



September 27, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
Attention: CMS-1717-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Submitted Electronically to <http://www.regulations.gov>

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc.

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), I am pleased to submit comments in response to the proposed CY 2020 Hospital Outpatient PPS. In addition to submitting these comments, the Alliance would like to request a meeting with CMS to further discuss the packaging of Cellular and/or Tissue Based Products for Skin Wounds (CTPs) and the proposed payment methodologies for these products.¹

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>.

Wound care is a national epidemic masked by co-morbidities. Chronic wounds impact nearly 15% of Medicare beneficiaries (8.2 million patients). If we include wounds as a secondary diagnosis, the cost for wounds may range from \$31.7 billion to \$96.8 billion per year.² The importance of this study is it shows that

¹ In 2013, the Alliance led a multi-year effort that engaged clinical practitioners, scientists and manufacturers to update the clinically inaccurate term of “skin substitutes” with a consensus agreement to name this class of products Cellular and/or Tissue-based Products for skin wounds (CTPs). This was adopted by the standard setting organization ASTM which developed its unique standard guide (F3163-16). We urge CMS to adopt and use this term that has been accepted by the wound care community and by many Medicare contractors in their LCDs on this subject.

² Nussbaum, Carter, Fife et.al., An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds, Value in Health Jan. 2018.

the **hospital outpatient settings** drove the greatest proportion of costs – demonstrating a **major shift in costs from hospital inpatient to outpatient settings**.

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. These patients have high rates of readmission, total cost of care, lengths of stay, and antibiotic utilization. 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.

There are several provisions in this proposed rule that impact wound care. Our comments will focus on those proposals. Our specific comments follow.

General Supervision for Hospital Outpatient Therapeutic Services

General supervision, as defined in 42 CFR 410.32(b)(3)(i), means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. As identified above, wound *management* is complex and treated with a multidisciplinary team of clinicians. While there are several procedures that are appropriate for general supervision, there are others that would not be appropriate. The Alliance appreciates that CMS is trying to ensure that patients receive the care they need – especially in rural areas - by lowering the level of supervision required for therapeutic services in the hospital outpatient setting from direct to general. However, **we are concerned about a broad sweep to move all therapeutic services from direct to general supervision.**

The Alliance does not agree with the Agency that all therapeutic services should move from direct to general supervision. While the Alliance agrees that some supervision rules need to be reexamined, we request to meet with the Agency prior to the proposed rule becoming final so as to help CMS identify what wound care procedures should be excluded from the general supervision requirement. At the very least, HBOT should be excluded.

One of our members, the American Association for Wound Care Management, submitted in its comments the rationale for keeping HBOT under direct supervision:

Under the current regulations which require direct supervision for HBOT, the supervising physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. Should a complication arise during a patient's HBOT session, the physician must be present, interruptible and available in order to respond.

Under general supervision, the supervising HBOT physician may not be present and would have to rely upon untrained individuals to manage these complications with instruction being given over the phone. In that scenario, the immediate response to an emergency could be left to a medical assistant or basic EMT whose primary responsibility is chamber operation and observation of the patient. The required assessments and medical interventions are beyond the scope of this potentially unlicensed individual.

As noted above, the occurrence of complications with HBOT is rare but when one does occur, it requires that a physician be able to physically assess and intervene. The current proposal to move supervision from direct to general for HBOT could compromise the quality of care and put patients at risk.

Many practitioners in the multidisciplinary area of wound care are under orders from a physician in which no supervision is required. The Alliance wants to ensure that this proposal does not impact them. If CMS does move forward with this proposal, there should be a caveat regarding the level of supervision required and specifically, that the supervision level should be based on what a State Practice Act allows a practitioner to perform. The carte blanche move to general supervision should only apply when a State Practice Act is silent on supervision requirements.

Finally, in consideration of physician supervision, we remind CMS that this should apply to all physician types, including podiatric physicians. Podiatrists are defined as physicians in Medicare under Section 1861(r)(3) of the Social Security Act.

