

# Government Intensifies Health Care Fraud Enforcement and Audits

DANIEL F. MURPHY

Over the past several years, Congress has steadily expanded the federal government's legal authority and ability to enforce health care fraud and abuse laws, such as the False Claims Act, against health care providers. At the same time, the government has greatly increased the number and scope of audits directed at participants in federal health insurance programs, such as Medicare and Medicaid.

National economic and political factors have contributed to the government's elevated efforts to scrutinize payments of federal funds to health care providers. First, Medicare expenditures continue to rise and politicians are under pressure to contain costs. In an otherwise highly polarized political environment, particularly concerning health care, both political parties have been able to agree that wasteful, incorrect, and fraudulently obtained payments should be eliminated. The government has decided to bring fraud and abuse laws, as well as audit tools, to bear in a rare area of political consensus concerning Medicare cost control. Second, as the economy remains weak after a prolonged recession, the federal budget deficit has soared, increasing the government's incentive to aggressively recoup improper and incorrect health care payments.

## **Stricter Fraud and Abuse Laws**

The Fraud Enforcement and Recovery Act of 2009 (FERA) became law on May 20, 2009. FERA expanded the scope of the federal False Claims Act (FCA) and increased funding for health care fraud and abuse enforcement efforts. Specifically, the law extended FCA liability to downstream subcontractors of government contractors (including health care providers) even if the subcontractor does not directly "present" a claim for payment to the federal government. Prior to FERA, case law interpreted FCA liability to require that a party who makes a "false claim" seek payment directly from the government. FERA also reduced the level of intent required to prove FCA liability; expanded "reverse false claims" provisions, which apply when a party retains improperly obtained payments; granted authority to a greater number of Department of Justice attorneys to commence FCA investigations; and increased federal funding for enforcement.

The health care reform law (Patient Protection and Affordable Care Act, PPACA) also strengthened existing fraud

and abuse laws. PPACA imposes new requirements on physicians relying on the "in-office ancillary services" Stark law exception for self-referred MRI, CT, and PET services, and eliminates the Stark law "whole hospital" exception. The law appropriates \$250 million for increased government enforcement of fraud and abuse laws over the period from 2011 to 2016. Compliance programs, which are currently voluntary, will eventually become mandatory under PPACA for certain health care providers determined by the Secretary of the Department of Health and Human Services. PPACA reduces the level of intent required for the government to prove violations of the Anti-Kickback Statute, and specifically requires, under the FCA, that health care providers to return Medicare overpayments within 60 days of discovering that an overpayment has been made. The law also expands the scope of the Civil Monetary Penalties law.

## **A Legion of Auditors**

Armed with enhanced fraud and abuse laws, the government has unleashed a number of auditors to identify and recover improper or simply erroneous payments made to health care providers. Some auditors, such as recovery audit contractors (RACs) and zone program integrity contractors (ZPICs), are recent creations. Others, such as state Medicaid Fraud Control Units (MFCUs) have been around for a long time, but have increased their levels of activity recently. Other members of the auditor alphabet soup include Medicaid Integrity Contractors (MICs), Program Safeguard Contractors (PSCs), and Comprehensive Error Rate Testing (CERT) auditors.

The number of potential auditors, who often have overlapping jurisdictions and missions, can be confusing and overwhelming, especially to smaller health care providers. For this reason, it is important for health care providers to task personnel and set up policies to deal with audits before an actual audit begins.

## **How to Prepare for Expanded Enforcement and Audit Efforts**

The recent laws and regulations concerning health care fraud and abuse enforcement and audits have tilted the playing field in the government's favor. Health care providers can best prepare for possible government inquiries and audits by implementing and operating effective compliance programs. The

*Continued on page 28*

# OSA

Orthopaedic  
Specialists of  
Alabama P.C.

*Is Proud To Introduce...*



**Ryan T. Cordry, D.O.**

*To our Medical West Location*

## **General Orthopaedics**

Fellowship Trained in Total Joint Replacement -  
Adult Reconstruction

Also specializing in Hip and  
Knee Arthroplasty

-----  
**Call 205-424-1160 for appointments**  
-----

975 9th Avenue SW, Suite 300  
Bessmer, AL 35022

**[www.OSADoctors.com](http://www.OSADoctors.com)**

## The Personal Touch, *continued from page 27*

laid the groundwork by developing a health informatics system that could support such a program under the guidance of William Stead, MD, director of the Informatics Center.

"We're in a very special position at Vanderbilt because of his foresight. If we hadn't begun biomedical informatics and a focus on delivering point-of-care decision support 10 years ago, I don't think we could begin to take advantage of the new opportunities around genome-guided care." Balsler added that such an effort would simply be impossible with a paper-based system. "Without intelligent decision support, the human genome is way too complicated for anyone ... no matter how smart ... to care for patients in real time."

