## Controlled Substances in Long Term Care Facilities: Where We Were, Where We Are, and Where We’re Headed

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Controlled Substances in Long Term Care Facilities: Where We Were, Where We Are, and Where We’re Headed

This webinar is brought to you by the Long Term Care, Senior Housing, In-Home Care, and Rehabilitation Practice Group

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Introduction

- The U.S. Census Bureau reported that there were nearly 40 million people aged 65 and older in the United States as of 2009.
- Studies report the prevalence of pain in older adults reaching up to 83%.
- Approximately 40% of those who reach the age of 65 will receive care, likely including pain relief medications, in a nursing home or long-term care setting.
Controlled Substances in Long Term Care Facilities: Where We Were, Where We Are, and Where We’re Going

- Susan Janeczko, Pharm.D., J.D.
- Jennifer L. Hilliard, M.M.H., J.D.
Regulatory Environment

- Many pain medications fall into the category of controlled substances regulated by the DEA.
- Controlled substances are categorized by the Controlled Substances Act (CSA) (21 U.S.C. § 812) and its implementing regulations (21 C.F.R. 1308) based on factors such as accepted medical use, abuse potential, and the possibility of psychological or physical dependence with use.
Regulatory Environment (cont.)

- Schedule I substances—no currently accepted medical use in treatment.
- Schedule II substances (e.g., morphine, oxycodone, and fentanyl)—currently accepted medical use, but also subject to the highest level of control because of their high potential for abuse and dependence.
- Schedule III-V substances have a potential for abuse and dependence less than Schedule II substances, and they are regulated to a lesser extent.
Regulatory Environment (cont.)

- Key regulations governing the process of dispensing controlled substance medications:
  - First, DEA registration is required of every person who dispenses any controlled substance as set forth in 21 U.S.C. 822(a).
  - To be eligible to obtain a DEA registration, the practitioner (individual or institution) must be licensed or otherwise authorized to dispense controlled substances by the State of practice or location. 21 U.S.C. 823(f)
Regulatory Environment (cont.)

Second, as set forth in 21 U.S.C. 829(a), controlled substances in schedule II may only be dispensed with a written prescription unless the situation is an emergency or the drug is being dispensed directly by the practitioner.

- In the case of an emergency, 21 C.F.R. 1306.11(d) allows the pharmacy to dispense a limited supply of medication based upon the oral authorization of the prescriber with a written prescription following within seven days.
Regulatory Environment (cont.)

- More flexibility is granted for schedule III and IV substances with the added allowance in all cases of oral prescriptions. 21 U.S.C. 829(b)
- Finally, prescriptions must be dated and contain the patient’s name and address; drug name, dosage form, quantity, directions for use; and name, address, DEA number, and signature of the practitioner. 21 C.F.R. 1306.05(a)
Regulatory Environment (cont.)

- Nursing home concessions:
  - Schedule II Rx written by a prescriber may be faxed in by the prescriber or the prescriber’s agent for a resident. 21 C.F.R. 1306.11(f)
  - LTCFs may use “emergency kits” stocked with commonly dispensed controlled substances. 45 Federal Register 24128, April 9, 1980
    - As nursing homes generally do not register with the DEA and cannot dispense controlled substances, these kits are considered part of the pharmacy with which the facility contracts to obtain medications for its residents.
    - It is important to note that a valid prescription must be delivered to the pharmacy for approval before the nursing facility staff removes any medications.
Nature of the Problem (cont.)

- Hospitals and Long-Term Care Facilities are Not Created Equal in the DEA’s Eyes
  - Changes in the interpretation and enforcement of the CSA by the DEA have made it more difficult to provide needed prescription medications to LTC patients in a timely manner.
  - For years, it was the standard of practice in LTCFs—as in hospitals—to allow the nurse to relay information between the physician and the pharmacist.
  - Unlike hospitals, however, LTCFs are not registered with the DEA.
  - This has created problems in the case of nurses acting as agents of the prescribing physicians as well as in the use of chart orders to transmit the prescriber's medication wishes to a pharmacy.
Nature of the Problem (cont.)

- DEA registration is required of every person who dispenses any controlled substance as set forth in 21 U.S.C. 822(a).
- To be eligible to obtain a DEA registration, the practitioner (individual or institution) must be licensed or otherwise authorized to dispense controlled substances by the State of practice or location. 21 U.S.C. 823(f)
- Hospitals have state authorization for independent controlled substance authority which allows them to register with the DEA--most LTCFs do not.
- Controlled substances at a LTCF must either be labeled as belonging to a specific patient or belong to the pharmacy, such as the emergency-kit.
Nature of Problem (cont.)