Prior Authorization

CMS identified 5 procedures which would require prior authorization including vein ablation. The Alliance does not agree with using prior authorization for procedures, especially when that procedure is utilized to treat chronic wounds that threaten both life and limb. Prior authorization creates delays in care that chronic wound care patients cannot afford. Using Medicare Advantage (MA) as an example, a recent study conducted by the Office of Inspector General (OIG) found that beneficiary and provider appeals of preauthorization and payment denials were overturned 75 percent of the time by MA plans reviewing their own initial denials, and further appeals were overturned at higher levels of review.³ The OIG noted that these findings raise concerns that MA beneficiaries are being denied services that they should have received. The report also emphasizes that beneficiaries and providers rarely use the appeal process, suggesting an even greater problem and supporting our previous statement that prior authorization leads to a delay in care or lack of access to care. Additionally, CMS has not historically conducted any analysis on the cost of care to those patients that are denied care. Prior authorization may be considered for elective procedures, but cannot and should not be considered for limb threatening issues where time is critical.

The basis for our response stems from the Prior Authorization model which CMS implemented for hospital outpatient clinic use of non-emergent hyperbaric oxygen therapy (HBOT) from 2015- 2018. The demonstration was implemented poorly with little to no oversight by CMS and the claim denial rate was inconsistent (60-70 % in one jurisdiction and only 15-20 % in the other two jurisdictions).

In reviewing the impact of the HBOT demonstration, CMS focused solely on cost savings and not on patient care, patient access, or patient outcomes when treatment was denied. So, while prior authorization may have theoretically saved some money, CMS did not conduct any analysis on the cost of care to those patients that

³ HHS Office of Inspector General (2018). Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials. OEI-09-16-00410. Downloaded from <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp> on February 27, 2019.

were denied HBOT. (In fact, there was NO cost savings to the system after the project was completed and evaluated).⁴ The cost to utilize other advanced adjunctive therapies and to continue some treatment protocol on those patients that were denied authorization should have been examined. In fact, patients sought treatment in jurisdictions that did not have the prior authorization requirements.

Furthermore, the burden on clinicians to demonstrate and document medical necessity per patient submitted for prior authorization was tremendous. As CMS is trying to eliminate documentation burdens on clinicians, as part of the Agency's Strategic Initiative of "Patients over Paperwork", requiring prior authorization goes contrary to that very notion and is not an initiative that our physician specialty societies and clinical association members can support.

Finally, once a clinician requests it, prior authorization is usually granted which only delays necessary treatment for patients who require the procedures being authorized. While 4 of the 5 procedures CMS has proposed to obtain prior authorization are cosmetic in nature, vein ablation to treat patients with a venous leg ulcer is not a cosmetic procedure and it should not be required to obtain a prior authorization which would delay necessary treatment for patients with a serious condition. Venous stasis ulcers affect millions of Medicare beneficiaries, carry with them significant morbidity and mortality as well as tremendous costs. Delaying and withholding care for this limb-threatening condition will certainly increase costs, prevent or delay access to much needed care, and negatively impact the associated morbidity. In fact, the New England Journal of Medicine⁵ recently published a study which shows that the sooner vein ablation is done, the sooner the wound will heal. To delay the procedure to obtain prior authorization is unwarranted and can have significant consequences for the patients who have a venous stasis ulcer who require a vein ablation procedure. The Alliance urges CMS to remove vein ablation from the list of services requiring prior authorization.

Payment Methodology for CTPs

General Comments

Over the course of the past few years, CMS has attempted to address the payment for CTPs in the hospital outpatient and ASC settings.. With the constantly fluctuating payment rates and perverse incentives, CMS has recognized that the high / low cost tier system created by the Agency has not worked. In the CY 2019 proposed rule, CMS solicited feedback on 4 possible payment methodologies moving forward. Two of the proposals were variations of the current system. The Alliance quickly dismissed those options as they would not have solved the issues at hand. The remaining two options, episodic payment and movement to a single APC, seemed to be better options but still required more information in order to ensure that the complexities of the wounds being treated were taken into consideration. In the CY 2022 rulemaking, the Agency is seeking continued feedback on these options.

