Legal Issues

By Janet K. Feldkamp, JD, RN, LNHA

Atypical Antipsychotics and LTC Liability

Last May, the Health and Human Services Office of Inspector General released a report about the use of atypical antipsychotic medications in nursing homes. While the OIG report focused on invalid Medicare-payment claims, a federal Departmental Appeals Board case and two recent medical malpractice complaints demonstrate how the improper prescription of atypical antipsychotics might jeopardize facilities legally.

Atypical antipsychotics such as aripiprazole, clozapine, risperidone, quetiapine, and olanzapine are currently approved by the Food and Drug Administration for the treatment of schizophrenia and bipolar disorder, and some are actually FDA approved for major depressive disorder.

Off-label uses include, but are not limited to, treatments for agitation in dementia, depression, obsessive-compulsive disorder, Tourette's syndrome, and autism.

In April 2005, the FDA began requiring labels ("black-box warnings") cautioning prescribers and consumers that atypical antipsychotics increase the risk of mortality among elderly people with dementia. Despite this warning, the latest OIG report claimed that many elderly nursing home residents with dementia continue to receive atypical antipsychotics for off-label uses and often for indications that either are not medically acceptable or don't exist.

A Federal Case

In September 2008, the Department of Health and Human Services upheld a finding of noncompliance at the "immediate jeopardy" level when a resident received excessive doses of the atypical antipsychotic risperidone.

The case involved a 68-year-old woman with an extensive medical history, including dementia and multiple strokes. In a hospital prior to transferring to the nursing home, the resident received 0.5 mg of risperidone twice daily. However, the discharging nurse did not include the decimal point on the medication reconciliation form, making the dose upon transfer risperidone 5 mg twice daily.

No physician, pharmacist, or nurse caught the error or adjusted the dosage before the resident experienced cardiac arrest and died 11 days after her nursing home admission. At that time there had been no diagnosis documented in the chart to indicate an order for risperidone.

Inspectors from the Centers for Medicare & Medicaid Services noted that, consistent with the drug's black-box warning, special consideration and care is necessary when administering risperidone to elderly people with dementia.

A Departmental Appeals Board found that the facility failed to appropriately respond to the irregular prescription and failed to monitor and respond to the resident's symptoms consistent with an adverse reaction to risperidone.

More relevant to the facility's liability than the physician's actions were the roles of the pharmacist and nursing staff. The CMS requires that services provided or arranged by the facility meet professional standards of quality, that pharmacists question every irregular medication order, and that residents be free from unnecessary drugs.

The appeals board found the facility in violation of these regulations: first, because the dispensing pharmacist and nursing staff failed to follow up on the risperidone order, despite the sizable dosage for a 102-pound, elderly woman; second, because no diagnostic indication for risperidone was documented; third, because the resident was also receiving concomitant lorazepam and sertraline, which can potentiate the effects of risperidone and should have raised an additional red flag; and fourth, because the staff failed to connect the resident's lethargy and falls (adverse reactions to risperidone) to the medication regimen.

Lawsuits Too

Lawsuits related to the improper use of atypical antipsychotics in long-term care facilities were recently filed in Florida and Illinois.

In Florida, the complaint involves a man who died after falling and suffering hip and femur fractures in a nursing home. The plaintiff alleges violations of two Florida statutes because the facility failed to recognize the adverse effects of risperidone, monitor the resident, and assess medication reactions and report them to physicians and other care providers in a timely manner.

The Illinois complaint involves a claim of medical negligence against a long-term psychiatric-care facility because employees allegedly violated their duty as reasonable health care providers. The plaintiff – a woman of unspecified age – alleges that risperidone was not indicated for her condition; that the staff failed to recognize that the plaintiff's neck pain, stiffness, and twitching were adverse reactions to risperidone; and that staff failed to report the symptoms to the plaintiff's physician or up the nursing chain of command.

The OIG report suggested that the frequency of off-label prescriptions resulting in erroneous Medicare payments is a problem perpetuated by the financial and contractual relationships among nursing homes, pharmacies, and drug manufacturers and distributors.

The report also recommended that the CMS explore ways to make nursing homes more accountable for Medicare claims for prescriptions that are unnecessary. Currently, facilities are not financially liable because Medicare Part D (the prescription drug benefit) claims for payment are submitted on behalf of individual residents rather than on behalf of their nursing homes.

In order to avoid administrative penalties, medical malpractice litigation, and perhaps at some point liability for submitting false claims to Medicare, it is imperative that nursing homes understand their responsibilities when it comes to the use of atypical antipsychotic medications:

- A medically indicated diagnosis must be clearly documented in the resident's chart.
- Nursing staff should understand appropriate dosages and be able to identify and respond to adverse reactions.
- When an atypical antipsychotic is needed to treat agitation in patients with dementia, clinicians should prescribe the lowest effective dose.
- Dose reductions should be done gradually and alternatives to drug therapy, such as behavioral interventions, must be implemented to decrease or eliminate a resident's need for the medication.
- The consulting pharmacist must be actively involved in reviewing and making recommendations for dosage adjustments and documentation requirements.

This column is not to be substituted for legal advice. The writer, JANET K. FELDKAMP, *practices in various aspects of health care, including long-term care survey and certification, certificate of need, health care acquisitions, physician and nurse practice, managed care and nursing related issues, and fraud and abuse. She is affiliated with Benesch Friedlander Coplan & Aronoff LLP of Columbus, Ohio.*

MEDICAL EXPERT PERSPECTIVE

The recent Office of Inspector General report on antipsychotic use in long-term care has generated increased regulatory scrutiny of the use of these medications in many states. Whether or not the findings of the report were presented in a balanced fashion, unquestionable facts remain: Truly inappropriate use of these medications does occur in some cases, and these medications carry significant risks.

Obtaining (and documenting) informed consent for these meds is of critical importance in providing competent patient care and managing risk. This should be a priority for nursing staff, pharmacy consultants, social services personnel, physicians, and other prescribing practitioners in skilled nursing facilities. And clearly – outside of emergency situations – these medications should be used only when truly necessary and when other measures have failed. AMDA has recently developed some talking points on antipsychotics and will continue to lead efforts at education and inclusion of the entire interdisciplinary team in addressing these medications (see www.amda.com/advocacy/brucbs.cfm).

In some states, notably California, recent developments have resulted in heightened requirements for the prescriber to personally obtain informed consent for the use of all psychoactive medications (including antidepressants, mood stabilizers, and anxiolytics). This applies not only to new prescriptions but also to medications being taken since before a patient is transferred into a nursing facility from the community or a hospital.

This is likely to exert a chilling effect on the use of medications, which will almost certainly result in some patients not receiving medically necessary medications.

Physicians and other prescribers must stay focused on the most important element of our work: enhancing the quality of life of our patients. Along the lines of our battles with the Drug Enforcement Administration over Schedule II controlled substance dispensing, we should not take the path of least resistance with psychotropic medications just because there are now more hoops to jump through to meet our patients' needs.

–Karl Steinberg, MD, CMD
Editor in Chief