April 28, 2014

Michelle Leonhart
Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODW
8701 Morrissette Drive
Springfield, VA 22152

Docket No. DEA-389

Dear Administrator Leonhart:

On behalf of the undersigned organizations, we urge the U.S. Drug Enforcement Administration (DEA) not to finalize its proposal to reschedule hydrocodone combination medications from Schedule III to Schedule II unless and until the agency develops a long-term care exception or other special procedure for patients in long-term care settings. We agree with the DEA that there has been an alarming increase in diversion and abuse of prescription opioids, and we remain committed to aggressively working together and with other stakeholders at the national and state level to combat this urgent public health crisis through a wide array of strategies. **However, rescheduling at this time would significantly limit appropriate pain management for an exceptionally vulnerable patient population.**

Our Organizations

For nearly five years, a cross-section of physician, pharmacist, and long-term care organizations have engaged together to address a major regulatory barrier to prompt dispensing of Schedule II drugs to patients in skilled nursing, rehabilitation, and assisted living facilities. Since 2009, the DEA's heightened enforcement of the Controlled Substances Act has created obstacles to the effective, appropriate, and timely administration of medication by the nurse (acting as agent on behalf of the patient's physician) to frail, chronically ill, and dying patients in nursing facilities. While we respectfully acknowledge your concerns with diversion, we remain concerned that the hydrocodone rescheduling will further exacerbate this problem.

The Long-Term Care Setting

Physicians in the Long-Term Care Setting. While every patient's medical care must be supervised by a physician, physicians are not always physically present in these facilities. Unlike in a hospital or physician's office, the prescriber is often not there when a patient experiences an acute pain episode, when the pain medication would typically be initially ordered. Very few nursing homes have staff physicians and, often, physicians are not office-based, seeing patients in multiple facilities. In addition, orders are often given after hours or when the physician is traveling or otherwise in a location not amenable to writing and faxing a prescription to the pharmacy. Prescribers are sometimes unable to immediately fulfill the paperwork requirements that a hard copy, practitioner-signed valid prescription be provided to the pharmacy before the drug is dispensed, particularly when a patient is in acute pain. Thus, it is critical that a facility nurse be able to receive a physician's medication order over the telephone and act as the prescriber's agent by documenting the order in the patient's medical record and transmitting it to the long-term care pharmacy.

Long-Term Care Facilities Differ from Hospitals. The long-term care setting is unique in multiple ways. First, nursing facilities do not have on-site pharmacies; most contract with an outside pharmacy that specializes in serving long-term care facilities. Second, nurses play a unique role in the long-term care

setting. As stated above, physicians are not often present when a patient experiences pain. The nurse is required to conduct an assessment and communicate the results of that assessment to the physician, along with other pertinent information, such as what medications the patient is currently receiving. In the normal course, the physician would then provide a telephone order to the nurse who would transcribe it to the patient's record and, acting as the agent of the physician, transmit the physician's order to the provider pharmacy. While the DEA permits hospital pharmacies to dispense controlled drugs based upon chart orders, it does not recognize chart orders when they originate from a nursing facility.

Long-Term Care Patients are Older and More Fragile. Long-term care patients are typically older and more medically complex, having multiple chronic conditions, and functional and cognitive limitations. They also are more likely to need palliative care and/or are suffering from a terminal illness. Long-term care residents who are treated with hydrocodone combination drugs for pain care are often hospice, cancer, or palliative care patients with physical limits like osteoarthritis or history of fracture and degenerative disk disease. In addition, this setting has a large population of post-acute stay patients who have just been transferred from the hospital setting after having been discharged following procedures such as hip replacements, knee surgeries, and other acute surgeries requiring pain medication. These patients are not chronic abusers of pain relievers, or diverters, but rather they are legitimate users of these medications. This patient population is more likely than the general population to have acute pain and suffer from unresolved pain care needs.

Protections Against Diversion in the Nursing Home Setting

The hydrocodone (HCP) rescheduling proposed rule provides the following reasons for the scheduling change from Schedule III to II.

- There are increasing trends in the adverse effects from abuse of HCPs, including emergency department visits.
- HCPs were diverted from rogue Internet pharmacies.
- Individuals are using HCPs on their own initiative rather than on the basis of medical advice.
- [Diversion] methods involve drug theft, doctor shopping, fraudulent oral (call-in prescriptions), fraudulent prescriptions, diversion by registrants.
- The rule also states there is greater use among high school and college kids.

