Achievable

PTCE DUMP SHEET

Federal laws

Controlled substances

Controlled Substances Act (CSA, 1970)

Places controlled substances in five schedules (I—V) by accepted medical use, potential for abuse, and risk of dependence

Refilling controlled medications

- **Schedule II:** no refills; a new prescription for every fill
- **Schedules III and IV:** no refills after 6 months or 5 refills, whichever comes first
- **Schedule V:** refilled as the prescriber authorizes; federal law sets no limit (many states do)

Combat Methamphetamine Epidemic Act (CMEA, 2005)

Limits sales of ephedrine, pseudoephedrine, and phenylpropanolamine to 3.6 g a day and 9 g per 30 days per purchaser; kept behind the counter and sold only with photo ID

Ryan Haight Online Pharmacy Consumer Protection Act (2008)

Prevents illegal distribution and dispensing of controlled substances over the Internet; requires at least one in-person medical evaluation

Drug approval, labeling & packaging

Durham-Humphrey Amendment (1951)

Distinguishes over-the-counter from prescription drugs

Kefauver-Harris Amendment (1962)

Passed after the thalidomide tragedy; requires manufacturers to prove a drug is effective as well as safe

Risk Evaluation and Mitigation Strategy (REMS)

Monitors drugs with serious safety concerns so their benefits outweigh their risks (e.g., isotretinoin, thalidomide, sodium oxybate)

Poison Prevention Packaging Act (PPPA, 1970)

Requires child-resistant packaging that children under 5 can't easily open

Workplace safety & waste

Occupational Safety and Health Act (1970)

Created OSHA, which sets and enforces standards for safe and healthful working conditions

Resource Conservation and Recovery Act (RCRA, 1976)

Regulates the disposal of solid and hazardous waste, including P- and U-listed medications and D-coded (characteristic) wastes