ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 6, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted Electronically to www.regulations.gov

RE: CMS-1654-P: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

Dear Acting Administrator Slavitt:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed Changes to the. The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds 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 that not only possess expert knowledge in complex chronic wounds, but also in wound care research. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org. Our specific comments follow.

Potentially Misvalued Services Under the Fee Schedule – Electrical Stimulation and Ultrasound Therapy

In the proposed rule, CMS states that it understands that therapy specialty organizations have pursued the development of coding changes through the CPT process for their modality and procedures services. As a result, CMS is seeking information regarding appropriate valuation for the existing codes. Of particular interest to the Alliance are two codes – 97032 (electrical stimulation) and 97035 (ultrasound therapy). Both of these treatment modalities are utilized to treat wound care patients. The American Physical Therapy Association (who is a member of the Alliance) and other specialty societies are working on coding changes through the CPT process for these modality and procedures services. The Alliance has reviewed the comments submitted by the APTA and we

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support its efforts to refine the physical medicine and rehabilitation code family and to survey the codes identified in this proposed rule. We recommend that CMS work with APTA prior to the issuance of the 2018 physician fee schedule so that appropriate valuation for these modalities is established.

GLOBAL PERIOD

The Alliance did not support CMS's proposals to eliminate the 10 and 90-day global surgical periods. Instead, we supported Congressional efforts to prohibit the elimination of the 10- and 90-day Global Surgical Packages, which was included in the Medicare Access and CHIP Reauthorization Act (MACRA). MACRA did require that data be collected from a representative sample of clinicians to establish resources used in furnishing global services. However, we believe that CMS has gone beyond what was intended by Congress. The proposed rule requires data collection from all physicians who provide a 10 and 90-day global service and not just a representative sample. While we are supportive of the data collection by a representative sample as mandated by Congress, CMS needs to ensure that it collects the appropriate data and is transparent in the descriptions, definitions and requirements.

CMS has adopted RAND's recommendation to use G codes rather than the existing CPT/EM codes for the purpose of claims based data collection. E/M codes are currently inadequate to capture the full scope of post operative care and the care provided in the office setting. CMS needs to refine, restructure and revalue the existing E/M codes. However, with in the description/definitions of the G codes identified, CMS distinguishes between typical and complex visits. CMS has defined a complex visit as "may involve management of a particularly complex patient, such as a patient with numerous comorbidities or a high likelihood of dying, management of a significant complication, or management or discussion of a complex diagnosis". The Alliance requests clarity on this definition. A complex visit involves the management of a complex patient or discussion of a complex diagnosis. CMS is utilizing complex to define a complex visit without further defining complex. Since most of the patients that our Alliance members treat have multiple comorbidities (as do most Medicare patients)– we would like to clarify that CMS would include in its definition of complex visit all of the wound care services that our members use when treating a patient with a chronic wound and not be so circular in its definition.

Furthermore, with respect to the G codes, CMS states in the proposed rule that " we are proposing this new set of codes because we believe it provides us with most robust data upon which to determine the most appropriate way and amounts to pay for physician fee schedule services"/ However, later in the proposed rule CMS states, "because these are new approaches to collecting data and in an area – global surgery – where very little data has previously been collected, we can not describe exactly how this information would be used in valuing services". We question then why CMS is collecting this data? The Alliance requests that CMS state how it will use the data collected and how the data collection will facilitate revaluation of global services.

Hyperbaric Oxygen

In the proposed rule, CMS has erroneously calculated the total oxygen consumption for hyperbaric oxygen therapy (HBOT) The Alliance would like to summarize the historical development of the facility charge for hyperbaric oxygen therapy in an effort to provide clarity to our claim. In 2005, CMS added a "practice expense" to 99183 (physician supervision of hyperbaric oxygen) using some practice inputs gathered at that time. The source for these values is unclear, as the methodology was flawed, as reflected in the assignment of only 50% of chamber equipment cost when obviously the patient uses the chamber for the entire treatment, and the volume of treatment gases, where the amount of air used far exceeded that of oxygen. These misrepresentations have served as a point of comparison for the 2015 CMS decision to alter the AMA RUC recommendations when 99183 was valued for the first time. While the Alliance understands and supports the change from C1300 to G0277 as the 30-minute interval for hyperbaric oxygen therapy, the methodology used by the American Medical Association RUC reflects more accurately the amount of oxygen that is used in a hyperbaric oxygen treatment. The calculations referenced in the proposed rule are not accurate and we believe the number of units permitted under this rule would actually cause sub-treatment.

