



DEA Overview of Laws and Regulations Concerning Disposal of Controlled Substances



Office of Diversion Control Mission



To prevent, detect, and investigate the diversion of controlled substances from legitimate sources while ensuring an adequate and uninterrupted supply to meet legitimate medical and scientific purposes.



References



- Controlled Substances Act (CSA)
- Code of Federal Regulations (CFR)
- Advanced Notice of Proposed Rule Making (ANPRM)
- Secure and Responsible Drug Disposal Act of 2010



Controlled Substances Act (CSA)



Ultimate User:

“a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.”

21 USC 802(27)



Long Term Care Facility



“a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.”

21 CFR 1300.01(25)

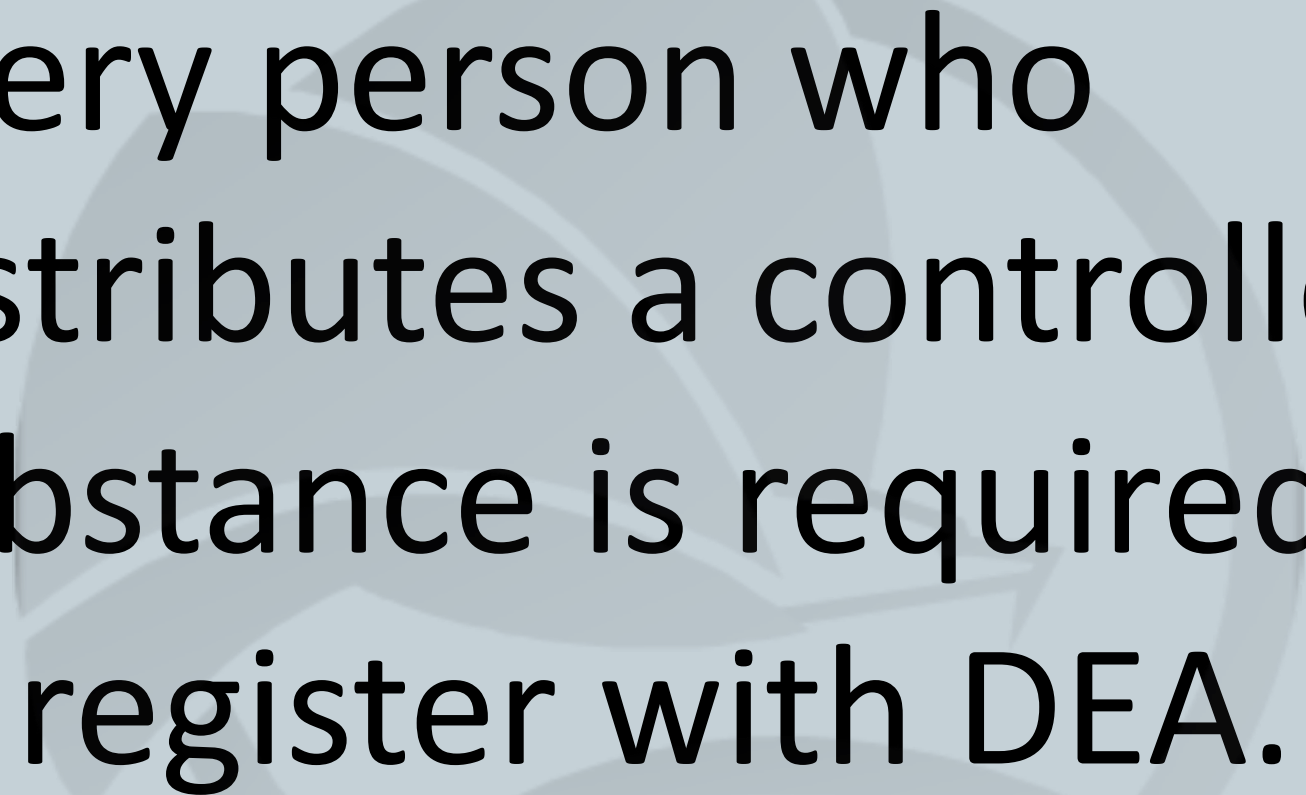


Distribute



“to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.”

