New Narcotic Regulations and How They Affect Your Assisted Living Facility

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Good Day Pharmacy

Who is the DEA?
- DEA - Drug Enforcement Administration
  - This is not the State Health Department
  - This is a law enforcement agency
  - The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States.

Which Drugs does the DEA Regulate?
- DEA regulates the Controlled Substances which also are referred to as:
  - Narcotics
  - Scheduled medication
  - CII = Schedule II
  - CIII-CV = Schedule III through V

What are Controlled Substances?
- Drugs or other chemicals that have the potential to be both:
  - Addictive
  - Habit forming
- Controlled Substances divided into 5 schedules CI=CV
  - Schedule I – Most dangerous drugs
  - No recognized medical use
  - Schedule V – Least dangerous drugs

Scheduled/Controlled Drugs
- Schedule I (CI) Drugs or other substances that have a high potential for abuse; no currently accepted medical use in the United States.
- Schedule II (CII) Drugs or other substances that have a high potential for abuse and physical or psychological dependence – have medical use.
- Schedule III (CIII) Drugs or other substances that have a potential for abuse and physical or psychological dependence less than Schedule I or II
- Schedule IV (CIV) Drugs or other substances that have a low potential for abuse and physical or psychological dependence relative to those listed in Schedule III
- Schedule V (CV) Drugs or other substances that have a low potential for abuse and physical or psychological dependence relative to Schedule IV

2009 – DEA Audits
- Audited both assisted living facilities and pharmacies
- Goal to determine compliance
  - There is a difference in the DEA regulations (rules/laws) between:
    - Hospital
    - Skilled nursing
    - Hospice
    - Assisted Living = Patient’s Home
  - The health care community has been treating them as similar for years and years
Are There New DEA Rules?

- The rules (regulations/laws) have not changed
- New interpretation of old regulations
- In the past:
  - The entire health care community treated a nurse in skilled or assisted living as an agent of the physician – including the DEA
  - Chart orders were valid
- Now
  - DEA has interpreted the rules differently – and exactly as they were written
  - The Law is the same – No new Laws (rules/regulations)

The DEA is Vigorously Enforcing the Controlled Substance (Narcotic) Regulations

- This has created many problems
  - Patients (residents) experienced delays in getting controlled substances
  - Many residents are in pain waiting for the physician to provide a valid prescription

Result of Audits for Assisted Living

- DEA does not Recognize:
  - The nurse (if you have one) at the facility as an agent of the prescribing practitioner
  - The chart orders/physicians orders as valid prescriptions
  - Unless they contain all the necessary information of a valid prescription.

In a Hospital – Chart Orders

- Order for: Vicodin 1 tablet po every 6 hours.
  - No need for quantity,
  - No need for refills
  - The patient will take this as directed until stopped.
  - But not in an Assisted Living

New Rules/Guidelines for Narcotics in the Assisted Living Setting

- Who can act as the physician’s agent?
- Who can write a prescription for CII-CV?
- Who can FAX a copy of a CIII-CV?
- Difference between a chart order and a prescription
- What you can do avoid delay in receiving medications from the pharmacy?
- Changes in the State Health Department ALF regulations.
- Counting Narcotics
- How to store controlled substances

Prescription Must Have:

(What green is what is usually missing)

- Date
- Signature of the prescriber
- Name and street address of the resident
- Drug:
  - Name
  - Strength
  - Dosage form (patch, pill, suppository)
- Quantity
  - Directions for use
  - Authorized refills for CIII-CV if it is to be refilled
**Prescription vs Chart Order**

- The DEA will no longer allow chart orders (signed Physician Orders) to act as a prescription.
- A valid prescription is:
  - Different from a chart order/physician order.
  - Different from a hospital discharge order or note.

**Need Quantity for Physicians Order to be a Prescription.**

- This should be on ALL of your forms.

"Unless otherwise stated, all medication ordered on this form are authorized for a quantity equal to a month's supply and refills PRN."

- If there are more than one page to your forms (physician orders): put this on all pages—especially the signature page.

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**Orders on a Physician Order Form**

<table>
<thead>
<tr>
<th>#</th>
<th>Medication</th>
<th>Quantity</th>
<th>Refills</th>
<th>Diagnosis</th>
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<tbody>
<tr>
<td>1</td>
<td>Vicodin 5/500mg PO q4 hrs prn pain</td>
<td>1</td>
<td>2</td>
<td>Pain</td>
</tr>
<tr>
<td>2</td>
<td>Ativan 0.5 mg one tab po q 8 hours</td>
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<td>2</td>
<td>Anxiety</td>
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**Transfer Orders from the Hospital**

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<td>Metformin HCL 1000mg</td>
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**Physician Order Sheet—Signed Quarterly**

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Who is an Agent of the Prescriber?

