ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

April 6, 2020

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

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Also Submitted Electronically to 1135waiver@cms.hhs.gov

Re: Time Sensitive - Request for Flexibility in Providing Wound Care Services and Products to Ensure COVID-19 Patients Receive Appropriate Care

Dear Secretary Azar and Administrator Verma,

The Alliance of Wound Care Stakeholders ("Alliance") is writing to request that the Centers for Medicare and Medicaid Services (CMS) provide temporary regulatory waivers and new rules to give flexibility to wound care clinicians to provide necessary (and at times life and limb saving) procedures and products to treat their patients in light of the COVID-19 pandemic. We appreciate the tireless hours that CMS staff has spent in waving or relaxing regulatory hurdles to help our members treat their patients more efficiently during the COVID-19 crisis and communicating them to us through the many conference calls, emails and website updates. We have used this information to educate our members on these updates and have a section on our website devoted to them.

The Alliance is a nonprofit multidisciplinary trade association which represents not only physician specialty societies, clinical and patient associations but also wound care clinics and business entities (manufacturers, tissue banks/processors, and distributors). Our mission is to promote evidence-based quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. This letter was written with the advice of all Alliance members. A list of our members can be found on our website: http://www.woundcarestakeholders.org/about/members.

REQUEST FOR TEMPORARY EMERGENCY RELIEF

The COVID-19 pandemic has caused unique challenges to providing good care to Medicare patients with active skin wounds. Patients with wounds have higher rates of ER visits, hospitalization, length-of-stay,

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amputation, and healthcare costs. Due to various orders and recommendations, non-essential healthcare services and procedures are being postponed or canceled. While clinical key opinion leaders and the Alliance believe that most wound care is an essential service, many hospital-based wound centers have temporarily closed and patients are being displaced. The Alliance issued a recent statement addressing the closure of wound centers and why most wound care is essential and helps to prevent utilization of hospital ER and inpatient services.
https://www.woundcarestakeholders.org/images/Final2_Statement_-_Wound_Care_as_Essential.pdf

One notable difficulty in coordinating wound care for patients is the breadth of sites of service where wound patients receive care including: hospital inpatient, hospital outpatient, emergency departments, surgical centers, skilled nursing facilities, physician offices, and in the home.

Also of great concern to us is that most wound patients are in a vulnerable group with comorbidities such as diabetes, obesity, and cardiovascular disease which puts them at higher risk for a more complicated course of COVID-19 and death.

Given the urgent need to unburden the healthcare system and keep our Medicare patients with wounds safe, the wound care community has recognized the changing dynamic in the pandemic model of care for wounds.

Shifting the Site of Service and Reducing Utilization

The Alliance and all its members believe that patients are safer at home and we are dedicated to providing as many services as possible in the home. This includes a reduced emphasis on hospital-based care and, through triage, a shift in care to less risky sites of service while continuing to provide assessments and escalate the patient's care when necessary. A major focus will be to shift as much care as possible into the home through telehealth, home health, provider visits, and patient self care.

Shifting the Emphasis on Goals of Wound Care

The goal and major focus of wound care has been to achieve complete wound healing in patients. However, in a pandemic model of care with shifting sites of care and reduced access and utilization, the major goal must be to reduce wound and diabetic foot-related hospitalizations and exposure to patients at risk for death from COVID-19. This shift means that managing wounds to prevent wound infections to avoid ER visits and hospitalizations will be paramount. It helps to reduce the burden on the health system and keeps our patients safe.

Specific Temporary Regulatory Relief Requests in Wound Care

Given the shifts in sites and types of care, we have identified specific hurdles to providing the best possible care to wound patients during this emergency and respectfully request temporary relief from these regulations or policies.

We request that CMS:

1) **Waive the 250 yard rule for hospital outpatient departments (HOPDs) to receive 100% APC fee if off-site.**
   This may have been accomplished in the March 30, 2020 CMS waiver on temporary expansion site where it allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the state or local pandemic plan. We request confirmation that this requirement has been waived. In addition, we want to ensure that if a provider based department is able to and does move off campus, then it will not receive a reduction in payment when care is provided, but instead will receive 100 % of the APC payment when off site.

