

Drug Enforcement Administration



Policy Update

20th National Conference on Pharmaceutical
& Chemical Diversion

Ft. Worth, TX

Policy Update

- Changes to a Controlled Substance Prescription
 - Pharmacist Adding DEA # on Rx
- Agent of a Practitioner – Statement of Policy
- Disposal of Controlled Substances by Ultimate User

Changes to a Schedule II Prescription

- On November 19, 2007, DEA published in the FR the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*.
- In the preamble to that Rule, DEA stated that “the essential elements of the CII prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) ...may not be modified orally.”

Changes to a Schedule II Prescription

- The instructions contained in the Rule's preamble are in opposition to policy posted on the DEA Diversion Website regarding changes a pharmacist may make to a CII prescription after oral consultation with the prescriber.

Changes to a Schedule II Prescription

- In a Q&A section, the website instructed regarding CII's that a “pharmacist may change or add the dosage form, drug strength, drug quantity, direction for use, or issue date only after consultation with and agreement of the prescribing practitioner.”

Changes to a Schedule II Prescription

- DEA recognized the confusion regarding this conflict and plans to resolve this matter through a future rulemaking.
- Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.

Changes to a Schedule III-V Prescription

- **What changes may a pharmacist make to a prescription written for a controlled substance in schedules III-V?**
 - The pharmacist may add or change the patient's address upon verification.
 - The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.

Changes to a Schedule III-V Prescription

- Such consultations and corresponding changes should be noted by the pharmacist on the prescription.
- Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions.

Changes to a Schedule III-V Prescription

- The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

Adding DEA # To Paper Schedule II Prescriptions

- Historically, DEA has not addressed it
- Regulation: 21 C.F.R. § 1306.05(a) Manner of Issuance
- Security Feature
- Many state pharmacy boards allow pharmacists to add DEA # to prescriptions
- DEA is internally looking at this issue

Adding DEA # To Paper Schedule II-V Prescriptions

- Impact on PMPs

Agent of a Practitioner

Statement of Policy

- Published in FR on October 1, 2010
- Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies
- By longstanding statutory requirement, a valid prescription issued by a DEA-registered practitioner is required for dispensing a controlled substance.

Agent of a Practitioner

- To be effective (i.e., valid), a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *United States v. Moore*, 423 U.S. 122 (1975); **21 CFR 1306.04(a)**.
- Thus, the practitioner must determine that a prescription for a controlled substance is for a legitimate medical purpose.

Agent of a Practitioner

- While the core responsibilities pertaining to prescribing controlled substances may not be delegated to anyone else, an individual practitioner may authorize an agent to perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient.

Agent of a Practitioner

- Who is an agent of an individual practitioner for the purpose of communicating a prescription for a controlled substance?
 - The CSA defines an “agent” as “an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser.” 21 U.S.C. § 802(3)
 - Under the CSA, the term “dispenser” includes “prescribing.”

Agent of a Practitioner

- Any agency relationship must preserve the requirement that medical determinations to prescribe controlled substances be made by a practitioner only, not by an agent.
 - (Nurse in an LTCF may not make the medical determination.)

Agent of a Practitioner

- Outlines DEA's existing statutory and regulatory requirements as to the proper role of duly authorized agents of individual practitioners.
- DEA anticipates the utilization of electronic prescribing by practitioners for controlled substance prescriptions will reduce the role of agents over time.

Agent of a Practitioner

- Prescriptions require specific information: Patient name, address, drug name and strength, quantity prescribed, directions for use and the name address and DEA number of the issuing practitioner. 21 C.F.R. 1306.05(a)
- All prescriptions must be dated as of, and signed on, the day when issued.
- Paper prescriptions must be manually signed by practitioner.

Agent of a Practitioner

- A prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. 21 C.F.R. 1306.05(f)
- The practitioner must sign the prescription, whether manually or electronically.
- Signature authority cannot be delegated to an agent.

Agent of a Practitioner

- Elements of a valid prescriptions must be specified by the practitioner and cannot be delegated.
- CII may be dispensed only pursuant to a written prescription, except in emergency situations.
- Emergency oral communication of a CII prescription may not be delegated to an authorized agent.

Agent of a Practitioner

- Generally, a valid CII prescription may not be communicated by facsimile.
- Exception: A CII prescription for persons in a Hospice or Long Term Care Facility may be communicated by facsimile and that communication may be delegated to an authorized agent.

Agent of a Practitioner

- Where a DEA-registered practitioner has made a valid oral prescription for a controlled substance in III-V by conveying all the required information to the his/her authorized agent, that agent may telephone the pharmacy and convey that prescription information to the pharmacist.
- Communication by facsimile of a valid prescription for CIII-V substance maybe delegated to an authorized agent.

Agent of a Practitioner

- Where an agent communicates a CS prescription on behalf of a registrant, it is important that:
 - The such person be clearly identified
 - Their activities be subject to evaluation to ensure they do not exceed the bounds of the agency relationship and the legal limits of an agent's role under the CSA.

Agent of a Practitioner

- Written authorization of an agent recommended.
- Sample Agency Agreement in Policy Statement

Disposal of Controlled Substances

Secure and Responsible Drug Disposal Act of 2009

- Enacted on October 12, 2010
- This Act amends the Controlled Substances Act to provide for disposal of controlled substances by certain persons.
 - Ultimate Users
 - Long Term Care Facilities
 - Survivor of decedent

Secure and Responsible Drug Disposal Act of 2009

- DEA desires the collection and disposal process to be accessible to all, but also safe and effective.
- DEA is in the process of drafting regulations to implement the Act.

