SOLUTIONS LAW PRESS
HEALTH CARE UPDATE

November 6, 2009

Renal Dialysis Faculties Encouraged to Review Current Protocols for Administering Erthropoiesis-Stimulating Agents

Renal Dialysis Facilities are encouraged to review and consider the advisability for further tightening of their current practices in light of the **Renal Dialysis Facilities' Dosage Protocols for Administering Erthropoiesis-Stimulating Agents**, (OEI-03-09-00010), posted by the OIG this week.

According to the report, OIG conducted the report in response to a request from Chairman Fortney Pete Stark of the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives in response to reported concerns by some members of Congress that dialysis facilities' protocols for administering ESAs may not be consistent with the current boxed warning for these drugs.

According to the report, OIG found that 93 percent of Medicare-certified dialysis facilities had protocols in place for administering erythropoiesis-stimulating agents (ESA), but only 56 percent of the facilities' protocols explicitly state a target hemoglobin range. OIG could not determine whether the remaining 44 percent of protocols were consistent with the boxed warning and Medicare's benefit policy because they do not specify a target hemoglobin range. Of the protocols that state a target hemoglobin range, 94 percent are consistent with the boxed warning on FDA-approved labeling and the Medicare benefit policy for ESAs.

While noting they are not required to do so, OIG commented that dialysis facilities may develop their own protocols for administering ESAs to patients with chronic kidney failure. The protocols may define target hemoglobin levels and dosage instructions for administering ESAs. According to the boxed warning on ESAs' labels, maintaining higher rather than lower hemoglobin levels in a patient with chronic kidney failure can adversely affect the patient's health and increase the risk of death. Specifically, the boxed warning states that providers should administer ESAs "to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL." The Medicare benefit policy for ESAs reflects the target hemoglobin range specified in the boxed warning. A separate Medicare policy for monitoring ESA payments states that CMS will reduce reported dosages upon which ESA claims are paid when patients' hemoglobin levels exceed 13g/dL.

OIG reported its review of protocols to determine whether they are consistent with selected guidelines on ESAs' labels revealed that some protocols contain information that differs from labeling guidelines regarding starting doses, dose adjustments, and withholding ESA doses. OIG also found that all of the protocols that include a target hemoglobin range or level at which to increase ESA doses conform with CMS's monitoring policy.

OIG concluded that although its review does not address the amount of ESAs that providers actually administer to patients at their dialysis facilities, it does demonstrate that just over half of facilities' protocols for administering ESAs are consistent with the boxed warning and Medicare's benefit policy

for ESAs. However, since almost half of the dialysis facilities either did not have protocols or did not specify a target hemoglobin range in their protocols, OIG reported it could not determine whether these facilities' policies target the hemoglobin range outlined in the boxed warning that FDA requires on ESA labels.

For More Information

We hope that this information is useful to you. If you need assistance with these or other health care public policy, regulatory, compliance, risk management, workforce and other staffing, transactional or operational concerns, please contact the author of this update, Curran Tomko Tarski LLP Health Practice Group Chair, Cynthia Marcotte Stamer, at (214) 270-2402, **cstamer@cttlegal.com.** Ms. Stamer has extensive experience advising clients and writes and speaks extensively on these and other health industry and other reimbursement, operations, internal controls and risk management matters. You can review other recent health care and related resources and additional information about the health industry and other experience of Ms. Stamer **here**.

If you or someone else you know would like to receive future updates about developments on these and other concerns, please be sure that we have your current contact information – including your preferred e-mail – by creating or updating your profile at **here** or e-mailing this information **here,** by subscribing to receive these updates in blog form **here** and/or by participating in the **SLP Health Care Risk Management & Operations Group** on LinkedIn**.** To unsubscribe, e-mail **here**.