Legal Issues

By Janet K. Feldkamp, JD, RN, LNHA

CMS Sharpens Focus on Medication-Related Adverse Events

Although prescribed to address conditions and diagnoses, medications are inherently dangerous if not administered and monitored correctly. Residents in PA/LTC facilities are prescribed numerous medications and are very vulnerable to medication-related adverse events. Not only are nursing facilities required to administer medications per appropriate physician orders, but also the facilities must consistently follow policies and procedures for monitoring medication levels for a number of medications. The Centers for Medicare & Medicaid Services issued a Survey and Certification Memo on July 17, 2015 (www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-47.pdf). highlighting the agency's concerns about the prevalence of medication-related adverse events. The concern over medication-related injuries is not a new concern for CMS, state survey agencies, or nursing facilities.

Failure to Monitor Anticoagulants

Medication-related adverse events have resulted in many regulatory citations with resulting civil money penalties and other sanctions imposed by CMS. Two Departmental Appeals Board (DAB) cases outline concerns cited related to anticoagulant therapy and the potential dangers to residents, with failure to monitor for potential negative resident outcomes and failure to follow the standards of care. A 2011 DAB appellate case of Universal Health Care-King (Dec. No. 2383, June 2011) upheld the immediate jeopardy determination with more than 180 days cited by the North Carolina state survey agency related to a failure to adequately monitor warfarin (Coumadin) anticoagulant therapy. The three-judge appellate panel upheld the administrative law judge's findings that the facility failed to timely obtain laboratory monitoring and also failed to timely notify the physician of critically high blood levels, which placed the resident at significant risk of bleeding. In this instance, one resident was receiving warfarin therapy with the need for daily laboratory monitoring. On several occasions, the facility failed to timely obtain the necessary laboratory testing, which resulted in wide fluctuations in the blood activity level of warfarin and placed the resident either at risk of excessive bleeding or of potential thrombotic complications. The state survey agency cited, and the administrative law judge and the appellate panel upheld, the significant length of time for the immediate jeopardy based upon the failure to monitor and the failure to fully implement an effective system to prevent medication-related adverse events, particularly for anticoagulants.

Similarly, the DAB administrative law judge upheld the Louisiana State Agency's immediate jeopardy citation to Grace Nursing Home (CR2250, September 2010) and the issuance of a per instance civil money penalty for the failure to monitor anticoagulant therapy resulting in one resident's hospitalization for warfarin toxicity. The facility failed to obtain the ordered laboratory tests to monitor the warfarin activity (using International Normalized Ratio [INR] levels) for more than a week. The resident's INR rose to a critical level, resulting in approximately one week's hospitalization. These cases are just two examples of a number of DAB cases challenging immediate jeopardy citations related to the failure to adequately administer and monitor anticoagulants.

Tools for Surveyors, Providers

The recently issued CMS S & C: 15-47-NH DAB decision discusses the importance of preventing adverse medication events for a variety of medication types. Medications have significant potential side effects, and careful administration and adequate monitoring are necessary to protect residents' safety and well-being. The CMS issuance discusses the Office of Inspector General's (OIG) report of February 2014 on adverse events for Medicare beneficiaries in skilled nursing facilities. The OIG report found that 37% of the adverse events were related to medication and that the second most frequent cause of medication adverse events is related to excessive bleeding from anticoagulants.

CMS also reported that it has developed and is now pilot testing a Focused Survey on Medication Safety. The newest Focused Survey's objectives include:

- Identifying preventable adverse drug events that have occurred or potentially may occur
- Determining if the facilities are identifying risk factors for adverse drug events and implementing individualized interventions to eliminate or mitigate the risk factors
- Determining if facilities are implementing effective systems to prevent adverse drug events and recognizing and responding appropriately if and when adverse drug events do occur

Included with the S & C issuance was a CMS Adverse Drug Event Trigger Tool (www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf). This tool was developed in collaboration with the Agency for Healthcare Research & Quality. Surveyors were instructed to utilize the tool to identify complaint investigations related to adverse events. Use of this tool by providers can strengthen risk management programs and can be used as an educational tool for clinicians and management personnel. The tool provides adverse drug events, risk factors, triggers of signs and symptoms, and triggers for clinical interventions and surveyor probes. The tool is provided in an easy to use matrix format that is divided by types of adverse events.

The prevention of adverse medication events is an important component for the delivery of quality care to post-acute care residents. Nursing facilities must have robust policies and procedures for medication administration and monitoring. Good policies and procedures must be coupled with ongoing and consistent clinical and laboratory monitoring to avoid potential negative effects of medications. Without diligent policies, consistent administration and monitoring, and knowledgeable staff, medication errors can cause significant injury and even death to residents.

This column is not to be substituted for legal advice. The writer, Janet 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, OH.*