

Federal Law Resources

Busy Day Tool Kit Preceptor Instructions

Learner level: IPPE and APPE Students

Estimated time to complete: May take several hours/days and can be done intermittently while completing other assigned projects.

Preceptor Instructions: Provide students with a question pertaining to a recently updated or new federal pharmacy law (or general question pertaining to law). Inquire about what resources students are already familiar with to approach answering a law question. Give a brief overview of each resource students are familiar with and discuss further resources.

Student Instructions: Receive a question specific to federal pharmacy law. Determine how you would approach answering the question and what resources you would use to find the appropriate information. List any resources that you feel you are unfamiliar with to discuss further.

Federal Law Resources

1. **Food & Drug Administration – <http://www.fda.gov>**
Provides a variety of information about drugs, vaccines, biologics, medical devices, foods, cosmetics and more.
 - Regulatory Information (found on bottom of homepage)
 - Recent guidance documents
 - Rules & Regulations
 - Laws Enforced by DEA
 - MedWatch: The FDA Safety Information & Adverse Event Reporting System (found under “for Healthcare professionals” → Resources for You at bottom of page)
 - New reports
 - Current year Safety Alerts
 - FDA Approved Safety Information
 - DailyMed: current drug prescribing information
 - Medication Guides
 - Postmarket Drug and Biologic Safety Evaluations
 - “Drugs” Tab at the top of the homepage holds even more useful information to explore
 - Recalls & Alerts
 - National Drug Code Directory
 - Orange Book Search

- Drug Shortages
- Drug Approvals
- Compounding (found under Drugs tab → “Guidance, Compliance & Regulatory Info”)
 - FDA’s Human Drug Compounding Progress Report: Three Years After Enactment of the Drug Quality and Security Act
 - Laws & Policies
 - Compounding Risk Alerts
 - Inspections, Recalls, and other actions
- Mobile Apps Available to keep track on-the-go
 - Drugs@FDA Express
 - Orange Book Express 2.0
 - NDC Express
 - Drug Shortages 2

2. **Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations – Orange Book**

Provides a unique search feature to determine therapeutic equivalence of generic medications.

- Variety of Search Options
 - Proprietary Name, Active Ingredient or Application Number
 - Applicant (Company)
 - Dosage Form
 - Route of Administration
 - Patent Number
- “Additional information and resources for the Orange Book” (found at top of page)
 - Find Orange Book Publications
 - Additional Resources – FAQ, additions/deletions, data files, etc.

3. **Purple Book: Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations – Purple Book**

Provides additional resources for background information related to biosimilar development, review, and approval.

- Available as PDF file
 - Product (Proper) Name
 - Proprietary Name
 - Date of Licensure
 - Interchangeable (I) / Biosimilar (B)
- Additional information on biosimilars (found on left side of page)
 - Biosimilar and Interchangeable Products
 - Biosimilar Development, Review, and Approval
 - Prescribing Biosimilar and Interchangeable Products
 - Biosimilar Product Information
 - Industry Information and Guidance
 - Webinars, Presentations, and Articles
 - Patient and Prescriber Outreach Materials

4. **Drug Enforcement Agency – <http://www.dea.gov>**

Provides a variety information with a specialized focus on controlled substances.

- Drug Information (found under “What We Do” in Menu tab)
 - Drug Facts – fact sheets on drugs
 - Drug Policy information
 - Drug Scheduling
 - The Controlled Substances Act

5. **DEA Diversion Control Department –**

<https://www.deadiversion.usdoj.gov/index.html>

Provides specific resources about controlled substances in healthcare – information for doctors, pharmacists and other professionals.

