

DEA ISSUE PAPER (8/09)

DEA Does Not Recognize the LTC Nurse as an Agent of the Practitioner

The Problem: In recent months, the Drug Enforcement Administration (DEA) has taken actions against several long term care pharmacies, using a stricter interpretation of the *Controlled Substances Act (CSA)*. *The way the DEA is interpreting the law, the nurse in a long-term care facility (LTCF) is not considered the "agent" of the practitioner, and therefore, a pharmacy cannot release a physician order for a controlled substance that is called in by the nurse, until the pharmacy receives a valid prescription from the physician.*

Background: Earlier this year, pharmacies in both Michigan and Ohio were visited, surveyed, and fined by the DEA for releasing controlled substances to nursing homes without first having a written physician prescription. On July 22, 2009, the DEA conducted simultaneous audits in four long-term care pharmacies in two additional states – Virginia and Wisconsin – neither of which are in the same DEA region as Michigan and Ohio. According to the audited pharmacies, the DEA conducted lengthy interviews with pharmacy technicians and froze the pharmacy's ability to release Schedule II drugs during the DEA's visit. The DEA also reviewed records and processes in several nursing facilities served by those LTC pharmacies. During the DEA visits, agents conducted reviews and sought documentation for the prescribing and dispensing of Schedule III-V controlled drugs and emergency-kit usage, in addition to Schedule II prescription and controlled substance required records. It is not yet known if any citations/penalties resulted from those visits.

The DEA's new strict interpretation of the CSA was articulated in a Notice and Solicitation of Information which was published in the *Federal Register* on April 25, 2001. Even though the law specifies that a pharmacist may only fill an order issued by the physician and communicated by the physician, the DEA turned a blind eye with regard to imposing the law and allowed LTC pharmacies and LTC providers to conduct business as they have done in the past. Since this Notice and Solicitation of Information, the American Association of Consultant Pharmacist (ASCP) met several times with DEA regarding the lack of congruency between regulatory direction and actual LTC practice. According to ASCP, the DEA offered no useful provider direction during these contacts. Now and for no other reason aside from curtailing incidents of drug diversion, the DEA has decided to enforce this stricter interpretation.

AHCA is concerned that new DEA interpretation will have a negative impact on the timely provision of pain medications. The American Medical Directors Association (AMDA) estimates that 40 percent of LTC physicians do not have a permanent office, most travel from facility-to-facility during the day to see patients, and do not have immediate access to a fax machine, which is needed to deliver valid prescriptions as required by the CSA.

The Coalition: A coalition led by ASCP, which includes AHCA, AAHSA, AMDA, NADONA, hospice organizations, providers and LTC pharmacies, met with the DEA on April 7, 2009. With urging from the coalition, the DEA agreed to issue a "Dear Registrant" letter to ensure that all physicians and pharmacies understand what needs to be done to be compliant. The "Dear Registrant" letter finally was released in mid August, but only after pressure from Senators Sherrod Brown (D-OH) and Sheldon Whitehouse (D-RI and member of the Judiciary Committee). Unfortunately, the letter avoided the issues related to the LTC nurses as agents of the physician and only focused on controlled substances needed in emergency situations. The letter offered that federal regulations require prescriptions for schedule II controlled substances to be made in writing and to be signed by a DEA registered practitioner. If the prescribing

practitioner determines that the situation is an emergency, however, a pharmacist may dispense a schedule II substance after receiving oral authorization from the DEA registered practitioner, as long as the prescription is received within 7 days, either delivered in person or by mail.

The coalition members have been active in trying to bring resolution to the controlled substance dispensing issues, developing language to amend the CSA and materials to educate providers. Coalition members also have met with staff for Senators Herb Kohl (D-WI and Chair, Special Committee on Aging) and John Cornyn (R-TX and member of the Judiciary Committee) and asked for assistance in finding reasonable solutions that address the needs of the DEA, while allowing medical professions to function within their scope of practice, and ensuring that frail, elderly long term care residents continue to receive timely medication.

While we are encouraged by the coalition efforts and the support from legislators, we do not expect a permanent resolution of these issues in the near future. Obtaining language changes in the CSA requires widespread support to amend the landmark law.

Immediate Request: The coalition continues to look for a workable solution (temporary and permanent) that can bring immediate relief to providers as they try to comply with the law and meet patient medication needs. Until a permanent fix can be obtained, AHCA urges LTC providers to alert us should DEA contact them about a survey or visit. We are eager to learn more about the DEA's visits and any issues that may help us ensure that providers' interests are represented equally with those of LTC pharmacies and to assess a LTCF's risk for future surveys in other states.

Next Steps to Finding a Solution

- Sign on to the coalition letter requesting DEA clarification about use of a provider signed agreement, establishing the practitioner/nurse agent relationship, and if such an agreement will allow the LTC nurse to act as the physician agent with regard to prescriptions for controlled substances.
- Survey nursing homes in OH who have made medication process changes, needed to comply with current law. The survey will identify any negative impact from process changes on treating and managing patient pain, complying with nursing home regulation and in meeting pain management measurement targets. Survey completion target date: mid October.
- Depending on survey results demonstrating adverse effects on LTCF's, disseminate survey findings to Senate Judiciary Committee staff to press for DEA modification of response.
- Work with Senators Whitehouse, Brown, Kohl and Conryn and support their efforts on holding a special Judiciary Committee hearing, or joint committee hearing with Special Aging, on DEA LTC actions and CSA interpretation.
- Finalize language changes to the CSA that recognizes the LTC nurse as an "agent of the practitioner." Share language with Senate staff. Determine appropriate legislative vehicle for CSA amendment. Identify potential House co-sponsors for companion bill.