2) **Allow HOPD wound centers to receive a facility fee for telemedicine originating from the center.**
   We understand that from the March 31, 2020 CMS call with health professionals, CMS staff stated that the Agency is working on this. This is important and request that CMS adopt this recommendation and release the guidance on this issue as soon as possible.

3) **Reimbursement Issues**

   In order for patients to continue receiving the care that they need in the least amount of visits to reduce their exposure to COVID-19, we would request that certain payment regulations be temporarily waived to allow physicians' flexibility in treating their patients. The issues provided below are immediate needs. Thus, we request that CMS:

   A. Provide payment for any procedure that is reimbursed in the physician office (POS 11) to be performed in the home (POS 12) during this time of national emergency and at the same level of payment as POS 11 services. We are requesting that this be permissible and are seeking confirmation from CMS that this issue has already been resolved in the March 30, 2020 interim rule.

   B. Temporarily waive the NCCI edits in order to provide reimbursement for total contact cast (TCC) (CPT 29445) on the same date of service as another procedure (e.g.,debridement or applying cellular and/or tissue based products for skin wounds [CTPs]).

      Rationale: Offloading with diabetic foot ulcers with TCC is the best practice and the pandemic is proving to be a barrier to patient access for TCC. Many local coverage determinations (LCDs) disallow the reimbursement for TCC on the same date of service as another procedure. Reimbursing for both procedures on the same date of service gives providers the flexibility to use both medically necessary procedures when convenient for the patient and provider.

   C. Provide reimbursement for DME Removable Cast Walkers (HCPCS L4361 and L4387) for patients with diabetic foot ulcers when other methods of offloading are not feasible.

      Rationale: Removable cast walkers (RCW) have been shown to be as effective in offloading/healing diabetic foot ulcers as a total contact cast, but they are only reimbursable for fractures, not diabetic foot ulcers. During the pandemic and increased use of telemedicine, a RCW provides an off-the-shelf option for offloading which can be sent to the patient.

D. Provide reimbursement for alternative methods of debridement which could be performed at home during the pandemic. Alternative methods of debridement are enzymatic (e.g. collagenase, a Medicare Part D benefit), maggot debridement therapy, and ultrasonic debridement. We also request that CMS waive the requirement for surgical debridement in order to proceed with advanced wound therapies/dressings.

Rationale: Currently, the best practice is to surgically debride wounds which removes necrosis and fibrosis, thus preventing infections and hospitalizations. However, the pandemic is causing patients to lose access to surgical debridement due to a number of factors including: a restriction of non-essential and outpatient procedures, closure of wound centers, and restriction of patient movement. Alternative methods of debridement could be prescribed by telemedicine or applied non-invasively in the home. Additionally, surgical debridement is not able to be performed during a virtual encounter when advanced wound dressings (DMEPOS) may be prescribed.

4) **Issue a blanket waiver to expand the types of providers eligible to furnish telehealth services as distant site practitioners under Medicare to include physical therapists and physical therapist assistants during the COVID-19 public health emergency.**

5) **Allow a simultaneous visit by home health agencies and providers by either telehealth (POS 11 with modifier 95) or house call (POS 12) when wound care is part of the home health plan of care**. This also may have been addressed in CMS's March 30, 2020 regulatory relief waivers but we request confirmation that this is permissible as our members continue to request clarification. For example, while we know that simultaneous visits may be permitted, we were told that only if wound care was part of the plan of care and only if the home health being provided was not in a way that the nurse would be considered auxillary staff to the wound care clinic. However, if a doctor is trying to evalutate the wound via telehealth in order to develop a plan of care, it is helpful to have the home health visit simultaneously so the nurse can accurately measure wound depth and infection. Is this permissible? We would appreciate clarification.

