HHS-OIG Report:
‘Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents’

In May 2011, the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) released a report titled "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents." The HHS-OIG utilized Medicare claims data (Part B and D) for the eight U.S. Food and Drug Administration (FDA) approved atypical anti-psychotic medications during the period Jan. 1, 2007 through June 30, 2007, in elderly nursing home residents (age > 65 years). The report was the result of a request from Senator Charles Grassley (R-Iowa) to evaluate the extent to which elderly nursing home residents receive atypical antipsychotic medications. Senator Grassley’s primary concerns with these second-generation anti-psychotic drugs were two-fold: a) use of atypical anti-psychotics for “off-label conditions” (i.e., conditions other than schizophrenia and/or mood disorders); and, b) whether Medicare is paying for therapies that may be inappropriate from both a clinical efficacy (i.e., off-label use) and patient safety standpoint (i.e., FDA Boxed Warnings – April 2005, FDA public health advisory regarding the increased risk of mortality when atypical anti-psychotics are used for the treatment of behavioral disorders in elderly patients with accompanying dementia).

Other concerns for the HHS-OIG include the potential for fraud, waste, and abuse (FWA) in any of the HHS programs. For example, in November 2009, the federal government reached a $98 million settlement with OMNICARE [a long-term care (LTC) pharmacy] to resolve allegations that it received kickbacks from pharmaceutical manufacturers (e.g., RISPERDAL) for recommending certain medications for nursing home patients. The Department of Justice also filed suit against the manufacturer and two subsidiaries alleging that the companies paid kickbacks to OMNICARE, Inc. to recommend RISPERDAL. Lastly, the federal government has also entered into a number of settlements with other manufacturers of atypical antipsychotics to resolve allegations that the companies knowingly promoted their products for uses that were not FDA approved and thereby not reimbursable under federal health care programs. Interestingly enough, a June 2009, Centers for Medicare and Medicaid Services (CMS) data analysis found that three of the top 10 medications paid for under the Medicare Part D program in 2006 were atypical anti-psychotics.

Major findings:

a) Out of 2.1 million elderly nursing home residents, approximately 14.5 percent (304,983 residents) had at least one Medicare claim for atypical anti-psychotics.

b) Eighty-three percent of Medicare claims for atypical antipsychotics for elderly nursing home residents were associated with off-label conditions of which 88 percent were associated with the condition specified in the FDA boxed warning.

c) Nearly 51 percent of Medicare atypical antipsychotic drug claims for elderly nursing home residents were considered erroneous, amounting to $116 million. As a result of an extensive medical record review the claims were found to be utilized for either non-medically accepted indications (50.2 percent) and/or as having not been administered to the nursing home resident (0.3 percent).

d) Twenty-two percent of the atypical antipsychotic drug claims were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes (e.g., excessive dosing or duration, etc.)

HHS-OIG recommendations to CMS included the following:

a) Facilitate access to information necessary to ensure accurate coverage and reimbursement determinations.

b) Assess whether survey and accreditation processes offer adequate safeguards against unnecessary antipsychotic use in nursing homes.

c) Explore alternative methods beyond survey and certification processes to promote compliance with federal standards regarding unnecessary drug use in nursing homes.

d) Take appropriate action regarding claims associated with erroneous payments.

References: