



OIG 2014 Work Plan Focuses On Compounded Pharmaceuticals Reimbursed By Medicare

02.12.2014

BY: BRIAN C. VICK

The Office of Inspector General for the U.S. Department of Health and Human Services (“OIG”) included two items in its recently-released 2014 Work Plan indicating a new focus on the quality and safety of compounded pharmaceuticals reimbursed by Medicare. Pharmaceutical compounding is the process by which prescription drugs are tailored to meet the needs of individual patients and is often used to obtain drug combinations or preparations that would not otherwise be available. Compounding has come under increased scrutiny in recent years following a meningitis outbreak in 2012 that was caused by contaminated batches of compounded steroids and that resulted in 64 deaths.

The 2014 Work Plan indicates that OIG will be issuing a report during Fiscal Year 2014 to define regulatory oversight of pharmaceutical compounding in acute care hospitals that are reimbursed by Medicare Part A. OIG will also be issuing a report that examines the policies and procedures used by Medicare Administrative Contractors (“MACs”) to review and process Part B claims in order to ensure that Medicare is not paying for compounded pharmaceuticals that are being sold in violation of the Federal Food, Drug, and Cosmetic Act (“FDCA”). These efforts by OIG come on the heels of legislation that tightened FDA regulation of compounding pharmacies and presage heightened scrutiny by OIG and the MACs of the propriety of claims filed with Medicare for reimbursement for compounded products.

Although these new items in the 2014 Work Plan do not necessitate immediate action by hospitals, pharmacies, and physician practices that are currently compounding, all such providers should keep close watch for further developments from OIG. Given the intense scrutiny that compounding has received recently, providers who are billing Medicare for compounded products are likely to be targeted with civil enforcement actions, recoupment actions, and/or False Claims Act litigation in coming years, and, as a result, should constantly monitor their compliance with federal and state regulations.

Related People

- Wyatt S. Beazley, IV – 804.420.6497 – wbeazley@williamsmullen.com
- Patrick C. Devine, Jr. – 757.629.0614 – pdevine@williamsmullen.com

Related Services

- Health Care
- Health Care Litigation