There is little or no evidence suggesting diversion and abuse occurs at a rate equal to or higher than what occurs in community-based or other settings. In addition, the long-term care setting has special and unique protections against diversion that are required by federal regulations and makes abuse and diversion far less likely to occur. For instance, as stated earlier, nursing home settings lack pharmacies and do not stock more than a 30-day supply of drugs. In addition, counting of narcotics is required at the end of each shift by two licensed nurses, and narcotic medications are stored in a double locked box or cabinet. While the DEA has stated they would allow emergency supplies of Schedule II medications to be available in an emergency kit ("E-kit") or controlled emergency kit, not all states allow this nor will all pharmacy suppliers allow this.

The nursing home population is unlikely to be drug abusers. Their health conditions often make them bed-bound or otherwise dependent on nurses for the administration of their medications. It is possible for limited diversion to occur at the staff level. However existing regulatory compliance standards and mandatory procedural checks in most cases make it difficult or impossible for any suspected abuse or diversion to occur over a sustained period of time.

Current Practices in Pain Care in the Nursing Home Setting

Current State. The current bifurcated state has created two different workflows in the long-term care setting: non-scheduled medication and Schedule II emergency medication. The two attached flow charts document the prescribing patterns in more detail. Under the first scenario, the nurse calls the prescriber with a patient assessment. The prescriber dictates a medication order to the nurse. The nurse transcribes the order and transmits it to the pharmacy. The pharmacy fills the order and sends it out for delivery to the facility. The medication is administered.

Under the second scenario, for Schedule II emergency medications, the nurse calls the prescriber with the assessment of the patient. The nurse records the conversation in the nurse's notes section of the medical record. The nurse may not record this as a verbal order. The prescriber must call the pharmacy and give a verbal order for the emergency fill (limited quantity-not a full prescription) of the Schedule II medication which is outside of the normal workflow. Long-term care pharmacies and physicians practicing in the LTC setting are not set up like retail pharmacy and office based practices where communicating between the two is optimal. There are many operational barriers in place on both ends that make communicating an emergency verbal order difficult. The pharmacist reduces this order to paper. The pharmacy fills this limited emergency prescription based on the verbal order from the prescriber and sends it out for delivery to the facility. The nurse typically has no knowledge that this is being done until it arrives, with a great time variation, depending on when the pharmacists and prescriber have spoken and on delivery times. When the medication arrives, the nurse logs it in, and locks it in the federally-mandated double locked narcotic system.

HCPs. This complicated system results in multiple instances where patients are in untreated pain. Currently, because of the enforcement of nurse agent rules one of the primary options for long-term care settings is to use a less optimal alternative medication or a work-around. HCPs are the current, albeit less preferred alternative because of its combination with acetaminophen, which has to be restricted in older adults due to toxicity risk. However, long-term care providers have been forced to use HCPs as a substitute for Schedule II drugs. These Schedule III drugs are more readily available for administration. Dispensing data from one of the country's leading long-term care pharmacy providers shows that nearly 1 in 5 nursing home patients had a prescription (including PRN orders) for a hydrocodone-containing drug during the first quarter of 2014. Clearly, any changes to access to HCPs will impact a substantial number of nursing home residents and may result in untreated pain due to the lack of other appropriate alternative drugs in Schedule III.

If the DEA moves HCPs to Schedule II, the remaining pain care options still under Schedule III are not as clinically effective in treating pain for the elderly as HCPs. In older adults codeine is less effective in providing pain relief. To achieve the same ("equianalagesic") effect as hydrocodone combination drugs, higher doses of codeine are necessary, yet the higher doses put the elderly and frail patients at greater risk of adverse side effects[1][2][3]. Right now, hydrocodone combination drugs are used when morphine (a

[1] McLachlan AJ, Bath S, Naganathan V, Hilmer SN, Le Couteur DG, Gibson SJ, Blyth FM. Clinical Pharmacology Of Analgesic Medicines In Older People: Impact Of Frailty And Cognitive Impairment. Br J Clin Pharmacol. 2011 Mar;71(3):351-64.

[2] Brooks, M. Is codeine cardiotoxic? Middle-ground painkiller ups CV risk in large study. www.medscape.com/viewarticle/790778_print Accessed April 15, 2014.