The provision of a hyperbaric oxygen treatment requires a pressure of greater than 1.4 ATA and a therapeutic dose of as close to 100% oxygen as can be achieved in the monoplace environment. Recent publications [1] that laid the foundation for a Department of Defense study clarified hyperbaric oxygen therapy "From a regulatory perspective, HBO2 is a combination product: medical-grade oxygen gas is a drug delivered in supraphysiologic concentrations by the hyperbaric chamber, a medical device. [1] The current drug dose for hyperbaric oxygen is as near to 100% as possible, to be delivered at the nasopharynx. Ideally, this level of oxygen delivery must be reached and maintained for the duration of the designated treatment time. Therefore, a treatment of 2.4 ATA for 120 minutes will require that the target chamber oxygen concentration be achieved at the same time as the designated pressure.

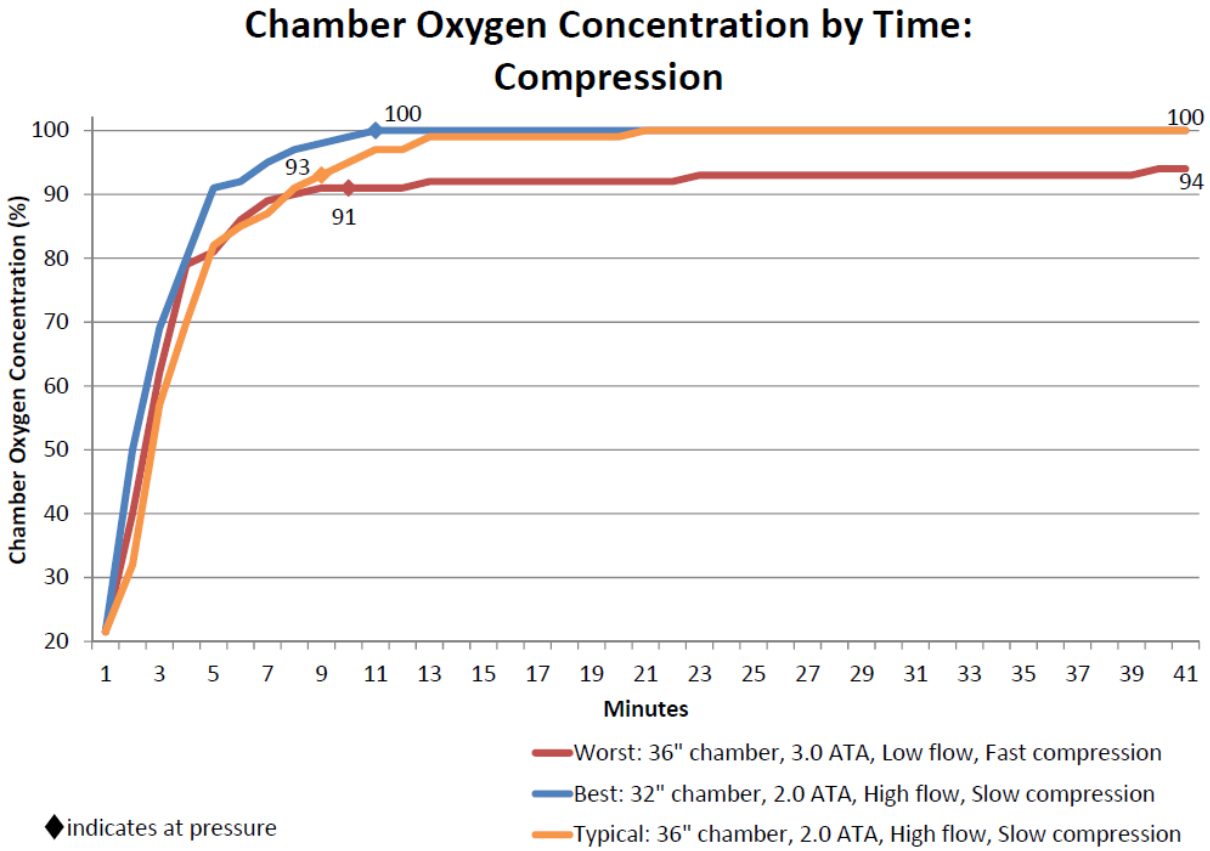
Eugene Worth, MD, M.Ed., presented scientific evidence to answer the questions of how long it takes to achieve the target oxygen concentration of close to 98% with varying flow rates[2].

	175 LPM	250 LPM	350 LPM
Time to reach TX depth 5 psi/minute	4 min 22 seconds	4 min 17 seconds	4 minutes 10 seconds
Time to reach 98% O2	27 minutes	15 minutes	11 minutes

[1] McCrary, BF., et al., Hyperbaric oxygen (HBO2) for post-concussive syndrome/chronic TBI *Product summary Undersea Hyperb Med 2013 40 (5) :443-467.*

[2] Worth E, et al. Oxygen concentration rise in a monoplace chamber. *Undersea Hyperb Med* 2005; 32(4):280.

