2010 Edition

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PHARP 582P: PHARMACY LAWS
SPRING, 2010

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Care has been taken to assure the accuracy of the material as of the revision date shown at the end of each chapter. Users should verify with available official sources the current status of any law or regulation cited.
Contents

Chapter 1. Introduction: The Law, Courts, and Laws ............................................ 5
Chapter 2. Becoming a Pharmacist, Intern, or Pharmacy Assistant .................29
Chapter 3. Establishing, Operating, or Closing a Licensed or Registered Practice Site or Business ................................................................. 63
Chapter 4. Providing Drugs and Medical Devices to Patients ........................ 103
Chapter 5. Controlled Substances .................................................................. 213
Chapter 6. Patient Information: Collection, Use, Quality Assurance, and Confidentiality ................................................................. 259
Chapter 7. Avoiding Discipline, Civil Lawsuits, and Employer/Employee Difficulties................................................................. 293
Chapter 8. Payment for Pharmaceutical Services and Third Party Payers ...... 339
Index ............................................................................................................... 399
Chapter 1. Introduction: The Law, Courts, and Laws

1. Legal Obligations and Consequences. To become a pharmacist is to voluntarily assume certain legal obligations; failing to fulfill these has consequences.
   a. Follow the laws and regulations relating to the Practice of Pharmacy or be disciplined by the Board of Pharmacy
      i. You may be fined
      ii. You may be put on probation
      iii. Your license may be suspended or revoked
   b. Violate certain laws, such as the Controlled Substances Act, and you may be prosecuted criminally in federal or state court
      i. You may pay a fine
      ii. You may go to jail
   c. Fail to perform according to legal and professional standards, and you may cause an injury to a patient, who can then sue you in state or federal civil court
      i. You may be forced to pay damages

2. A Pharmacy License is a Revocable Privilege Granted by the State. Your license as a pharmacist, or the license of your pharmacy, gives you privileges that aren't available to most patients, and distinguishes you from other health professionals.
   a. Carrying out your professional duties, and being able to use your training to the fullest, requires an understanding of just how extensive these privileges are, and how to make the most of them.
   b. Once you've earned the license, however, you do have property and liberty interests that are protected by the Constitution, and your license may not be taken or restricted without due process of law (see 14th Amendment).

3. Pharmacists are Presumed to Know the Law. Ignorance of a law does not excuse a person from suffering the penalties for its violation.
   a. The law generally presumes that citizens – and especially licensees in certain professions – are able to learn the laws that apply to them. Boards of Pharmacy actually require pharmacists to pass an examination regarding pharmacy law to demonstrate that they understand it well enough to practice lawfully.
   b. It is a requirement, however, that if an individual is to be held responsible for compliance with a law, the law itself must be clear and unambiguous, and not in conflict with other laws.

4. Divisions of the Law. Three important divisions of the world of law may affect the pharmacist, and determine the consequences of his or her actions.
a. Administrative law
   i. This is the law that is created and enforced by government agencies.
   ii. It applies only to individuals or entities (such as licensees) under the jurisdiction of the particular agency.
      a. The Board of Pharmacy can discipline pharmacists, interns, pharmacy assistants, wholesalers, and others who are required to be licensed by the Board. It has no direct authority over patients, and cannot discipline physicians, nurses, or other health professionals, who are under the jurisdiction of other disciplinary boards (e.g., Nursing, Medical Examiners).
   iii. The possible consequences of discipline are limited to placing restrictions on your license (probation, suspension, revocation), or, in some cases, to assessing fines or the costs associated with a hearing.
   iv. A decision by the agency that is adverse to a registrant or licensee can be made on the basis of evidence at a hearing by the agency. The current standard of evidence in Washington for decisions involving the license of pharmacists, physicians, and nurses, as well as ancillary personnel licensed by the Department of Health, is a “clear, cogent, and convincing proof” standard, which is more stringent than a preponderance of evidence standard, and less stringent than a requirement of proof beyond a reasonable doubt. (See also chapter 7)
   v. The licensee has an opportunity to appeal an agency decision in state or federal court.

b. Civil law
   i. This law applies to disputes between individuals, corporations, or other entities. The types of disputes are primarily classified into the following:
      • Contracts, which are voluntary agreements between parties who are legally and actually capable of entering into those agreements. Warranties and guaranties are forms of contracts, as are employment agreements, leases, and sales of property.
      • Torts, which are intentional acts committed by one individual that harm another. Common examples of torts include:
         o Assault and battery
         o Slander and libel

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1 Bang Nguyen v. Dep’t of Health, 144 Wn.2d 516, 29 P.3d 689 (Wash. 2001).
2 Ongom v. Dep’t of Health, 159 Wn.2d 132; 148 P.3d 1029 (Wash. 2006); Cert. denied, 126 S.Ct. 2115 (2007).
Negligence, which includes professional negligence (also called malpractice).

ii. Remedies that can be ordered by the courts in civil suits include payment of damages, restraining orders (preventing one party from doing future acts), and enforcement of contracts.

iii. Verdicts in civil cases can be by judges or by juries. The evidence used in the decision is presented at a trial. The verdict must be based on the preponderance of evidence (a majority of the evidence) favoring one party or the other.

c. Criminal law

i. This law covers acts of individuals “against the state,” in which the lawsuit is filed by a state or federal prosecutor (prosecuting attorney, district attorney, attorney general, etc.).

ii. Crimes are generally divided into misdemeanors, gross misdemeanors, and felonies. Certain felonies (such as premeditated murder) may be “capital crimes” in which the death penalty can be inflicted.

iii. Penalties for a criminal conviction can include fines, imprisonment, or loss of life. Restitution of damages may be awarded to compensate victims of a crime.

iv. Trial by jury is guaranteed in criminal cases. Conviction of a crime requires the prosecutor to present evidence that proves the offense beyond a reasonable doubt.

v. Under the US and most state constitutions, no person may be compelled to testify against him or herself in a criminal matter.

d. Relationships among the divisions of law can be complex. It is important to understand that a given act, however, can give rise to actions in more than one arena.

Robert Ray Courtney’s case is an example of this. Courtney gained notoriety for operating a pharmacy in Kansas City in which he compounded chemotherapy drugs, and, for a number of years deliberately diluting these drugs to increase his profit margin. He entered a guilty plea in federal court to numerous counts of criminal acts. The Missouri Board of Pharmacy revoked his pharmacist’s license and the license of his pharmacy. He also was the subject of a civil trial in Kansas City in which the jury awarded the plaintiffs $200 million in actual damages, and $2 billion in punitive damages, for the largest verdict ever assessed against a pharmacist ($2.2 billion).

The O.J. Simpson case illustrates how the different levels of evidence required can lead to opposite outcomes. In
his criminal trial, Simpson was acquitted of murder of Nicole Simpson (his ex-wife) and Ron Goldman, who was with her at the time of the murder. However, a civil jury found him liable for damages to the estates of Simpson and Goldman.

Table 1-4. Overview of divisions of law.