Schedule II drug) is not clinically warranted, yet more than acetaminophen (Tylenol) is needed. However, rescheduling these drugs to Schedule II, without a long -term care carve out or special procedure for long-term care, will take away this pain care option for many patients.

Patient Care

In long -term care settings, the DEA's limited interpretation of policies allowing nurses to act as agents of prescribers has impeded patient access to adequate pain medications. The HCP rescheduling will further harm patient care as follows:

Delays in Treatment

A 2009 survey of 900 clinicians by the Quality Care Coalition for Patients in Pain, found that patients are experiencing inhibited access to pain care in the long-term care setting. Key findings include:

- **65 percent of respondents found they were experiencing delays in getting controlled drugs to their patients. 40 percent reported delays of up to one day and another 40 percent reported delays up to two days.**

- **31 percent of respondents reported a change in prescribing patterns for patients newly admitted to long-term care settings. For existing patients, 26 percent reported a change in prescribing patterns.**

Delays are more likely with after-hours care. Admissions over weekends and holidays often result in residents having to wait until the following Monday to receive their medications. Physicians have indicated that problems most often arise with patients who are newly admitted to the facility because they lack either a temporary supply or a prescription for the medications they were taking just prior to the admission. This is particularly the case if they were discharged from a hospital to the facility. These delays are further compounded for rural facilities that may be a distance away from the pharmacy.

Rehabilitation Patients. Patients' ability to participate in post-surgical rehabilitation is impeded, which typically delays their recovery and extends the need for skilled care. Nursing homes have advised that many, if not most, rehabilitation patients come from hospitals to the nursing facility in late evening. These individuals are virtually all in need of pain medication, many having had hip or knee surgery. Often, these patients wait the longest to receive adequate pain care.

Hospital Readmissions. Decreasing hospital readmissions is a national policy goal. However, without the ability to provide adequate pain control, a number of nursing homes have reported having to send residents back to the hospital for readmission for pain management. In fact, a survey by AMDA-The Society for Post-Acute and Long-Term Care Medicine, found that one quarter of its members reported their facility had to send patients to the hospital to obtain Schedule II controlled substance medications because they could not obtain the necessary pain medication at the long-term care facility in a timely manner due to limitations under the Controlled Substances Act. In addition, transferring patients unnecessarily increases costs to Medicare.

Access to Emergency Medications. As described earlier, long-term care settings have access to emergency Schedule II medications in a limited supply. While there may be a controlled emergency kit

[3] Solomon DH, Rassen JA, Glynn RJ, Garneau K, Levin R, Lee J, Schneeweiss S. The Comparative Safety of Opioids for Nonmalignant Pain in Older Adults. Arch Intern Med. 2010 Dec 13;170(22):1979-86

or an E-Kit with the needed medications available for an initial dose, residents have had to remain in pain while waiting for the physician to notify the pharmacy and for the pharmacy to authorize the opening of the E-Kit. It could be several hours before authorization is obtained in order to remove the needed medication from the E-Kit. If the required medication is not available in the E- Kit, delivery may be further delayed. Additionally, some states do not allow Schedule II medication to be kept in controlled emergency kits or E-kits.

Recommendations to Ensure Protection of Frail Long-Term Care Residents

As DEA prepares the final HCP rescheduling rule, we strongly urge you to consider and implement one of the two following recommendations in order to ensure that vulnerable patient populations do not lose access and needlessly suffer:

1) **Modify the current DEA interpretation of policies defining agency relationships and how they apply to Schedule II medications, or promulgate regulations to accomplish this.**

2) **Allow an exemption for residents in long-term care facilities who require controlled substances.**

Additionally, we ask that DEA convene a stakeholder meeting with the undersigned organizations to assess the impact of rescheduling medications to Schedule II on patients receiving medication from long-term care facilities as well as DEA's interpretation of agency relationships in this setting.

If you have questions or comments, please contact Alex Bardakh at AMDA: The Society for Post-Acute and Long-Term Care Medicine at (410)-992-3132 or abardakh@amda.com.

Sincerely,

AMDA: The Society for Post-Acute and Long-Term Care Medicine
American Association of Nurse Assessment Coordination (AANAC)
American Geriatrics Society (AGS)
American Health Care Association (AHCA)
American Medical Association (AMA)
American Society of Consultant Pharmacists (ASCP)
LeadingAge
National Community Pharmacists Association (NCPA)
Omnicare, Inc.