



September 24, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Re: CMS-1695-P, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for Potential CMS Innovation

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 2019 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems as well as changes to the Quality Reporting Programs. 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

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)

care research. A list of our members can be found on our website:
<http://www.woundcarestakeholders.org/about/members>

GENERAL COMMENTS

CMS has proposed four payment methodologies for consideration related to the packaging of CTPs. However, the lack of significant detail is impacting our ability and those of other stakeholders to provide meaningful specific comments on CMS's approach. As such, any recommendation or suggestion that the Alliance provides with respect to the proposed payment methodologies is general in nature and we would welcome the opportunity to work with CMS in developing a payment methodology that will not negatively impact the patients that our members treat.

Most wound care patients have serious multifaceted and/or chronic comorbid medical conditions. Non-healing wounds occur among patients with diabetes, peripheral vascular disease (nearly as common as coronary artery disease and stroke), or as a result of unique medical problems (e.g., sickle cell anemia, vasculitis), or in association with immunosuppression (e.g., AIDS, steroid use or transplantation medications). Chronic wounds are clinically devastating and have an extraordinary impact on Medicare beneficiaries. Wound healing is a complicated process directly influenced by the status of medical comorbidities, the local wound environment and also by the overall physical condition of the individual. The process of wound healing involves metabolic, structural, biochemical, and patient factors in a unique way. Wound healing is not a single event; it is a result of intricate overlapping processes. Despite guideline-suggested interventions, there are many combinations of individual wound characteristics which contribute to the challenges of healing a wound. The order and combinations of treatments used are varied and may be directed anywhere along the wound healing cascade. CTPs are one of several advanced therapies that our members utilize in treating their patients with chronic non-healing wounds and as such we offer the following specific comments.

SPECIFIC COMMENTS

CTP Packaging and Payment Methodology

Data

The Alliance recommends that in 2019, CMS return to the basics of coding, coverage, and payment for CTPs by paying for the products separately from the procedure based on the reported invoice price of the CTP and by paying for the add-on procedure codes. By returning to this methodology, CMS will be able to collect data built on accurate clinical application, quality information and true product costs. If the Provider-Based Departments (PBDs) are required to report data and are educated how to accurately 1) select the right size product for the wound, 2) report the number of sq.cm. applied as well as the sq. cm. wasted 3) report the invoice price per sq. cm. on their submitted claims, 4) report the application code and the add-on code to reflect the size of the wound, and 5) require that clinicians report CTP outcome data in a wound care specific qualified clinical data registry (QCDR) or a QCDR which contains specific wound care quality measures. CMS should begin to see a shift from volume-based usage to value-based usage. After collecting this data, CMS and the wound care stakeholders should have accurate clinical and cost data which could be used for

adjusting payment methodologies. This information would then be available to stakeholders which will provide transparency that has been lacking in the current system.

CMS continues to hear concerns from stakeholders that the packaging policies may be hampering patient access or resulting in other undesirable consequences. CMS notes that given that aggregate spending and utilization continue to increase for covered outpatient services, it is unclear what, if any, adverse effect packaging has on beneficiary access to care. The Alliance applauds CMS for recognizing that the current payment system for these much-needed products is seriously flawed.

The Alliance recognizes that CMS is concerned about the following:

- The escalation in overall health care spending, and along with that the rising costs associated with the use of CTPs.
- Potential inappropriate use of CTPs, which may not lead to good outcomes or improved patient care, but results in wasteful spending of healthcare dollars.
- The current two-tier packaged payment methodology is not having the intended results of slowing cost growth; but instead has created the potential for 1) manufacturers to manipulate the reimbursement rate formula (mean unit cost [MUC] and per day cost [PDC]) by inflating product prices in an attempt to be classified as a high cost product, and 2) Provider Based Departments (PBDs) to only select high cost products which are more profitable and/or products with pass through status which are the most profitable.

Prior to the packaging of CTPs, the Alliance met with CMS and submitted very detailed comments as to why we believed packaging was not appropriate for CTPs. The information we submitted back in 2013 is still appropriate today; thus, we have **included those comments along with their corresponding Attachment A and B as we did when we submitted our comments to CMS in 2017.**

Since 2014, CMS has issued regulations to package CTPs. From the inception of these regulations, CMS created perverse incentives which have resulted in unintended consequences. Instead of controlling costs, packaging has forced PBDs to significantly reduce or cease using CTPs for the sickest of patients that require product greater than 25 sq. cm., choose products based on cost/reimbursement rather than clinical efficacy, and virtually eliminate the low cost products which are less costly to the patient and the payer.