<table>
<thead>
<tr>
<th></th>
<th>Civil Law</th>
<th>Criminal Law</th>
<th>Administrative Law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example parties</td>
<td>Miller v. Thomas</td>
<td>State v. Lewis</td>
<td>In re License of Johnson</td>
</tr>
<tr>
<td>Applies to</td>
<td>Matters between private parties; torts, contracts</td>
<td>Violations of criminal statutes, enforced by state</td>
<td>Violations of administrative law and regulations by licensees</td>
</tr>
<tr>
<td>Possible consequences</td>
<td>Payment of damages, enforcement of contracts, payment of court costs/attorney fees, restraining orders or injunctions</td>
<td>Fines, incarceration, capital punishment</td>
<td>Suspension or revocation of license, fines</td>
</tr>
<tr>
<td>Evidentiary standard</td>
<td>Preponderance of evidence</td>
<td>Beyond a reasonable doubt</td>
<td>Clear, cogent, and convincing (WA) or preponderance of evidence</td>
</tr>
</tbody>
</table>

5. Courts. There is a hierarchy (ranking) of courts in which decisions are rendered and take precedence.
   a. Trial Courts. At both the state and federal level, lawsuits usually begin at trial courts. Federal trial courts are called “district courts.” In Washington, the trial courts are located in each county, and are called “superior courts.” A pharmacist living in Spokane who is to be tried for diversion of a controlled substance would be tried in either the “Superior Court of Washington for the County of Spokane,” or in the “United States District Court, Eastern District of Washington,” which is located in Spokane (the district also has courtrooms in Yakima, Richland, and Walla Walla). Decisions of
federal trial courts are often published, but state trial court decisions are not generally collected and published.

i. A variety of special courts or lesser courts are also established at both the state and federal level.
   1. State special courts include Municipal Courts established by cities, Family Courts (divorce), Juvenile Courts, and courts dealing with drug abuse or drunk driving.

b. Appeals Courts. Decisions at the trial court level may be appealed to the next higher court. In Washington, this court is called the Court of Appeals, and it is divided into three divisions. Eastern Washington is covered by Division III, located in Spokane. Federal appeals courts are called the Circuit Courts of Appeals, and cases from Washington are heard by the 9th Circuit Court of Appeals, with headquarters in San Francisco. Appellate court opinions at both the state and federal level are collected and published, and trial courts within the jurisdiction of a particular appellate court must follow the rules set down in those decisions.

c. Supreme Courts. The highest courts at both the state and federal level are supreme courts: the United States Supreme Court and, in Washington, the Washington State Supreme Court.
   i. These courts resolve conflicts among lower courts, and resolve challenges to laws based on constitutional grounds.
   ii. Criminal defendants and parties to civil cases generally have a right to appeal decisions to courts of appeal; appeals to supreme courts normally require permission of these courts. The US Supreme Court has a special name for the document it issues when it accepts an appeal: a writ of certiorari.
   iii. Decisions of state supreme courts may be appealed to the US Supreme Court on constitutional grounds.
   iv. Decisions of a state supreme court are binding on all courts within the state. Decisions of the US Supreme Court are binding on all courts in the US.

   a. “The Law” is a broad term that encompasses a set of societal expectations that can be enforced by government power. It is a form of social control that spells out requirements in the following ways
      i. It may require a person to act in a certain way
• All pharmacies must maintain a record of each prescription dispensed.
• All persons operating a motor vehicle on the public highways of Washington must have a valid driver’s license.

ii. It may permit a person to undertake a specific action
• Pharmacists may enter into collaborative practice agreements with physicians.
• A person may designate another to act in his or her behalf to purchase property.

iii. It may prohibit a person from acting in a certain way.
• A pharmacist may not dispense a legend drug unless he or she has been presented a valid prescription.
• An individual may not park their automobile within five feet of a fire hydrant.

b. Hierarchy of Laws. Just as there is a hierarchy of courts, there is also a hierarchy of laws.

i. Constitution. The highest law of the land is the US Constitution. Any law, or treaty, that is in conflict with the Constitution may be challenged, and can be declared unconstitutional by federal courts. Ultimately, the Supreme Court is the final arbiter of a law or treaty’s conformance to constitutional law. Within a given state, on matters that are left to the States under the US Constitution, the state constitution is the supreme law. The state courts, and ultimately the state supreme court, decide whether a law is in conformance with the state constitution.

ii. International Treaties. Treaties approved by Congress with foreign powers, once established, create international law that has precedence over other state and federal laws.
   1. Federal treaties with Native American tribes and nations are considered a form of international treaty, and the Native American treaty parties have many sovereign powers.
   2. States are allowed to create compacts with Native American nations and tribes, and may also have compacts as allowed by Congress with other countries.

iii. Legislation. Acts of Congress, which begin as bills in either chamber, create federal statutes. Acts of the Legislature, which begin as bills in the state legislature, create state statutes.
   1. Federal preemption of state laws. When Congress passes a federal statute in an area of its authority (for example, to regulate interstate commerce), federal law preempts state laws governing the same conduct,
unless the federal statute allows for states to create their own laws. Three types of preemption exist:

a. Explicit preemption. In this type of federal law preemption, the Congress includes specific language in the statute that preempts state law, which may include language that certain types of state law are allowed.
   i. For example, the Device Amendments to the FDCA (see Chapter 4) explicitly preempt state regulation of medical devices (21 U.S.C. § 360k(a)):
   “Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
   (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
   (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”
   ii. An example of a federal statute that allows some state regulation is the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191, 104th Congress), which explicitly preempts state laws that are in conflict, but specifically allows the Secretary of the Department of Health and Human Services to permit state laws or regulations that are more stringent in protecting patient privacy (see section 1178 of the Act.)

b. Conflicts preemption. If Congress is not explicit about a statute preempts any state regulation, then it may result that state and federal law will conflict. Either it will be impossible for a person to simultaneously comply with federal and state law, or it may be found that the state law interferes with the achievement of the goal or objective of federal law.
   i. The federal Controlled Substances Act (see Chapter 5) requires that all prescriptions for Schedule II drugs be in
writing, and current DEA regulations interpret the law to require that prescriptions be issued on an actual piece of paper physically signed by the prescriber. Washington law requires prescriptions to be hand printed, typewritten, or electronic. Thus, Washington law allows electronic Schedule II prescriptions, but they can’t be used yet because the federal rules are controlling. But, since Washington laws allow hand printed prescriptions, there is no actual conflict. If Washington were to mandate electronic prescribing, then a clear conflict would exist, and the federal rules would prevail.

ii. Unlike the Device Amendments, the FDCA as it pertains to drugs does not contain an explicit preemption statement. More recently, the FDA has issued a “preemption preamble” to its regulations on drug labeling, indicating that State laws which would require different warnings than are contained in the approved package insert are in conflict with federal regulation.³ The Supreme Court has rejected this rule as establishing federal preemption of lawsuits against drug manufacturers for not including stronger warnings in the package insert. (See below)

c. Field Preemption. The third type occurs when federal law has been held to “occupy the field” and it is apparent that Congress intended the law to preempt state law.

i. Federal courts have repeatedly held that when Congress passed the Employee Retirement Income Security Act (ERISA), it intended to “occupy the field” of employment benefit law for plans subject to the Act. As discussed in Chapter 8, many attempts by pharmacy organizations to challenge the operations of 3rd party payment plans in

state court have been affected by the federal preemption doctrine.

d. **US Supreme Court Preemption Cases.** In 2008, the US Supreme Court took up 3 federal preemption cases relating to the FDCA.

1. In [*Riegel v. Medtronic*][4], the Court held that the regulatory scheme for Class III medical devices explicitly preempts any State requirement relating to a regulated device concerning the safety or effectiveness of the device.

2. In [*Warner-Lambert v. Kent*][5], the Chief Justice recused himself from participating in the decision due to his ownership of stock in Warner-Lambert’s parent company, and the remaining 8 justices split 4-4. The divided court resulted in affirming of the 2nd Circuit’s ruling that the plaintiffs could continue their lawsuit involving Rezulin® under Michigan law, by asserting that W-L obtained approval of Rezulin by fraud.

3. At the beginning of the 2008 Fall Term, the Court heard arguments in the case of [*Wyeth v. Levine*][6]. The plaintiff was injured by Phenergan® injection administered by IV push, and sued Wyeth alleging that IV push administration should not have been recommended in the package insert. Wyeth asserted that “FDA’s comprehensive safety and efficacy authority under the FDCA preempts state law claims that different labeling judgments were necessary to make drugs reasonably safe for

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use.” In 2009, the Court ruled that under the facts of Levine, the FDCA does not preempt state laws related to product liability. It held that the FDA’s preemption preamble was in conflict with prior FDA positions, and that manufacturers could improve the labeling of their products without violating FDA rules.

4. Subsequent trial and appellate court decisions have held that the FDCA does not preempt product liability suits against generic manufacturers of prescription drugs.7

iv. **Regulations.** Congress and legislatures may pass statutes that create administrative agencies, and extend limited rule-making power to those agencies. Such rules made by administrative agencies are called *regulations* or *administrative rules.* As long as the regulations are *promulgated* (developed and announced) in accordance with the authority granted by the statute, they have the force of law.

1. In most states, the **Legislature maintains oversight** over state agencies and persons affected by a proposed or enacted regulation may appeal to legislative oversight bodies to review the regulation to assure it is within the scope of the powers of the agency or that it was enacted following a statutorily-mandated process. In Washington, the review body is the Joint Administrative Rules Review Committee (JARRC).
   o An example of how this process can alter Board actions arose in November 2005, when the Board of Pharmacy, acting in the place of the Department of Health, approved a regulation setting forth record keeping requirements for retail sales of methamphetamine precursor products (WAC 246-889-070 thru 110). The regulation was enacted without completion of a legislative rulemaking analysis or a small business economic impact statement, and the DOH indicated it was exempt from these requirements since “the rule does not cause any significant material changes to

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7 See, e.g., Mensing v. Wyeth et al., No. 08-3850, 4th Cir., November 27, 2009.
statute.” The Washington Food Industry association appealed to JARRC, alleging that the rule did create a material change by enacting several provisions that were not set forth in the enabling statute (ESHB 2266; 2005 c 388). Following a JARRC hearing on December 8, 2005 the Board revised the rule on December 14.

- As with statutes, persons affected by a regulation who allege that it infringes a Constitutional right or violates a Constitutional limitation on government power may also seek a ruling by the courts as to the constitutionality of the regulation.

2. In Washington, the Pharmacy Practice Act (RCW 18.64), established the State Board of Pharmacy, and gave it specific powers and duties (see RCW 18.64.001 to 18.64.009). The Board of Pharmacy is part of the Department of Health, which was established by RCW 43.70. The criteria for regulating health professions, which governs the purposes and scope of the Board’s rules, is specified in RCW 18.120, and its powers for disciplining pharmacists are described in the Uniform Disciplinary Act, RCW 18.130.

3. Washington’s universities are also state agencies, established by statute under the authority of Article XIII of the State Constitution. The Regents have regulatory authority and do issue regulations that govern the universities.

v. **Constitutionality challenges.** An individual affected by legislation or regulations who alleges that the legislation impairs a Constitutional right, or exceeds the powers granted to Congress or the Legislature, may seek a ruling in court as to the constitutionality of the legislation. For a good example of this, see the discussion of Western States Medical Center v. Shalala, 238 F.3d 1090 (9th Cir. 2001), in Chapter 4.

vi. **Sovereign Immunity and Eminent Domain.** Throughout most of Western history, the King – also known as the Sovereign – had absolute power over his domain and subjects. Particularly in England, from which the US obtained most of its legal tradition, this meant that the Sovereign was considered unable to commit a legal wrong, and could take or give control of land as it pleases. In the early 13th century, arising from disagreements among Pope Innocent III, King John, and a lobby of powerful barons over the rights of the King, John agreed to the terms of the Magna Carta, which is the most conspicuous example of limitations
on the power of the Sovereign. Among its enduring legacies is the right of *habeas corpus*, by which an accused is entitled to know the charges against him. Persistent to this day are notions that the Sovereign may not be sued against its will, and that the Sovereign may take property (now only with just compensation) to meet its needs.

1. **Sovereign Immunity in the US.** In the US, the federal government and the states retain sovereign immunity, within Constitutional limits, and cannot be sued without their permission. Most states, including Washington, have by statute allowed the states to be sued for torts or certain breaches of contract. The federal government allows itself to be sued for torts, under the Federal Tort Claims Act, and has waived immunity for claims related to contracts to which the government is a party (under the Tucker Act). However, common law claims, such as unjust enrichment, or unfair practices, are not easy to bring in courts, but require legislative action to remedy (e.g., claims of Japanese Americans interned during World War II were only resolved by Congress, not the courts.)

2. **Eminent domain in the US.** Eminent domain in the US is the right of governments to seize an individual’s property, or restrict his or her use of or rights in the property, without his or her consent. The legal process of taking the property is called condemnation. It is not uncommon for local independent retailers, such as community pharmacists, to find that their store is to be torn down to make way for highway construction. Protection against inappropriate use eminent domain is provided in the Fifth Amendment to the Constitution (the “Takings Clause”). It is allowed only for “public use,” and the individual must be justly compensated for the property. That does not mean the compensation will be for its highest or best use, or what the owner would hope to receive. In the states, legislatures have extended the power of eminent domain to counties and municipal corporations. Recent Supreme Court decisions (particularly *Kelo v. City of New London*\(^8\) in 2005) have extended the definition of what constitutes “public use” such that very little justification is actually needed to meet Constitutional limits. In *Kelo*, the Court approved of a New London, CT, condemnation of private property in

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order to transfer property from one private owner to another as part of an economic redevelopment plan. Under *Kelo*, a city might be able to close a group of small retail shops in order to build a shopping center which would be dominated by big box retailers. In response to the *Kelo* decision, President Bush issued Executive Order 13406\(^9\) prohibiting federal agencies using eminent domain "for the purpose of advancing the economic interest of private parties to be given ownership or use of the property taken." A number of states have legislatively or by initiative reformed their eminent domain laws in response to the *Kelo* decision.

vii. **Common Law.** Common law is a body of law that is created by courts when decisions are made in specific cases in which there is no specific statute that applies.

1. When the United States was established, at the moment that the Constitution was ratified, there were no specific federal laws in force. However, the country was not without federal law. Courts continued to render decisions based on the common law that was brought from England. (State laws and constitutions were in effect prior to ratification of the Constitution, and the Constitution appears to have given authority to treaties – such as the Peace Treaty of 1783 – that were enacted prior to its adoption.)

2. Common law does interpret existing constitutional law and statutes. For example, the “Miranda Warning” arose not from specific statutes, but from a history of cases dealing with claims that the police had coerced a defendant into an “involuntary confession.” The Fifth Amendment to the Constitution states that no person “shall be compelled in any criminal case to be a witness against himself.”

3. Congress and legislatures may enact specific legislation to supersede common law. For example, concern in the mid-1970s about the effects of court decisions concerning medical malpractice led the Washington legislature to enact “tort reform” law that put into statute specific rules for negligence suits relating to health care (see RCW 7.70). As regards the issues covered by these statutes, prior common law is no longer applicable in Washington.

viii. **Codes** are a means to organize the many statutes and regulations into a meaningful and usable form. If not for

\(^9\) 71 Fed Reg 36973, 6/23/06.
codification, it would be almost impossible to track the currently applicable law. For example, the Pharmacy Practice Act we operate under today was first passed in 1935. When the Legislature passes a change to a current law, it does so by passing a new statute, but the new statute may be quite short, affecting only a portion of the original Act. The Washington Legislature refers to each law it enacts as a session law, and these acts are collected at the end of each session and numbered as “chapters” of that session’s enactments. For example, the 1935 Pharmacy Practice Act was chapter 98 of the 1935 session laws, and is cited as “1935 c 98.” Subsequent revisions to the Act occurred via session laws in 1963, 1971, 1979, 1981, and 1984. Imagine if you had to publish copies of all of these acts to track down the various changes! Instead, Washington has a legislative agency called the Office of the Code Reviser, and that agency maintains two major collections of code.