⁴CMS reports can be found on line at : <https://innovation.cms.gov/Files/reports/mpa-hbo-fnlevalrpt-fg.pdf> and <https://innovation.cms.gov/Files/reports/mpa-hbo-fnlevalrpt.pdf>

⁵ Gohel, Manjit S.et.al A Randonized Trial of Early Endovenous Ablation in Venous Ulceration, N Engl J Med 378:22 May 31, 2018; 2105-2114

We believe that the information that CMS continues to provide on these options is so vague that it is difficult to take a position, make a recommendation, or offer meaningful substantive comments. **Therefore, the Alliance is not recommending any of these options for CMS to put in place for CY 2020 but have given the Agency issues to consider when evaluating them.** We suggest that CMS answer the following questions as the Agency evaluates the various payment options:

- Would the payment be retrospective or prospective?
- Would the payment be per wound?
- How will CMS take into consideration the comorbid conditions and other complexities presented by a wound care patient requiring a CTP?
- How would any complexity adjustment be determined and measured?

Chronic wound patients are a heterogenous group and thus, the treatment is highly individualized to not only patient severity (comorbid conditions such as diabetes, peripheral vascular disease, malnutrition, etc) and wound severity (wound duration, depth, size, etc), but numerous socio-economic factors. As such, a patient's rate of healing when utilizing a CTP is also very individualized making the establishment of an episode of care, a single APC or C-APC very challenging.

The Alliance is committed to helping CMS find a sustainable payment solution that will improve clinical outcomes for Medicare beneficiaries while addressing CMS costs.

Specific Comments

CMS has recognized that treating patients with chronic wounds is complex and any payment methodology will need to consider those patients. The current proposed rule is seeking feedback on a number of different issues which the Alliance will address in the following order including:

1. Whether to continue to freeze the current payment system
2. An episode of care payment methodology
3. A single APC payment methodology

The Alliance has also addressed a C-APC payment methodology as well as a requirement for data collection.

Freeze of the Current System

The Alliance agrees that CMS should in fact freeze the current payment system for CTPs and placement of products until a new payment methodology is created and implemented as there is too little known about the other options discussed in the proposed rule and would result in lack of predictability and disruption in provider services.

The Alliance believes that there should not be any new payment system in which CMS is still seeking feedback to be put into place in FY 2020. The information provided by CMS on any of the payment systems identified in this proposed rule is extremely vague and the Alliance agrees that any payment system CMS is still seeking feedback on should not be put into place in CY 2020. The skeletal information that CMS has put forward (as well as information placed in proposed rules in the past few years) still leaves many

questions to be answered before meaningful, detailed comments can be provided or any system can be supported by our membership. Wound care is too complex and it appears that CMS is still not taking this fact into consideration when developing options for a payment methodology change.

CMS has requested feedback on a number of different initiatives. The Alliance was hoping that CMS would have been able to provide more detailed information on how the roll out of any new payment methodology would be implemented. There are issues with each of these payment approaches. While not taking a specific position on any of the proposals, the Alliance requests that CMS consider the following when considering the options:

Episode of Care

In this proposed rule, CMS is seeking further comments on a lump-sum episode based payment for a wound care episode, including addressing some issues that commenters have identified in previous discussions of such a methodology. In addition, CMS notes that it is seeking comments on a similar possible policy construct on the establishment of a payment period for CTP application services between 4-12 weeks with the applications ranging from 1-3 CTPs and would assign the codes to comprehensive APCs with the option for a complexity adjustment to a small number of cases that require more intensive treatment. As we have stated in our previous comments there is ambiguity in this methodology and we still have a number of questions as well as items for CMS to consider including the following:

- Does CMS intend to consider each wound as its own episode? Literature shows that most patients have 2.2 wounds.⁶
- How will CMS recognize multiple wounds being treated?
- How will CMS account for the patient that requires more than 12 weeks and 3 applications in order to heal their wound?
- What is the data CMS is utilizing to determine 4- 12 weeks and 1-3 applications?
- What is the literature CMS has utilized to support 1-3 applications? The number of applications cited in this policy is contrary to published studies.
- If 4 weeks is defined as an episode, but the wound has not healed at the end of the 4 weeks, will another 4 week episode be approved and payable at the same rate as the first 4 week period even if less resources are required in the second episode from that of the first due to pregression of healing?
- Are proper measures in coding, claim submission and processing in place to account for multiple concurrent wound episodes?
- With respect to the C-APCs discussed in this section, would CMS utilize the existing APCs (5053, 5054, 5055) or create new ones?

With respect to the complexity adjustment, CMS has developed a process for identifying and applying complexity adjustments to certain combinations of codes as a part of the comprehensive APC policy. The Alliance not only supports the complexity adjustment as an important tool to help ensure payment under the comprehensive APC methodology is adequate, but we also believe that for the treatment of chronic wound care patients, it is mandatory. That said, we have concerns regarding how CMS applies complexity criteria

⁶ Fife, Caroline; "Keeping Skin in the Game" for the Quality Payment Program" Today's Wound Clinic vol 11 Issue 6 June 2017

and the resulting APC assignments for codes within comprehensive APCs, and we believe that important opportunities to refine the methodology remain.

As stated repeatedly, while wound care patients are complex, they have have different levels of complexity. The Alliance would appreciate the opportunity to meet with CMS to define these levels of complexity.

It is imparative that complexity adjustments be made when treating patients who require a CTP, however, CMS has not identified any information in the proposed rule addressing the complexity adjustments for patients requiring a CTP except to state, that complexity adjustments “could be applied for the relatively small number of cases that require more intensive treatments”.

The Alliance asks:

- How will CMS determine what patients will be permitted to receive a complexity adjustment?
- Why does the Agency believe that there will only be a small number of cases that require intensive treatments?
- What factors will CMS utilize the make that determination?
- How will CMS define the all the different levels of complexity?

The Alliance would be happy to work with CMS to address these necessary and important issues.

Single APC

With respect to a single APC, we note that CMS has neither proposed the idea nor provided sufficient specifics for us to comment on this concept of a single APC other than in general terms. While it might be easy to implement, we believe that there are too many different CTP products and too much variability in sizes of these products for just one payment category. We also maintain there is too much variability in the patient and wound severity in those beneficiaries receiving these products which should play a role in the payment determination. Combining the low-cost and high-cost CTPs into one APC level could undervalue higher cost products and overvalue lower cost products. This will likely continue to incentivize providers to make treatment choices based on product cost, and not overall patient care or product efficacy.

Since the single APC is paid on each encounter, this methodology also incentivizes providers to utilize less expensive products that may require more frequent applications. Furthermore, as stated, wound care patients are complex and no two patients are the same. The Alliance questions how will CMS take into account the significant differences in resource use for some patients in this payment option? Furthermore, a single APC has the potential to make treatment of larger wounds cost-prohibitive, which increases morbidity and utilization of more costly healthcare resources.

Since the single APC proposal has already been floated by CMS last year, it is disappointing that CMS has not provided more information regarding how the Agency would implement such a change given the feedback it recieved last year. As with last year’s proposal, more information is needed in order to provide substantive feedback and comment.

C- APC

During the Hospital Outpatient Advisory Panel meeting held in August 2019, the Panel recommended that CMS consider creating a C-APC for CTPs after performing an analysis to consider this methodology as an alternative. Prior to this recommendation, CMS indicated that they had already collected data for this payment system, yet that information was not fully discussed or disclosed during the Panel deliberations.. The proposed rule contains no detailed information on this mechanism either; and thus, the Alliance does not support implementation of this payment system for CY 2020. Nonetheless, the Alliance would like to address the Panel recommendation in our comments. The Alliance is concerned that again, not enough information has been provided regarding this payment methodology even during the panel deliberations before the Panel made this recommendation. CMS would need to provide a more complete payment concept that fully details the methodology, an adequate and transparent timeline in order for meaningful comments to be provided.

