



Dedicated To Long Term Care Medicine

**American
Medical
Directors
Association**

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November 5, 2010

Mark W. Caverly
Chief, Liaison and Policy Section
Office of Diversion Control
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Dear Mr. Caverly,

We the undersigned organizations are writing to respond to the Drug Enforcement Administration's (DEA) October 6, 2010 Statement of Policy entitled "Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies." We appreciate that the policy intended to clarify rules on communicating controlled substance prescriptions to pharmacies, especially via agents of prescribing physicians, such as nurses. We further appreciate the DEA's exception of allowing an agent of the practitioner in a long-term care facility to transmit the prescriber-signed prescription to a pharmacy via facsimile. However, we have serious concerns that it does not resolve the delays that physicians have experienced in providing Schedule II pain medications to some residents who urgently need them.

Specifically, the policy states "where a DEA-registered individual practitioner has made a valid oral prescription for a controlled substance in Schedules III-V by conveying all the required prescription information to the practitioner's agent, that agent may telephone the pharmacy and convey that prescription information to the pharmacist...an agent may not

call in an oral prescription for a Schedule II controlled substance on behalf of a practitioner even in an emergency circumstance.”

The policy further specifies two circumstances in which a faxed Schedule II controlled substance prescription may serve as the original prescription: A practitioner or a practitioner’s authorized agent may transmit a valid, physician-signed Schedule II prescription to a pharmacy via fax for a patient enrolled in a hospice program or residing in a long-term care facility.

We recommend that the agent be allowed to represent the prescriber for Schedule II controlled substances when transmitting the prescription orally. Fifty percent of AMDA members who responded to a survey on the DEA’s June 29, 2010 Notice reported that they prescribe Schedule II substances daily. While 71 percent of respondents said that the delays in obtaining prescriptions for controlled substances apply to all schedules, respondents reported that the problem is worse for Schedule II controlled substances.

Schedule II medications, as is the case with analgesics listed in other Schedules, are important components of the treatment regimen for long-term care residents with moderate to severe pain, many of whom have been carefully placed on scheduled use of these analgesics during a preceding acute care hospitalization, and the care team at both the acute hospital and the long-term care facility are focused on ensuring that the transition in care is effective, especially regarding continuity of needed medications. Prompt and adequate control of pain is a well-described quality of care measure given its importance in restoration of daily function and as a key measure of quality of life. Pain that is not promptly treated, due to avoidable delays in receiving Schedule II analgesic medications, can lead to difficulty with self-care, behavioral difficulties, anxiety, depression, difficulty sleeping, and poor appetite, in addition to the signs and symptoms of drug withdrawal, including diarrhea and abdominal cramping, bone pain, and severe malaise and myalgias, as well as extreme dysphoria.

In addition, without an agent’s ability to transmit the prescription orally to a pharmacist,

especially in emergency situations, our fear is that physicians may order only Schedule III substances, such as hydrocodone 5 mg with acetaminophen 500 mg (Vicodin), 2 tabs every 4 hours – which in many cases would be ineffective and place the patient at increased risk for acetaminophen-induced hepatotoxicity.

We further recommend that the DEA revise its policy because it conflicts with the Centers for Medicare & Medicaid Services (CMS) guidance and efforts to improve quality of care. CMS' guidance to state surveyors includes several F-Tags related to pain management. Specifically, the nursing facility structure is supposed to allow for rapid relief of pain symptoms as noted in the *State Operations Manual, Appendix PP - Guidance to Surveyors for Long Term Care Facilities*. One of the regulations requires residents to be given rapid relief of “excruciating pain” as defined in F-Tag 309. The potential conflict may cause nursing facility staff to either inadequately treat pain by not prescribing the needed medication (e.g., Schedule II substances) and fail to comply with CMS guidance or risk failing to comply with the DEA's Statement of Policy.

Second, CMS' Minimum Data Set 3.0 quality indicators require nursing facility staff and practitioners to provide quality of care to all patients by addressing moderate to severe pain promptly and at all times. Failure to do so has substantial mental, physical, and emotional consequences for the patient and social, ethical, and legal ramifications for the respective facility and its staff. As written, the current regulation on prescriptions for Schedule II controlled substances will severely impede nursing home staff and the practitioner's ability to provide quality care to its residents.

Should you have any questions regarding our comments please direct them to Kathleen Wilson at kwilson@amda.com.

Sincerely,

AMDA-Dedicated to Long Term Care Medicine
American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine

American College of Osteopathic Family Physicians
American Geriatrics Society
American Medical Association
American Osteopathic Association

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