1. **Revised Code of Washington.** The Revised Code of Washington (RCW) constitutes a current compilation of Washington statutes. The RCW is divided into 91 titles. Each title covers a particular area of legislation. For example, Title 18 contains statutes relating to Businesses and Professions. The titles are subdivided into chapters, and Chapter 64 of Title 18 of the RCW is the section containing statutes relating to Pharmacists. The chapters are further divided into sections. The Definitions of terms used in the Pharmacy Practice Act are in Section 011 of Chapter 64 of Title 18 of the RCW. The citation of an RCW section is in the form RCW 18.64.011.

2. **Washington Administrative Code.** The Washington Administrative Code (WAC) is the current compilation of the various regulations promulgated by state agencies. Like the RCW, the WAC is divided into Titles, Chapters, and Sections. WAC Titles are organized by agency. Each independent agency is assigned a title of the WAC. The Department of Health’s regulations, which include those issued by all boards (such as Pharmacy) within the department, are placed in Title 246. Chapters are organized by subject matter. Most of the regulations of the Board of Pharmacy are contained within a consecutive series of chapters starting at Chapter 856 and ending with Chapter 907. The citation of a WAC section is in the form WAC 246-863-100. Note the use of dashes instead of periods as separators.
3. **Federal Codes.** Federal law and regulation is organized into codes, also. Federal statutes are collected in the United States Code (USC), and federal regulations are collected in the Code of Federal Regulations (CFR). Both codes are divided into Titles and Parts. In general the Titles of the USC correspond to the Titles of the CFR, so that Food and Drugs is in Title 21 of the USC and in Title 21 of the CFR. Citation of these codes is in the form, 15 USC 2079(a) or 21 CFR 1700.1.

ix. **Restatements of Common Law.** Just as codes help organize statutes and regulations, common law is organized by “restatements,” which, in the US, are developed by the American Law Institute. Each deals with a general area of law, such as Contracts, Torts, Agency, Trusts, and Unfair Competition. There are currently upwards of 20 restatements, but the two of greatest importance to pharmacists are the Restatement of Torts and the Restatement of Contracts. Both are in their 2nd edition, but a draft of the Restatement of Torts, 3d, is in its final stages of adoption.

c. **Locating Decisions and Opinions.** To understand the application of common law, one may often wish to be able to find specifics of the common law or read the opinion in a key case.

i. Court opinions in specific cases are often available on Internet search engines, and on the web site of the issuing court (at least for recent cases). The major source for court decisions, however, is a series of “reporters” published by Thompson-West Publishing, in which the important decisions in a given jurisdiction are collected and published.

ii. **Federal court decisions** are published in three major categories of reporters.

1. **US Supreme Court** decisions are published in the Supreme Court Reports (S.Ct.) and in the United States Reporter (U.S.)
2. **Federal appellate court** decisions are published in the Federal Reporter (F.)
3. **Federal district court** decisions are published in the Federal Supplement (F.Supp.)

iii. **State supreme and appellate courts** also publish their decisions, which are reprinted in individual state reporters, such as the Washington Reporter (Wn.), and are also printed in regional reporters, which assemble opinions from all the courts in geographic regions of the country. The seven regional reporters are Atlantic (A.), Northeastern (N.E.),

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10 www.ali.org
Northwestern (N.W.), Pacific (P.), Southern (So.), Southeastern (S.E.), and Southwestern (S.W.).

1. Each volume of a reporter is bound into a fairly large book, and is numbered. When referring to a specific volume, the number is customarily placed ahead of the abbreviation for the reporter. So, the 100th volume of the United States Reports would be referred to as “100 U.S.”. Eventually, the numbers get too large to place on the spine of the book, so a new “series” of volumes is started, after volume 999 is published. The 100th volume of the second series of the United States Reports would be referred to as “100 U.S.2d.” Some reporters (F., S.W.) are in their 3rd series, abbreviated “3d.” The starting page number of a particular decision (“opinion”) is placed after the volume number and abbreviation, so an opinion starting on page 409 of the 100th volume of the second series of the United States Reports would be cited as “100 U.S.2d. 409.”

iv. **Electronic Opinion Databases.** Two major services provide electronic access to court opinions (and also to many other legal resources): Westlaw and LexisNexis. Both services are available to the public on a per-use basis (via credit card payment), or may be available in university libraries. For example, LexisNexis Academic is available to faculty and students at UW and WSU. An opinion found on Westlaw will be cited in a manner similar to 2004 WL 68993 (Westlaw citation #68993 in 2004); Lexis citations will appear similar to 2008 U.S. Courts LEXIS 12345).

v. **Citation Format.** An opinion in a specific case is cited by the names of the parties, with the plaintiff listed first, then the defendant, thus: McKee v. American Home Products. If the opinion is reported in one of the published reporters, the reporter is cited, along with the date and jurisdiction. In some instances, multiple reporters will be cited for a given case. An important case forming Washington common law is the McKee case. The official case title was *Elaine McKee, Appellant, v. American Home Products Corporation et al., Respondents*. It may be cited as *McKee v. American Home Products*, 113 Wn.2d 701, 782 P.2d 1045 (1989).

1. In the case of an appeal, the parties are often denoted the appellant and the respondent or appellee. The order in which they are listed may vary. In *McKee v. American Home Products*, McKee was the appellant and American Home Products the respondent.
vi. Citation formats for other countries are summarized in an article on Wikipedia.11

7. Structure of Government.
   a. Executive Branch.
      i. Federal Executive. The President is the chief executive officer of the US (currently George W. Bush), and heads the executive branch. The President is supported by a Cabinet, consisting of the Vice President and the heads of the 15 major divisions of the executive branch, which are called Departments. Under Article II, Section 2 of the US Constitution, the President “may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices.”

1. Cabinet (as of January 1, 2010)
   a. Acting Secretary of Agriculture – Thomas Vilsack
   b. Secretary of Commerce – Gary Locke12
   c. Secretary of Defense – Robert M. Gates
   d. Secretary of Education – Arne Duncan
   e. Secretary of Energy – Steven Chu
   f. Secretary of Health & Human Services – Kathleen Sebelius
   g. Secretary of Homeland Security – Janet Napolitano
   h. Secretary of Housing & Urban Development – Shaun L. S. Donovan
   i. Secretary of the Interior – Kenneth Salazar
   j. Attorney General (Department of Justice) – Eric H. Holder, Jr.
   k. Secretary of Labor – Hilda L. Solis
   l. Secretary of State – Hillary Clinton
   m. Secretary of Transportation – Ray LaHood
   n. Secretary of the Treasury – Timothy Geithner
   o. Secretary of Veterans Affairs – Erick K. Shinseki
   p. Vice President – Joseph Biden
   q. Cabinet-rank Officials
      i. White House Chief of Staff – Rahm Emanuel
      ii. Environmental Protection Agency Administrator – Lisa P. Jackson

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12 Secretary Locke was Governor of Washington from 1997-2005.
iii. Office of Management & Budget
   Director – Peter Orszag
iv. U.S. Trade Representative –
   Ambassador Ronald Kirk
v. U.S. Ambassador to the UN –
   Ambassador Susan Rice
vi. Council of Economic Advisors – Chair
   Christina Romer