6) **Relax required documentation of advanced wound products prior to initiation of these therapies, or during therapy (e.g. collection of thirty day wound progression), or depending upon the language in the NCD/LCD, requiring validation that there has been 30 days tried and failed of other standard therapies before allowing select advanced modalities.**

Rationale: This requirement is an administrative burden that impedes patient care, due to the difficulty to acquire medical records across care settings during a period of reduced hours/staff in this time of a national emergency.

7) **Request for Durable Medical Equipment (DME) relaxed access with specific criteria requiring in-person pre-service interactions**. The 1135 DME blanket waiver addresses only replacement DME to allow beneficiaries' existing DME to be replaced when lost, destroyed or damaged in an emergency. That waiver has little utility in the COVID-19 emergency as DME is not being destroyed or damaged. This emergency is preventing patient access for new prescriptions for medically necessary at-home DME because NCD/LCD medical necessity criteria require in-person interactions that cannot occur during this crisis.

Recommendations:

A. **Relax LCD/NCD medical necessity DME criteria requiring in-person pre-service interactions.** Allow medical equipment suppliers to provide virtual demonstrations/training on medical devices to fulfill LCD 33829 and NCD 280.6 medical necessity criteria that currently require the patient receive pre-service in-person "initial treatment" with device to show that patient can operate device and tolerate treatment.

Rationale: During the pandemic, in-person patient interaction is not desirable or even possible in many cases yet patients still have clear medical need for DME covered by LCD/NCDs with in-person pre-service medical necessity requirements. Therapeutic DME (example: pneumatic compression devices to treat lymphedema) provides at-home treatment which is highly desirable with the current limited access to clinics and medical professionals. Virtual demonstration/training provided post-delivery meets the spirit of the criteria by allowing the patient to work with a trained specialist who can conduct a virtual training and walk the patient through physical application of the device to confirm ability to operate, apply and tolerate the treatment prior to claim submission.

B. Allow HOPDs and MDs to bill for the professional service of furnishing disposable NPWT during the pandemic when providing wound assessment and instruction to patients in their home via telehealth, in order to enable critical therapy but without in-person interaction.

8) Allow waivers of co-pays (for Medicare patients with no secondary coverage) for CTPs and other higher cost treatment in POS 11 and 12.

9) Allow manufacturers to provide discounts of their CTPs during the emergency without affecting the Average Sales Price that the manufacturers submit to CMS quarterly which establishes reimbursement amounts.

10) Wound Care Supplier Specific Temporary Regulatory Relief Requests

A. Requests Related to the Surgical Dressing Benefit outlined in Local Coverage Determination (LCD) Surgical Dressings (L33831) and associated Local Coverage Article (A54563).

i) **Relaxed regulation and definition of "qualifying wound**".

Issue: Policy Article (A54563) states that surgical dressings are covered when a qualifying wound is present. A qualifying wound is defined as either of the following:

- A wound caused by, or treated by, a surgical procedure; or,
- After debridement of the wound, regardless of the debridement technique.

The current 1135 Waiver guidelines allow a more relaxed use of telehealth, creating less face-to-face patient/practitioner encounters and limitations in performing debridement(s) and/or other surgical procedures.

Recommendation: We request that CMS temporarily waive the "qualifying wound" requirement thus allowing Medicare patients to be **seen via telemedicine** so as to receive needed advanced

surgical dressings on a wound of any etiology. With this temporary relief, the wound will meet all descriptive characteristics, in accordance with the underlying Surgical Dressing Policy Article and LCD, subject to any other limitations outlined in 10b.

ii) **Relief of certain elements of the wound evaluation hampered by telemedicine**

Issue: The Policy Article states that wound evaluations (both initial and/or ongoing) in the treating practitioner's medical record, nursing home, or home care nursing records must specify the following: wound drainage, wound size (length xwidth x depth) and wound thickness (e.g. staging and/or grading).

The current 1135 Waiver guidelines allow a more relaxed use of telehealth, creating less face-to-face patient/practitioner encounters and limitations in performing these evaluations accurately.