Although genetic information will ultimately be used to better predict risk factors for developing certain diseases and potentially allow for preventive measures to delay or stop progression, Roden was quick to point out that isn't where Vanderbilt's Personalized Medicine program is at this point. Instead, he noted, "The first bedside use of new genomic information is to pick better drugs for patients, pick better doses, and to avoid certain drugs altogether in patients at high risk for serious side effects. It's about getting the right drug to the right patient at the right time."

He continued, "The way we envision this is your genetic information, that is important for your drug response, is already embedded in your electronic health record before you need it."



Dr. Dan M. Roden

Roden said the logical way to start is to look at a group of individuals likely to get a drug requiring genetic testing in the near future. For example, everyone who has hip surgery takes warfarin, a blood thinner, for several weeks afterwards. "The dose varies from 1 mg a day to 10 mg a day. A lot of that variation is genetic," Roden pointed out. By conducting the genetic test for warfarin response prior to surgery and embedding the information in the patient's EHR, it eliminates the current 'trial and error' method to achieve an optimal response.

Roden and Balsler are keenly aware of privacy concerns that come with broad-based genetic profiling. Balsler was quick to point out that although Vanderbilt has nearly 100,000 de-identified DNA samples through their BioVU knowledge engine, the Personalized Medicine program is different. "This is patient care ... not research," he said, adding that a patient would have to opt to participate, and the DNA information would be part of a patient's confidential EHR. Roden added, "At the beginning, we're going to focus exclusively on genetic variances that have

nothing to do with your health status but (on) how you react to drugs."

One of the most visible arms of the new effort is the Personalized Cancer Medicine Initiative at Vanderbilt-Ingram Cancer Center (VICC). With its July launch, VICC became the first cancer center in the Southeast and one of the first in the nation to offer cancer patients routine tumor genotyping to help direct therapy.

Led by William Pao, MD, PhD, director of Personalized Cancer Medicine for VICC, the program began laying the groundwork more than a year ago. "We think this is the future of cancer medicine, where the genetic makeup of tumors will help us prioritize treatment," he said.

Initially, the program is focusing on lung cancer and melanoma with colon cancer on the horizon. "We're looking specifically at non-squamous, non-small cell lung cancer and melanomas. We're looking for about 40 recurrent, somatic mutations that have relevance to existing or emerging targeted therapies," Pao explained.

Pao referenced the Aug. 26 edition of the *New England Journal of Medicine* that reported the findings of specifically targeting the V600E B-RAF mutation in some melanomas. The targeted therapy shrunk tumors at a response rate not seen before in chemotherapy and immunotherapy for those with the mutation but had no effect for those without it.

Similarly, he noted only about 10 in 100 non-small cell lung cancer patients respond effectively to Tarceva or Iressa,

which inhibit activity of the epidermal growth factor receptor (EGFR). "We want to be able to figure out who those patients are so we can best treat them appropriately, and we want to figure it out ahead of time," Pao said, adding that such targeted therapy was not only more effective but was also more cost efficient and typically resulted in fewer side effects.

"With chemotherapies, we don't know until we give it to our patients if it's going to be effective," Pao explained. "Here, based on the molecular fingerprint ... or tumor profile ... we can say that based on studies, '70 percent of people have had this response.' We have a much more rational approach to the treatment of the disease."

For patients, such targeted, personalized care should result in improved outcomes.

## Government Intensifies Health Care Fraud,

*continued from page 25*

Office of Inspector General (OIG) recommends that health care providers have compliance programs in place, and has published detailed guidance by provider type on the elements of effective compliance programs. OIG compliance program guidance, including for physician groups, medical billing companies, and hospitals, can be found at <http://www.oig.hhs.gov/fraud/compliance-guidance.asp>. Among other benefits, effective compliance programs can help health care providers identify potential compliance issues before they occur and address problems proactively.

With respect to audits, such as those performed by RACs, health care providers should identify personnel responsible for managing government audit responses before an actual audit commences. Providers should also have policies and processes in place to set parameters for the conduct of audits. For example, timelines are very important in RAC audits, and providers should therefore track deadlines and log correspondence with the auditors. Audit response strategies can be incorporated into a health care provider's overall compliance program.



Daniel Murphy is an associate in Balch & Bingham's Healthcare Practice Group. His practice focuses on healthcare industry regulation and transactions.



**In-home services** that match seniors who want to provide help with seniors who are looking for help.



**SENIORS Helping SENIORS®**  
...a way to give and to receive®

sbaldwinshs@gmail.com

Stephen C. Baldwin • 137 Narrows Peak Circle • Birmingham, AL 35242 • 205-981-1926