



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



May 24, 2018

Jule Crider  
Executive Director  
The American Association of Wound Care Management  
P.O. Box 193  
Kensington, MD 20895

Dear Ms. Crider:

I am writing in response to your letter dated April 18, 2018, regarding your concerns related to our recent audit, *Wisconsin Physicians Services Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply With Medicare Requirements (A-01-15-00515)*. I appreciate the opportunity to address the concerns you raised in your letter.

As part of our mission, the Department of Health and Human Services (HHS), Office of Inspector General (OIG), conducts oversight of HHS programs to ensure compliance with Medicare laws and regulations. This work protects the integrity of HHS programs and the health and welfare of program beneficiaries.

OIG conducts audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed to obtain sufficient, appropriate evidence providing a reasonable basis for OIG findings and conclusions. We make every effort to ensure that we interpret and apply criteria correctly. When conducting reviews pertaining to Medicare or Medicaid, we work closely with our legal counsel, the audited entity, and, when appropriate, the Centers for Medicare & Medicaid Services (CMS).

In your letter, you state that the “OIG/OAS Outpatient Medical Record Check List” makes it appear “that OIG expected providers to produce documentation illustrating compliance with this [30-day] rule for *all* claims in the sample, not just those with a diagnosis of diabetic ulcers to the lower extremities.” You are correct that this is how the checklist reads, but the checklist does not reflect the criteria as OIG ultimately applied them, after consultation with both OIG counsel and CMS. Specifically, OIG discussed the “30-day requirements” with CMS to confirm that the requirements only apply to the 15th covered condition—diabetic wounds of lower extremities—and state this requirement on page 3 of our audit report. Furthermore, we worked with the medical reviewers to ensure that they only applied this requirement to Medicare beneficiaries in our sample who had diabetic wounds of lower extremities and no other covered condition. Wisconsin Physicians Services reviewed the documentation and agreed with our findings.

As to your concern regarding our request of supporting documentation from providers, OIG sent a request letter and checklist to each provider in our sample to request all medical records

associated with the hyperbaric oxygen therapy (HBOT) services contained in the 120 sampled outpatient claims. We also contacted the hospital compliance officers through phone calls and emails to tell them about the audit and answer any questions. We requested that the compliance officers provide all documentation necessary to determine whether the HBOT services billed met Medicare requirements. Furthermore, our detailed checklist also included a statement that the items listed on the checklist was not all inclusive and that the providers should “provide all medical records to support that HBO therapy was provided in accordance with Medicare requirements as treatment for at least 1 of the 15 covered conditions.” We obtained the medical records for all sample items.

We submitted all medical record documentation we received to our medical reviewers. The medical reviewers assessed the documentation for completeness. They then provided us with a list of sample items that were missing specific documents or support or both. For each sample item missing pertinent documentation, we followed up with the hospital by email or phone to clarify what was missing. For example, we followed up with a few providers to request “clinical evidence (biopsy, pathology reports, etc.) to support that the patient had soft tissue radionecrosis” if it was not initially provided. We then sent any additional documentation submitted by the providers to the medical reviewers. The medical reviewers then made a final determination for each sampled outpatient claim.

We believe the criteria are clear regarding the requirements for the Medicare reimbursement of HBOT therapy. However, providers should contact their Medicare Administrative Contractor if they have any questions related to this issue. Thank you for the opportunity to respond to the concerns raised in your letter.

Sincerely,

/Gloria Jarmon/  
Deputy Inspector General  
for Audit Services