

# CLIENT ALERTS

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## OIG Releases 2016 Work Plan

11.6.2015

On November 2, 2015, the Department of Health & Human Services (“HHS”), Office of Inspector General (“OIG”) issued the 2016 Work Plan detailing new and ongoing OIG audits, evaluations, and certain legal and investigative initiatives related to HHS programs and operations. In its 80-page Work Plan, the OIG details sixty-eight (68) New or Revised Initiatives that it will add to its ongoing reviews. With over 180 identified initiatives, the Work Plan is a must read for anyone participating in HHS-related programs, as it provides a glance at the current focus of the OIG 2016 to assist healthcare providers and suppliers in their compliance efforts. Below are a few of the more interesting initiatives that are in the OIG’s plans for FY 2016:

### **IT and Security Initiatives**

In 2016, the OIG will look at the FDA’s oversight of hospitals’ networked medical devices to determine the adequacy of the protections associated with electronic patient health information (“ePHI”) and beneficiary safety in light of the increased threats to the security and privacy of electronic medical records, and the development of larger health networks. The OIG will also review the Office for Civil Rights (“OCR”) oversight over the security of ePHI, noting that past audits determined OCR had not assessed the risks, established priorities or implemented controls for periodic audits of covered entities and business associates, leading to numerous vulnerabilities in the systems and controls to protect ePHI at selected covered entities.

### **Billing & Payment**

There are a number of billing and compliance and payment initiatives the OIG will undertake in FY 2016, notably reviews of :  
(a) hospital payments related to Medicare credits for replaced medical devices; (b) Medicare payments made during the MS-DRG payment window; (c) Skilled Nursing Facilities (“SNF”)

### **Related Services**

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documentation for therapy claims; (d) reasonableness of orthotic brace payments in comparison for non-Medicare payers, and documentation to support their medical necessity; (e) medical necessity of certain increased ventilator claims; states' methodology for assigning Managed Care Organizations' ("MCO") payments to different Federal medical assistance programs and their reimbursement to MCO long-term care plans; and (f) CMS' procedures for preventing and recouping Medicare payments unlawfully made for items and services to present and incarcerated beneficiaries.

### **Quality**

The OIG has identified a few new quality-related initiatives that it will undertake in FY 2016. One such initiative will focus on CMS's oversight system related to ambulatory surgery centers ("ASC"), particularly its oversight of State survey agencies and ASC accreditors and the lack of quality data available to the public. In addition the OIG will be reviewing accountable care organizations ("ACOs") that participate in the Medicare Shared Savings Program for quality and cost savings performance and the strategies for and challenges to achieving quality and cost savings. The OIG will also be reviewing CMS's validation efforts related to hospital inpatient quality reporting data for the hospital value-based purchasing program. Other quality-related reviews will involve state verification of deficiency corrections in SNF surveys, as well as state and CMS oversight and verification of provider ownership information, exclusions and payment suspensions during investigations involving "credible fraud allegations."

### **Part D/Pharmacies**

A number of new Initiatives are included in the 2016 Work Plan related to the Part D program and pharmacy suppliers. In response to a June 2015 national healthcare fraud takedown, much of which involved alleged prescription drug and pharmacy fraud, the OIG will be looking at CMS's ability to oversee Part D pharmacies. The OIG will also determine the extent to which pharmacies that bill for part D drugs, particularly those that are identified as high risk, are enrolled in Medicare. The OIG will also be looking at the changes in the reimbursement rate for brand name drugs under Part D for the period of 2010-2014 in comparison to the rate of inflation for the same period. According to the OIG, pricing for the most commonly used brand-name drugs increased nearly 13% in this 2013—an increase eight time greater than the rate of inflation. The OIG will also be reviewing the states' specialty drug pricing and reimbursement methodologies.

### **Reasonable and Necessary Services**

The OIG will undertake a number of reviews related to medical necessity of services. One of the more notable reviews will focus on services, supplies and durable medical equipment ("DME") referred/ordered by physicians and non-physician practitioners. Under the Affordable Care Act, certain services, supplies and/or DME are only reimbursable if ordered/referred by a physician or non-physician practitioner that is enrolled in the Medicare program. In addition, the OIG will be reviewing Part B claims for anesthesia services to determine if they were provided to a beneficiary who had a related Medicare service. The OIG will also be initiating new reviews related to Evaluation and

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Management (“E&M”) services. The first is to determine if Medicare payments to physicians for E&M home visits were appropriate, rather than an office or outpatient visit, while the second will look at the reasonableness of “prolonged” E & M services, which are considered “rare and unusual.”

With more than \$3 billion in expected recoveries in FY 2015, with 4,112 exclusions, 925 criminal actions and 682 civil actions, the OIG does not appear to be slowing down in FY 2016. From cyber security to home health to reimbursement and drug pricing, the OIG has set out an aggressive agenda. If past results are any indication the OIG will find billions of dollars in fraud, waste and abuse. Adopting reasonable and comprehensive effective compliance measures is likely the only way that providers and others have to address these matters before they become grist for the OIG mill. We encourage you to undertake measures to protect your interests, your patients and the success of your enterprise. Let us know how we can help.

For more information on the OIG Work Plan, and other healthcare compliance or regulatory matters, contact a member of Butzel Long’s Health Care Industry Group, the authors of this alert, or your regular Butzel Long attorney.

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