2. Department of Health & Human Services. Agencies within the DHHS are critical to pharmacy and medicine. The major agencies that administer programs or regulate in areas important to pharmacy are
   a. AHRQ – Agency for Healthcare Research & Quality. This agency is responsible for studying health care delivery. Major research into the effectiveness of pharmacists’ services is funded by this agency.
   b. ATSDR – Agency for Toxic Substances and Disease Registry, which administers federal regulations related to hazardous waste and toxic substances.
   c. CDC – Centers for Disease Control & Prevention. In addition to dealing with research into epidemic diseases, and monitoring for outbreaks, the CDC is the principal source of information on vaccines and on travel medicine recommendations.
   d. CMS – Centers for Medicare & Medicaid Services. This agency administers Medicare and Medicaid, which together provide for over 40% of health care funding in the US. (See chapter 8)
   e. FDA – Food & Drug Administration. Regulates food, drugs, cosmetics, and medical devices. (See Chapter 4)
   f. HRSA – Health Resources & Services Administration. Charged with assessing and addressing health care manpower needs and providing programs to improve access to health care. Provides funds for education of health professionals, including administration of federal student loan repayment programs for pharmacists who work in underserved areas or certain government positions.
g. **IHS** – Indian Health Service. A major employer of pharmacists, supporter of research and education programs, and leader in many innovations in pharmacy practice.

h. **NIH** – National Institutes of Health. Major source of federal research funding related to health care.

i. **OIG** – Office of Inspector General. Oversees fraud control programs for the Department. (See Chapter 8)

j. **SAMHSA** – Substance Abuse & Mental Health Services Administration. Among its many duties, oversees the Office-based Narcotic Maintenance Program. Also a source of significant research and information on substances of abuse and mental health. (See Chapter 5)

3. **Department of Justice – Drug Enforcement Administration.** The DOJ is the principal prosecution arm of the federal government, with US District Attorneys in every state in the nation. Of particular importance to pharmacy, the Drug Enforcement Administration is part of the DOJ (see Chapter 5.)

ii. **State of Washington.** The structure of Washington’s government parallels that of the federal government. Both are divided into three branches: executive, legislative, and judicial. As with the federal system, there exists a balance of power among the three branches in Washington’s government. The Governor (Christine Gregoire) is the chief executive officer of the state, and all agencies (and all state employees) ultimately report to the governor, although there is not a direct chain of command for many state employees. The heads of the major departments do report directly to the governor, and they are appointed by the governor, but require the approval of the Senate.

1. The **Department of Health** is one of the major departments of state government. It has several divisions, including the Division of Health Systems Quality Assurance (Karen Jensen, Assistant Secretary). The Office of Health Professions and Facilities is the organization within HSQA that deals with the licensing of health professionals. The HPQA office oversees all the various health care boards and

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13 [www.doh.wa.gov](http://www.doh.wa.gov)
14 [http://www.doh.wa.gov/hsqa/HPF.htm](http://www.doh.wa.gov/hsqa/HPF.htm)
commissions, such as the Board of Pharmacy. The Medical Quality Assurance Commission, and the Nursing Care Quality Assurance Commission, which regulate medicine and nursing, are currently semi-independent commissions within the DOH. Although the boards have certain independent powers, the executive director and staff of these boards are state employees that report through the chain of command to the Secretary of the Department of Health (currently Mary C. Selecky).

2. The Department of Social and Health Services manages health care delivery programs paid for with state (and federal matching) funds, as well as a variety of state programs that provide services to the most vulnerable citizens of the state. The current Secretary is Susan Dreyfus. The DSHS division that interacts most directly with pharmacists is the Health and Recovery Services Administration (HRSA – the current head is Doug Porter, Assistant Secretary), which was formerly known as the Medical Assistance Administration. The DSHS HRSA manages 45% of the total DSHS budget, and provides services to 750,000 citizens.

b. Washington Legislature. The Legislature is bicameral, as is Congress (only Nebraska maintains a unicameral legislature). The state is divided into 49 legislative districts. Two members of the House of Representatives are elected from each district, and serve two-year terms; there are 98 state representatives. One senator is elected from each of the legislative districts, so the Senate has 49 members, who are elected for four-year terms. The Legislature meets annually, starting on the second Monday in January. In odd-numbered years, when the biennial budget is determined, the Legislature meets for 105 days; in even-numbered years the session is scheduled for 60 days.

i. Redistricting. State legislative and congressional district boundaries are subject to revision every 10 years following conduct of the U.S. Census. The next Redistricting Commission will be established in 2011 and new district boundaries will be set to be effective in 2012.

15 http://www.dshs.wa.gov/
16 http://www.redistricting.wa.gov/website/Geolegislative1/
c. **Courts.** The general structure of the courts\(^\text{17}\) has been described above. In addition to state courts, there are a number of municipal (city) courts, district (county) courts, and special courts, such as juvenile courts.

8. **The Board of Pharmacy** is a sub-agency of the Department of Health, and is part of the Executive Branch. It consists of seven members, appointed by the governor, with the “advice and consent of the Senate.” Five members must be pharmacists, and must, at the time of their appointment, have been licensed to practice in Washington for at least five years, and they must remain licensed during their term on the Board. The statute (RCW 18.64.001) requires the governor to select members who are representative of all areas of practice and geographically representative of the state of Washington. Two “lay members,” or “public members,” are appointed by the governor, subject to Senate approval; these members must not be affiliated with pharmacy in any way. Board members serve four year terms, and may be reappointed for a second term.

a. **The Board’s powers and responsibilities** are set forth in RCW 18.64.005:

i. Regulate the practice of pharmacy and enforce the laws related to pharmacy and drugs.

ii. Prepare and supervise examinations for licensure (by agreement has delegated this to NABP).

iii. Establish qualifications for licensure of pharmacists or interns.

iv. Conduct hearings for revocation or suspension of licenses.

v. Issue subpoenas and perform other judicial functions

vi. Assist law enforcement agencies in enforcing laws pertaining to drugs, controlled substances, and the practice of pharmacy

vii. Promulgate rules regulating pharmacy … “for the protection and promotion of the public welfare and safety.”

viii. Adopt rules regarding continuing education requirements for pharmacists and other licensees

ix. Be immune from suit based on official actions as board members

x. Suggest strategies for eliminating drug diversion, misuse, and abuse

xi. Conduct educational programs to reduce drug diversion, misuse and abuse by health care practitioners or facilities.

xii. Monitor trends of drug diversion, misuse and abuse

xiii. Enter into written agreements with other state and federal agencies for a variety of purposes.

b. **The Board’s staff members** are employees of the Department of Health, and are overseen by an Executive Director. As of

\(^{17}\) [http://www.courts.wa.gov/](http://www.courts.wa.gov/)
December 2009, the Executive Director is Susan Teil Boyer. Field staff members are called investigators, and undertake a variety of activities, including inspection of licensed premises and investigation of complaints and possible criminal violations of legend drug and controlled substances laws. Some members of the investigative staff are designated as enforcement officers, and are thereby empowered as “peace officers” and have police powers related to enforcement of laws under the Board’s jurisdiction (see RCW 18.64.099).

