



Michael D. Maves, MD, MBA, Executive Vice President, CEO

August 30, 2010

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

Re: Docket No. DEA-337N, "Dispensing of Controlled Substances to Residents at Long Term Care Facilities"

Dear Mr. Caverly:

On behalf of the American Medical Association (AMA), I am writing to respond to the Drug Enforcement Administration (DEA) request for information on dispensing of controlled substances to patients in long term care facilities. The AMA was pleased to meet with you one year ago to discuss our concerns about the impact that DEA enforcement efforts are having in delaying timely dispensing of needed medications to nursing home patients. The "Dear Practitioner" letter of August 6, 2009, that you provided to us to circulate to physicians was helpful in clarifying the rules that physicians need to understand in order to help address this problem.

At the same time, it has become increasingly clear to us that these regulations need to be modified. The DEA notice suggests the agency is contemplating regulatory changes that would remove major barriers to rapid dispensing for nursing facility patients, particularly those affecting Schedule II drugs. For example, question 27 of the information request asks about the possibility of designating certain persons at the facility to act as agents of DEA-registered physicians in communicating controlled substance information from the physician to the pharmacy. **The AMA strongly supports changing federal policy to allow nurses at long term care facilities to act as agents of physicians in communicating with pharmacists and urges the DEA to move forward as soon as possible to define, regulate and legally allow this practice.**

We also encourage the DEA to give careful consideration to the information provided in response to this request by organizations representing physicians who specialize in long term care medicine, such as the American Medical Directors Association (AMDA). In a survey of

AMDA members, 91% of respondents said their facility has experienced delays in obtaining controlled substance medications for patients, 93% said they had patients who experienced uncontrolled pain due to these delays, half reported that these problems are a daily occurrence, and one quarter said that their facility has had to send patients to the hospital to obtain controlled substance medications because they could not obtain the necessary pain medications at the long term care facility in a timely manner. Physicians indicated that problems most often arise with patients who are newly admitted to the nursing facility because they lack either a temporary supply or a prescription for the medications they were taking just prior to their admission, especially if they are discharged from a hospital to the long term care facility. Delays are also more likely with after hours care.

Delays in dispensing controlled drugs are causing needless suffering for long term care patients, including those in hospice care. Patients who are admitted to nursing homes to receive palliative care need to be able to count on getting that palliation, whether or not the severity of their pain has been accurately anticipated prior to their admission or during the physician's face-to-face visit following admission. **The current regulations are preventing the delivery of compassionate and high quality care and need to be changed.**

The AMA and several medical societies have been looking for solutions and working with other professionals to try and better understand the reasons for the delays. Many long term care pharmacy providers are simply overwhelmed and do not have the resources to provide the personal interaction between pharmacists and physicians that the recent DEA enforcement activities appear to require. Physicians who attempt to call the pharmacy to speak directly with the pharmacist often must instead leave a voice mail message and wait for a call back. Time that pharmacists spend trying to track down physicians to return these calls is time that they are not filling prescription orders. Time that physicians spend waiting to hear back from pharmacists is time away from patient care. Sometimes physicians have no choice except to provide a verbal order because they are on the road without access to a fax machine or the ability to write a prescription. Sometimes return calls are not made until hours after the prescription was originally ordered, and by the time the two health professionals actually connect it may be days. These lengthy delays are clearly unacceptable.

As noted above, AMA staff met with DEA officials and discussed this issue in August 2009. We are concerned that these serious problems have persisted for more than a year, and we are also concerned that some of the solutions that have been proposed could further postpone their ultimate resolution. For example, solutions that would require state legislatures to adopt new laws, state pharmacy boards to adopt new rules for their states, and/or facilities and facility medical directors to assume entirely new roles with respect to pharmaceutical products beyond prescribing could take years to accomplish and could have unintended consequences. Changing federal policy is also a lengthy and complex process. In an effort to provide some immediate help to patients and physicians, the AMA joined with other medical societies that are committed to compassionate and high quality long term care to develop the attached "tip sheet" for DEA-registered physicians. We are working to disseminate the tip sheet widely to the physician

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community to help them take steps to avoid delays in drug dispensing and make sure their patients receive treatment in a timely manner.

We appreciate the DEA's continued focus on better understanding the problems that recent enforcement activities have caused and identifying solutions. If the AMA can provide any assistance to you in this matter, please do not hesitate to contact Sandy Marks in our Washington office at (202) 789-4585 or Sandy.Marks@ama-assn.org.

Sincerely,

A handwritten signature in black ink that reads "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA

Attachment