Will the Long Arm of the OIG Reach Out for Neurologists?

Providers who participate in Medicare and Medicaid know the OIG’s annual work plan reveals areas of scrutiny for the coming year.

Each fall the Office of the Inspector General of the US Department of Health and Human Services publicizes a “Work Plan” for the coming fiscal year. This plan highlights areas where the OIG will focus efforts to assess progress of specific initiatives or uncover incidences of overpayment. Often observers note that the OIG seeks to weed out fraud and abuse.

The Fiscal Year 2009 (FY09) Work Plan is a 115-page document that highlights a spate of initiatives across various HHS programs and agencies (It’s available for download at oig.hhs.gov/publications/docs/workplan/2009/WorkPlanFY2009.pdf). Within the Medicare-related topics, two may apply specifically to neurologists.

Neurology-Specific Targets

Polysomnography. Perhaps the OIG’s focus area of most direct relationship to neurology is the “Appropriateness of Medicare Payments for Polysomnography.” Noting that Medicare payments for polysomnography increased from $62 million in 2001 to $215 million in 2005, the OIG says it will “examine the factors contributing to the rise in Medicare payments for sleep studies and assess provider compliance with Federal program requirements.” Furthermore, scrutiny will fall on the appropriateness of Medicare payments for sleep studies. According to the CMS Medicare Benefit Policy Manual, sleep studies are reimbursable for patients with symptoms consistent with sleep apnea, narcolepsy, impotence, or parasomnia.

Independent Diagnostic Testing Facilities. Also of potential significance to neurology will be the focus on “Geographic Areas With a High Density of Independent Diagnostic Testing Facilities.” Says the OIG, “We will review services and billing patterns in geographic areas with high concentrations of independent diagnostic testing facilities (IDTF).” Based on a 2006 OIG review that found that Medicare made potentially improper payments of $71.5 million to IDTFs, the OIG is clearly seeking to reign in costs.

Based on a 2006 OIG review that found that Medicare made potentially improper payments of $71.5 million to IDTFs, the OIG is clearly seeking to reign in costs. CMS has established performance requirements that IDTFs must meet in order to maintain Medicare billing privileges; that same 2006 review found numerous instances of non-compliant IDTFs.

General Issues

Practice Expenses. OIG says it will review “Medicare Practice Expenses Incurred by Selected Physician Specialties,” though it does not indicate which specific specialties will fall under scrutiny. In the words of the report:

We will review the actual expenses of selected physician specialties. Physician services include medical and surgical procedures, office visits, and medical consultations. Physicians are paid for services pursuant to the MPFS, which covers the major categories of costs including the physician professional cost component, malpractice costs, and practice expense. The Social
Security Act, 1848(c)(1)(B), defines “practice expense” as the portion of the resources used in furnishing the service that reflects the general categories of expenses, such as office rent, wages of personnel, and equipment. We will determine whether Medicare payments for physician services performed by selected specialties are comparable to the actual expenses incurred by the physicians in providing services and operating their practices.

Nurse Practitioners and Physician Assistants. If your practice employs a nurse practitioner or physician assistant (or is considering adding one), note that the OIG will undertake a review of “Physicians’ Medicare Services Performed by Non-physicians.” Medicare provides reimbursement for services and supplies performed “incident to” the professional services of a physician (generally speaking, this is when the patient is already under the care of the physician for a specific diagnosis or diagnoses, but the non-physician provider renders care relevant to that diagnosis). But OIG asserts, “these services may be vulnerable to over-utilization or put beneficiaries at risk of receiving services that do not meet professionally recognized standards of care.” With this in mind, OIG calls for examination of the qualifications of non-physician staff that perform “incident to” services and “whether these qualifications are consistent with professionally recognized standards of care.”

**HIPAA.** Given that CMS is responsible for overseeing compliance with the HIPAA Security Rule (data security standards required under sections 261 and 262 of the HIPAA), OIG says it plans to review the agency’s “oversight, implementation, and enforcement” of the Rule. In addition to providers that provide Medicare and Medicaid services, OIG says it will also assess the compliance of various Medicare-related programs, as it seeks to “determine the adequacy of oversight provided by the Office for Civil Rights for the HIPAA Privacy Rule.”

---

**Foreign Clinical Trials Under Scrutiny**

In addition to Medicare and Medicaid, the OIG has oversight over various other programs and agencies, including the FDA. Within it’s FDA-focused efforts, the Office says it will address the influence of foreign research on US drug approvals.

It’s well-known that some of the data used to support new drug applications comes from international trials. The fact that many drugs earn approvals outside the US before the FDA gives its consent virtually guarantees that some international data will predate the Agency’s action. Such data are allowable, and there are established criteria related to the qualifications of clinical investigators and participating sites.

The OIG says it will, “review the extent to which drug manufacturers use foreign clinical trials to support new drug applications (NDA) submitted to FDA,” with emphasis on trends in the past five years and NDAs supported solely by foreign trial data.

OIG says that data gathered for a 2007 report suggest that 20 to 30 percent of data used in NDAs come from foreign clinical trials, but FDA is often unaware that foreign trials have been conducted until after the results are submitted in NDAs. Notes the OIG, “FDA is prohibited from disqualifying foreign trial data if the trials are conducted in accordance with ethical principles acceptable to the world community.”