ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

December 22, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Submitted Electronically to www.regulations.gov

RE: CMS-1612-FC: CY 2015 Physician Fee Schedule

Dear Ms. Tavenner:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the final CY 2015 Physician Fee Schedule with comment period. The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations 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. Our clinical specialty societies and organizations not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org. Our specific comments follow.

Global period

The Alliance is concerned that CMS seems to have ignored all clinical organization comments with respect to the global period. Again, the Alliance reiterates our concerns.

Our concerns are with the Agency's proposal to unbundle 10- and 90-day global surgical services, revalue these services as 0-day global services through a still yet-to-be-determined methodology, and make these changes effective in CY 2017 (for 10-day global services) and CY 2018 (for 90-day global services). Separate payment would be made as medically reasonable and necessary pre and post-procedure visits.

CMS has not put forward a sound methodology for unbundling global surgical services – which allows for meaningful public comment. That methodology should include fair and accurate values for base procedures as 0-day global services. It should also be reflective of direct and indirect practice expense costs. Until CMS can put forth a methodology with appropriate public notice and comment, the Alliance urges CMS to not move forward with this proposal.

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410 | F 301.530.7946
marcia@woundcarestakeholders.org

Furthermore, the Alliance has significant concerns that by having separate payment being made for medically reasonable and necessary pre and post procedure visits, there will be an increase in scrutiny concerning the medical necessity of every post procedure visit, as well as an increase in claims volume and associated costs.

CMS has not outlined an impact analysis or how it believes their contractors will be able to handle the increase in claims volume. The AMA estimates that the elimination of the global period will result in 63 million additional claims being filed with Medicare contractors to account for post-surgical evaluation and management services. There is also the additional administrative burden on the practice to submit all these additional claims. Ultimately, this proposed change will drive up the cost of healthcare. It will be burdensome for CMS and practitioners and appears to add no value to the health system.

The Alliance urges CMS not to implement this proposal to transition all 10- and 90-day global bundles to 0-day global codes for medically reasonable and necessary visits during the pre- and post-operative periods outside the day for the surgical procedure.

Qualified Clinical Data Registry

The Alliance is pleased that CMS did not finalize the proposal to increase the number of outcome measures required for reporting through a QCDR to three (or in lieu of three outcome measures, EPs can report at least 2 outcome measures and 1 resource use, patient experience of care, or efficiency/appropriate use measure). Furthermore, we also agree with the language to increase the maximum number of non-PQRS measures for which quality data can be submitted, from 20 to 30, and the Agency's decision to extend the deadline for QCDRs to submit quality data to April 30 of the year following the applicable reporting period (that is April 30, 2016 for reporting periods in 2015).

NQF Endorsement

The Alliance understands the need for quality measures to be evidence based and consensus driven. However, the Alliance disagrees with the CMS belief that all PQRS quality measures must be endorsed by the NQF, at least with the current NQF mechanism for implementation. The current NQF process has serious problems which can negatively impact the efficient development of quality measures. The process of NQF endorsement is slow and may take years to achieve, during which new evidence may come to light requiring a revision of the measure even before it is finalized. In addition, the NQF has rigid categories for measures to even be considered for endorsement. These categories create a bias against measures from fields such as wound care which do not fit logically into the current NQF categories. The Alliance spent several years in dialogue with the NQF simply attempting to identify a mechanism by which various wound care measures could undergo review. If CMS is going to mandate NQF endorsement, then the NQF process needs radical restructuring to facilitate measures submission.

Furthermore, the NQF submission and endorsement process is expensive, putting NQF endorsement of measures out of reach for small organizations, subspecialties or areas which are not represented by an organized medical specialty at all, such as wound care. Unless CMS is going to fund the NQF submission process, quality measures in fields like wound care will not be able to achieve NQF endorsement because no medical specialty society exists to fund the endorsement process. Lastly, the NQF endorsement process is inflexible making it difficult for areas such as wound care to achieve their threshold of evidence required if held to the same

standard for example, as cardiovascular measures. These barriers have prevented much needed measures in the area of wound care which do not have multiple RCTs with thousands of patients. That limitation is now being addressed through the QCDR process. The QCDR process provides a mechanism for evidence based quality measures to be efficiently launched by specialty organizations and we strongly support the this process.

CMS may select measures under an exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed or adopted by a consensus organization. The Alliance believes that consensus amongst relevant stakeholders can be achieved through a rigorous measure development process, which includes a public comment process and incorporates patient representatives, when feasible. Therefore, we urge CMS to consider revisiting the requirement that all PQRS measures be endorsed by NQF unless the current NQF endorsement mechanism is made less cumbersome, less costly, more efficient and less unwelcoming to small organizations. Alternatively, CMS will need to provide support (financial or administrative) to defray the very large burden of NQF endorsement for measures which address a gap in practice but are not logically the purview of a medical specialty society. Another option is that the NQF develop a "fast track" pathway of endorsement for quality measures which have successfully been reported within a QCDR by using data acquired from it.

Negative Pressure Wound Therapy as a DHS

The Alliance was disappointed to learn that CPT codes 97607 and 97608, two new disposable negative wound therapy (NPWT) codes, have been added to the list of "designated health services" (DHS) that cannot be submitted to Medicare when/if the physician has a financial relationship with the entity that provides the item.