Our clinical members are providing excellent care to their patients with wounds. Yet, despite the use of appropriate debridement, dressings, off-loading, compression, etc., a subset of patients fail to heal and require advanced modalities such as CTPs. The current Outpatient Prospective Payment System (OPPS) packaged payment of CTPs and of add-on codes, as well as allowing pass-through status of CTPs, has resulted in unintended consequences for both patients and payers. At a time when CMS claims to be focusing on the Triple Aim (Improving the patient experience of care [including quality and satisfaction]; Improving the health of populations; and, Reducing the per capita cost of health care) and emphasizing value rather than volume, the OPPS payment system for CTPs has resulted in higher costs for both patients and payers.

CMS has already stated that there have been unintended consequences due to the current system of packaging CTPs. The Alliance has identified some of those unintended consequences and have outlined solutions for CMS to consider. We have detailed these in the chart below.

Stakeholders	Unintended Consequences	Recommended Solutions
<p>Hospital owned outpatient wound care provider-based departments (PBDs)</p>	<ul style="list-style-type: none"> • Packaging of product and application of add-on codes created perverse incentives for PBDs to choose products that either had pass-through status OR were in the high cost tier. • Inaccurate coding and charging significantly skews claims data. • Data from both the manufacturers and CMS has failed to recognize that patients have on average 2.2 wounds (all types of wounds are considered) and patients with venous ulcers average 3 wounds per patient. Because packaging reduced the size of the product that the PBDs can afford to use, it is not possible for all wounds to be treated at the same time. Thus, wounds are treated in sequence. This contributes to the average patient requiring treatment for more than 7 months while each wound is treated – one at a time. (Using data from the US Wound Registry [USWR] which provides information that cannot be obtained from claims), the average number of CTP applications PER WOUND is 3, but since wounds are treated one at a time, the average number of applications PER PATIENT is higher) 	<p>Require PBDs to purchase the right size product for the right size wound</p> <p>Eliminate packaging of CTPs and CTP application add-on codes and require the PBDs to submit the HCPCS code that represents the product used, the number of units purchased, the application code and add-on code(s) which would reflect the actual size of the wound, and their invoice price per sq. cm in field 19 of a paper claim (or collected via a SMART app for efficient analytics later).</p> <p>Pay for the CTP, the application code and the add-on codes separately.</p> <p>Eliminate pass-through status for all CTPs effective January 1, 2018.</p> <p>Publish all the reported ASPs submitted to CMS for the CTPs on the drug and biological file so the physicians have transparency to view the relative costs of the products.</p> <p>Educate providers about the precise requirements through the CMS OPPI Final Rule, Medlearn Matter Articles, MAC webinars, etc.</p>
<p>Patients</p>	<ul style="list-style-type: none"> • The most important impact of package pricing has been to create a racial disparity in access to CTPs. Since the inception of CTP package pricing, the use of CTPs among patients of color has decreased, in large part due to the dramatic increase in copays. Given the unintended consequences of packaged payment on communities of color and low income patients, CMS should exercise caution that these disparities are not further compounded. (Information from the USWR) • The vast majority of CTPs are applied to patients who have Medicare plus a supplemental insurance plan, so low income patients of any ethnicity have been unable to be treated with CTPs or their treatment has 	<p>In addition to the solutions listed above, CMS should collect data based on true wound sizes, correct sized CTPs, true cost of CTPs, primary diagnoses and comorbidities, outcomes, recidivism, etc. This data can be acquired from wound-specific qualified clinical data registries or QCDRs with specific wound care quality measures, along with claims data. CMS will need to work with registries to ensure that they can obtain the needed discrete data as part of the measure reporting process (e.g., direct from EHR data transmission or FHIR interface)</p> <ul style="list-style-type: none"> • In addition to risk stratified healing rates available for venous ulcers and diabetic foot ulcers, CMS could work with wound specific Qualified Clinical Data Registries (QCDRs) to develop an “all cost” quality measure that