- Hospital registration with the DEA as a practitioner also allows dispensing of controlled substances using chart orders instead of full prescriptions.
  - As set forth in 21 U.S.C. 829(a), controlled substances in schedule II may only be dispensed with a written prescription unless the drug is being dispensed directly by the practitioner.
  - In this case, the physician, nursing staff, and pharmacy staff are all acting as agents of the registrant, the hospital, and are together considered the practitioner under the law. Federal Register/Vol. 75, No. 124/ Tuesday, June 29, 2010/Notices, page 37468.
Complicating Factors

- Regulatory requirements for pain management
  - F-Tag 309, SOM Appendix PP
- Demographic changes in nursing home populations
  - Older, sicker residents
  - Post-acute rehab patients
- Hospital discharge practices
- Nursing home physician practices
  - Residents’ right to see physician of their choice
  - Shift away from office-based practices
Extent of Problem

QCCPP Survey (Nov. 2009)
- 899 responders representing 46 states
- 65% reported experiencing delays
  - Up to 1 hour: 8%
  - Up to 1 day: 40%
  - 1-2 days: 40%
  - 2+ days: 12%
- Heartbreaking anecdotes
Timeline

- 1970
  - Enactment of Controlled Substances Act (CSA)

- 1971
  - Implementing regulations for CSA promulgated

- 1995
  - Facility nurse recognized administratively by DEA as agent of prescriber for Schedule III-V controlled substances

- 2001
  - Facility nurse “unrecognized” administratively by DEA as agent of the prescriber for Schedule III-V controlled substances
Timeline (cont.)

■ 2009
  □ DEA begins enforcement actions against LTC pharmacies in several states
  □ August - DEA issues “Dear Practitioner” letter

■ 2010
  □ March
    ■ Senate Special Committee on Aging “Listening Session”
  □ July
    ■ OH Board of Pharmacy waiver request submitted
  □ October
    ■ DEA “Policy Statement” issued
Timeline (cont.)

- **December**
  - Dec. 1 - Kohl places hold on Leonhart nomination
  - Dec. 22 – Kohl receives assurances from DOJ re: legislative solution; releases hold on nomination
- **2011**
  - **March**
    - Legislative language drafted and sent to associations, DOJ for review
  - **August**
    - Still waiting . . . and running out of time
Possible Outcomes – Status Quo

- DEA Policy Statement
  - Schedule III – V only
  - Permits designation of specific individual vs. position
  - Pharmacists’ duty of additional inquiry
  - Byzantine structure that is basically unworkable
Possible Outcomes – OH Waiver

- OH Board of Pharmacy Petition
  - Supported by OHBP/NABP
  - Calls for **optional** state licensing and DEA registration
    - Use as model would require action by all 50 states and recognition by DEA
    - Facility medical director or pharmacist responsible for state license
    - Similar DEA registration category to hospitals
      - LTCF administrator would be DEA “registrant”
Possible Outcomes – OH Waiver (cont.)

- OH Board of Pharmacy Proposal/Petition
  - Applies to Schedule III-V substances
  - Recognizes chart orders, verbal orders
  - Requires LTCF ownership of stock drugs
    - Non-stock emergency supplies require outpatient script
  - Permits 30-day supplies
  - Currently being considered by DOJ
Possible Outcomes – Original Kohl/DOJ Legislative Agreement

- Amends CSA
- Schedule II – V medications
- No DEA registration for LTCFs
- LTCF designates agents and communicates to pharmacy
  - Nurses or other licensed health care professionals
  - Practitioners permitted to opt out with respect to certain employees
- Verbal or fax orders
Possible Outcomes – Original Kohl/DOJ Legislative Agreement (cont.)