i. **Staff Contacts at the Board as of October 2009 are as follows:**¹⁸
   1. Office – 360/236-4946
   2. Susan Boyer, Executive Dir. – 360/236-4853
   3. Doreen Beebe, Program Manager – 360/236-4834
   4. Tim Fuller, Pharmacist Consultant – 360/236-4827
   5. Cathy Williams, Pharmacist Consultant – 360/236-4875
   6. Leann George, Secretary Senior – 360/236-4946

c. **Limits on the Board’s Authority.** The Board’s authority to regulate is constrained by the provisions of RCW 18.120.010(2):
   (2) It is the intent of this chapter that no regulation shall, after July 24, 1983, be imposed upon any health profession except for the exclusive purpose of protecting the public interest. [Emphasis added.] All bills introduced in the legislature to regulate a health profession for the first time should be reviewed according to the following criteria. A health profession should be regulated by the state only when:
      (a) Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
      (b) The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and
      (c) The public cannot be effectively protected by other means in a more cost-beneficial manner.
   (3) After evaluating the criteria in subsection (2) of this section and considering governmental and societal costs and benefits, if the legislature finds that it is necessary to regulate a health profession not previously regulated by law, the least restrictive alternative method of regulation should be implemented, consistent with the public interest and this section:
      (a) Where existing common law and statutory civil actions and criminal prohibitions are not sufficient to eradicate existing harm, the regulation should provide for stricter civil actions and criminal prosecutions;
      (b) Where a service is being performed for individuals involving a hazard to the public health, safety, or welfare, the regulation should impose inspection requirements and enable an appropriate state agency to enforce violations by injunctive relief in court, including, but not limited to, regulation of the business activity providing the service rather than the employees of the business;

(c) Where the threat to the public health, safety, or economic well-being is relatively small as a result of the operation of the health profession, the regulation should implement a system of registration;
(d) Where the consumer may have a substantial basis for relying on the services of a practitioner, the regulation should implement a system of certification; or
(e) Where apparent that adequate regulation cannot be achieved by means other than licensing, the regulation should implement a system of licensing.

Rev. 12/30/09
Chapter 2. Becoming a Pharmacist, Intern, or Pharmacy Assistant

1. Pharmacists
   a. What is a pharmacist? Throughout most of the industrialized world, pharmacists are individuals who have been trained in an academic setting within a generally recognized curriculum related to drugs, their development and production, their storage and distribution, and their therapeutic uses. So, one answer to the question is a pharmacist is someone who has been trained as a pharmacist. From the perspective of the law, however, proper training is only one part of the equation. A pharmacist, by law, is a person licensed to practice pharmacy in a given jurisdiction. So, the answer to the question is entirely dependent upon the Legislature.
      i. RCW 18.64.011 (10): “Pharmacist’ means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy.”
      ii. As seen below, a pharmacist in Washington is a person who can dispense, administer, or, under protocol, prescribe medications. Not all states allow pharmacists to prescribe, and some states do not allow administration of drugs by pharmacists.
   b. Practice of Pharmacy in Washington. The practice of pharmacy in Washington is defined in RCW 18.64.011 (11), and it includes the “practice and responsibility for:”
      i. Interpreting prescription orders;
      ii. Compounding, dispensing, labeling, administering, and distribution of drugs and devices;
      iii. The monitoring of drug therapy and use;
      iv. The initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs;
         1. This portion of the definition is what established authority for pharmacists in Washington to engage in “collaborative practice agreements,” or to exercise “prescriptive authority.”
      v. The participating in drug utilization reviews and drug product selection;
      vi. The proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof;
vii. The providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

c. **Other important definitions.** Several terms in the definition of the practice of pharmacy are key to an understanding other laws and rules. Among the more critical definitions a pharmacist needs to learn are the following (RCW 18.64.011 (15-18; 22-23):

i. "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

ii. "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

iii. "Distribute" means the delivery of a drug or device other than by administering or dispensing.

iv. "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

v. "Labeling" shall mean the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

vi. "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

The statute does not define “monitoring of drug therapy,” so the Board of Pharmacy has done so by regulation (WAC 246-863-110):

The term “monitoring of drug therapy” used in RCW 18.64.011(11) shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. Monitoring of drug therapy shall include, but not be limited to:

1. Collecting and reviewing patient drug use histories;
2. Measuring and reviewing routine patient vital signs including, but not limited to, pulse, temperature, blood pressure and respiration; and
3. Ordering and evaluating the results of laboratory tests relating to drug therapy including, but not limited to, blood chemistries and cell counts, drug levels in blood, urine, tissue or other body fluids, and culture and sensitivity tests when performed in accordance with policies and procedures or protocols applicable to the practice setting, which have been developed by the pharmacist and prescribing practitioners and which include appropriate mechanisms for reporting to the prescriber monitoring activities and results.

Note that patient counseling is not part of dispensing, as defined in the statute, and that “administer” and “dispense” are quite different actions.
d. **Do you need to be working in a pharmacy to be practicing pharmacy?** Because the practice of pharmacy includes both the physical processes of dispensing as well as many functions that involve interpreting information and providing advice about drug therapy, a person may be engaged in the practice of pharmacy without dispensing drugs. Pharmacists working in health systems or educational institutions, for example, are practicing pharmacy whenever they “advis[e] of … hazards and the uses of drugs.” Participating in a formulary committee, speaking to the public about drug use while holding oneself out to be a pharmacist, or consulting with other health care providers about drug use are all examples of practicing pharmacy without being involved in drug distribution. Even giving your neighbor advice about his or her drug therapy “over the fence” involves you in the practice of pharmacy if your neighbor has reason to know or believe that you’re a pharmacist.

e. **License Required for Practice.** It is unlawful to practice pharmacy without a license, or to operate a pharmacy without placing a licensed pharmacist in charge. (RCW 18.64.020)

i. **Retired or Inactive pharmacists.** Some persons trained as pharmacists are no longer in practice – such as a retired pharmacist or a person who has let his license lapse because he is engaged in a non-pharmacy business such as real estate. These individuals should refrain from giving advice about drugs to others, and should refer the person to a licensed pharmacist. Note that retired physicians and attorneys routinely adhere to this rule.

ii. **License must be displayed.** A copy of the pharmacist’s (or technician’s or assistant’s) current license must be displayed openly in any licensed pharmacy location where the pharmacist is practicing. (RCW 18.64.140). Pharmacists who work in several locations should have a copy for each location.

1. **Can you obscure your address on your license?** Pharmacists and technicians often inquire whether they may obscure their home address on their license or certificate copy when posting it to the public. I believe they can, and Board of Pharmacy staff members have generally agreed with this position. Although there is no specific rule regarding this, the Legislature has established protections for professionals’ address and phone information.
a. When communicating in writing to a person who has made a complaint concerning a health professional, the Department of Health is prohibited from disclosing the licensee’s address and phone number (RCW 18.130.085).

b. Information regarding a licensee’s personal address and phone number, among other information, is protected from disclosure under Washington’s Public Records Act (RCW 42.17; RCW 42.56 after 7/1/06).

c. A licensee who is the victim of domestic violence, sexual assault, or stalking may apply to the Secretary of State to participate in the Address Confidentiality Program (see next section).

iii. **Licenses will display any restrictions.** Credentials issued by the Board after October 2008 will contain notations of any restrictions that have been placed on the license. For example, a pharmacist who is on probation will see “Active on Probation” printed on his or her license. Other restrictions are indicated by “Active with Restrictions.” It is improper for the licensee to alter or obscure these statements on the posted copy of his or her license.

iv. **Notification to Department of changes.** The licensee must promptly notify the Department of any change in his or her

1. Name (WAC 246-12-300); or
2. Address (WAC 246-12-310)

a. Note: Washington Law (RCW 40.24.030, WAC 434.840) allows certain persons to participate in an [Address Confidentiality Program](http://www.secstate.wa.gov/acp/) overseen by the Secretary of State. This program allows individuals who are victims of domestic violence, sexual assault, or stalking to obtain an alternate mailing address for all legal purposes, and thereby conceal from public disclosure their actual street address, school address, or work address. Mail is sent to the ACP address, and is then forwarded by the Secretary of State to the addressee.