	<p>been limited. (Data from US Wound Registry)</p> <ul style="list-style-type: none"> CTP products were often selected based on the PBDs' possible profit margins Patients with large or multiple wounds that total >25 cm² have not received treatment with CTPs because packaging of the product and the add on procedure codes make application of very large products not cost effective Patients often stay in service for months since all the wounds cannot be treated simultaneously 	<p>captures the entire episode of care in the outpatient setting and its cost, reportable through the SMART app. These data can be used to design future reimbursement strategies. The Alliance is available to discuss how these data collection tools can be easily accessible.</p>
Manufacturers	<ul style="list-style-type: none"> Incentivized by FDA to perform clinical trials with wounds that have no resemblance to real world patients due to exclusion criteria. This leads to RCT data that is without value in selecting CTPs in clinical practice Incentivized by CMS to manufacture high cost CTPs and disincentivized to manufacture low cost CTPs Incentivized to develop CTPs that could gain pass-through status and be assigned to the high cost package 	<ul style="list-style-type: none"> Require manufacturers to perform studies to evaluate the effectiveness of their product in real-world patients. This could be done with registry data if reporting was mandated. The necessary fields are already collected by 130 PBDs as proof of concept. In addition to solutions above, require manufacturers of all CTPs to report their ASPs on a quarterly basis. CMS should publish ASPs of all CTPs which are submitted to the Agency every quarter to provide transparency of the relative costs for each product from the ordering physicians As stated above, require PBD to report invoice price per sq. cm. on claims
Medicare Administrative Contractors (MACs)	<ul style="list-style-type: none"> MACs inconsistently provided coverage for CTPs. Medicare patients are not being treated equally In some jurisdictions, coverage policies prohibit real world patients from receiving CTPs, while in others there is no apparent standard, with some MACs not publishing CTP LCDs 	<ul style="list-style-type: none"> Require MACs to cover products with comparative effectiveness studies that meet FDA standards or retrospective studies utilizing real world evidence. Require MACs to set the limitations for application of a CTP to weekly for up to 12 weeks unless the FDA label states otherwise.

The Alliance highly recommends that CMS consider the Alliance's proposed solutions so that accurate outcome and cost data can be collected. After several years of accurate data are reported, CMS and wound care stakeholders should clearly determine the role of CTPs in aligning with CMS's Triple Aim and value-based goals. Without transparency, accurate reporting, adequate payment, PBD education, and aligned incentives, we believe that any of the options presented in the proposed rule will be fraught with more unintended consequences in the future. The proposed solutions should help CMS guide the PBDs to:

1. Use the right product for the wound, as well as the right size product for the wound
2. Reduce waste of product
3. Reduce total cost of care
4. Focus on achieving the best outcomes
5. Lower the potential for recidivism
6. Feel assured that they will be paid correctly when they need to use CTPs for chronic wounds particularly for the worst wounds that exceed 25 sq. cm.
7. Ensure adequate reimbursement for manufacturers to innovate and invest in a still young industry
8. Collaborate with manufacturers to achieve the Triple Aim with CTPs when appropriate

The Alliance requests to work with and be a resource to CMS as the Agency moves forward in addressing the provision of CTPs in the hospital outpatient setting.

Proposed Payment Methodology

CMS's own data shows chronic wounds are a significant economic burden, yet CTPs represent a relatively small cost. The Agency's data shows that nearly 15% of all Medicare beneficiaries receive treatment for chronic wounds. CMS spends an estimated \$28-\$31 billion in direct costs, and as much as \$96 billion in indirect costs for Medicare beneficiaries with chronic non-healing wounds (Nussbaum, Carter, Fife et al. "An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds" *Value in Health* 2017) However, the entire CTP market is valued less than \$1 billion dollars, thus it represents between 1-3% of the total expenditures for chronic wounds. The largest contributors to costs are complications related to chronic ulcers, resulting in hospitalizations, surgeries, and prolonged outpatient care when wounds don't heal.

When examining the total costs to CMS associated with chronic wounds, CTPs comprise a relatively low percentage. Therefore, the Alliance believes CMS should examine ways to solve the previously mentioned issues without using measures aimed at decreasing utilization of CTPs, as this will likely result in poor clinical outcomes and higher overall spending.

