

## Using law resources

Pharm 543  
Autumn 2005  
Tom Hazlet

1

## Outline

- USC | CFR | FR, RCW | WAC | SR
- WA stuff
  - Trip through the Salmon Book
  - BOP website
  - WA Legislative website → RCW, WAC, SR
- Federal stuff
  - GPO Access → USC, CFR, FR
  - FDA, DEA, CPSC
- UW stuff
  - Lexis-Nexis, other “law” databases
  - Current Contents
  - NAPBLaw Online

2

## “codified”

- how a bill becomes a law ...
- law (statute) authorizes agencies to promulgate regulations (rules)



## “codified” 2

- Federal
  - United States Code
    - Title 5 Government Organization & Employees [Administrative Procedures]
    - Title 21 Food & Drugs [& DEA]
    - Title 42 Public Health & Welfare
  - Code of Federal Regulations
    - Title 16 Commercial Practices [CPSC]
    - Title 21 Food and Drugs [FDA, DEA]
    - Title 42 Public Health [HHS, CMS]
    - Title 45 Public Welfare [Human Subjects, “welfare”, other]

4

## "codified" 3

---

- RCW – Revised Code of Washington
    - Title ??? <Administrative Procedures>
    - Title 18 Businesses And Professions
    - Title 69 Food, Drugs, Cosmetics, And Poisons
    - Title 70 Public Health And Safety
  - WAC – Washington Administrative Code
    - Title 245 - Health Services Commission
    - Title 246 - Health, Department of
    - Title 247 - Health Care Facilities Authority
    - Title 248 - Health, Board and Division of (Social and Health Services, Department of)
- 

5

## Pharmacy Lawbook 2003 "Salmon Book"

---

- Organization
  - Table of Contents
  - Index
  - Stuff in between
- RCW – 18, 69, 70
- WAC – 246
- 21CFR1301, 1306
- Miscellaneous
  - RCWWAC for other practitioners
  - licensed health care entities

\*Importance of reading WAC's in context of RCW's

---

6

## BOP Website

---

- [www.doh.wa.gov/pharmacy](http://www.doh.wa.gov/pharmacy) [works]

<https://wvs2.wa.gov/doh/hpqa-licensing/HPS4/Pharmacy/default.htm>

- Noteworthy
    - Forms & Applications
    - Provider Credential Search
    - Laws
      - hotlink to Legislature / Search
      - "Compile the complete chapter as a single file" trick; use CRRL-f to search
    - Links (most other state Boards)
- 

7

## WA Legislature Site

---

- [www.leg.wa.gov](http://www.leg.wa.gov)
    - search (upper right hand corner)
    - read the instructions when first opening; they go away
      - truncation/multiple word forms – "\*" and "word1-word2"
      - Boolean operators (and, not, or)
      - "character string enclosed in quotes"
      - note thing with WAC – have to use "\" to include the hyphen
    - Remember to check all the boxes you want
- 

8

AG Opinions

RCW & Supplement

State Register

WAC

Search Bills, RCW, WAC, and State Register:

word

Search (help)

Select the area(s) you wish to search:

- Attorney General's Opinions
- Amendments 2005-06
- Bills 2005-06
- Bill Reports 2005-06
- Bill Information 2003-04
- Bill Information 2001-02
- Ethics - As of February, 2005
- Executive Orders - As of March 24, 2005
- RCW & Dispositions - As of January 20, 2005
- RCW Supplement 2005
- State Register 2005 - As of 05-17
- State Register 2004
- State Register 2003
- State Register 2002
- State Register 2001
- State Register 2000
- State Register 1999
- State Register 1998
- State Register 1997
- WAC - As of August 24, 2005
- Washington Constitution

## Federal Stuff

Government Printing Office  
[www.gpoaccess.gov](http://www.gpoaccess.gov)

USC

CFR

FR

Suggest browse, search features

**GPO Access Resources by Branch**

**Legislative Resources**

- View All
- Congressional Bills
- Congressional Record
- Public and Private Laws
- United States Code

**Executive Resources**

- View All
- Code of Federal Regulations
- Federal Register
- Presidential Materials

**Judicial Resources**

- View All
- Supreme Court Web Site

10

## CFR

browse

scroll to Title 21

select recent year (updates in April)

select part, subpart

Note standard format

- scope
- definitions

PDF can be slow

Also available from Lexis-Nexis

Title 21--Food and Drugs

---

CHAPTER II--DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1306--PRESCRIPTIONS

- 1306.01 Scope of part 1306.
- 1306.02 Definitions.
- 1306.03 Persons entitled to issue prescriptions.
- 1306.04 Purpose of issue of prescription.
- 1306.05 Manner of issuance of prescriptions.
- 1306.06 Persons entitled to fill prescriptions.
- 1306.07 Administering or dispensing of narcotic drugs.
- 1306.11 Requirement of prescription.
- 1306.12 Refilling prescriptions.
- 1306.13 Partial filling of prescriptions.
- 1306.14 Labeling of substances and filing of prescriptions.
- 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.
- 1306.21 Requirement of prescription.
- 1306.22 Refilling of prescriptions.
- 1306.23 Partial filling of prescriptions.
- 1306.24 Labeling of substances and filing of prescriptions.
- 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
- 1306.26 Dispensing without prescription.
- 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

## Federal Register

browse & scroll

- date
- page
- docket number

search (terminology)

types

- proposed rule
- final rule
- notice

structured format

57300 Federal Register / Vol. 70, No. 189 / Friday, September 30, 2005 / Notices

---

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Centers for Medicare & Medicaid Services

[CMS-1307-CN]  
RIN 0938-2A74

**Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2006; Correction Notice**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.  
**ACTION:** Correction notice.

