Federal & State Agencies ...

that might get in your face
besides the obvious ones

Tom Hazlet

Pharm 543

Autumn 2008

Menu

- One more try at the Act→USC→CFR thing

Federal Agencies

- Justice→DEA
- HHS→CMS (previously HCFA)
- CPSC
- EPA
- OHSA
- FTC

State Agencies

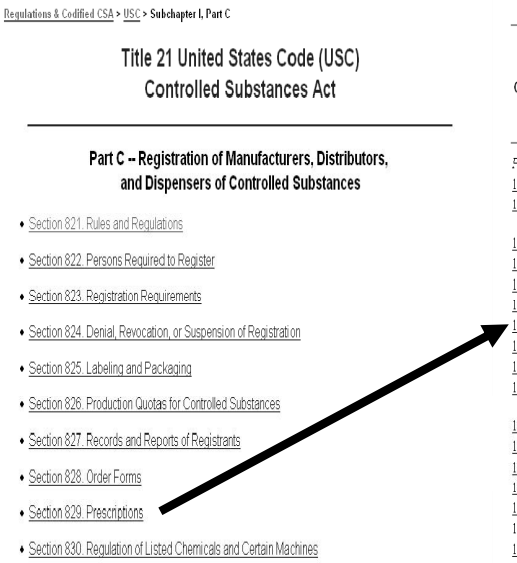
- DOH
  - Professional Boards
  - Facility & Services Licensing
- DSHS
  - MAA
    - Alcohol & Substance Abuse
    - Mental Health
    - Pharmacy
- DOE
- HCA

Federal Agencies DEA

- Department of Justice
  - Drug Enforcement Administration
    - Controlled Substances Act → 21USC13 -- DRUG ABUSE PREVENTION AND CONTROL
    - Regulations – 21CFR1300-1399
  - Pharmacist Manual

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm

CSA → DEA Regulations



Regulations & Codified CSA > USC > Subchapter I, Part C

Title 21 United States Code (USC)
Controlled Substances Act

Part C -- Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

- Section 821. Rules and Regulations
- Section 822. Persons Required to Register
- Section 823. Registration Requirements
- Section 824. Denial, Revocation, or Suspension of Registration
- Section 825. Labeling and Packaging
- Section 826. Production Quotas for Controlled Substances
- Section 827. Records and Reports of Registrants
- Section 828. Order Forms
- Section 829. Prescriptions
- Section 830. Regulation of Listed Chemicals and Certain Machines

Title 21-Food and Drugs

(This index contains parts 1300 to End)

CHAPTER II--DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

Part	
1300	Definitions
1301	Registration of manufacturers, distributors, and dispensers of controlled substances
1302	Labeling and packaging requirements for controlled substances
1303	Quotas
1304	Records and reports of registrants
1305	Orders for schedule I and II controlled substances
1306	Prescriptions
1307	Miscellaneous
1308	Schedules of controlled substances
1309	Registration of manufacturers, distributors, importers and exporters of list I chemicals
1310	Records and reports of listed chemicals and certain machines
1311	Digital certificates
1312	Importation and exportation of controlled substances
1313	Importation and exportation of precursors and essential chemicals
1314	Retail sale of scheduled listed chemical products
1315	[Reserved]
1316	Administrative functions, practices, and procedures

Section 829. Prescriptions

Schedule II substances

(a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

Schedule III and IV substances

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

Schedule V substances

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

Non-prescription drugs with abuse potential

(d) Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(Pub.L. 91-513, Title II, Section 309, Oct. 27, 1970, 84 Stat. 1260.)

EDITORIAL NOTES

References in Text. Schedules II, III, IV, and V, referred to in text, are set out in section 812(c) of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a), (b), and (d), is Act June 25, 1938, c. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (section 301 et seq.) of Title 21 U.S.C.A., Food and Drugs. Section 503(b) of that Act is classified to section 353(b) of Title 21.

Effect of Scheduling on Prescriptions. Pub.L. 101-647, Title XIX, Section 1902(c), Nov. 29, 1990, 104 Stat. 4852, provided that: "Any prescription for anabolic steroids subject to refill on or after the date of enactment [Nov. 29, 1990] of the amendments made by this section [enacting sections 802(41) and 812(c) Schedule III(e) of this title and this note] may be refilled without restriction under section 309(a) of the Controlled Substances Act (21 U.S.C. 829(a)) [subsec. (a) of this section]."