CMS has proposed four possible solutions to reduce cost as the current high-low cost threshold has, as CMS has stated, "created perverse incentives and is not working." **A majority of the Alliance members recommend the elimination of the tiered payment system and any variation of this type of payment methodology as it rewards multiple applications of CPTs when fewer may be adequate to heal a wound and incentivizes clinicians to utilize high cost products and products with pass through status.**

Two of the payment methodologies that CMS has proposed: creating a 3rd "middle of the road" package or somehow fixing the current 2-packaged system with a new threshold methodology will not correct the perverse incentives which are increasing total cost of care (and reimbursement) that a packaged system, such as the one that is currently in place, creates. These approaches are simply variations of the tiered system and, like the current system, will not be successful. The Alliance does not support either of these payment methodologies.

As stated in our general comments above, the information provided regarding the remaining two options are so vague that it is difficult to take a position, make a recommendation or provide meaningful substantive comments. For example, if CMS moves towards a single APC or episodic payment methodology, there are many questions that would need answers such as (but not limited to): Would the payment be retrospective or prospective? Will the rates include technical fees, facility fees etc.? Would the payment be per wound? How will CMS take into consideration the comorbid conditions and complexities presented by a wound care patient?

As stated above, patients with chronic wounds heal differently and require treatment that is individualized. Comorbid conditions, underlying etiology, and variations in wound characteristics, such as depth, location, size, presence of ischemia/infection, malnutrition, etc., determine what care is necessary. These patients have high rates of readmission, high total cost of care, longer lengths of stay, and increased antibiotic utilization. Those with chronic wounds often have multiple comorbidities such as diabetes, heart failure, chronic kidney and vascular disease, and their bodies respond differently at various times to various wound healing components. The age of the wound, severity of the underlying venous disease and comorbid conditions, frequency of debridement, patient follow-up intervals, and receipt of and compliance with supportive measures such as 4-layer effective compression bandaging (for venous leg ulcers) or off-loading devices (for diabetic foot ulcers), are important factors in wound healing. As such, a patient's rate of healing when utilizing a CTP is also very individualized making the establishment of a single APC or episodic payment very challenging.

A payment approach that either creates a single APC or provides a single payment for a 12-week episode of care with CTPs would eliminate:

1. CMS artificially creating "winner" (i.e., highly reimbursed) and "loser" (i.e., low reimbursed) CTP categories,
2. Year-to-year risk of movement of CTPs from high to low package as thresholds climb, and
3. The incentive that "more applications" beat "fewer" applications.

However, there are issues with each of these payment approaches.

In terms of the proposed single APC, the Alliance does have a member who believes that while episode payments are a positive approach, there are too many operational challenges to put that system into effect by 2019. This member believes the single APC could serve as a bridge to get to episode payments once the policy details are sorted through. However, a majority of our members are not supportive of a single APC. They believe that a single payment amount for each clinic visit will not address the perverse incentive to keep patients coming back to the clinic for repeat CTP applications or providers to make treatment choices based on product cost and not the most appropriate CTP for patient care. Again, we submit that more information is needed in order to provide substantive feedback and comment.

With respect to the episodic payment of CTPs, the Alliance urges CMS to work with stakeholders in developing an episodic payment methodology for CTPs in order to build this type of system properly and to reduce the types of unintended consequences that are present in the current system. There are issues within an episodic payment system for CTPs that would need to be adequately and accurately addressed. The Alliance could not support an episodic payment methodology unless:

1. The data is addressed as identified above
2. The episodic payment is per wound per patient.
3. There is a mechanism put in place to risk stratify (e.g. by wound size, wound type, patient co-morbid conditions, healing likelihood such as using the Wound Healing Index, etc.).
4. There is an outlier policy.
5. There are multiple levels of payment. The reasons for this includes but is not limited to the following:
 - Clinical outcomes are affected by many factors including wound duration, wound size, number of wounds, risk factors, age, social conditions and especially the type and number of comorbid disease. All of these would need to be taken into consideration.
 - Patients with two or more comorbidities and risk factors will require more treatments than patients with only one comorbidity. For example, a diabetic patient, over the age of 70 that smokes and has sickle cell disease with a diabetic foot ulcer (DFU) on the heel will not heal as easily as a 70-year old with only diabetes and hypertension and a DFU on the dorsal aspect of the foot. There are potentially hundreds of possible combinations and differences in patient histories that CMS would need to consider. Therefore, there **MUST** be risk stratification for any episodic payment for CTPs.
6. CMS is transparent in the data utilized to establish the payment.
7. CMS works with wound care stakeholders to establish the new payment system.