CMS introduced the general concept of comprehensive APCs (C-APCs) in the CY 2014 Outpatient Prospective Payment System rule. Since that time, the Agency has continued to create additional comprehensive APCs (C-APCs) and to make modifications to the policies governing the development and use of these payment groupings.

C-APCs were first used on Medicare claims in CY 2015. The CY 2017 OPSS rates represented the first full year of claims data used for rate setting since the establishment of C-APCs. The Alliance has concerns regarding whether the rates associated with the comprehensive APCs adequately or accurately reflect all the procedures and costs associated with those APCs especially as CMS continues to expand the number of packaged and bundled services – including now for the use of CTPs.

We also question how a C-APC can be implemented for just CTPs since by definition a C-APC is more encompassing? The Alliance would not support a C-APC for all of wound care and is very concerned about how CMS would create this type of methodology for just CTPs.

Data Collection

As in previous comments submitted on this topic, the Alliance urges CMS to ensure that the data the Agency is collecting and reviewing to set the rates for any payment system is accurate. CMS's ability to calculate appropriate payment rates depends on the accuracy and completeness of the claims data. To ensure that the agency has the data it needs, the Alliance continues to urge CMS to require complete and correct coding for CTPs. This will ensure that appropriate payment is being established for any payment methodology established by CMS. CMS should never see the number "one" unit being billed for these products. CMS and its contractors do reviews for these services all the time. If the contractor sees "one" unit being billed, it should kick the claim out of the system in the same way that it would for an overpayment. The contractor, in this case, should then request that the billing facility correctly bill for the products.

Unless CMS establishes edits to accurately reflect the number of square centimeters (units) that have been applied, the APC Group assignment will continue to be inaccurate. APCs are evaluated every year. It is the Alliance's recommendation - and has been for the past three years - **that CMS educate facilities on the correct coding and billing of CTPs.** This will ensure that appropriate APC Group assignments are made which reflect the true costs of the CTPs. Our other recommendations include:

- CMS mandates its Medicare Administrative Contractors to establish edits that reject claims whose CTP codes reflect one wound size and whose products codes do not reflect a similar size reflected in the units reported. If only one unit is coded and billed for wounds that are 20 sq.cm in size, or if less than 100 units of sq. cm of product is reported when the procedure is reported for a 100 or more sq. cm size wound, then the claim should be kicked out of the system.
- CMS should also edit for facilities that do not purchase CTPs to adequately cover the base of the entire wound and the wound margins which are not large enough to allow for the surgeon's choice of the fixation. The contractor should request that the facility purchase the right size product to cover the entire wound and correctly code the correct number (units) of sq. cm applied.
- The Alliance urges CMS to issue a Medicare Learning Network Matters® (MLN Matters®) article and initiate edits to describe the proper coding and reporting of units. This will ensure that accurate, appropriate claims are submitted – which in turn will ensure accurate, appropriate APC Group assignments for CTP products. Accurate claims reporting is absolutely necessary and it is up to CMS to ensure this occurs.
- In the meantime, CMS needs to use other data to establish accurate APC groups for packaged CTPs.

While we have consistently made these recommendations – CMS has stated in the response to comments that it is not the Agency's responsibility to monitor whether hospitals are accurately billing for these products. However, **the Agency's ability to calculate appropriate rates for any payment methodology adopted depends on the accuracy and completeness of the data used to make this calculation.** As such, the Alliance requests that CMS go back to utilizing ASP data rather than claims data for establishing its pricing for these products or at the least invoice pricing.

ASP data comprises manufacturer-certified actual sales prices for these therapies, which provide a more accurate reflection of true market cost than the hospital claims data, which estimate costs from product-specific charges reduced by departmental ratios of cost-to-charges overall. It is well established that claims-based cost data are subject to charge compression and do not reflect accurate costs for individual treatments. Alliance members previously submitted evidence to CMS that ASP data for these products are quite consistent with hospital acquisition cost data. However, CMS could also check the ASP against the ECRI report information in which hospitals have to report. This would allow for a check and balance in the rates to ensure that manufacturers are not inflating their ASP data.

