

Long-Term Care Survey Alert

Adverse Drug Events: Expect A New Level Of Intense Scrutiny From Surveyors

Trial lawyers and surveyors take aim at adverse events related to Coumadin.

If you're a nursing home provider or clinician, be forewarned: you'll soon need to weather a perfect storm of adverse drug events — especially those related to the drug warfarin (the generic version of the blood thinner Coumadin).

Background: Attention to medication-related adverse events problems began to build last year, with the release of a report from the **HHS Office of Inspector General** (OIG) in February. Titled Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries, the report revealed that one in three skilled nursing facility (SNF) residents experienced an adverse event or "temporary harm event" within the first 35 days of a facility stay. Additionally, the report noted, 37 percent of these adverse events were medication-related, with excessive bleeding related to anticoagulant use at the number-two spot on the list (second only to "medication-induced delirium or other changes in mental status").

Fast forward a few months: That's when the respected organization **ProPublica** picked up on the OIG's concerns about blood-thinner-related adverse events. Working with The Washington Post, ProPublica cast a spotlight on its own analysis of CMS survey data — analysis that highlighted that during the period 2011 to 2014, "at least 165 nursing home residents were hospitalized or died after errors involved Coumadin or its generic version, warfarin." Furthermore, ProPublica said, "studies suggest that there are thousands more injuries every year that are never investigated by the government."

Completing the "perfect storm": Within days of the ProPublica analysis, the **Centers for Medicare & Medicaid Services** (CMS) issued a somewhat defensive Survey and Certification memo (S&C: 15-47-NH) introducing a draft Adverse Drug Event Trigger Tool to "assist surveyors as they investigate medication-related adverse events and to assess whether facilities have implemented effective systems to prevent adverse drug events," noting that the agency is "very concerned about the prevalence of adverse events involving [high-risk] medications."

Soon, trial lawyers' websites were also lighting up with new cautions of Coumadin's high-risk profile.

How To Respond

As with any new survey focus area, it's best to proceed with quality improvement in mind. Take these steps to fare well at survey time and reduce your facility's share of medication-related adverse events:

Recognize the challenge. An estimated 1 in 6 of the nation's nursing home residents takes an anticoagulant — and while most nursing home residents are prescribed blood thinners for clinically valid reasons, peer-reviewed studies confirm that Coumadin and other drugs in the class are all potentially dangerous drugs. For example, a study on Coumadin use by nursing home residents published in the American Journal of Medicine in 2007 suggests that residents "suffer 34,000 fatal, life-threatening, or serious events" annually. In addition to requiring careful routine monitoring to achieve optimum effect, it is essential to recognize that substances as common as acetaminophen and antibiotics interact with Coumadin, alter its clotting ability in significant ways. AMDA's series of Dangerous Drug Interactions alerts is one good source of information.

Clinicians should be careful when researching answers to potential warfarin-drug interactions, however, suggests **Marietta Anthony, PhD**, lead author of a study published recently in the journal *Clinical Pharmacology & Therapeutics* ("Warfarin Interactions With Substances Listed in Drug Information Compendia and in the FDA-Approved Label for Warfarin Sodium." *Clin Pharmacol Ther.* 2009; 86:425-429.) "This study provides evidence that there is little concordance among commonly used drug compendia and product labels with respect to interactions involving warfarin," Anthony concludes, noting that only 7.7 percent of problem medications/food/substances were listed in all three of the top compendia.

Ask yourself: What quality checks are currently in place to catch mistakes such as inadequate monitoring? Careful documentation and systematic quality checks are essential when dealing with any high-risk medication. The article in the *Washington Post* told the story of a patient who went without monitoring for an extended period of time. An internal review revealed that the need for monitoring was entered incorrectly.

To avoid such situations, make good use of checklists and other systematic tools that can help catch such errors. Checklist items should include: Are laboratory orders present and correct in the medical record? Are laboratory values present in the chart under the appropriate tab? Has the physician been notified of any abnormal lab values?

Learn from real-world "horror stories." ProPublica's analysis effectively triggered media attention and a response from the feds in part because, in addition to alarming statistics, it relayed shocking stories of residents' suffering secondary to providers' simple but serious oversights. For example, the *Post* article led with the story of **Loren Peters**, who died from bleeding after the nursing home administered the wrong lab test to measure clotting because, as one nurse told surveyors, "it never occurred to her [to check the medical record] to see if the blood work was for what the physician ordered." In the same case, another nurse who had documented unusual bruising told surveyors that it "never occurred to her that this resident was on Coumadin" and needed his blood monitored.

Ask yourself: Are we communicating well about warfarin (and other medications)? Specifically, how well do facility staff members communicate with each other and with clinicians in other settings regarding medication management? One strategy that has been shown to improve warfarin management is the approach known as SBAR (Situation, Background, Assessment, and Recommendation). Such "structured communication strategies" can be used to guide telephone discussions between nursing home staff with off-site prescribers, explains **Jerry H. Gurwitz, MD**, professor at the **University of Massachusetts Medical School**. To learn more, go to <http://www.ihl.org/resources/Pages/Tools/SBARToolkit.aspx>. You can also check out the article "Randomized trial of a warfarin communication protocol for nursing homes: an SBAR-based approach" (*American Journal of Medicine.* 2011; 124:179).

Step up training. Start by cross-referencing CMS's draft tool, so you can get an idea of surveyors' perspective on anticoagulant-related adverse drug events (see page 76). Then get your staff up to speed on any area related to the surveyors' red flags.

Ask yourself: When was your facility's last in-service focusing on warfarin and other anticoagulants? If you have not had a session recently, schedule one now, including information on not only warfarin but also the newer anticoagulants such as Elquis, Pradaxa, and Xarelto. Staff training about the risks of warfarin and the other anticoagulants is a must, and not just for nurses. Front line caregivers can help recognize and report potential warning signs, such as unusual bruising.