The Alliance would like to be clear – any episodic payments for CTPs **should not be, an all- inclusive bundled payment for all outpatient wound care – including physician payments. Under an episodic payment mechanism for CTPs, other wound interventions such as negative pressure wound therapy (NPWT), hyperbaric oxygen therapy (HBOT), etc. would continue to be paid as they are currently and outside of the episode payment, and physicians would continue to be separately paid for their professional services.**

The Alliance is aware of a CMS contractor, Acumen, who has been working to establish episodes of care for a diverse range of diseases including stroke, coronary artery disease and lower extremity disease. While most of the projects that Acumen has already undertaken are fairly straight forward, the Agency should consult with Acumen to see how it would address and establish a significantly more complex/complicated episode of care – and specifically for wound care. **The Alliance would be very interested in working with CMS to establish the parameters and work with the Agency and its contractor, Acumen, in creating the payment methodology for CTPs based upon real-world data collected from accurately submitted claims and the information from wound care specific qualified clinical data registries over the course of at least two years. In the interim, the Alliance recommends that CMS go back to unit pricing – which is more reliable than the current methodology and will eliminate the perverse incentives that currently exists.**

Finally, the Alliance highly recommends that no matter what payment methodology is put forward and implemented in future years after real world data is collected, 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 in a small sample area before it is rolled out nationally.

Guidelines

The Alliance recommends that CMS collaborate with all stakeholders in the wound care community to leverage the collective expertise, evidence and emerging science to establish guidelines based on the most current evidence that will improve patient outcomes, minimize inappropriate and unnecessary use of CTPs, decrease waste and lower the net health costs for wound episodes. Guidelines should include:

- More detailed guidelines for a “Good Wound Care” (GWC) protocol that considers the type of wound, wound etiology and other risk factors that can impair healing. These guidelines should be based on evidence, experience and emerging science to increase healing rates for GWC and lower the need for CTPs.
- Updated coverage guidelines for CTPs based on evidence, experience and emerging science in an effort to improve the healing rates when CTPs are used. For example, when is the patient and the wound in the best position to heal? What tests and interventions should be completed before treatment with a CTP? When should a CTP be used as a first line of treatment?
- Allow use of predictive models according to instructions for use (IFU), that enable earlier treatment for patients at high risk of failure with standard wound care. For example, patients with multiple comorbidities and risk factors should be able to skip the 4 weeks of standard wound care as long as other factors that can impair healing are addressed.
- Exemptions for very high-risk cases where amputation is highly likely without rapid improvement in the wound status. Guidelines are needed to prevent prolonged CTP treatment without evidence of improvement.
- More clear evidence-based guidance on when to cease CTP treatment due to lack of progress, and high likelihood of treatment failure.
- Criteria that will allow for extra treatments beyond the typical 10-12 currently allowed by LCDs, when there is documentation of progress.
- Payment for combined use of advanced therapies for high risk patients (i.e. CTP with NPWT, HBOT, Total contact cast, Unna boot)
- Inclusion of evidence tables for products that have quality clinical trials to educate physician decision making in appropriate product choice.

Again, the Alliance requests to be a resource for the Agency. Our clinicians are experts in the field and represent all aspects of wound care.

Pass Through Status – PuraPly™

The Consolidated Appropriations Act of 2018 contained a provision which extended pass through status for products classified in the Drugs and Biologics category which were set to expire on December 31, 2017. This provision impacted PuraPly which is the only biologic product identified in this proposal (but not specifically identified in the statute) and currently the only product of its kind that still maintains pass through status in this category. PuraPly is a CTP. CMS changed the pathway for pass through status for CTPs in 2014. Now, any CTP that applies for pass through status is required to submit a medical device pass

through application. PuraPly was the last product to apply for and be granted pass through as part of the drugs and biologics application process.

Since then, there have been many products in this space that have applied for pass through via the medical device application process (including several in this proposed rule) and to date, none have been granted pass through status. Prior to the requirement of CTPs going through the medical device pass through process, many CTPs applied for and were granted pass through status. All of those products were granted pass through for 2-3 years and no longer. While the Consolidated Appropriations Act of 2018 does permit the grandfathering of Drugs and Biologics, we believe that the intent of this provision was to address the expiring pass through for the drugs identified in this proposed rule and not this one biologic – which simply received this extension as a result of when its pass through status ended.