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20 RCW 9A.60.020 – Forgery.
21 [http://www.secstate.wa.gov/acp/](http://www.secstate.wa.gov/acp/)
b. Address changes may be mailed, faxed or e-mailed to the Board of Pharmacy. Mail should be sent to the HPQA Customer Service Office, P.O. Box 47865, Olympia, WA 98504-7865. Faxes may be made to 360-236-4818. E-mail may be directed to CSC@DOH.wa.gov.22
Include your complete identification and your license number(s) that are affected by the change.

v. License Renewal. The license must be promptly renewed upon its expiration, which occurs annually on the licensee’s birthday (WAC 246-12-030). There is a penalty for late renewal, but, more important, the person whose license has not been renewed is not able to practice legally until the renewal and penalty fee are paid. A license that has expired for more than one year will require payment of a penalty fee plus completion of other requirements (WAC 246-863-090).

1. The Department of Health will send a renewal notice to the address on file with the Board, but this is considered only a “courtesy” reminder – the licensee is responsible for renewal even if this reminder is not received.

vi. Continuing Pharmacy Education Pharmacists in virtually all states must complete continuing pharmacy education to be eligible to renew their licenses. Requirements differ among states, but most states require a minimum of 10 hours per year, measured either in contact hours, or Continuing Education Units. One contact hour equals 0.1 CEUs.

1. Washington state requires 1.5 CEUs (15 contact hours) per year for pharmacist license renewal. (WAC 246-861-090)

   a. Qualifying programs include programs provided by approved program providers or programs approved for individual pharmacists by the Board. Programs may be live, on-line, by correspondence, or in written format. Topics must cover one of the following areas:

      1. Legal aspects of health care
      2. Properties and actions of drugs and dosage forms
      3. Etiology, characteristics, therapeutics, and prevention of the disease state; or
      4. Specialized pharmacy practice (WAC 246-861-055)

5. Note: “business management” programs generally do not qualify for CE
   b. Approved providers may be either Board-approved or can be accredited by the Accreditation Council for Pharmaceutical Education (ACPE)
      1. All programs approved by ACPE qualify for Washington requirements, and do not require individual approval by the Board
      2. Non-accredited programs require approval by the Board. Individuals may submit programs for approval using a form on the Board’s website.23
   c. Patient Education Training incentive: A pharmacist may claim an incentive of 0.15 CEU for each hour of a qualified patient education training program (up to a maximum of 1.2 CEU) – see WAC 246-861-090 for details.
   d. First renewal for newly-licensed pharmacists. The Board has established a policy that newly-graduated pharmacists do not need to submit CE for their first license renewal if the original license was issued within 12 months of graduation.24

vii. Inactive Licenses (WAC 246-863-070; WAC 246-12-090)). A pharmacist may apply for an inactive license, which does not allow the pharmacist to practice, but maintains a credential with the Board of Pharmacy. The annual license fee is the same for an inactive license as for an active license. The inactive license may be reactivated without payment of a penalty fee.

viii. Retired Pharmacist Licenses (WAC 246-863-080). A pharmacist who has been licensed in WA for 25 consecutive years or more may maintain a retired pharmacist credential upon application to the Department. This credential does not allow the pharmacist to practice, but the annual fee is currently only $20, and allows the pharmacist to continue to receive mailings from the Board. This license may be reactivated without payment of a penalty fee.

ix. Reactivation of inactive, expired, or retired licenses (WAC 246-12) require similar procedures, based on length of time

that the license has been inactive and whether the pharmacist has been in active practice elsewhere:

1. Within less than 3 years, pay a reactivation fee and provide evidence of having met the CE requirements.
2. After more than 3 years –
   a. If have been active in another state, provide evidence of active status and retake the MJPE for Washington.
   b. If have not been active in another state, but apply for reactivation within 5 years, must take and pass the MPJE for Washington, and serve 300 hours of internship or pass a practical exam specified by the Board in specific cases.
   c. After more than 5 years without being active in another state, must take the MPJE for Washington and complete 300 hours of internship.

x. **Allowing Unlicensed Practice.** Allowing another person to practice pharmacy without a license is a basis for discipline (RCW 18.130.180 (10)). The Board of Pharmacy has specifically identified the following as professional responsibilities that the pharmacist may NOT delegate to pharmacy assistants (WAC 246-863-095):

1. Receipt of a verbal prescription other than a refill authorization;
2. Consultation with the patient regarding the prescription and/or regarding any information in the patient medication record;
   a. Note, however, that the Board has recently approved a technician utilization plan at Good Samaritan Hospital in Puyallup which allows specially trained technicians to interview patients to obtain medication histories for medication reconciliation purposes (see below).
3. Consultation with the prescriber regarding the patient and the patient’s prescription (see also WAC 246-901-010(1) for a definition of “consultation”);
4. Extemporaneous compounding of the prescription (except for bulk compounding from a formula by a technician or preparation of IV admixtures by a technician in accordance with WAC 246-871);
5. Interpretation of the data in a patient medication record system;
6. Ultimate responsibility for the correctness of a dispensed prescription (see also WAC 246-901-010(10) for a definition of “verification”);
7. Providing patient information as required by WAC 246-869-120;
8. Signing of documents or registry books that require a pharmacist’s signature;
9. Professional communications with physicians, dentists, nurses and other health care practitioners;
10. Decision to not dispense lawfully-prescribed drugs or devices or to not distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies.

xi. **Supervision of Interns Required.** As discussed under Internship, below, a pharmacy intern may perform any function that is part of the practice of pharmacy when under supervision of a licensed pharmacist.

xii. **Other Professions Share Authority.** Remember that other health professionals, including nurses and physicians, are allowed by their own licenses to perform many of the same functions, as can pharmacists. For example, nurses may administer drugs, and may consult with patients about their drug therapy. To do so is part of the practice of nursing, not the practice of pharmacy.

xiii. **Penalties.** What can happen when a person performs functions for which they are not licensed? A [recent case in Washington](http://www.doh.wa.gov/Publicat/2003_News/03-205.htm) resulted in criminal charges being filed against a Registered Counselor who administered flu vaccines in his clinics. A [Seattle Post-Intelligencer report](http://seattlepi.nwsource.com/local/154737_flu31.html) indicated that Bellevue’s Shahid Shiekh was being charged with nine felony counts, and that the counselor may have administered outdated vaccine. The report noted that physicians, pharmacists, and nurses are licensed to give flu shots, but not counselors.

f. **Qualifications for Licensure.** Washington’s statutory requirements for licensure are specified in RCW 18.64.080. In Washington, as well as in the US generally, pharmacists must provide evidence of having the following qualifications to be licensed:
   i. 18 years or older;
   ii. Good moral and professional character, including freedom from impairment by reason of mental or physical illness, or abuse of alcohol or other chemical substances.

