

Drug law and controlled substances

Act	Year	Enforced by	Act	Year	Enforced by
Food, Drug, and Cosmetic Act	1938	FDA (within HHS)	Occupational Safety and Health Act	1970	OSHA
Controlled Substances Act	1970	DEA (Department of Justice)	Needlestick Safety and Prevention Act	2000	OSHA

Five schedules, ordered from greatest to least abuse potential:

Schedule	Abuse potential and use	Examples
I	High; no accepted medical use; cannot be prescribed	Heroin, LSD, marijuana (under federal law), MDMA, peyote
II	High, may lead to severe dependence; accepted medical use	Hydrocodone combination products, oxycodone, morphine, fentanyl, methadone, methylphenidate (Ritalin), amphetamine (Adderall)
III	Less than I or II; moderate or low physical, or high psychological, dependence	Codeine up to 90 mg per dosage unit (Tylenol with Codeine), ketamine, buprenorphine, testosterone and other anabolic steroids
IV	Low relative to III; limited dependence	Alprazolam (Xanax), diazepam (Valium), lorazepam (Ativan), clonazepam (Klonopin), zolpidem (Ambien), tramadol
V	Lowest; limited quantities of narcotics, as antitussives, antidiarrheals or analgesics	Codeine up to 200 mg per 100 mL (Robitussin AC), diphenoxyate with atropine (Lomotil), pregabalin (Lyrica)

- ✓ **Refills:** Schedule II none, a new prescription every time; III and IV up to 5 times within 6 months of writing. The stricter of state and federal law applies
- ✓ **DEA registration number** is valid 3 years and appears **only** on controlled-substance prescriptions
- ✓ **Storage:** locked cabinet or safe of substantial construction, keys in a locked authorized-access area, separate from non-narcotics
- ✓ **Inventory at least annually; records kept 2 years**
- ✓ **Destruction takes two authorized people:** log the date, drug, strength, quantity, reason and both signatures
- ✓ **A prescription must carry:**
 - Date of issue
 - Provider name and address
 - Strength
 - **Quantity written out** (14 [fourteen])
 - Refills
 - Whether a generic is acceptable
 - Patient name and address
 - Drug name
 - Dosage form
 - Directions
 - NPI and signature (**manual for controlled substances**)

Vaccines

Type	Examples	Type	Examples
Live-attenuated	MMR, varicella, smallpox, yellow fever	Subunit / recombinant / conjugate	Hib, hepatitis B, HPV, pertussis, pneumococcal, meningococcal, Shingrix
Inactivated	Hepatitis A, injectable influenza, injectable polio, rabies	mRNA	COVID-19
Toxoid	Diphtheria, tetanus	Viral vector	COVID-19 (Janssen)

- ✓ **Capital letter = full-strength component, lowercase = reduced.** Td is full tetanus with a smaller diphtheria dose
- ✓ **VIS documentation:** edition date, date the VIS was given, date administered, name/title/address of the administerer, manufacturer and **lot number**
- ✓ **Live-virus contraindications:** another live vaccine within 28 days, pregnancy or possible pregnancy within a month, immunocompromise, chemotherapy or high-dose steroids, recent transfusion or immune globulin