Advisory Panel on Hospital Outpatient Payment
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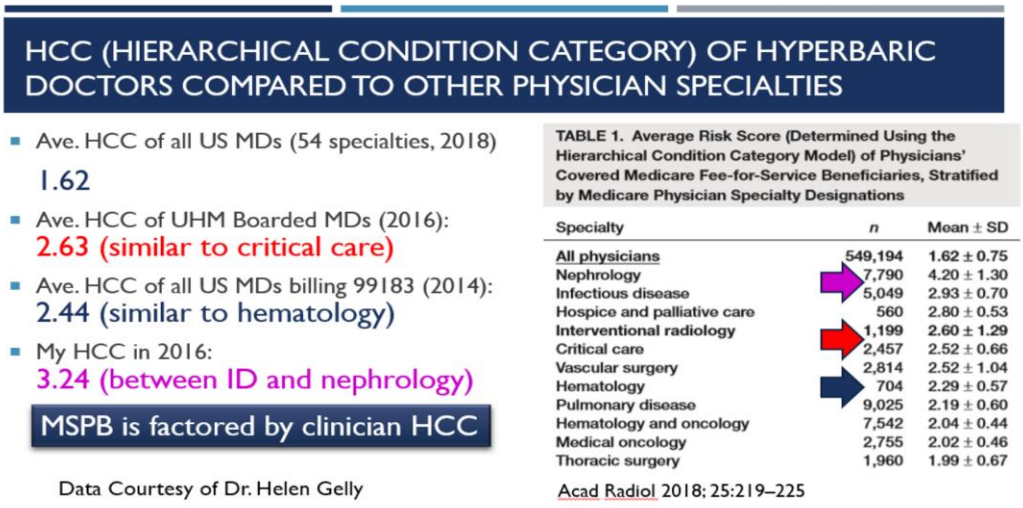
Dear Members of the Advisory Panel on Hospital Outpatient Payment:

The Undersea and Hyperbaric Medical Society (UHMS) along with the American College of Hyperbaric Medicine (ACHM) respectfully wishes to comment on the proposal to amend the existing regulation at §410.27(a)(1)(iv) to provide that the default minimum level of supervision for each hospital outpatient therapeutic service is "general."

General supervision, as defined in our regulation at 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.

The UHMS and ACHM maintain that the limited number of critical access hospitals (CAHs) and rural hospitals utilizing hyperbaric medicine services (HBO2) to be less than 5% and these hospitals do not treat the typical hyperbaric patient seen in full-service hospitals and the panel's conclusions that they are the same as non-CAHs is a critical error and poses a real threat to patients' and providers' safety and outcomes.

The UHMS and ACHM argue that **direct supervision should be maintained for HBO_2 services due to the complexity of the hyperbaric patient which is defined by the Hierarchical Condition Category (HCC) score and two, to maintain a high level of care and efficacy for patients needing hyperbaric care.**



Due to the complexity of the hyperbaric patient as defined by the HCC score, hyperbaric physicians are required to be immediately available during the entirety of the hyperbaric treatment.

In the Mathematica Policy Research report: Evaluation of the Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen (HBO): Final Report Appendices (attached), the authors stated, "Beneficiaries with diabetic lower extremity wounds are generally a group at very high risk for adverse events. Thirty-nine percent of beneficiary-quarters included an emergency department visit and 31 percent experienced an unplanned hospitalization in the baseline period."

Hyperbaric physicians have known that hyperbaric patients are at higher risk for complications including death for decades and in 1993, published the document Physician's Duties in Hyperbaric Medicine (attached) which defines best practices for physicians practicing HBO_2. Additionally rapid analysis of registry data of 11,240 at 87 facilities showed that patient's undergoing HBO2 therapy generally suffer from multiple serious comorbidities and require medications, which increase the risk of HBO_2 , necessitate the presence of a properly trained hyperbaric physician (attached).

Additionally, hyperbaric oxygen therapy often involves having health care providers attend to patients in the hyperbaric chamber itself, while under pressure. There have been incidents and fatalities of healthcare providers caring for patients during and after hyperbaric oxygen therapy treatments and the treating physician must be present and immediately available to avoid additional risk for these providers.

In the October 2000, the Office of Inspector General outlined in their report, Hyperbaric Oxygen Therapy: Its Use and Appropriateness (attached), the author concluded "While attendance is not specifically required, our medical review showed a correlation between certain quality of care factors and physician attendance."

The authors also stated, "The guidance provided by the Health Care Financing Administration (HCFA) has been limited only to specifying covered disease conditions. As a result, carriers and intermediaries have varied payment guidelines (e.g., physician attendance, credentialing requirements), medical review procedures (i.e., use of diagnosis edits and post-payment review policies), and documentation requirements. While practice protocols and standards of care have been proposed by the HBO2 industry, HCFA has not incorporated either into its coverage policy."

"Over 75 percent of [MAC] medical directors agree that physician attendance is necessary to promote either safety or quality of care or both."

"Our review indicates physician attendance is strongly correlated with quality of care and the reduction of inappropriate billing. Almost two-thirds of medical directors do support the notion that physician attendance is necessary to achieve quality. Similarly, our medical review results supported this concept, showing a significant relationship ($p<.001$) between quality of care variables and physician attendance and between compliance with HCFA guidelines and physician attendance ($p<.001$). These relationships provide support for requiring physician attendance during all treatments. For example, 74 percent of the payments termed "inappropriate" by our reviewers did not appear to have a physician in attendance. We cannot be certain that physician attendance would have corrected all of these payments, but the strong relationship between quality and attendance suggests a potential for reducing inappropriate payments.[17]"

To summarize, the American College of Hyperbaric Medicine (ACHM) and the Undersea and Hyperbaric Medical Society (UHMS) request exclusion from the general supervision change and maintain direct supervision requirements and ‘incident to’ requirements for G0277.

Sincerely,

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