Recommendation: We request that CMS provide temporary relief, either as a direct waiver of theses requirements or as modification to these requirements, when a clinical access restriction is documented (e.g. patient seen by telemedicine) be given. Suggested modification(s) include the ability of the practitioner to obtain as much information as possible in "good faith" from the beneficiary and document telemedicine as a restriction.

iii) **Relief of documentation requirements for continued need and refill of supplies**

Issue: For ongoing use of previously prescribed supplies, there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary. Due to the limitations associated with COVID-19, patients in need of surgical dressings could be faced with a shift of site of service, lack of ability to get to practitioner appointments and outpatient offices, or delayed visits. In addition, telehealth visits and dictation of need could be slowed through modality changes being allowed within the current 1135 Waiver. This includes further issues with refill documentation, when more supplies are necessary.

Recommendation: For an established patient, it is requested the following elements substitute the evaluation requirements as stated in the Policy Article:

- wound(s) that were previously prescribed dressing(s) are still active and needing treatment as defined in the Local Coverage Determination (LCD): Surgical Dressings (L33831),
- the patient is continuing to use previously prescribed dressing(s) as instructed by the prescribing practitioner,
- the patient is at/or near exhaustion of supplies, and within 10 days of completing current supply order

To encourage continued access to an unchanged dressing protocol, we are requesting an allowance of a refill of supplies to occur without the stated new order requirements within the Policy.

B. Requests related to fulfillment of "reasonable and necessary" requirements outlined in both the Local Coverage Article, Standard Documentation Requirements for All Claims Submitted to

DME MACs (A55426) and Local Coverage Determination (LCD) Surgical Dressings (L33831); specifically pertaining to elements of the "Standard Written Order (SWO)"

Issue: A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. A treating practitioner's signature is a required element necessary to complete an SWO. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary. Additionally, if the signature is missing from an order, MACs, SMRC, RAC, UPIC and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received). However a supplier may dispense necessary product(s) without a doctor's signature. Typically, it takes an average of 30 days to collect a physician/practitioner signature. Due to physicians/practitioners being unavailable due to COVID-19 emergent matters, the average of days has been increasing, and is expected to continue to expand, causing further financial obligation and burden for the DME suppliers.

Recommendation: We request that CMS provide a temporary waiver of the SWO "Practitioner's Signature Requirement" allowing suppliers to bill without a practitioner's signature.

C. **Request related to the Medicare Claims Processing Manual; specifically leniency on the potential overlap of Part A and Part B benefits-**

Issue: Presuant to current 1135 Waivers, Skilled Nursing Facilities (SNFs) and Home Health Agencies (HHAs) have expanded access to provide patient care. This access is resulting in unintended consequences for DME suppliers billing the Part B benefits. Due to lack of timely reporting of usage of the Part A Medicare benefit from a SNF or HHA, DME suppliers could provide and bill the Medicare Part B benefit with lack of visual of Part A benefit usage. This will cause suppliers billing the Part B Medicare benefit a denial in coverage, resulting in loss of revenue.

Recommendation: We request that CMS consider an overlap of coverage within the two separate benefits of Part A and Part B. This request would provide leniency to suppliers on part B billing, allowing patients to have the supplies provided. This would avoid detrimental consequences to the business functions of the supplier organizations. All efforts will be made to ensure supplies are not provided when a patient is in use of the Part A Medicare benefit, with an established good faith effort of confirmation of the beneficiary's current status, such as documented eligibility checks. Furthermore, we are suggesting a limitation of no more than 30 days of overlapping services between March 1, 2020 and December 31, 2020. Should the national emergency continue on into the subsequent year, an additional 30 day overlap period will be requested.

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these requests. Each requests made serves 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 would be pleased to provide you with additional rules and anlysis for these recommendations if you have questions about them. In addition, we are having active conversations about the future of wound care after the pandemic and look to provide you with additional recommendations and

proposals on such initiatives as: remote patient monitoring and case management. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

c.c. Demetrios Kouzoukas (Principal Deputy Administrator for Medicare)
Elizabeth Richter (Deputy Administrator)