ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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 Alliance of Wound Care Stakeholders ("Alliance"), 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 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 their 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 its continued work to educate and communicate with health care professionals through its series of conference calls and website updates.

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We are in agreement with the Agency on the following provisions contained in this second interim final rule with comment period addressing COVID 19:

- Increasing the payment for remote patient encounters.
- Enabling clinicians to deliver evaluation and management services through telemedicine visits and receive payment as if the encounter was within the office setting.
- Permiting the use of a cellphone with audio and visual capabilities to qualify as a telemedicine platform.
- Permiting audio only to quality as telemedicine platform and increased the reimbursement for those "visits".
- Clarifying that non-physician practitioners can perform patient care duties within the limits of their licenses, and utilize telemedicine when appropriate.
- Providing assurances that clinicians utilizing telemedicine to deliver care, and acting in good faith, will not be subject to civil money penalties or other HIPAA enforcement actions.
- Allowing for physical therapists to be able to provide telehealth services and more recently, clarified that institutional settings can now bill outpatient therapy when furnished via telehealth.

The Alliance is providing our specific comments on the following issues:

- Specific recommendations regarding the codes which should be utilized by Provider Based Departments (PBD) when billing for wound care services via telehealth that has been temporarily relocated to a patient's home
- Concerns regarding the competitive bidding program
- Issues on which we are still seeking clarification

Specific Comments

Temporary Relocation Sites

The Alliance fully supports the provision which allows a provider based department to "temporarily relocate" to a patient's home. This is a great solution to keep patients out of the outpatient facility while still being able to receive the care needed. As CMS addresses "Hospitals Without Walls", the Alliance had taken this concept and adapted it to our sector of health care and have titled it "Wound Centers Without Walls."

Prior to COVID 19, when services were provided to a wound care patient – it was a team effort. The nurses would prep the patient for the physician/Qualified Health Professional (QHP) visit by conducting a systems review, taking vitals etc. Once the physician/QHP visit was over, the nurse would provide the post care coordination.

During this PHE, these same services are being provided. While CMS has determined that the physician/QHP would be reimbursed for their services whether their services are being performed in the office, the hospital or via telehealth, the PBD is being paid just the origination fee despite providing the same services – if not more. Thus, the Alliance has concerns that the $26.00 origination fee that CMS has proposed as the reimbursement for services provided when performed in this temporary relocation site is not adequate for the services that are actually being performed on a regular basis. The $26.00 fee suggests that

CMS does not believe that any significant services are being provided during these visits. The Alliance disagrees. Our rationale is as follows:

Wound care treatment is complex and the treatment of wound care patients is also complex. The most common wounds are a result of a co-morbid condition such as diabetes, venous or arterial insufficiency, or pressure injuries, making these patients particularly susceptible for death from COVID-19 infection. As a result, wound centers are now triaging and managing the most vulernable patients while they are at home. However, the services provided by the PBD wound nurses, as well as the digital resources being utilized, to support the telehealth visits provided by the wound physicians/other qualified healthcare professional (QHPs) warrants more than the $26.00 reimbursement fee. In this time of increased telehealth services, it is helpful to state what is done during a wound care telehealth visit to justify our request to increase the reimbursement. All of the the resources used and time spent should be taken into consideration by CMS. For example, the typical services currently being provided by the PBD wound nurses are as follows:

During the 15- 20 minute pre-service, the PBD nurse:

- Begins the encounter by calling the patient and reminding them to look for the digital invite.
- Begins the telehealth visit by obtaining consent, and verifies the patient's identity.
- Reviews the COVID screening questions with the patient and/or caregiver.
- Reviews and documents the current wound care products being used (i.e.,dressing/cellular and/or tissue-based product for skin wounds/negative pressure wound therapy, off loading device) and assesses the wound drainage and odor, patient's pain and review of systems since the last visit.
- Reviews and documents medication reconciliation, review of allergies, social, family and psychosocial issues.
- Records vitals such as: temperature, respiratory rate and blood pressure if the patient has a home blood pressure machine.
- Reviews smoking history
- Observes the patient removing their dressing/device, monitors this process and uses this opportunity to educate the patient on how to evaluate the wound, the surrounding skin, the products being used and the progress thus far.
- Connects the patient to the physician's/QHP's digital technology.