- A facility nurse is NOT an Agent of the physician.
- Only nurses (or office staff) *directly employed* by the prescriber are agents
- A facility nurse can be an agent if:
  - Has an agent contract with the provider
    - Each provider

Does Having a Medical Director Change the Rules?

- If you have a Medical Director:
  - Is the facility nurse an agent if the Medical Director
    - NO
    - Must have an agent contract
  - Pharmacist can only fill a narcotic prescription directly from:
    - The prescriber
    - An agent of the prescriber

Agent Contract

Regulations

- The Regulations for Schedule II and Schedule III-V medications are *DIFFERENT*
- Regulations for Hospitals and Hospice are also different from Assisted Living
- Each STATE is different - depending on the state laws.

Who is a Providers AGENT?

- Someone the practitioner has contracted with to do one or all of the following:
  1. To prepare, for my signature, written prescriptions for controlled substances in those instances....
  2. To convey to a pharmacist by telephone oral prescriptions for controlled substances in Schedules III, IV, and V in those instances ....
  3. To transmit by facsimile to a pharmacy prescriptions for controlled substances in those instances ....

Can an Agent Do Everything a Prescriber Can Do?

- **The Prescriber** (Physician or Nurse Practitioner with DEA license)
  - **ALL CONTROLLED SUBSTANCES** - CII and CIII-CV
    - (Morphine, Fentanyl patch, Percocet and Vicodin, Tylenol with Codeine, Lyrica, Lortab)
  - **CII**—original prescription in writing—Morphine, Ritalin, Oxycontin
  - **CIII-CV** they can fax
The Prescriber’s Agent

- Only CIII-CV (Vicodin, Ativan, Ambien, Lyrica, Lortab)- NOT C-II
- Agent =
  - Doctor’s own Nurse
  - Office Employee
  - Assisted Living Nurse that has a contract IN WRITING as an agent with THAT PHYSICIAN.

What Can the Agent Do?

- Call the prescription (CIII- CV) to the pharmacy
  - from a verbal order from the prescriber
- Can FAX a copy of the signed prescription to the pharmacy
  - Remember, Assisted Living must have a copy of the sign order by the prescriber to be valid

Controlled Substance Orders/Prescriptions from ALF

- Require Valid Prescriptions
  - Date, signature of the prescriber, name and street address of the resident, drug name, strength, dosage form, quantity, directions, authorized refills
  - CIII-CV
    - An original, valid, signed prescription given to the pharmacy
    - Faxed copy of that original prescription- FAXED by an AGENT
    - Phoned to the pharmacy by the prescriber or the prescriber’s AGENT.
  - CII
    - Original written prescription.
    - The original prescription must be given to the pharmacy before the medication is left at the ALF.
    - FAX IS NOT ALLOWED

How to get a CII (Schedule II) Prescription Filled or Re-Filled

- CII- Morphine, Fentanyl Patch, Ritalin, Oxycontin...
  - The prescriber must supply an original written prescription to the pharmacy
  - NOT a FAXED COPY
  - No e-prescribing

Schedule II Controlled Medication-

- Contact physician about the pain
- Physician "orders" Percocet (or morphine, Fentanyl patch)
  - Pharmacy must obtain the ORIGINAL PAPER copy of the SIGNED prescription- because it is a CII
  - No Verbal Orders from Prescriber
  - No Faxed Orders from Prescriber
  - No e-prescribing

Options for the Assisted Living Resident if Unable to get a New CII Prescription

- Non controlled medication-Plain Tylenol, Tramadol, Ultram, Ultracet
  - Would a CIII-CIV be effective? (Vicodin, Lortab, Norco)
    - Faxed or phoned to the pharmacy
    - Assisted Living regulations require a written and signed order to give the medication
**Other Options**
- Increased dose of a medication the resident already has.
- Taking Vicodin or Tramadol along with their CII
- Urgent Care or Emergency Room to get a prescription
  - *Don’t let them go into withdrawal*

**Have Refills Available**
- Add to requests for orders
  - "Unless otherwise stated, all medications ordered on this form are authorized for a quantity equal to one month supply (31 days) and refills PRN for one year"
- Will have refills available when you reorder CIII-CV (for 6 months)

**HOSPICE ONLY**
(This is a regulation specific to HOSPICE in all locations- SNF, ALF, Home)
- Pharmacy can accept:
  - A FAXED (or original hard copy) from the prescriber
  - Even for Schedule II (CII) – Morphine, Fentanyl
  - Must be a VALID prescription
  - MUST note that patient is a Hospice patient or terminally ill on the prescription
- May partial fill a Schedule II up to 60 days
  - – ONLY FOR HOSPICE –
  - BUT... many insurances **will not allow a partial fill.**

