

DEA Controlled Substance Regulations

ISSUE: Nursing home and hospice providers in several states are experiencing significant delays in obtaining controlled substances prescriptions for their residents because of recent enforcement actions by the Drug Enforcement Agency (DEA) against long-term care pharmacies pursuant to the Controlled Substances Act (CSA) and its implementing regulations. These enforcement actions, designed to reduce theft and diversion of Schedule II-V controlled substances, are instead resulting in sick and dying residents being left for hours—and even days—without adequate symptom relief to treat pain, seizures, psychiatric and end of life symptoms, among others. Such delays almost certainly will put providers at risk for survey deficiencies related to pain management.

The regulations implementing the CSA require that all prescriptions for controlled substances on Schedules II-V be written, signed by the prescriber, and presented to a pharmacy for fulfillment. Specifically, 21 C.F.R. 1306.05 provides that “prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner.” In the case of Schedule II prescriptions for nursing facility residents, subsection (f) of 1306.11 permits the practitioner or the practitioner’s agent to transmit the prescription to the pharmacy by facsimile; however, the prescription must be signed by the prescriber in accordance with 21 C.F.R. 1306.5. As a result, the CSA and its implementing regulations prohibit verbal orders except in “emergency situations” as provided in 21 C.F.R. 1306.11(d). The definition of “emergency situations” is the responsibility of the Food and Drug Administration (FDA), but the enforcement authority for 21 C.F.R. 1306.11 in general is vested in the DEA. The DEA has very narrowly construed the emergency exception so as to apply only when immediate administration of the medication is required (i.e., within minutes, not hours or the next day).

In long-term care, hospice and other care environments in which a resident’s physician is not always physically on site, nurses play a vital role in communicating information to physicians and other practitioners, recording the physician’s verbal orders, ensuring that those orders are carried out, and monitoring the resident’s condition. For example, if a nurse’s assessment indicates a change in the resident’s condition possibly requiring a change in medication or other treatment, the nurse contacts the physician, usually by telephone, to describe the resident’s symptoms, relay data such as vital signs and provide whatever additional information the physician needs to make a treatment decision. The nurse then records the physician’s verbal order in the resident’s clinical record creating what is known as a “chart order,” and makes sure that the physician’s orders are acted upon (similar to the process that occurs in the hospital setting). Thus, if a physician orders a new drug or makes any change in a resident’s drug regimen, it is the nurse’s responsibility to create and fax the chart order to the pharmacy so that the pharmacy can dispense the medication. Through this process, nurses ensure that medications are acquired timely to meet residents’ changing and emergent medical needs. In such respects, the nurse is acting as the *de facto* agent of the physician.

Direct communication between the physician and the nurse in the facility is critical both to quality care and ensuring that licensed nursing facility and hospice providers comply with state and federal regulatory requirements governing quality and timeliness of medical and pharmaceutical care. Failure to comply with regulatory requirements, including delays in notifying a physician or in responding to the residents’ needs can affect the facility’s state

licensure and federal certification status. If the failure to comply with a regulatory requirement causes actual harm to a resident, the facility could be fined or even decertified resulting in the loss of federal funding and ultimately, closure.

Chart orders routinely are used in hospitals and are especially important in the nursing home and hospice fields for several reasons. First, nursing homes and hospices receive residents at all hours of the night and day, and on weekends. These residents are often coming directly from hospitals and are in need of pain medication—hospital physicians do not provide prescriptions to individuals being discharged to another institution. Second, approximately 40% of physicians working in the long term care environment do not have an office-based practice. Many work from their vehicles and do not have an established office or staff. As a result, requiring an original or faxed prescription necessarily will result in delays getting the medications to the nursing home resident. In addition to causing significant distress to the resident, any such delay can form the basis of a citation against the facility under the nursing home regulatory enforcement rules.

Although the regulations concerning requirements for prescriptions for controlled substances have been on the books since the 1970s, they were not enforced by the DEA. The DEA was aware of the practice of using chart orders to obtain controlled substance prescriptions for nursing home residents, but chose not to enforce the CSA regulations. Since 2001, however, the DEA has taken the position that under no circumstance does a legal agency relationship exist between a facility nurse and the resident's physician. DEA's refusal to recognize the nurse/agent relationship in nursing facilities or for hospice patients even extends to situations in which the nurse and physician are employed by the same entity.

In 2009, the agency began auditing institutional pharmacies that serve nursing facilities and hospices to enforce the regulations. Long-term care pharmacies in Ohio, Michigan, Wisconsin and Virginia have been targeted by the DEA for inspection and now face huge fines. For example, one independent pharmacy was cited with over 3,000 violations and faces fines of over \$32 million. Other pharmacies have changed their policies to reflect DEA regulations, resulting in significant delays in the delivery of pain medication to nursing facility residents.

In 2009, CMS issued new surveyor guidelines that specifically address the importance of pain management¹. In the long-term care and hospice environments, any delay in providing a resident with needed pain medication places the resident at risk for rehospitalization and violates quality of care standards. While CMS has been made aware of the DEA's enforcement activities and the resulting delays in the ability of nursing facilities to obtain controlled substance prescriptions for their residents, the agency has said that it must nevertheless enforce its own regulatory requirements.

SOLUTION: Legislation designed to recognize “chart orders” in nursing facilities and hospice. A coalition of associations representing pharmacists, long-term care providers, hospice providers

¹ CMS Survey and Certification Letter No. S&C-09-22, *Nursing Homes - Issuance of Revised Quality of Care Guidance at F309, including Pain Management as Part of Appendix PP State Operations Manual, Additional Minor Changes Made to Appendices P and PP as Described Below (1/23/09)*, available at: <http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCletter09-22.pdf>.

and physicians are seeking a legislative solution to the issue and have received the backing of Senator Herb Kohl (D-WI), Chairman of the Special Committee on Aging, and Senator Sheldon Whitehouse (D-RI), among others. Hearings on the issue are slated for late winter/early spring 2010, with legislation to amend the CSA to be introduced shortly thereafter.

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