[Section 1902(d) of Pub.L. 101-647 provided in part that section 1902 and the amendments made by such section shall take effect 90 days after the date of enactment of Pub.L. 101-647, which was approved Nov. 29, 1990.]

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Section 829. Prescriptions

Schedule II substances

Schedule III and IV substances

Schedule V substances

Non-prescription drugs with abuse potential

EDITORIAL NOTES

Section 829. Prescriptions

Schedule II substances

Schedule III and IV substances

Schedule V substances

Non-prescription drugs with abuse potential

EDITORIAL NOTES

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. In addition, a prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the Administrator under §1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of §1301.28(e). Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for as well as the signature of the physician.

(c) An official exempted from registration under §1301.22(c) shall include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 56 FR 25026, June 3, 1991; 60 FR 36641, July 18, 1995; 62 FR 13966, Mar. 24, 1997; 68 FR 37410, June 24, 2003; 70 FR 294, Jan. 4, 2005; 70 FR 36343, June, 23, 2005]

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Health & Human Services CMS

- HHS→FDA, CMS, NIH, CDC, lots of others

http://www.hhs.gov/

http://www.hhs.gov/about/orgchart.html

[Trick: use employee directory]

http://directory.psc.gov/employee.htm

- Centers for Medicare & Medicaid Services

http://www.cms.hhs.gov/

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Consumer Product Safety Commission

- 16 CFR PART 1700--POISON PREVENTION PACKAGING

Drugs, Oral Prescription All Exceptions	PPPA	1700.14(a)(10) (i)-(xx)	
Drugs controlled	PPPA	1700.14(a)(4)	Regulatory Summary for PPPA Clinical Trial Letter Child Resistant Packaging Guide Healthcare Professionals Guide
Drugs iron containing	PPPA	1700.14(a)(12)	Regulatory Summary for PPPA Clinical Trial Letter Child Resistant Packaging Guide Healthcare Professionals Guide
Drugs oral prescription	PPPA	1700.14(a)(10)	Regulatory Summary for PPPA Clinical Trial Letter Child Resistant Packaging Guide Healthcare Professionals Guide
Drugs over the counter	PPPA	1700.14(a)(30)	Regulatory Summary for PPPA Clinical Trial Letter Child Resistant Packaging Guide Healthcare Professionals Guide

http://www.cpsc.gov/businfo/dreg.html

Federal Trade Commission

- **Sherman Antitrust Act, 1890; 15USC1-7**
- "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal" (see 15 U.S.C. § 1).
- "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony [. . .]" (see 15 U.S.C. § 2).
- The Act put responsibility upon government attorneys and district courts to pursue and investigate trusts, companies and organizations suspected of violating the Act.
- **... authority over OTC drug advertisements**
- **antitrust & competition**
  - i.e., pharmacists banding together to ....
- http://www.ftc.gov/

http://en.wikipedia.org/wiki/Sherman_Antitrust_Act

EPA & OSHA → DOE & L&I

- Federal
  - Environmental Protection Agency
  - Occupational Safety & Health Administration
- State
  - Department of Ecology
  - Labor & Industries

WA Department of Health

- Professional Boards

http://www.doh.wa.gov/licensing.htm

- Facilities Licensing

http://www.doh.wa.gov/hsqa/FSL/Default.htm

Department of Social & Health Services

- Health & Recovery Services Administration
  - Alcohol & Substance Abuse
  - Mental Health
  - Pharmacy

http://fortress.wa.gov/dshs/maa/

Department of Ecology

- http://www.ecy.wa.gov

- Quality Assurance Project Plan: Screening for Pharmaceuticals in Wastewater Treatment Plant Effluents, Groundwater, and Surface Water in the Sequim-Dungeness Area

http://www.ecy.wa.gov/biblio/0403104.html

Sheila Lockwood -- lockwood@u... http://www.ehs.washington.edu

Health Care Authority

- Basic Health Plan
- Uniform Medical Plan

- http://www.hca.wa.gov/

Questions

Points of Emphasis

- Relationship between [act, statute, law], agencies, and [regulations, rule]
- Federal and state agencies