21 USC 802(11)

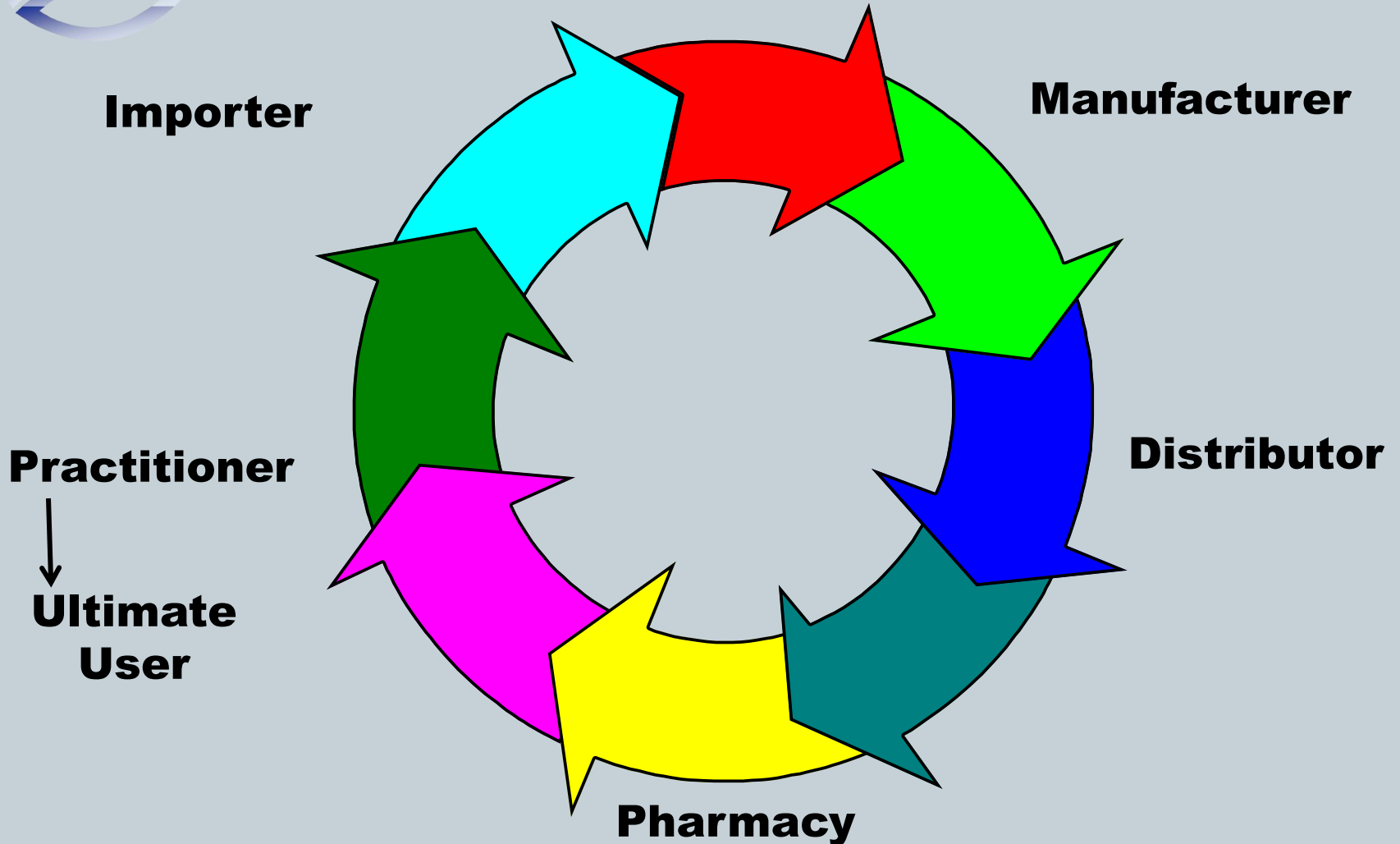


Every person who
distributes a controlled
substance is required
to register with DEA.

21 USC 822(a)



Closed System of Distribution





Exception



Ultimate Users are not required to register and may lawfully possess a controlled substance.

21 USC 822(c)(3)



Exemption



Requirement of
registration is waived for
law enforcement
officials.

21 CFR 1301.24



ANPRM



- “Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration”
- Published on January 21, 2009



ANPRM



156 Comments received

- Ultimate Users
- Publicly Owned Treatment Works
- Concerned interest groups
- Hospice
- Pharmacies
- Reverse Distributors
- State Regulatory Agencies
- Long Term Care Facilities



Secure and Responsible Drug Disposal Act of 2010

Public Law 111-273

Enacted on October 12, 2010

- Ultimate Users
- Long Term Care Facilities (LTCF) on behalf of residents
- Survivor of decedent



Considerations When Promulgating Regulations



- Public health and safety
- Ease and cost of program implementation
- May not require any entity to establish or operate a delivery or disposal program



Authority



The authority to promulgate regulations under the CSA has been delegated to the Administrator of DEA by the Attorney General.

28 CFR 0.100



Collection/Disposal Concerns



- Diversion of collected controlled substances
- Record keeping/Accountability
- Destruction consistent with Federal/state/local laws and regulations