Public Meeting

- On January 19-20, 2011, DEA held a Public Meeting in Washington, D.C.
- Input was received from Federal and State agencies, and the Pharmaceutical and Disposal Industry.
- 175 attended.
- Transcript is available on DEA's website at www.deadiversion.usdoj.

Public Meeting

- Common Themes Heard:
 - Options
 - Education
 - Communication
 - Define “Unrecoverable”
 - Convenience
 - Cost Effectiveness

Regulatory Challenges

- Disposal Diversion - How Do We Prevent?
 - 5-27-2011 - Yorkville Deputy Policy Chief arrested for stealing medication from take back program
 - 2nd Highest Ranking Official
 - Charged with felony possession of controlled substances and theft of government property

Law Enforcement Involvement

- Registration is waived for “Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.”

21 CFR 1301.24(a)(2)

DEA 2nd National Take Back Day

- April 25, 2011
- More than 5,300 collection sites
- Approximately 3,800 state and local agency participants
- Collections in all 50 states, Puerto Rico, Guam, and the Virgin Islands

Got Drugs?

Turn in your unused or expired
medication for safe disposal
Saturday, Sept. 25th

Visit www.dea.gov
for a collection site near you.



CLEAR CHANNEL

DEA - Office of Diversion
Control

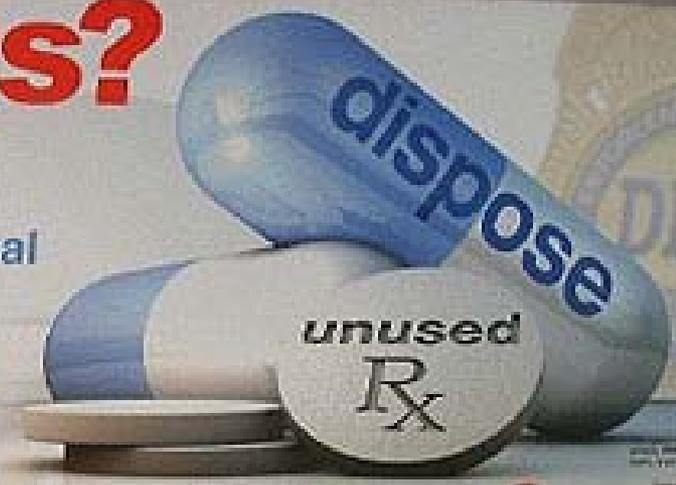
Baltimore, MD

self
ers

Got Drugs?

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unused or expired
medication for safe disposal
Saturday, Sept. 25th

Visit www.dea.gov
for a collection
site near you.



PHILL
CORRETT
1984
1985
1986
1987



Please Stand
When the Train
is Moving



No Smoking

Got Drugs?
Turn in your unused (or expired)
medication for safe disposal.
September, April 2016

Visit www.dispose.gov
for a collection
site near you.

dispose
unused
Rx

EXIT

The Blue Man Station, located
at Philadelphia's Main Station,
will accept unused prescription
drugs and over-the-counter
drugs for safe disposal.

EXIT

DEA - Office of Diversion
Control

Philadelphia, PA

Got Drugs?

Make your home
medicine cabinet safe

Saturday, Sept. 25th

Visit www.dea.gov for a collection site near you.

Visit www.dea.gov for a collection site near you.

Turn in your unused or expired
medication for safe disposal.

Visit www.dea.gov
for a collection site near you.

www.dea.gov

THE MOST HATED MAN IN NEW YORK

abc NEWS

POLICE CHIEF MERL HAMILTON SAYS HE'S

DEA - Office of Diversion
Control

OF REPLACING NELSON

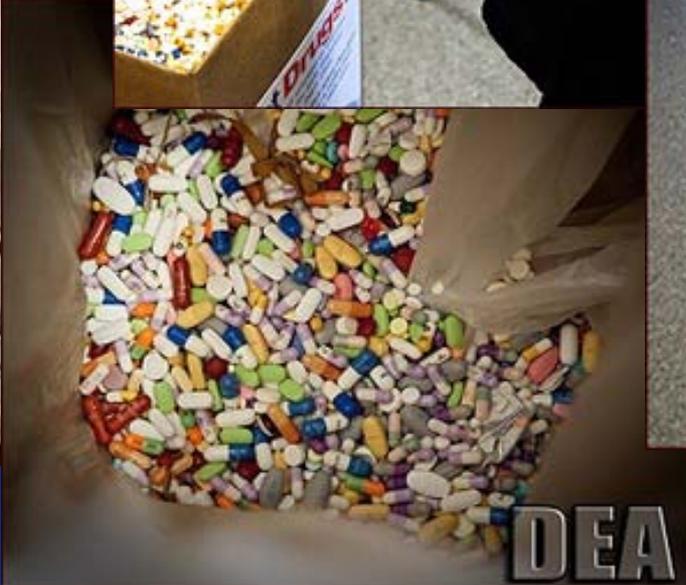
New York **ESNY**

ARENAS, WIZARDS TOLD NOT TO DISCUSS

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for a collection site near you.



DEA

DEA - Office of Diversion Control



Results

- April 25, 2011:
 - 376,590 lbs (188 tons)
- September 30, 2010:
 - 242,000 lbs (121 tons)

Coming Soon: 3rd DEA National Take Back Day

- October 2011
- More Information: www.dea.gov

Comments / Questions?