Dr. Weaver and his team at LDS Hospital in Salt Lake City Intermountain Health presented the following data at a recent UHMS scientific meeting.



This study was done using a 70 kilogram body equivalent and measurements were taken at the level of the simulated oropharanx. In an average hyperbaric treatment, the time to achieve the designated pressure is between 10-15 minutes, depending on the depth and the ability of the patient to accommodate changes in barometric pressure. In order to achieve as close to 98% oxygen in the chamber, the flow rate must be at least 300 LPM. Higher flow rates are necessary to ensure pressure is maintained while adequate ventilation is provided to control for carbon dioxide, water vapor, and patient cooling. Additionally, the provision of air breaks throughout the hyperbaric treatment to reduce the risk of oxygen toxicity seizures has been demonstrated to lower in-chamber oxygen concentrations, and the flow rate must be high in order to restore therapeutic levels of oxygen in the chamber. (Raleigh GW. Air Breaks in the Sechrist 2500-B Monoplace Chamber. *J of Hyperbaric Medicine* 1988). This study was done at a flow rate of 400 LPM, and demonstrated that after an air break, 8 minutes was required to achieve therapeutic levels. It should also be noted that both of these referenced studies were performed in monoplace chamber varying from 32 inch to 36-inch diameter sizes. There is a current trend in many hyperbaric facilities to utilize monoplace chambers in the 40-41-inch diameter size, to improve patient tolerance and comfort, especially for larger patients. It is expected that flow rates and total oxygen volume used in these chambers will be even higher. At least

one study is currently in progress to confirm these values and should be used to assist CMS in their evaluation.

Many Alliance members provide HBOT to treat their patients and are experts in this treatment modality as well as the research surrounding it. As such, the Alliance respectfully requests that CMS review the methodology used to determine the total oxygen consumption during a hyperbaric treatment, and accept the RUC recommendation. The Alliance further recommends and requests that CMS utilize the methodology used by the AMA RUC regarding the amount of oxygen that is used in a hyperbaric oxygen treatment. As stated, the flow rate of at least 390 LPM must be used in order to deliver as near to 100 percent oxygen to patients requiring HBOT. The manufacturer of this chamber – Sechrist – has submitted comments to CMS validating our recommendation – specifically that the flow rate of at least 390 LPM must be used in order to deliver as near to 100 percent oxygen.

Medicare Diabetes Prevention Program

CMS has proposed to expand the Diabetes Prevention Program model as the Medicare Diabetes Prevention Program (MDPP) beginning in January 2018. The Alliance is supportive of this effort. The incidence and prevalence of diabetes in the United Sates is on the rise and as such so are the number of patients that require care to treat diabetic foot ulcers. Diabetic foot ulcers (DFU) impose a substantial burden on public and private payers in the U.S. doubling the cost of care per patient compared with diabetic patients without foot ulcers. Ulcer care adds $9 - $13 billion annually to the direct yearly costs associated with diabetes. By taking action to help prevent this disease, CMS will help to meet its goal of Better Care, Smarter Spending, and Healthier People. We are hopeful that this nationwide program for diabetes will decrease the number of DFUs and related amputations.

While we defer to the recommendations submitted by our member organizations, we would like to offer the following comments with respect to two aspects of the proposed rule on MDPP: First, CMS proposes eligibility criteria in order for a Medicare beneficiary to receive services under this program. The criteria proposed includes:

- Enrolled in Medicare Part B
- As of the first date of attendance at the first Core Session a BMI of at least 25 if not self-identified as Asian and a BMI of at least 23 if self-identified as Asian.
- Have within the 12 months prior to attending the first Core Session a hemoglobin A1c between 5.7 and 6.4 percent or a fasting plasma glucose of 110-125 mg/dl, or a 2-hour post-glucose challenge of 140-199 mg/dl.
- Have no previous diagnosis of Type 1 or Type 2 diabetes (OK to have a previous diagnosis of gestational diabetes)
- Does not have ESRD

The Alliance agrees with CMS's determination to include HgA1c as a criterion to determine eligibility. However, we do not agree with the BMI levels proposed by CMS. The BMI levels proposed by CMS differ from those issued by the Centers for Disease Control and prevention (CDC)

in its Diabetes Prevention Recognition Program. In order to create consistency in recommended levels of BMI, the Alliance recommends that CMS utilize the CDC BMI levels.

Additionally, CMS requested feedback on quality metrics under this program. The Alliance would like to recommend that HbA1c be used as a quality metric along with lipid levels and blood pressure. These should be measured and reported to demonstrate program effectiveness.

Conclusion

The Alliance appreciates the opportunity to provide CMS with our comments. If you require additional information or have any questions, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R. Ph.

Marcia Nusgart, D.Ph.
Executive Director