Legal Issues

By Janet K. Feldkamp, JD, RN, LNHA

Focus on Restraints Turns From Physical to Chemical

The use of restraints in nursing homes has long been an important resident safety issue. While the least restrictive use of physical restraints remains as important as ever in nursing homes, regulatory attention has shifted to chemical restraints in the form of antipsychotic medications such as haloperidol, quetiapine, and olanzapine.

By law, nursing home residents have the right to be free from "any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms." In 2008, the Centers for Medicare & Medicaid Services published a report applauding the success of practitioners, providers, advocates, and agencies in decreasing the percentage of nursing home residents physically restrained daily from 21.1% in 1991 to under 5% in 2007.

Recently, surveyors have begun focusing on chemical-restraint assessment and documentation. An antipsychotic medication is considered a chemical restraint if it is used to treat dementia-related behavioral and psychological symptoms.

A 2010 CMS report found that more than 17% of nursing home residents daily receive an antipsychotic at a higher-than-recommended dose. A July 2012 report from the Office of Inspector General found that among nursing home residents who were receiving antipsychotics, 99% of records were not in compliance with Medicare assessment requirements. Eighteen percent of the medical records did not indicate that care plans for these residents were followed through. The reports have triggered heightened enforcement of regulations governing the use of antipsychotics in nursing homes.

Potential Penalties

Two recent Health and Human Services Departmental Appeals Board cases illustrate federal action in this area. One case from 2011 upheld an F-tag 329 citation for unnecessary medications against Washington Christian Village in Illinois.

A 78-year-old woman with dementia was exhibiting nervousness, anxiety, and behavioral difficulties at the time of her admission to the nursing facility. The attending physician switched an existing order for haloperidol to quetiapine 25 mg twice daily for "dementia/agitation." The resident's agitation persisted and she fell several times while ambulating to the point of exhaustion. After she was hospitalized for high sodium and low alertness and then returned to the nursing home, the resident's attending physician ordered a combination of antipsychotics – quetiapine and olanzapine – despite the fact that the resident's alertness remained low.

The judge found that the facility neither justified the combination and dosages of the antipsychotic drugs nor adequately monitored for side effects or the feasibility of reducing dosages. She ruled that the facility had an "independent responsibility" to address the risks, benefits, and ultimate justification for administration of two antipsychotics simultaneously. The facility did not fulfill this responsibility because staff failed to question the doctor about the order when it was unaccompanied by a diagnosis or explanation. The fact that the resident was receiving any antipsychotic, let alone two, while lethargic was deemed problematic.

The symptoms were deemed inappropriate to justify an antipsychotic. The judge also stated that a continuance of a year-and-a-half-old olanzapine order (from another facility) for "dementia with physically aggressive behaviors" was insufficient justification. While a physician order may deviate from the norm, she said, any such deviation must be accompanied by a current and convincing justification.

Finally, the facility failed to monitor the therapy by not watching for antipsychotic side effects such as loss of appetite, lethargy, and uncontrolled muscle movements. The staff failed to track behavioral symptoms and medication side effects on a monthly flow record. The judge admonished the facility that an "absence of careful monitoring makes it impossible to tell where [the resident] benefited or suffered as a result of the medications."

In an even more recent Departmental Appeals Board case early this year, a 70-year-old female resident was discharged from a hospital to the Golden Living Center–Colonial Manor in Wisconsin with an order for haloperidol for delirium that developed during the hospitalization. The resident received the antipsychotic medication at bedtime per the order until she was assessed by a psychologist more than 20 days later. Upon the advice of the psychologist, a nurse practitioner attending to the resident discontinued the haloperidol at that time.

The judge upheld the deficiency because the resident's record did not contain a care plan for antipsychotic medications. Additionally, there was no documentation of an initial assessment in support of continuing the haloperidol upon transfer from the hospital.

New Initiatives

In addition to more vigilant enforcement actions, CMS is rolling out new programs to address antipsychotic drugs in nursing homes. In May of this year, CMS announced a Partnership to Improve Dementia Care with the goal of reducing antipsychotic use in nursing homes by 15% by the end of the year through enhanced training and increased use of alternatives to antipsychotics. Training includes an educational series for nursing homes as well as behavioral health training for state surveyors (see page 12).

CMS's most recent Nursing Home Action Plan, released in July, outlines the agency's plans to improve nursing home safety and quality. Inappropriate antipsychotic use is addressed under the heading "Promote Quality Improvement." Included are metrics and evidence-based training activities aimed at Quality Improvement Organization performance and increased emphasis in state surveys on antipsychotic use. Also as a part of this plan, the CMS Nursing Home Compare website for consumers has recently added "rate of antipsychotic use" to its quality indicators.

Nursing homes must closely analyze their antipsychotic medication prescribing policies and procedures, both for the well-being of residents as well as to prepare for closer scrutiny from state surveyors. Facilities and their personnel should be ready to use the same vigilance in prescribing, assessing, monitoring, and documenting antipsychotic medications that they use to address physical restraint devices. Outdated policies or poor documentation may be detrimental to resident quality of life and leave facilities at risk for serious survey deficiencies.

Some other recommendations from a legal perspective would include engaging the medical director to educate physicians about the importance of detailed documentation related to antipsychotic prescriptions for diagnosed psychiatric disorders; ensuring that an antipsychotic medication care plan is in place and being followed; documenting all attempts to taper dosages, the emergence of symptoms for which antipsychotics are indicated, and any reason for deviating from a recognized standard of care or from the resident's care plan; and training nursing staff to identify duplicate orders for antipsychotics and to question an antipsychotic order not accompanied by a credible clinical rationale.

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

There is no doubt that we will see an increase in civil litigation and regulatory actions related to antipsychotics. The lawsuits have already begun in several states. Federal legislation is in the works, and it contains a provision requiring informed consent for these medications. Certainly as prescribers, we should do our best to ensure that risks, benefits, and alternatives for medications are understood by our patients and/or their decision makers.

The culture that has brought us to the over-reliance on antipsychotics in situations where other methods should be used is multifactorial, and its remedy will require a broad strategy that is already being implemented by the Centers for Medicare & Medicaid Services and many stakeholder organizations, including AMDA. While nursing homes cannot prescribe these agents, there is a sense that by the time the nurse calls the physician to report problematic behaviors of a dementia patient, the nurse is really asking for medication orders. And staff may sometimes just want a quick fix that in fact is a chemical restraint.

We need to move away from this culture and do root cause analysis, doing our best to determine antecedents and, whenever possible, remove stimuli that are contributing to behavioral decompensation in our dementia patients.

At the same time, we need to maintain some understanding, amid the media's and advocacy organizations' frenzy, that there are situations where these medications are not only indicated but really a godsend. They can be successful in treating distress, and that is what we are supposed to do. But, except in emergencies, we should do it only in situations where other methods have failed.

Documentation and appropriate care planning, with prescriber input, are important. All of us need to be judicious in our use of these medications, but let's not throw the baby out with the bath water.

–Karl Steinberg, MD, CMD, Editor in Chief