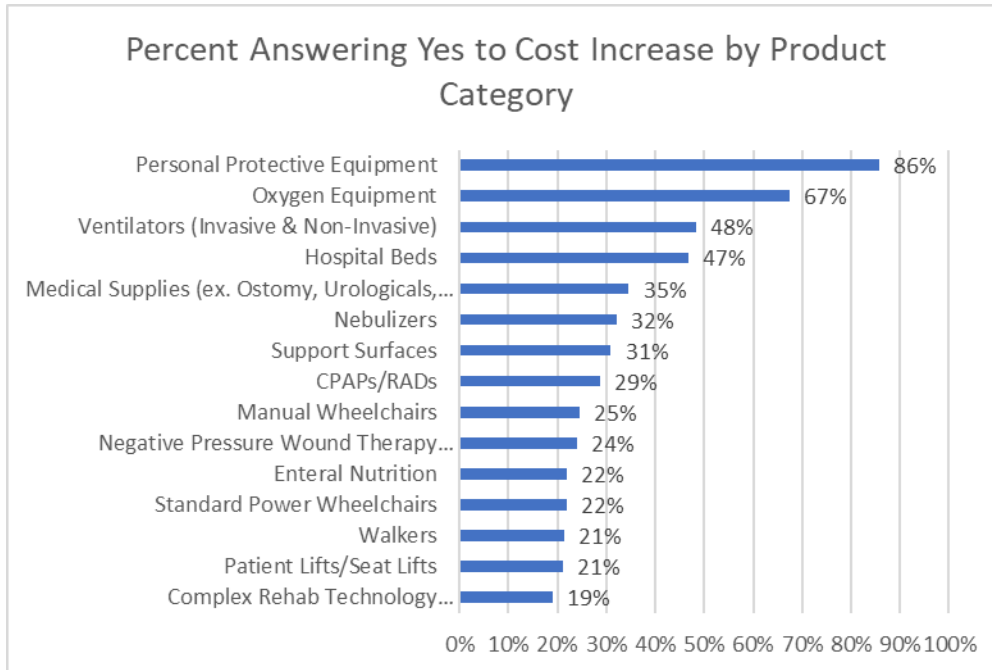


Exhibit 5 contains the percent of companies reporting increased costs by whether the product categories are directly used for COVID-19 patients or collateral to COVID-19. Just over half of companies reported cost increases for direct product categories whereas 25 percent of companies reported such increases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

## Exhibit 5

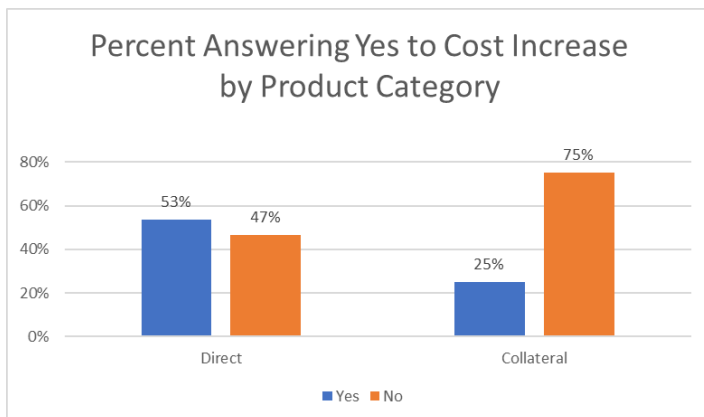
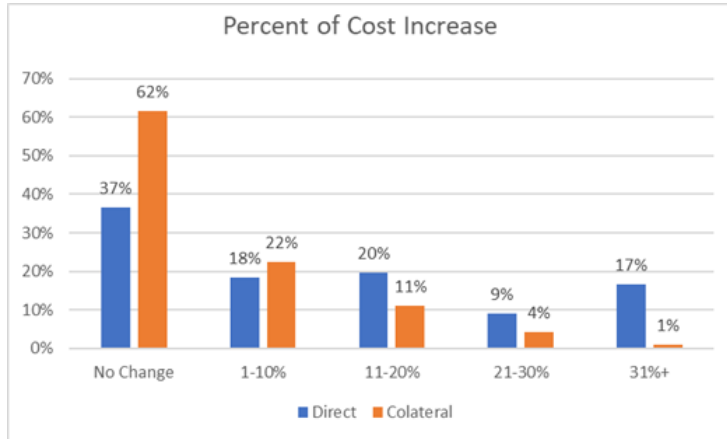


Exhibit 6 contains the percentage increase that companies reported for the direct and collateral product categories. As can be seen in Exhibit 6, approximately 63 percent of products directly related to care of COVID-19 patients and approximately 38 percent of collateral products saw a price increase.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

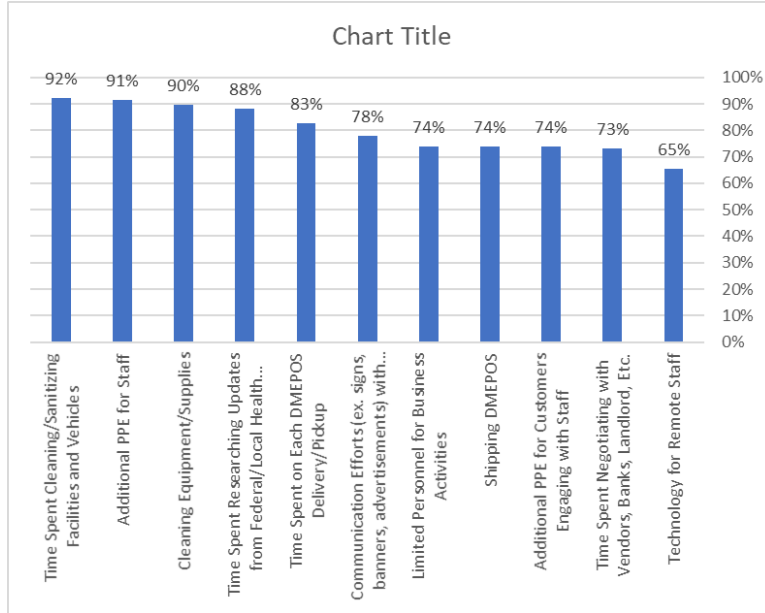
*In order to assess any additional operating expenses your business may have incurred as result of the COVID-19 pandemic, please indicate if any of the following business activities have resulted in increased costs (or lost business revenue) for your business?*

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.

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## 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 Corona-virus 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.



# Detailed Study Findings

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## 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

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## **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.

# Detailed Study Findings

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## 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.

# Detailed Study Findings

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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.