

Listening to the Government

David S. Szabo

Edwards Angell Palmer & Dodge LLP

One of the questions I often hear is: “What can we expect next from government regulators in healthcare?” Sometimes, it’s difficult to predict what the government will do next, or when regulators will act. In other cases, however, the government tries to tell us what they are thinking, or what they plan to do next. In these cases, it is our own fault if we don’t listen.

For example, one of the key regulators for providers that participate in Medicare is the Office of the Inspector General, or ‘OIG’. According to its own web site, the mission of the OIG is to protect the integrity of Department of Health and Human Services’ programs, as well as the health and welfare of the beneficiaries of those programs. The OIG has a responsibility to report program and management problems both to the Secretary of Health and Human Services and to the Congress and to make recommendations to correct those problems. The OIG’s duties are carried out through audits, investigations, inspections and other functions performed by OIG components. The OIG has the authority to investigate potential violations of Medicare regulations, and to bring administrative actions, or with the help of the Department of Justice, to bring civil or criminal cases. The OIG’s influence also can be seen in Advisory Rulings it issues under the anti-kickback laws, the safe harbor regulations, its fraud alerts, along with its various reports and analyses that it releases to Congress and the public.

One important source of information about the OIG is its annual workplan. The OIG Work Plan sets forth various projects to be addressed during the fiscal year by the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General. The Work Plan includes projects planned in each of the Department’s major entities: the Centers for Medicare & Medicaid Services; the public health agencies; and the Administrations for Children, Families, and Aging. Some of the projects described in the Work Plan are required by law, such as the audit of the Department’s financial statements, which is mandated by the Government Management Reform Act. Other priorities are determined by the OIG itself, in consultation with other agencies and government offices.

The workplan, then, is an important source of information on OIG priorities and initiatives. It tells us what this particular government regulator is concerned about. The most recent workplan for FY 2011, *The Office of Inspector General Work Plan for Fiscal Year 2011* provides brief descriptions of activities that the Office of Inspector General (OIG) plans to initiate or continue with respect to the programs and operations of the Department of Health & Human Services in fiscal year 2011. Significantly, several provisions of the FY 2011 workplan directly concern sleep physicians, sleep labs, and suppliers of CPAP.

Appropriateness of Medicare Payments for Polysomnography

The OIG's Office of Evaluation and Inspections plans to review the appropriateness of Medicare payments for sleep studies. OIG notes in the workplan that Medicare payments for polysomnography increased from \$62 million in 2001 to \$235 million in 2009, and that coverage was also recently expanded. The OIG will examine the factors contributing to the rise in Medicare payments for sleep studies and assess provider compliance with Federal program requirements, including medical necessity and documentation standards. This is a new initiative, and the report is scheduled to be released during FY 2012.

Medicare Payments for Sleep Testing

The OIG's Office of Audit Services also plans to review the appropriateness of Medicare payments for sleep test procedures provided at sleep disorder clinics. OIG states that a preliminary OIG review identified improper payments when certain modifiers are not reported with sleep test procedures. They plan to examine Medicare payments to physicians and independent diagnostic testing facilities for sleep test procedures to determine whether they were in accordance with Medicare requirements. This project is currently in process and a report is expected during the current fiscal year.

Geographic Areas With a High Density of Independent Diagnostic Testing Facilities.

OIG plans to review services and billing patterns in geographic areas with high concentrations of independent diagnostic testing facilities ("IDTFs"). This review is highly likely to include sleep labs that are organized as IDFTs. IDTFs must meet regulatory performance requirements set forth in Medicare regulations as a condition of obtaining and maintaining Medicare billing privileges. According to the workplan, a 2006 OIG review found numerous problems with

IDTFs, including noncompliance with Medicare standards and potential improper payments of \$71.5 million. The OIG also plans to also examine billing patterns in areas with a high density of IDTFs. This report will be issued by the Office of Evaluation and Inspections, and will be released in 2011. It is currently in progress.

Independent Diagnostic Testing Facilities' Compliance With Medicare Standards

OIG also plans to review selected IDTFs enrolled in Medicare to determine the extent to which they comply with selected Medicare standards. According to the OIG, IDTFs received payments of about \$860 million in 2009. OIG plans to review these selected IDTFs for their compliance with the 17 performance standards set forth in Medicare regulations. Such standards include requirements that IDTFs comply with all of the Federal and State licensure and regulatory requirements that are applicable to the health and safety of patients, provide complete and accurate information on their enrollment applications, and have on duty technical staff members who hold appropriate credentials to perform tests. OIG also plans to attempt to identify billing patterns associated with IDTFs that were not compliant with selected Medicare standards. This report will be prepared of the Office of Evaluation and Inspections, is already in progress, and is expected by FY 2011.

Medicare Enrollment and Monitoring for Suppliers of Durable Medical Equipment

OIG plans to review Medicare contractors' processes for enrolling and monitoring suppliers of durable medical equipment. Under Medicare regulations, Medicare contractors are required to conduct pre-screening, verification, and validation of Medicare supplier enrollment applications. OIG states that a recent study found that suppliers omitted information, or provided inaccurate information, on enrollment applications, which resulted in improper enrollment. OIG plans to assess Medicare contractors' use of enrollment-screening mechanisms and post-enrollment monitoring activities to identify applicants that pose fraud risks to Medicare and the extent to which applicants omitted ownership information on enrollment applications. This report will be carried out by the Office of Evaluation and Inspections, and is expected to be issued in the current fiscal year.

Putting Information to Use

Knowing what the government is looking for is good, but putting that information to use is even better. Sleep labs and CPAP suppliers would be well advised to use the workplan as a guide for focusing their own compliance efforts. Here are a few suggestions.

- Make sure that you can document that you have met all rules for coverage of each sleep study, including physician orders from the treating physician and medical necessity of the study.
- Make sure your clinical and coding personnel know the proper use of modifiers for each CPT code, and verify that the right code is being used. Consider randomly sampling a sub-set of claims before submitting them to Medicare and Medicaid.
- If your lab is enrolled as an IDTF, review all of the performance standards, and validate that your lab meets each one. Remedy any non-compliance as soon as possible.
- Validate the accuracy of your Medicare enrollment information. If it is incorrect or outdated, correct it. Remember that changes in staff, equipment, and medical direction all require updates to enrollment information.

You can't foresee all of the changes that might come from Medicare or government regulators, but when they take the trouble to tell us what they are thinking, we should try to put that information to good use.