The Alliance submits that CMS permitting PuraPly to maintain extended pass through status goes against the very rationale for the changes CMS is proposing to make in other sections of this proposed rule. As we indicated in earlier parts of this comment letter, CMS has already created perverse incentives to utilize certain products over others. It is not the policy of the Alliance to comment on the efficacy of products but to address inconsistencies or our concerns with CMS's processes. Thus, our concern is CMS granting continued pass through status to PuraPly which could result in creating incentives for clinicians to utilize it over others given the uncertainty of reimbursement for all other products. As such, the Alliance questions why CMS would extend this product's pass through status? The Alliance does not agree that PuraPly should be granted extended pass through and recommends that CMS not move forward with permitting this product to gain the continued advantages of pass through which they have already enjoyed – like all other CTPs before them- for 3 years.

Methods to Control Unnecessary Increases In The Volume of Outpatient Services

CMS has proposed to pay the physician fee schedule payment rate for clinic visits beginning in CY 2019 as well as to excepted off campus provider-based departments. The Alliance attended the meeting of the Advisory Panel on Hospital Outpatient Payment in August, 2018. During the meeting the Panel voted unanimously to oppose the proposal to pay the physician fee schedule payment rate for clinic visits. The Alliance agrees with the Panel and recommends that CMS does not finalize this proposal within the Hospital Outpatient Prospective Payment System.

Price Transparency

The health care system is complex, and, frequently, neither providers nor payers fully understand the cost of a service until after it is performed. The Alliance applauds CMS for trying to tackle this issue. However, if a specific price transparency initiative is undertaken, we caution CMS to carefully consider the definition of cost. Given the complexities of health care, the term “cost” is inherently misleading, as is evidenced by the fact that CMS is soliciting comments on how to define it. Providers charge different amounts to different payers, whether they are uninsured consumers, Medicare, or Medicaid. Charges even vary between commercial payers. Moreover, providers are rarely reimbursed at the rate they charge, and, again, the rate of reimbursement varies across payers. We also note that as the health care system begins to pivot toward

accountable care and quality-based payment, standard charges will become even more misrepresentative of actual cost.

Given these complexities, we recommend that CMS devote additional resources to consumer education before imposing additional burdens on providers. Unless consumers know what questions to ask and to whom, there is a significant likelihood they will not find the answers they need. We suggest that any public information on price be accompanied by basic information on co-payments, deductibles, network issues, and visit limitations that will alter any information a consumer may receive. Unless the information given to consumers is accompanied by the appropriate explanations, CMS risks making the task of navigating the health care system more ambiguous than it currently is. Patients will over-rely on data, not taking into account their particular situation, and consequently be left with surprise financial responsibilities not initially anticipated.

Ways to Control Unnecessary Costs

Finally, in this proposal, CMS is seeking feedback from stakeholders on other ways to control unnecessary costs including prior authorization. The Alliance does not recommend utilizing prior authorization as a means to control unnecessary costs. 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 MAC jurisdiction and only 15-20 % in the other two MAC 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 in CMS's analysis, CMS did not conduct any analysis on the cost of care to those patients that were denied HBOT. The cost to utilize other advanced adjunctive therapies and to continue some treatment protocol for those patients that were denied authorization should have been examined. In fact, some patients sought treatment in bordering states 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, requiring prior authorization is contrary to that very notion and is not a concept that our clinicians can support.

Finally, with respect to the Triple Aim, and specifically, improving the patient experience of care (including quality and satisfaction) the Alliance's clinicians found that the patient experience was far from improved when prior authorization was implemented for HBOT. Many patients were significantly dissatisfied. Our members know of patients who, once they heard that their HBOT was not approved in their jurisdiction, either went to another jurisdiction for their care and ended up with a leg amputation, or whose cost of care increased when they had to receive other treatment modalities. These are not the types of scenarios which meet the Triple Aim goals.

For the reasons stated above, the Alliance does not believe that CMS should utilize prior authorization to control costs.

CONCLUSION

The Alliance appreciates the opportunity to provide our comments to CMS. The Alliance is the unified voice for wound care and we welcome the opportunity to work with CMS as the Agency addresses the payment methodology for CTPs. We will be contacting the Agency to set up a meeting to further discuss our recommendations. Should you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Marcia Nusgart R.Ph.".

Marcia Nusgart R.Ph.
Executive Director