**Review- ALF New Narcotic Order**
- In an Assisted Living = Home
  - CII –
    - Original Prescription (NO FAX or e-prescribing)
    - Valid and signed by prescriber
    - Prescriber = Physician or Nurse Practitioner ONLY
    - Hospice can FAX
  - CIII-CV
    - Faxed copy from PRESCRIBER or AGENT
    - Prescriber or prescriber’s agent may call the prescription into the pharmacy
    - Agent = Doctors employee or AGENT with CONTRACT

**Schedule II**
Percocet, Morphine, Fentanyl Patch, OxyContin
- NO REFILLS
- Must have an original prescription each time it is filled
- FAX only for HOSPICE patient
- Must fill it for the EXACT amount written on the prescription
  - *Can not partial fill-send ½ now and ½ later*

**Review Hospice**
- Hospice ONLY
  - CII
    - Faxed copy of Original Prescription or original prescription
    - Valid prescription (all the necessary information)
    - Signed by prescriber
    - Prescriber = Physician or Nurse Practitioner
  - CIII-CV
    - Faxed from prescriber
    - Must be a valid prescription and signed by prescriber
    - Called in to pharmacist by prescriber or agent
How to Not Run Out

- When a Controlled (Narcotic) medication comes to the facility
  - It is usually marked with a C
  - If it is a routine medication, write on the card (bottle) but NOT ON THE LABEL...
  - Date to reorder. Use a red marker
    - Put this on all the cards – if you got 4 cards write on all cards
  - Reorder date of at least 7 days before it is due:
    - If you got 30 days supply reorder in 23 days
    - If you got 21 days supply reorder in 14 days.
    - Also order 1-2 days earlier if that order date is on a weekend or holiday or holiday weekend.

Emergency C-II Rxs - not really a workable option

- If it is a valid EMERGENCY and must also fax a copy of the original prescription. Must be Physician to Pharmacist
  - No physician or pharmacy will do this
  - There are exact criteria that all must be met by the ordering physician (usually on-call physician not PCP)
  - If not done - the pharmacy must contact DEA – starts and investigation of the facility, physician, and pharmacy
  - Remember, Assisted Living must have a written, signed order for a medication to be given

Thank You!

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New ALF State Health Dept. Regulations

- Section 7.2 –
  - Controlled substances must be:
    - Stored under double lock
    - Counted and signed for at the end of each shift in the presence of either two QMAPS or a QMAP and qualified manager.
  - If that is not possible, then the QMAP going off duty must count for the controlled substances and the next on duty QMAP must verify the count and sign.
  - If the count cannot be verified, the discrepancy must be reported immediately to the administrator.

Colorado State Health Department New Requirements

- Narcotic Counts - (Controlled Substances)
  - Accurate perpetual counts must be kept for each drug
  - Must be counted at the change of each shift
  - Count verified by both QMAP coming on and QMAP going off
  - Overstock narcotics kept other than on the med cart must be counted
    - Not necessarily each shift – per Health Dept.
    - Each time meds are taken out to unit remaining stock must be counted.
Narcotic Count Sheet for Each Medication

- You sign out the dose you are giving.
- The next number is the number remaining.
- Example: there are 28 left.

Count Sheet for Each Medication

Shift Verification of Controlled Substances Count

- One for each cart or storage unit.
- Count confirmed each change of QMAP.

New ALF State Health Dept. Regulations

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If there is a Discrepancy Must Notify the Administrator Immediately

- Narcotic Drugs for Destruction- Contains DEA Required Information for Destruction
All Narcotics Must be Kept Under Double Lock

- Med carts:
  Med Cart lock + Narcotic lock box = double lock
- Refrigerator is locked + a second locked door - med room door = double lock
- Refrigerator is locked + Lock box in Refrig. = double lock
- Destruction cabinet/overstock cabinet is locked and there is another locked door or box in the cabinet

Examples

- Small lock boxes can be used in a refrigerator
- External locks can be put on refrigerator
- Remember all narcotics that are refrigerated must be double locked

New Regulations – Compliance (Continued)

- Medication supply will be observed for:
  - Regulatory compliance with doubling locking requirement.
  - System for counting and verifying the count will be reviewed for regulatory compliance.
  - Any discrepancies in the counts will be reviewed to ascertain actions taken to rectify the problem.
  - Other areas of deficient practice may be considered such as reporting occurrences of drug diversion, and compliance with physician orders.

Facility tools that may need to be created and/or updated to reflect the current standards of practice.

- Forms
  - Controlled Medication Administration Record
  - Controlled Medication Count Form
  - Disposal / Release of Medications Form
  - Med Discrepancy Report Form
  - Med Self-Admin Assessment Form
  - Narcotic / Medication Count Sheets

Facility tools that may need to be created and/or updated to reflect the current standards of practice.

- Medication Administration Policies & Procedures
  - Controlled Medications / Narcotics
  - Medication Administration Discrepancies / Occurrence Reporting
  - Medication Administration Record / MAR
  - "PRN" or "As Needed" Medications
  - Self-Administration of Medications
  - Storage of Medications

Thank You!

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