**SUMMARY:** This document corrects technical errors that appeared in the general notice with comment period published in the Federal Register on September 23, 2005 entitled "Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2006; Correction Notice."

Dated: September 26, 2005.  
Jacquelyn Y. White,  
Director, Office of Strategic Operations and Regulatory Affairs.  
[FR Doc. 05-19611 Filed 9-29-05; 8:45 am]  
BILLING CODE 4120-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Food and Drug Administration**  
[Docket No. 2005D-0385]

**Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Using Electronic Means to Distribute Certain Product Information."

**SUPPLEMENTARY INFORMATION:**  
I. Background  
The timely dissemination of communications about recalls of FDA regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health. We have encouraged manufacturers to provide such information in a timely manner to distributors, doctors, and others. Over the years, we have worked with manufacturers to promote the use of electronic methods of communication and encourage the use of innovative technologies to disseminate safety information, particularly those that provide a public health benefit. We are making clear in the draft guidance that manufacturers may disseminate the communications discussed in §§ 7.49 and 200.5 (21 CFR 7.49 and 200.5) by e-mail or other electronic methods. The draft guidance also applies to those...

12

## Federal Agencies

- Food & Drug Administration  
www.fda.gov
- Drug Enforcement Administration  
www.usdoj.gov/dea
  - Pharmacist Manual  
www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm
- Consumer Product Safety Commission  
www.cpsc.gov

13

## UW Stuff

- Lexis-Nexis
  - use CTRL-f
  - reformat for printing
  - stuff in [brackets] often refers to page numbers
- Current Contents
- Healthlinks → Search for “newspapers”

14

## NAPBLaw Online

- class website → restricted access
  - see Instructions hyperlink
  - username / password(s)
  - log out when done (limited slots)
- Use “expert search”
  - Boolean operators, “ordered proximity”
- Select all localities, or specific state
- “Show document excerpts in the results list”
  - small, medium, large

15

The screenshot displays the NAPBLaw Online search interface. At the top, there is a search bar with a 'Search' button and a 'Choose search form' dropdown menu circled in red. Below the search bar is a 'Query terms:' input field. A 'Show document excerpts in the results list' dropdown menu is also circled in red, with 'Off' selected. Below this is a 'Search Syntax Summary' table with columns for Operator, Example, and Result. The table lists various search operators like 'And', 'Or', 'Not', 'Exclusive or', 'Phrase', 'Single character wildcard', 'Multiple character wildcard', 'Ordered proximity', 'Unordered proximity', 'Stemming (word form)', and 'Synonym' with their respective examples and results.

Operator	Example	Result
And	one two one & two one and two	Finds documents with both 'one' and 'two'.
Or	me   you me or you	Finds documents with either 'me' or 'you'.
Not	*him not him	Finds documents that don't contain 'him'.
Exclusive or	apples - oranges apples xor oranges	Finds documents with either 'apples' or 'oranges', but not both.
Phrase	'to be or not'	Finds documents with the exact phrase 'to be or not'.
Single character wildcard	wom?n st??	Finds documents with 'woman', 'women', etc., or 'this', 'that', 'them', etc.
Multiple character wildcard	*n *work	Finds documents with 'an', 'addition', 'assign', etc., or 'work', 'works', 'working', etc.
Ordered proximity	*corporate tax law*/10	Finds documents with 'corporate', 'tax' and 'law' within 10 words, in the order given.
Unordered proximity	'technical resource acquisition'@5	Finds documents with 'technical', 'resource' and 'acquisition' within 5 words, in any order.
Stemming (word form)	run% run%	Finds documents with 'run', 'ran', 'runs', and 'running'.
Synonym	alert\$ alert\$	Finds documents with 'alert', 'active', 'aware', 'quick', etc.

## search "counsel%"

---

Print Doc Next Doc Prev Doc Next Search Prev All Docs Next All Docs Clear Highlights Reference Print Bookmark Sync Contents SLIDE Show

WV PracAct 33-24-136

Filing Written Memorandum of Prescription, Labels Generally; Prescription Defined; Counseling and Patient Profiles.

(a) Every person who prepares, compounds, processes, packages or repackages, dispenses, fills or sells or offers for sale, at retail or in connection with operation of a health care facility, any prescription, shall place the written memorandum of the prescription in a separate file marked and kept for that purpose, and shall affix a label to the container in which the prescribed substance is dispensed bearing the name and address of the pharmacy and registration number of the dispensing pharmacist, or of the prescriber if the dispenser is an intern, the date on which the prescription is filed in the pharmacy's files, the name of the person who prescribed the substance, the name of the patient or customer for whom the prescription was made and directions for use by the patient as directed on the prescription by the prescriber.

(b) "Prescription" means an order for medication by a person licensed and authorized by the State Board of Medicine, the State Board of Dental Examiners, the State Board of Nursing, the State Board of Registration in Podiatry, the State Board of Examiners in Optometry, or the State Board of Veterinary Medicine which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. Each prescription memorandum shall be maintained and open for inspection by agents of the Board for a period of two (2) years from the date it is filed.

(c) Pharmacists shall offer to and shall counsel patients if requested, concerning and in conjunction with drugs dispensed pursuant to a new prescription.

(d) Pharmacies shall maintain patient profile records of the dispensing of drugs pursuant to a prescription.

(e) Notwithstanding subsection (a) of this section, if, in the opinion of the pharmacist, an emergency exists whereby the prescriber of the prescription cannot be contacted for authorization and there is a need to refill the prescription, the pharmacist may provide up to a seventy-two (72) hour supply, or the smallest available unit, of the previously prescribed drug, except a controlled substance. Nothing in this subsection shall be construed to require a pharmacist to refill the prescription in the absence of authorization from the prescriber.

Updated 7/2005.

## questions?

---

- Reminder – after ethics section
- Groups 1-6 for project discussion