ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

May 29, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: 1744-IFC - Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit comments in response to the Interim Final Rule (IFC) with comment period - 1744-IFC - Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. In addition to submitting these comments, the Alliance has participated on most of the CMS "Office Hours" phone calls and submitted several emails and letters to CMS requesting clarification and guidance during this unusual time. The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose 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. These comments were written with the advice of Alliance clinical specialty societies and organizations who not only possess expert knowledge in treating complex chronic wounds, but also in wound care research. A list of our members can be found on our website: http://www.woundcarestakeholders.org/about/members.

The Alliance greatly appreciates actions taken by CMS creating flexibilities for providers during this time in order to allow for the continuity of care to our patients while minimizing risk of 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. We thank the Agency for their continued work.

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, whether provided by visiting nurses/physicians or via telehealth. 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.

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Wound care is a national epidemic masked by co-morbidities. Patients with chronic wounds heal differently and require treatment that is individualized. Variations in wound characteristics, such as depth, location, size, presence of ischemia/infection, malnutrition, etc., determine what care and treatment modalities are necessary to heal a specific patient's wounds. Those with chronic wounds often have multiple co-morbidities such as diabetes, heart failure, chronic kidney and vascular disease, and their bodies respond differently at various times to various wound healing components. The co-morbidities that these patients have are also on the list of conditions that put them at higher risk for COVID 19 so it is imperative that these patients reduce their risk as much as possible.

The coronavirus pandemic demands that health care policy makers, payers, and providers reconsider how care is delivered to reduce the risk of further spreading infection. With intensifying concerns surrounding the COVID-19 pandemic, access to telehealth has become of paramount importance to ensure the safety of patients and their providers. As the Agency works to address unnecessary regulatory burden, we believe it is critical that what is best for Medicare beneficiary safety and public health remain the foundation for any new policy changes.

We support the following provisions in this first IFC including but not limited to:

- reimbursement for telehealth at the physician non-facility rate, as appropriate, when submitted with a 95 modifier and the place of service corresponding to where that service would have been provided had the service been rendered in person;
- expansion of telehealth services generally and ongoing consideration of additional services that can be provided via telehealth;
- choice of medical decision making or total time when determining the level of office/outpatient E/M furnished via telehealth;
- facility E/M services provided via telehealth;
- ability to provide virtual check-ins, telephone E/Ms, and e-visits to both new and established patients;
- ability to provide direct supervision via real time interactive audio and video technology; and
- separate coverage and payment for telephone evaluation and management services
- while not in the original IFC, we also support the ability of physical therapists to provide telehealth services

In addition to supporting the Agency's implementation of the above provisions, we are still seeking clarification on the following provisions that were outlined in our April 6th letter to the Agency that still have not been addressed:

LCD/DME ISSUES

We appreciate the wide variety of CMS-initiated calls devoted to answering general questions ("Office Hours") and specific ones from professional sectors (ie., nurses, home health).We respectfully request that one be added for wound care which may only be for a few calls as well as one for DME suppliers/providers and manufacturers of medical equipment. . There are many unanswered questions for which we have tried unsuccessfully to gain some guidance. We would appreciate not only a response to the questions below but also to have CMS schedule these specific calls. Some of the issues include the following:

1. **Requests Related to the <u>Surgical Dressing Benefit</u> outlined in Local Coverage Determination (LCD) Surgical Dressings (L33831) and associated Local Coverage Article (A54563).**

   a) **Relaxed regulation and definition of "qualifying wound**"

   <u>Issue:</u> As stated in the Policy Article (A54563) of the Surgical Dressing LCD, 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.

   <u>Recommendation:</u> We request that CMS temporarily waive the "qualifying wound" requirement thus allowing Medicare patients who are <u>seen via telemedicine</u> and therefore cannot undergo debridement to receive needed advanced surgical dressings on a wound of any etiology. With the 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. This way, coverage can be determined by medical necessity without the need to bring the patient out of their home for a debridement if the provider thinks that can be safely avoided. We are not asking for the debridement clinical need to be waived but rather the debridement requirement for a qualifying wound in order to receive surgical dressings.

   b) Relief of certain elements of the wound evaluation hampered by telemedicine

   <u>Issue:</u> 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 x width 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.

   <u>Recommendation</u>: We request that CMS provide temporary relief, either as a direct waiver of these 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.

2. **Relief of documentation requirements for continued need and refill of supplies**

   <u>Issue</u>: 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 request an allowance of a refill of supplies to occur without the stated new order requirements within the policy

3. **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.

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

Issue: Pursuant 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.

5. **Request that CMS 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.

6. **Request that CMS provide reimbursement and increased access for alternative methods of debridement which could be performed at home during the pandemic.** Alternative methods of debridement are enzymatic (e.g. Santyl◊ collagenase ointment, a Medicare Part D benefit), maggot debridement therapy, and ultrasonic debridement. We also **request that CMS waive any requirements for surgical debridement in order to proceed with advanced wound therapies/dressings if applicable as well as other barriers that may prevent, delay or restrict access to treatment with these alternative methods of debridement**.

   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 may not able to be performed during a virtual encounter when advanced wound dressings (DMEPOS) may be prescribed.

7. **Request that CMS 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.

GENERAL WOUND CARE REQUESTS/CLARIFICATIONS

1. While we recognize that CMS and the OIG have waived certain aspects of the Stark and Anti-kickback statute, **we would like some guidance as to whether CMS will allow waivers of co-pays (for Medicare patients with no secondary coverage) for Cellular and/or Tissue based Products for skin wounds (CTPs) and other higher cost treatment in POS 11 and 12**.
2. Similarly, CTP companies are required to submit ASP information to CMS on a quarterly basis. If a manufacturer provides a discount of their CTP during the PHE – their reimbursement will be impacted after the emergency. Many manufacturers would like to offer a discount and **we request that CMS 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.**
3. 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 are disallowing payment in these places of service even though Medicare policy allows physician payment in these settngs**. We request that CMS issue guidance to MACs on the importance of enabling patients to be treated at all approparete sites of care outside traditional office and hospitals settings.**

TELEHEALTH REQUESTS/CLARIFICATIONS

1. Allow HOPDs and MDs to bill for furnishing disposable Negative Pressure Wound Therapy (NPWT) reported with CPT codes 97607 & 97608) during the pandemic when providing wound assessment and instruction to patients in their home on the application of this therapy via telehealth. This would enable this critical therapy to be provided in a way that does not necessitate in-person interaction between the clinician and the patient.
2. Recognize SNFs, rehabilitation agencies, hospital outpatient departments, and home health agencies as eligible to bill for outpatient therapy services furnished via telehealth provided by physical therapists, occupational therapists, and speech language pathologists under the Medicare Physician Fee Schedule using the UB-04 claim form.

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.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart, R.Ph.
Executive Director