- Recordkeeping and notice requirements
  - LTCFs
    - Logs/records of orders
    - List of authorized agents
      » Immediate notice of changes
    - Acknowledgement of responsibility and liability under CSA by designated agents
  - Pharmacies
    - Logs/records of orders
    - Contact with practitioner within 48 hours
  - Practitioners – Written prescription to pharmacy within 10 days of order transmission
- Status – Superseded by version 2.0
Possible Outcomes – Kohl/DOJ Legislation Version 2.0

- Amends CSA
- Applies to Schedules II – V medications
- Applies to “Institutional Long Term Care Facilities”:
  - Medicare and Medicaid-certified nursing homes
    - Private pay facilities?
  - Any other entity designated by Attorney General
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Permits Practitioner to authorize “Administrator” of LTCF to designate individuals to act as agents for the Practitioner with respect to dispensing controlled substances to a LTCF resident
  - Authorization must be in writing
  - Administrator defined as corporation, company, partnership, or other entity that:
    - Owns, operates or manages a LTCF; and
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- May be held liable, by law or by consent, for the acts or omissions of agents (of practitioners) in connection with the dispensing of controlled substances, including liability for any civil penalties under Part D of the CSA

- Administrator must have written policies and procedures in place that specify:
  - Responsibilities and duties of agent; and
  - Scope of Agency – Schedules II-V or Schedule IIIs only

- Practitioner may rescind authority of any agent at any time, or modify scope of agency
  - Must be in writing
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Agent
  - One or more individuals
  - Direct employees of LTCF
  - RN, Advanced Practice Nurse, Physician’s Assistant, or “equivalent professional”
    - Licensed, certified, registered or otherwise permitted to provide professional nursing or healthcare in jurisdiction where employed
  - Agency may not be redelegated
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Administrator required to maintain list and provide to all pharmacies and Practitioners
  - Must contain:
    - Name and address of LTCF
    - Name of LTCF Administrator
    - Name of Practitioners, agent(s) authorized to act on behalf of each Practitioner, and scope of agency.
  - Updated regularly and promptly upon any change
    - Redistributed to pharmacies, Practitioners
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Transmittal of Valid Oral Prescription
  - Practitioner’s requirements:
    - Resident’s full name
    - Drug name, strength and dosage form
    - Quantity of drug being ordered
    - Directions for use; and
    - Practitioner’s name, address and DEA registration number
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Agent’s obligations
  - Document oral prescription in writing
    - All information provided by Practitioner
    - Name and address of LTCF
    - Date and time that agent received the order
    - Affirmation from agent that he/she personally spoke with Practitioner and all required information was provided by the Practitioner
  - Transfer written document to pharmacy
    - Fax permitted
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- **Schedule II Drugs**
  - Emergency situation only
    - Otherwise must be in writing signed by Practitioner
  - Quantity limited to amount adequate to treat patient during the emergency situation

- **Record of Oral Prescriptions**
  - Practitioner to create contemporaneous record of each
  - Maintain in written or electronic log
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- May not be delegated to pharmacy or LTCF
- Regulations forthcoming

- Verification of Oral Prescription
  - Pharmacy requirements
    - Determine agent’s authority
    - Memorialize cross-check of list
      - Pharmacist’s initials
      - Date and time
    - Send copy of prescription document to Practitioner
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Within 72 hours after dispensing medication
- Fax permitted
- Must show that medication was dispensed

- Practitioner requirements
  - Sign copy of prescription document received from pharmacy
    - After verification, attestation
  - Return document to pharmacy within 5 business days
    - in person, by mail, by fax or by other appropriate means of delivery

- Pharmacy must attach endorsement to prescription document
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- LTCF Recordkeeping
  - Logbook
    - Contents
      - Record of each transmittal of oral prescription by agent on behalf of a Practitioner
      - Name, address, phone of pharmacy
    - Written or electronic
    - Maintained by “corporate parent”
    - 5-year retention period
    - Must make copies available for inspection by AG
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Generally
  - LTCF must keep on premises:
    - Logbook
    - Copies of written agreements with Practitioners
    - Copies of policies and procedures
    - Any rescissions of authority
    - List of practitioners and agents

- Penalties
  - Floor of $5,000 for diversion CMPs
  - Floor of $3,000 for recordkeeping CMPs
  - Increase in criminal penalties
Possible Outcomes – Kohl/DOJ Legislation Version 2.0 (cont.)

- Rule of Construction
  - Nothing in this subsection allows an LTCF, or an LTCF Administrator, agent or employee who is not a practitioner to prescribe, administer, dispense, distribute, deliver, possess, maintain, stock, or otherwise use a controlled substance except as provided in the language above.

- Status – Reviewed and marked up by DOJ; delivered to Senate Judiciary staff; details not yet available.
Reading the Tea Leaves

• Odds of implementation
  – Status Quo – 100 to 1
  – OH Waiver as a model – 50 to 1
  – Legislation – Even Money

• Complicating factors
  – Likely changes
  – Vagaries of the legislative process
  – Republican support?

• Nursing home residents will continue to experience unacceptable delays in getting needed pain medication and other controlled substances
Questions
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