The physician/QHP then engages the patient using their digital technology to:

- Conduct a physical exam which can include eyes, mouth, neck, extremities, digits and nails, mental status and psychological status.
- Provide a detailed evaluation of the wound and peri-wound skin including attempts at measurement and a qualitative assessment of the wound bed and surrounding skin.
- Review past medical history
- Ask questions surrounding the current status of contributing chronic co-morbid medical conditions
- Provide recommendations.
- Decide upon a treatment plan and explain that treatment plan to the patient and family.
- Review anticipated healing course and next steps including visit frequency.

After the physician/QHP completes their telehealth exam/visit, the PBD wound nurse conducts a 10 – 15 minute post visit care coordination. This includes the following:

- Observing the patient apply their dressing/NPWT/off-loading device and educating the patient ~~h~~how to improve their technique.
- Reviewing the findings of the telehealth visit.
- Scheduling the next visit in the system and closing the visit.
- Ordering all dressings, dNPWT and all other supplies/equipment as needed by the patient
- Organizing home health visits if necessary

If, during the telehealth visit, the physician/QHP determines the patient would benefit from a diagnostic test, application of a cellular and/or tissue-based product for skin wounds, hyperbaric oxygen therapy, etc, a face-to-face encounter is scheduled. This allows the wound care clinical team to triage which patients need clinic visits and which patients can be safely cared for virtually. Although the amount of time, resources used, and documentation are comparable between face-to-face visit and the telehealth visit, the current originating site reimbursement is not comparable. The current $26 reimbursement is not adequate for the services being provided by the PBD wound nurse and for the digital technology resources utilized.

Recommendations: Since medical care continues to be delivered, the Alliance is providing below the following recommendations to CMS for its consideration in order to alleviate this dilemma:

1. Before CMS established the G0463 code, CMS required PBDs to create a clinic visit mapping system for the new patient clinic visits (99201-99205) and for the established patient clinic visits (99211 – 99215). PBDs still use their clinic visit mapping system to determine the clinic visit codes reported to private payers. These codes are currently on the list of Medicare Eligible Telehealth Services.

   Therefore, the Alliance recommends that the clinic visit levels determined by the PBD's mapping system should be used to report the PBD work that supports the physician/QHP's telehealth services. In their electronic health records, the PBDs can indicate that the clinic visit was provided via telehealth by stating "telehealth" in the "other" section of the EHR. Based on the acuity scoring, the facilty would bill the appropriate level code, which the Alliance believes would, in most cases, be 99211, 99212 or 99213 Therefore, the PBD telehealth claim would include the appropriate level of clinic visit, the PO modifier to indicate the on-campus PBD is temporarily relocated to the patient's home, and the CR modifier to indicate the telehealth service is catastrophe/disaster related. While CMS has not set an APC relative weight for these CPT codes since CY 2013, even the 2013 rate would be more appropriate than the current $26. This is an easy fix to what we believe is inadequate reimbursement.

   We recommend that CMS should permit hospital owned outpatient wound/ulcer management provider-based departments to use the clinic visit levels that are determined by their mapping tools for their services of supporting the telehealth vists provided by their wound/ulcer management physicians/QHPs. In most cases, the mapping systems will track to 99211, 99212 or 99213. This will allow for increased, but appropriate, reimbursement for services that are being performed by the provider based department to support the telehealth visits provided by their wound/ulcer management physicians/QHPs.

2. CMS could establish an enhanced origination site code which would increase the reimbursement currently being provided. Should CMS determine that this an option, we request that CMS provide guidance or examples of what services would qualify for use of the enhanced origination site code.
3. Finally, CMS could simply just increase the origination site fee to be more representative of the services that are actually being provided.