- Registration Validation (found on homepage under “Registration Support”
 - Search application that allows to validate that a DEA number that belongs to a physician or other registrant is currently active
- Information found under Resources Tab along top of webpage:
- CMEA (Combat Methamphetamine Epidemic Act of 2005)
 - PDF files of the act & general information
- Controlled Substance Schedules
 - Multiple lists of controlled substances – including ordering of information in a variety of ways for easy reading and list of exempt products
- Data Waived Physicians
 - Information about requirements for prescribing
 - Comprehensive Addiction and Recovery Act
 - Medication Assisted Treatment for Opioid Use Disorders
- Marijuana
 - Documents and notices referring to rescheduling and establishing new drug code
- Drug Disposal Information
- Publications & Manuals
 - Pharmacist’s Manual: An Informational Outline of the Controlled Substances Act (Revised 2010)
 - *Guide to assist pharmacists in their understanding of the Federal Controlled Substances Act & its implementing regulations as they pertain to the pharmacy profession*
- Title 21 Code of Federal Regulations
 - Registration of dispensers of controlled substances, labeling/packaging requirements, records, prescriptions, etc.

6. **AccessPharmacy Federal Law Chapter**

- Provides a review of the following:
 - Controlled Substances Act (CSA) Summary
 - Food, Drug, and Cosmetics Act (FDCA) Summary
 - Poison Prevention Packaging Act Summary
 - Federal Law Practice Scenarios & Questions

7. AccessPharmacy Pharmacy and Federal Drug Law Review e-Book

- Provides a review of United States Pharmacy Law and Drug Regulation including:
 - New Drug Approval and Development
 - Prescription Drug User Fee Act (PDUFA)
 - Food and Drug Administration Modernization Act
 - Biologics
 - Orphan Drugs
 - Over-the-Counter Regulations
 - Drug Enforcement Administration Registration
 - Transferring a Pharmacy Business
 - Transferring Prescriptions
 - Expiration or Beyond Use Dates
 - Safety Closures and Containers
 - Record Keeping
 - Inventory Requirements

8. United States Environmental Protection Agency Management of Pharmaceutical Hazardous Waste – <https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste>

Provides information about how pharmaceutical hazardous wastes are regulated and various resources for hazardous waste.

9. National Association of Boards of Pharmacy –

<https://nabp.pharmacy/publications-reports/publications/>

Provides a central location for information from different boards of pharmacy, information regarding pharmacist boards and CE credit.

- Publications
 - Survey of Pharmacy Law – annual guide presented in the form of summary charts & explanations; available for purchase for \$195
- Initiatives
 - AWARxE Prescription Drug Safety – “Pharmacist Resources”
 - Addiction Treatment Resources
 - Rules for Collecting Controlled Substances at Pharmacies and Long-Term Care Facilities
 - Federal Agency Resources

10. Health & Human Services – HIPAA – <https://www.hhs.gov/hipaa/index.html>

Provides information concerning HIPAA for both patients and professionals.

- HIPAA for Professionals (tab found on top of page)
 - Summary of definition of HIPAA
 - Health Insurance Portability Act
 - Privacy, Security & Enforcement Rules
 - Breach Notification Rule
 - Special Topics (drop down on left hand side of page) – HIV, mental health and substance disorders, emergency response, LGBT, etc.

11. **American Society of Health-Systems Pharmacists (ASHP) - [Link to PDF](#)**
Link to a PDF file that discusses various health-related laws and the Society's position on the current rules/laws/regulations.

12. **Centers for Medicare & Medicaid Services HCPCS Release & Code Sets – [Link to List](#)**
Provides an alpha-numeric list of HCPCS procedure and modifier codes with descriptions and applicable administrative/coverage/pricing data.

13. **Miscellaneous Resources**

- [HIPAASpace](#) Healthcare Data Lookup Tools – [Link](#)
 - Provides a “one-stop shop” for looking up various services in the healthcare industry: NPI, HCPCS codes, NDC, Animal Drugs, ICD-10 codes, CLIA codes, and many others
- Guide to Federal Pharmacy Law, 9th Edition by Barry S. Reiss & Gary D. Hall
 - Comprehensive guide to current federal pharmacy law – designed to help one review the most important laws, as well as new changes
 - Good for candidates preparing for pharmacy law exams – includes 350 practice federal law questions & answers

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