It is our understanding that the Stark definition of "referral" does not include services personally performed by the referring/ordering physician. For the typical patient provided with a disposal NPWT device, significant clinical interaction from the physician is necessary to thoroughly clean the wound prior to application of a disposable negative pressure wound therapy device. Specifically, the wound is assessed to ensure no sinus tracts or exposed vessels are present. The skin around the wound is cleansed thoroughly and prepared for dressing application. Gauze or foam dressing material is placed into the depth of the wound with cutting of the foam to size and moistening the gauze with normal saline. At every step of the process, including when tubing and suction apparatuses are attached, the physician is in direct contact with the patient, which, by definition, would appear to exempt these CPT codes from Stark self-referral rules.

Therefore, the Alliance does not understand the rationale for CMS placing these codes as a DHS under the Stark regulations. As such, we respectfully request the Agency remove these codes from the DHS list.

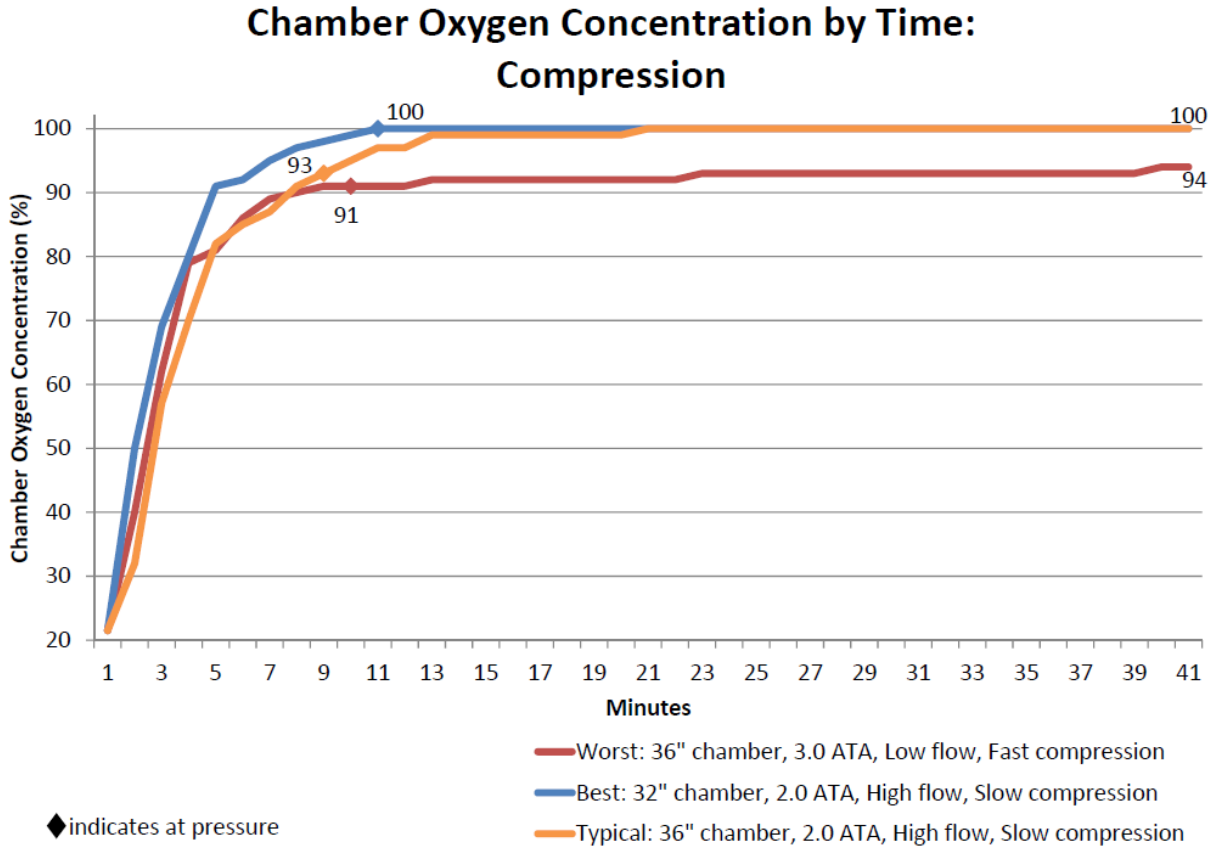
Hyperbaric Oxygen

While the Alliance understands and supports the change from C1300 to G0277 as the 30 minute interval for hyperbaric oxygen therapy, we feel that the methodology used by the American Medical Association RUC reflects more accurately the amount of oxygen that is used in a hyperbaric oxygen. The calculations referenced in the final 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. 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 must 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.

	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

Worth 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.,J of Hyperbaric Medicine. Air Breaks in the Sechrist 2500-B Monoplace Chamber, 1988). This study was done at a flow rate of 400LPM, and demonstrated that after an air break, 8 minutes was required to achieve therapeutic levels.

We respectfully request that CMS review the methodology used to determine the total oxygen consumption during a hyperbaric treatment, and accept the RUC recommendation. The marked disparity in the PE in 2005 was due to incorrect data collection, as 180 LPM of oxygen and 187 cubic feet of air per minute are not consistent with any monoplace hyperbaric chamber operation. These values are more in keeping with a multiplace environment where the compression gas is air, and the treatment gas is oxygen (more air than oxygen). However, even in that environment, the hood flow rate would have resulted in much higher oxygen consumption. In the monoplace environment, where the majority of the treatments are given, to achieve the physician ordered concentration of oxygen within the accepted treatment time parameters, a flow rate of at least 300 LPM is required.

As such, the Alliance recommends and requests that CMS continue to utilize 47,000 units of oxygen for the 120 minutes of time.

****

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions of would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph

Marcia Nusgart, R.Ph
Executive Director