Tools for Fighting Methadone Abuse

Using Federal and State Law to Address the Supply of Methadone

Distributing/Dispensing = DEA Registrants

Distributors

Prescribing Physicians

Dispensing Physicians

NTPs

Pharmacies

Ultimate User
Reports and Records

Distributors

Prescribing Physicians

Dispensing Physicians

NTPs

Pharmacies

Ultimate User

DEA

Lawful Purposes for Dispensing Methadone

Distributors

Prescribing Physicians

Dispensing Physicians

NTPs

Pharmacies

Ultimate User

Pain

M & D

Pain

Pain
Federal Requirements for NTPs

- Must have NTP registration – 21 USC 823(g)
- Can dispense (but not prescribe) for maintenance and detoxification - 21 CFR 1306.04(c)
- Must keep records – 21 CFR 1304.24
- Maintenance and detoxification treatment are defined at 21 CFR 1300.01(b)(10) and (26)

Federal Requirements for Practitioners

- Physicians and pharmacies must have registration – 21 USC 823(f)
- Cannot dispense for maintenance and detoxification
- Prescription must be issued in the usual course of professional practice for a legitimate medical purpose – 21 CFR 1306.04(a)
Usual Course of Professional Practice

- *U.S. v. Moore* (1975) – valid prescription is based on medical history and diagnosis, and the prescribed drug is medically useful to treat diagnosed disease/symptoms
- Failing to comply with State law is outside the usual course of professional practice – *United Prescription Services*, 72 Fed. Reg. 50397 (2007)

Tennessee State Law on Treating Pain

- Documented medical history
- Physical examination by the physician providing the drug
- Written treatment plan
- Written record of drugs prescribed

Some states require specific training in pain management and/or written warning to the patient about abuse and addiction of narcotics
So What?

- State prosecution – “Except as authorized by this Act, it shall be unlawful to dispense…”
- Federal prosecution – 21 USC 841
- Civil Penalty – 21 USC 842(a)(1)
- Administrative action to revoke DEA registration

Federal Administrative Proceedings

- Administrative proceedings run parallel to –
  - Criminal proceedings under the CSA (21 USC 841 or 843)
  - Civil proceedings under the CSA (21 USC 842(a))
  - State criminal and/or administrative proceedings

“Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.” 21 USC 824(c)
Common Causes for Revoking DEA Registration

Failure to comply with Federal or State law (21 U.S.C. § 823(f)(4))
  - Lack of valid prescription
  - Violation of state laws

“Such other conduct which may threaten the public health and safety” (21 U.S.C. § 823(f)(5))

State license revoked/suspended (21 U.S.C. § 824(a)(3))

--- Basis for Summary Disposition

Immediate Suspension Order (ISO)

Immediate Suspension of a DEA registration
  - Must have a basis to revoke the registration under 21 USC 824(a)
  - Must show that continued registration poses an imminent danger to public health and safety
  - Hearing conducted 30-60 days after service of ISO
  - Seal or remove for safekeeping all controlled substances
  - Execute administrative inspection warrant or criminal search warrant when serving ISO
Big Finish

• PGA Tour v. European Tour

• Go Gators or Roll Tide or Go Vols…
  – State law matters
  – State licensing matters

• Stop the Doctor