G0463 Clarification

The Alliance members and/or staff have participated on every CMS office hour call and every MAC call related to COVID 19 and the waivers. Despite that, most of our members as well as most participants on these calls still are confused about when to utlize the G0463 code and need clarification. CMS has repeatedly stated that indviduals should look at the FAQ/Guidance document issued by the Agency or could go the MAC to obtain clarification. Yet, the MACs state on their conference calls that they do not have the authority to make waiver changes and are simply following guidance provided by CMS. Several months have gone by and CMS still has not provided the type of specific guidance needed on when to utilize the G0463 code. Unfortunately, the Frequently Asked Questions/Guidance document that CMS points to when responding to callers questions is not specific enough to address the concerns and issues being posed.

Recommendation: The Alliance respectfully requests that CMS publish information so there is no confusion as to when to use or not use this code since this has been requested multiple times by all stakeholders.

Appropriate Use Criteria (AUC) Program Relief

The Alliance further recommends that CMS delay implementation of the Appropriate Use Criteria (AUC) program in CY 2021, and instead urge CMS to continue the AUC Educational and Operations Testing Period through CY2021. The AUC program is currently in a voluntary education and testing period through the end of 2020 and the mandatory program is set to begin on January 1, 2021. However, due to the PHE, providers are unable to fully learn and test the program.

Recommendation: The Alliance recommends that the AUC program should be delayed.

Merit-based Incentive Payment System (MIPS) Program Relief

As a result of the current PHE, providers are limited in the number of services they are providing; thus satisfying MIPS reporting requirements for performance year 2020 has become challenging, especially as it pertains to the quality performance category and its 365-day reporting period. While we appreciate that CMS has granted relief to providers and offered a neutral adjustment for CY 2021 for those who were unable to complete data submission in CY 2019 due to the pandemic, we urge to implement the following recommendations since they would significantly help providers during this very uncertain and challenging time.

Recommendations:

- Modify the reporting period for all MIPS categories for CY2020 to any 90-day period, and

- Extend its 2019 automatic and application-based Extreme and Uncontrollable Circumstances policy to the 2020 performance year to protect clinicians and group practices that are unable to satisfy the program requirements this year.

Competitive Bidding

During the PHE, the Alliance recommends that the competitive bidding program (CBP) be paused. While 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 way the cost of caring for these patients must be allocated over a shorter period of time.

Recommendation: The Alliance 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.

Additional Recommendations and Areas in Which We Are Still Seeking Clarification

In addition to our specific comments and recommendations, we are still seeking clarification on the following provisions that were outlined in our April 6th letter to the Agency, as well as contained in our May 29, 2020 comment letter to the Agency on the first interim final rule with comments that still have not been addressed:

GENERAL WOUND CARE REQUESTS/CLARIFICATIONS

1. COVID-19 has also led to the necessity of treating many wound patients in their residences--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 skin 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 the MACs on the importance of enabling patients to be treated at all appropriate sites of care outside traditional office and hospitals settings.**
2. While we recognize that CMS and the OIG have waived certain aspects of the Stark and Anti-kickback statutes, **we request 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, 12 and 22.**
3. 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.**
4. **Allow PBDs and physician offices 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.

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 Surgical Dressing Benefit outlined in Local Coverage Determination (LCD) Surgical Dressings (L33831) and associated Local Coverage Article (A54563).**

   a) **Relief of certain elements of the wound evaluation hampered by telehealth**

   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 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.

   Recommendation: 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 telehealth) 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 telehealth as a restriction.

2. **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 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 temporarily waive the NCCI edits in order to allow for appropriate quality of care to be provided so total contact casting (TCC) (CPT 29445) can be provided 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. Current NCCI Edits disallow for TCC on the same date of service as another procedure. Permitting both medically necessary procedures to take place on the same date of service allows for appropriate quality of care to be provided to the patient while minimizing their risk of exposure.

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.

Sincerely,

Marcia Nusgart, R.Ph.
Executive Director