

PUBLICATION

OIG Work Plan – October 2017 Update

October 20, 2017

The OIG added five new items to its Work Plan with its October 2017 monthly update. This is a decrease from the nine new items added to the Work Plan with the September 2017 update. (For more information on last month's Work Plan update, see "OIG Work Plan – September 2017 Update").

Last month, the Secretary of the Department of Health and Human Services (DHHS), Tom Price, resigned from his position as Secretary after news broke that he had used private charter flights and military aircraft at taxpayer expense. The OIG will review whether Secretary Price's use of private charter flights was in compliance with applicable federal regulations and DHHS policies and procedures.

The rising cost of drugs for rare and complex conditions has become an issue of concern for state Medicaid programs. While high-cost specialty drugs are a small portion of the total of all drugs dispensed, they represent a disproportionate and growing share of total drug spending. Further complicating this issue is that there is no standard definition for specialty drugs, posing challenges in management of specialty drug costs. The OIG will examine how state Medicaid programs define specialty drugs and review strategies on management of specialty drug costs, such as formularies, cost sharing, step therapy, and prior authorization.

The OIG will be evaluating the Food and Drug Administration's (FDA) efforts to increase the number of prescribers who receive training on pain management and decrease inappropriate opioid prescribing practices. Under the Food and Drug Administration Amendments Act of 2007, the FDA has the authority to require pharmaceutical companies to develop Risk Evaluation and Mitigation Strategies (REMS) when the FDA determines that the risk of using a drug outweighs its benefit. Recently, the FDA has taken steps to stem the tide of opioid misuse and abuse and is now requiring opioid manufacturers to follow REMS. The OIG will examine how the FDA is holding opioid REMS manufacturers accountable for REMS goals to mitigate risks of misuse, abuse, addiction, overdose, and serious complications because of medication errors.

In addition, the OIG will be examining the effectiveness of drug product tracing requirements established under The Drug Supply Chain Security Act (DSCSA). The DSCSA was enacted to prevent the introduction of harmful and counterfeit drugs into the supply chain by requiring trading partners to exchange drug product tracing information when they take ownership of the drugs. The OIG will be testing the accuracy of the drug product tracing records.

Lastly, the OIG will examine Medicare payments for bariatric surgeries to determine whether services performed met the conditions for coverage. This review is in response to the Comprehensive Error Rate Testing program's special study of certain Healthcare Common Procedure Coding System (HCPCS) codes for bariatric surgical procedures, which found that approximately 98 percent of improper payments lacked sufficient documentation to support the bariatric procedures.

Announced	Agency	Title	Component	Report Number(s)
October 2017	Office of the	Secretary Price's Use of Chartered	Office of Audit	W-00-17-59431

	Secretary	Aircraft for Federal Travel	Services	
October 2017	Centers for Medicare & Medicaid Services	Specialty Drug Coverage and Reimbursement in Medicaid	Office of Evaluation and Inspections	OEI-03-17-00430
October 2017	Food and Drug Administration	FDA Oversight of Risk Evaluation and Mitigation Strategies to Address Prescription Opioid Abuse	Office of Evaluation and Inspections	OEI-01-17-0051
October 2017	Food and Drug Administration	Drug Traceability Test	Office of Evaluation and Inspections	OEI-05-17-00460
October 2017	Centers for Medicare & Medicaid Services	Review of Medicare Payments for Bariatric Surgeries	Office of Audit Services	W-00-17-35226