COALITION OF
Wound
Care
Manufacturers

July 3, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5531-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850.

Submitted electronically through www.regulations.gov

RE: CMS-5531-IFC - 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

Dear Administrator Verma:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments in response to the second Interim Final Rule (IFC) with comment period - CMS-5531-IFC issued by HHS related to COVID-19 - 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.

The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. We greatly appreciate actions taken by CMS creating flexibilities for providers during this time in order to allow for the continuity of care to patients while minimizing risk of their contracting the COVID-19 virus. It is clear that CMS recognizes the challenges providers are facing in a time of uncertainty, particularly with regard to adoption of telehealth and documentation requirements and the increasingly complex clinical decision making due to the risks associated with COVID-19. However, there are also issues that are facing the wound care supplier and manufacturing communities which we are requesting that CMS address. Our specific comments regarding these issues follows.

Specific Issues

Competitive Bidding

In the second IFC, CMS provides clarification of CARES Act provisions that revise fee schedule amounts for certain DME and enteral nutrients and supplies furnished to beneficiaries in non-

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410
www.woundcaremanufacturers.org

CBAs—both rural and non-contiguous areas and other areas where competitive bidding did not take place. Furthermore, CMS has indicated that it will not move forward with an original proposal to include non-invasive ventilators in the next round of competitive bidding. While both of these are important proposals, CMS does not discuss details of the next round of the competitive bidding program.

During the PHE, we believe that the competitive bidding program (CBP) must be paused for the following reasons:

- The immediate future of the pandemic is still relatively unclear.
- The bid amounts submitted did not anticipate the increased cost of providing these products, increased need and cost of personal protective equipment (PPE), or new labor-related costs.
- The Round 2021 bid amounts also did not contemplate the increase in the number of acute patients and the different ways the cost of caring for these patients must be allocated over a shorter period of time.

Therefore, the Coalition recommends that CMS delay moving forward with CBP until either 12 months after the end of the PHE or after December 31, 2021 – whichever is later.

Other Provisions Related to DME

In addition to our request to postpone the start of the next round of competitive bidding, the Coalition is providing additional recommendations to CMS for its consideration to improve beneficiary access to DME and other home equipment during this PHE. These include:

- Streamline Medicare billing for disposable negative pressure wound therapy (NPWT) furnished at home onto the standard form used by home health agencies (HHAs), eliminate the requirement to separately account for time spent applying this technology, and eliminate the requirement that a second condition be treated for HHAs to receive credit for a home visit when disposable NPWT is applied.
- DMEPOS suppliers should be categorized as "essential services" to allow delivery to quarantined areas.
- Prioritize DMEPOS suppliers' access to personal protective equipment for treating COVID-19 patients in their homes.
- Allow an extension of the expiration date of written orders for an additional nine months from the date orders currently expire, for recurring medical supply orders and ongoing DME rental claims during the PHE.
- Waive during the emergency period all pre-authorization requirements for DMEPOS patients, since DME MACs and Medicare Advantage plans are having difficulty processing these requests in a timely manner.
- Waive during the emergency period geographic restrictions for DMEPOS providers suppliers, such as the state licensure rule or zip code.
- Allow all Medicare Advantage plan patients with chronic conditions to have out-of-network benefits for medically critical DMEPOS equipment and supplies.
- During the emergency period, extend appeals deadlines, postpone Medicare audits, and defer overpayment recoupment for an additional 90 days, so that DMEPOS providers and suppliers can focus on caring for patients and provide meaningful products and services to impacted patients.
- Open a separate hotline for monitoring patient access to the most appropriate DMEPOS products, especially for chronic care patients at risk for infections that could confound morbidity and mortality of COVID-19, e.g. UTIs for catheter patients in spinal cord

injury patients, peristomal skin breakdown for ostomy patients with history of cancer and/or immune suppressive medication.

We believe that implementing these recommendations will help DME suppliers provide timely access to medical equipment to a vulnerable at risk population while minimizing risk to the patient.

Disposable Negative Pressure Wound Therapy (dNPWT)

The Coalition recommends that CMS add the following codes for negative pressure wound therapy using disposable, non-durable medical equipment to the eligible telehealth list:

> 97607 Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
>
> 97608 Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

The patient population that typically receives dNPWT are vulnerable. An example of a type of patients that would benefit from dNPWT are elderly patients with diabetic lower extremity ulcers. Diabetes has been identified as a risk factor for severe disease and mortality with COVID-19; therefore, it is important to limit exposure for these patients. Without a telehealth benefit to furnish dNPWT, patients requiring this therapy currently risk exposure by not being able to visit their physician office or hospital outpatient clinic which may lead to the wound being untreated and risk infection.

These procedures are not included under the current scope of telehealth services, but they meet the criteria to be added to the list and would enable critical care for vulnerable wound patients. Healthcare professionals can provide proper guidance and training for patients or their caregivers to perform these procedures via 2-way audio-visual telecommunication technology. The ability to deliver the dNPWT services via a telecommunications system allows patients with wounds to benefit from the demonstrated clinical benefits of dNPWT, thereby decreasing the number of subsequent therapeutic interventions and number of future hospitalizations or physician visits. During the COVID-19 PHE, allowing patients to access dNPWT via telehealth mitigates risk of exposure for patients and for healthcare professionals.

As such, the Coalition recommends that CMS add the dNPWT codes to the list of telehealth codes available.

Provision of Wound Care in every POS

COVID-19 has also led to the necessity of treating many wound patients in their residence, often at home (POS 12), an assisted living facility (POS 13) or nursing facility (POS 32). While some MACs recognize and pay for wound care services, such as disposable NPWT and application of cellular and/or tissue based products for wounds (CTPs) in these sites of care, others disallow payment in these places of service even though Medicare policy allows physician payment in these settings**. With the CMS goal of minimizing risk to all patients while maintaining access to**

care, we request that CMS issue guidance to the MACs on the importance of enabling patients to be treated at all appropriate sites of care outside traditional office and hospital settings. We believe that even in the absence of waivers and flexibilities, these POS are indisputably appropriate and payable sites of care. During the midst of the PHE, payment of these services is even more pressing. We urge CMS to instruct the MACs to stop disallowing these POS to facilitate access to these therapeutic treatments for wound care patients.

Conclusion

We again appreciate your consideration of each of these requests—each of them serve to remove barriers to treat wound care patients efficiently and effectively during this pandemic while at the same time keeping them as safe as possible while they receive the necessary care. We also would like to reiterate our appreciation of the work that CMS has already done to remove barriers to care during this uncertain time. Please call on us to answer any questions regarding our recommendations to the Agency.

Sincerely,

Karen Ravitz, JD
Health Care Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296