Pepper Hamilton LLP
Attorneys at Law

OIG Issues HHS Fiscal Year 2016 Work Plan

CLIENT ALERT | November 17, 2015

Judith L. O'Grady | ogradyj@pepperlaw.com
Julia C. Weisberg | weisbergy@pepperlaw.com
Bradley J. Crowell | crowellb@pepperlaw.com

THE WORK PLAN DESCRIBES MORE THAN 100 INITIATIVES, INCLUDING 43 NEW INITIATIVES FOR THE UPCOMING YEAR.

On November 2, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued its annual Fiscal Year 2016 Work Plan, which describes more than 100 initiatives, including 43 new initiatives for the upcoming year. OIG will focus on an array of health care entities in 2016, including pharmacies, hospitals, nursing homes and home health services, as well as pharmaceutical and medical device manufacturers. Prescription drug and pharmacy-related fraud continues to be an area of concern for OIG. In addition, several OIG initiatives focus on controlling the cost of prescription medications.

Relevant initiatives include evaluation of (1) adherence to Medicare Part D requirements, (2) compliance with the Medicaid Prescription Drug Program requirements, (3) prescription drug pricing, (4) the impact of reimbursement surpluses created by 340B discounts, (5) Medicare Part B drug coverage criteria compliance, (6) FDA utilization of and manufacturers' compliance with FDA's post-marketing requirements and (7) the adequacy of protection for electronic health care information stored by medical devices.

Medicare Part D Prescription Drug Program. Medicare's Part D Prescription Drug Program provides prescription drugs for more than 37 million beneficiaries. Past OIG reports have identified oversight of Medicare Part D and pharmacy-related fraud as areas of concern. In June 2015, more than 240 subjects were charged with defrauding Medicare and Medicaid in the largest national health care fraud takedown in history. Much of the fraud involved prescription drugs and pharmacies.

In 2016, OIG will continue to review compliance with Part D requirements. Areas of investigation will include (1) oversight of and compliance with the Open Payments Program (created by the Physician Payments Sunshine Act), including the number and nature of financial interests reported to the Centers for Medicare and Medicaid Services (CMS) and the extent of CMS oversight of manufacturers' and group purchasing organizations' compliance with reporting requirements; (2) Part D sponsors' adherence to requirements for reporting direct and indirect remunerations, such as rebates, subsidies and other price concessions from any entity, including manufacturers and pharmacies; and (3) compliance with Medicare's Part D Prescription Drug Event record submission requirements by certain retail pharmacies previously identified by OIG as having questionable Part D billing practices.

In a new initiative, OIG will evaluate CMS' ability to oversee pharmacies that participate in the Part D program. As part of this, OIG will evaluate the extent to which pharmacies that bill for Part D drugs are enrolled in Medicare. In another new initiative, OIG will compare the increase in Part D pharmacy reimbursement rates for brand-name drugs between 2010 and 2014 to the rate of inflation during the same time period.

Medicaid Prescription Drug Program. Federal and state governments jointly fund Medicaid, which provides medical assistance to low-income individuals. In 2016, OIG will continue to investigate fraud, waste and abuse under the Medicaid Prescription Drug Program by (1) evaluating manufacturer compliance with reporting average manufacturing prices (AMPs) to CMS, (2) examining whether manufacturers are incorrectly calculating AMPs by including sales of authorized generics to secondary

manufacturers, (3) evaluating states' collection and reporting of manufacturer rebates and (4) analyzing generic drug prices over a period of time to determine whether the price increases exceed inflation rates.

In a new initiative, OIG will determine how state Medicaid agencies define "specialty drugs" —expensive drugs used to treat rare conditions, such as Hepatitis C, HIV and certain cancers — and will evaluate how much states pay for these drugs, the methodology applied to calculate payments and any differences in reimbursement amounts between states.

Medicare Part B Drug Pricing Evaluations. Medicare reimburses costs for Part B drugs using a method based on the average sales price (ASP). OIG compares the ASP with the AMP and notifies the HHS Secretary when an ASP exceeds an AMP by 5 percent. In 2016, OIG will continue to evaluate prices of Part B-covered drugs and identify prices that exceed the designated threshold. When the threshold is exceeded, OIG can disregard the ASP in setting reimbursement rates and limit the amount of reimbursement.

340B Discount Sharing. The 340B Drug Discount Program allows eligible health care providers to purchase drugs at discounted prices. The amount of Medicare reimbursement, however, does not change based on the 340B discount. Under the current rules, the surplus between Medicare's reimbursement and the 340B-eligible providers' cost is retained by the provider. Encouraged by policymakers, OIG will continue to evaluate the impact of a shared savings arrangement that would allow Medicare and its beneficiaries to share in the cost savings from 340B discounts.

Part B Drug Reimbursement for Covered Uses. CMS reimburses costs for Medicare Part B drugs that are prescribed for "medically acceptable" purposes. On-label use as well as off-label use, if supported in major drug compendia or by clinical evidence in authoritative medical literature, are considered medically acceptable purposes. In 2016, OIG will continue to review whether CMS' oversight activities are effectively ensuring reimbursement for Part B drug costs such that Medicare and its beneficiaries are not paying for drug uses not considered medically acceptable.

Compliance with FDA Post-Marketing Requirements. As part of the 2007 Food and Drug Administration Amendments Act, FDA may impose post-marketing requirements (PMRs) for an approved drug or device. In 2016, OIG will continue to evaluate FDA's utilization of PMRs and its processes for ensuring sponsors' compliance with these requirements.

Safety of Patient Data Stored in Medical Devices. In a new initiative, OIG will evaluate the sufficiency of FDA's oversight of hospitals' networked medical devices that are integrated to electronic medical records, including dialysis machines, radiology systems and medication dispensing systems. Medical device manufacturers are required to provide Manufacturer Disclosure Statements for Medical Device Security to assist health care providers in assessing the risks associated with electronic records transmitted by these devices. OIG will examine whether FDA's oversight of these devices adequately protects patients' electronic health care information.

For additional information on these and other initiatives, the full Fiscal Year 2016 Work Plan is available at http://www.oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf.

If you have any questions regarding the Fiscal Year 2016 Work Plan, please contact John W. Jones Jr. (http://www.pepperlaw.com/people/john-w-jones-jr/), Judith L. O'Grady (http://www.pepperlaw.com/people/judith-l-ogrady/) or the Pepper attorney with whom you normally consult.