To further delineate our recommendation to utilize ASP pricing and to validate those CTPs being utilized in the hospital outpatient or ambulatory surgical center settings for wound closure, CMS should request manufacturers segregate out those products' Stock Keeping Units (SKUs), or other product identifiers, that are specific to CTPs 15271-15278 and C5271, C5273, C5275, C5277 (APC 5053 and 5054) during their quarterly ASP reporting and only use those codes to determine the ASP. Many CTPs have applications that are outside of the jurisdiction of the proposed rule (e.g. those used in association with CPT 15777) and those price considerations should not be utilized to determine the cost of the product in the settings under this proposal. This request is consistent with using the claims data on the 2018 proposed rule. To ensure manufacturers comply with the reporting, CMS should establish a reporting threshold commensurate with the upper limit of a wound treated in a hospital outpatient department. The Alliance along with the United States Wound Registry is happy to work with CMS in identifying the upper limit.

Additionally, while submission of quarterly ASP data is made to the CMS ambulatory services department that processes ASP data for drugs and CTPs, this is not the group that oversees that outpatient payment policy. It is our understanding that an agreement made with the outpatient group on ASPs for CTP sizes used on wounds treated in outpatient settings is not binding on the group responsible for ASP reporting, as stated above. Thus, in order to maintain accurate data, the Alliance maintains that only ASP reporting for CTPs used to treat wounds in the hospital outpatient setting should be used to accurately establish the APC rates. Lastly, CMS should publish all the of the reported ASP prices for CTPs.

Finally, we also urge CMS to examine ways to ensure transparency of the data being used for these calculations.

In conclusion, the Alliance highly recommends that no matter what payment methodology is put forward and implemented in future years, accurate data must be utilized, and most importantly, the Agency must work with wound care stakeholders in the development of that methodology, be transparent in the process and in the data utilized to establish the payment rates, and should implement the methodology on a small scale or as a demonstration project in a small sample area before it is rolled out nationally. The Alliance requests the opportunity to meet with CMS to work with the Agency to find a good, long term and equitable solution on these issues

Advisory Panel on Hospital Outpatient Payment Meeting Schedule

The announcement for the HOP Panel meeting along with the deadline for submitting statements is usually published in the Federal Register several months prior to display or publication of the proposed rule. Historically, proposed rules are published with enough time for stakeholders to analyze the proposals and submit relevant comments for the Panel's consideration and at the same time with adequate time for the Panel to review the comments submitted. In recent years, delayed release of the proposed rule has led to a shortened period of time for stakeholders to develop comments for the Panel meeting – necessitating an extension of the deadline for statement submissions. This year, the proposed CY 2020 rule was released on July 29, 2019, one day before the initial deadline (July 30th) for filing statements. While CMS did extend the statement filing deadline from the initial date of July 30th to August 5th, statements for the Panel meeting were still due only 4 business days following release of the massive proposed rule. This led to a very hasty and truncated period for stakeholders to analyze the rule and to submit relevant comments.

This process has proven to be ineffective for the past three comment cycles. A reasonable period between publication of the rule and submission of statement is needed to allow stakeholders an opportunity to fully comprehend proposed changes and to synthesize those changes into coherent and meaningful recommendations for the Panel members consideration. Continuing to relegate stakeholders to such an abbreviated period for filing comments is a disservice to both stakeholders and Panel members. It is imperative for CMS take action to resolve this issue. As such, the Alliance recommends that the approach to setting deadlines for the meeting statements be modified to avoid this situation from arising in the future. **The Alliance recommends that the Panel meeting should be established 21 days from the display of the proposed rule.** This will allow for a reasonable timeframe for analysis and statement development by stakeholders as well as time for Panel members to review and absorb the comments submitted.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. We look forward to meet with you to discuss our comments in the upcoming months ahead. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." The signature is written in a cursive, flowing style.

Marcia Nusgart R.Ph.
Executive Director