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iii. Graduation from an accredited school or college of pharmacy. Currently, graduates must hold a bachelor’s degree or Doctor of Pharmacy degree. Only the PharmD degree will be accredited in the US for graduates who receive the degree in 2010 or thereafter.
   1. The Washington Board of Pharmacy allows pharmacists who graduated after 1994 from Canadian pharmacy programs to take the NAPLEX without completing the Foreign Pharmacy Equivalence Exam, under Board Policy Statement No. 30.

iv. Completion of a period of practical experience (internship) prior to licensure (see Interns, below).

v. Successful completion of an examination demonstrating fitness for practice, and completion of a jurisprudence examination.

vi. RCW 70.24.280 requires all licensees of the Board of Pharmacy to have completed four or seven hours of HIV/AIDS prevention and information education. Such training shall include: etiology and epidemiology; testing and counseling; infection control guidelines; clinical manifestations and treatment; legal and ethical issues to include confidentiality; and psychosocial issues to include special population considerations. (WAC 246-12-270). Pharmacists must have seven hours of HIV/AIDS education as a requirement for licensure (WAC 246-863-120). The WSU and UW pharmacy programs have certified to the Board that our curriculum provides this content for all graduates after 1989. Pharmacists transferring their licenses from other states who cannot already document completion of seven hours of HIV/AIDS education may find a list of training resources on the Department of Health website.27

g. Refusal to Issue Licenses. The Board may refuse to license an otherwise qualified pharmacist who has (1) engaged in fraud, misrepresentation, or deceit in procuring a license; or (2) has violated laws relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or the rules of the Board of Pharmacy, or has been convicted of a felony. (RCW 18.64.165).

h. License Fees. The original fee for a pharmacist’s license in Washington is $130.00, and the fee for renewal is $170.00 (WAC 246-907-030(6)). Licenses expire on the registrant’s birthday. A late payment penalty fee is equal to half of the renewal fee, or $85.00. Note, however, that during the period between the expiration of the annual license period, and the payment of the fee to the Department, the pharmacist is not eligible to practice.

i. **Discipline.** Pharmacists in Washington are subject to the Uniform Disciplinary Act for health professionals. (RCW 18.130 – See the Chapter on Avoiding Discipline and Liability.)

j. **Pharmacists in Federal Facilities.** Pharmacists who practice in federal facilities (Veterans’ Affairs, Public Health Service, Indian Health Service, federal prisons, or the military) in Washington do not need to be licensed in Washington, unless they also practice outside of these facilities. To be a federal pharmacist, however, you must maintain a license in at least one US state or territory. Under federal policy, federal pharmacists and federal pharmacies must adhere to the standards of care in the state in which they are located.

2. **Interns**
   a. **What is an intern?** In Washington, an intern is a person registered by the Board pursuant to its rules to “engage in the practice of pharmacy, and the selling of items restricted to sale under the supervision of a licensed pharmacist, only while the intern under the direct and personal supervision of a certified preceptor or a licensed pharmacist designated by the preceptor to supervise that intern during the preceptor’s absence from the site.” (See WAC 246-858-040(2))
      i. **Allowed activities.** Because interns are allowed to practice pharmacy, they may perform any act that their supervising pharmacist allows within the scope of practice of a pharmacist (other than supervising technicians or checking IV admixtures prepared by technicians). Not all states’ laws are interpreted to allow interns to do certain acts.
         1. One such act is the transfer of refill information to another pharmacy concerning controlled substances prescriptions. Interns may do this in Washington.
         2. Interns in Washington may also sell Schedule V controlled substances and sign the record book.
         3. Interns may take oral prescriptions over the phone.
         4. It is not necessary for the supervising pharmacist to perform a final check on every prescription an intern dispenses, although the pharmacist is liable for any errors made by an intern under his or her supervision.
   b. **Eligibility.** “Any person enrolled as a student of pharmacy in an accredited college may file with the department an application for registration as a pharmacy intern ....” (RCW 18.64.080(3))
      i. The Board defines “**student of pharmacy**” as a person enrolled in an accredited college or school of pharmacy or any graduate of an accredited college or school of pharmacy. (WAC 246-858-020(1)). The Board’s definition may seem to include students in a college of pharmacy who are not actually studying pharmacy, such as PhD students
enrolled in a graduate program. However, the underlying statute is clear that the intern must be a “student of pharmacy.”

ii. To remain registered as an intern, the student must make **continuing satisfactory progress** in completing the pharmacy course. (WAC 246-858-020(2)(c))

   1. Release of educational records by colleges of pharmacy is governed by the requirements of the Family Educational Rights and Privacy Act (FERPA), also known as the Buckley Amendment. In general, colleges will not provide information about educational decisions (such as decertification from the PharmD program) to others without the written permission or request of the student. Currently, the Board does not make routine requests to colleges for information on student progress. However, a student who has been decertified or placed on probation and required to retake one or more pharmacy courses before proceeding in the curriculum, is not entitled to retain an internship certificate and will be practicing pharmacy without a license during the period of decertification or probation. The student is obligated to report to the Board, and failure to so report, if discovered at a later date, could result in the Board’s refusal to issue a license, or in other discipline.

iii. **Intern Application Form.** The Board requires completion of an [application form](http://www.doh.wa.gov/hsqa/professions/Pharmacy/documents/Intern_USA.pdf), which includes questions about prior registration, fitness for practice, use of controlled substances, or prior convictions or lawsuits, and requires granting of permission to the Board to obtain health and other personal information. The applicant agrees to notify the Board regarding any convictions (including for driving under the influence) or changes in mental or physical conditions that might impair his or her ability to practice. The applicant certifies that he or she has read RCW 18.130.170 and 18.130.080 of the Uniform Disciplinary Act. Any evasions or misleading answers on this application can result in refusal by the Board to grant a license to practice pharmacy.

iv. **When can a pharmacy student apply for internship?** Students may apply for internship upon acceptance into the PharmD program, and upon completion of enrollment into the University. They may work as interns as soon as certified by the Board, but the hours spent in internship activities will not count until the student has completed the first term (semester or quarter) of the PharmD program.
c. **Supervision by a preceptor.** Interns must generally be supervised by a licensed pharmacist who is certified by the Board as a preceptor. The Board envisions that an intern works at a particular site, and the intern is required to notify the Board prior to starting internship at that site. However, interns may change sites without Board permission, as long as they notify the Board of the new site prior to earning internship hours. The Board will notify the intern if the site and preceptor are approved. (WAC 246-858-040(1)). The intern is responsible for submitting training reports to the Board. These must be submitted within 30 days after the intern has left the site with no intention of obtaining future experience at that site. (WAC 246-858-050). Thus, interns working over the summer at a pharmacy, and intending to work as interns at the same pharmacy the following summer, do not need to file a report at the end of each summer. The final reports of all intern experience — by both the intern and any preceptors — must be on file with the Board 30 days prior to taking the NAPLEX or MPJE. (WAC 246-858-070(4))

i. **When the preceptor is absent.** The Board allows interns to continue to work at a site if their preceptor is not present for periods of time (for example, during lunch), provided the preceptor has designated another pharmacist at the site to supervise the intern. If that pharmacist is not a preceptor, the time spent working at the site that is not under a preceptor’s supervision does not count towards the time required for internship.

ii. **Qualifications for preceptors.** Pharmacists who wish to be preceptors must be actively practicing in a Class A pharmacy in Washington, and must complete a Board-approved training program every five years. A pharmacist must have been licensed and actively practicing pharmacy for 12 months prior to becoming a preceptor. (WAC 246-858-060(1,2)) These requirements would seem to eliminate the possibility of externship or clerkship training in non-traditional settings, such as physician’s offices, nursing homes, or other patient care settings that are not pharmacies. However, the Board can approve special internship programs, and by practice has accepted those programs that are conducted under the auspices of the UW or WSU. This policy would also be implied by the Board rule that gives credit for experiential classes as part of accredited pharmacy programs.

1. The Board provides preceptors with an **Experiential Training Manual** that may be downloaded from its website. Successfully completing an examination over the material in the manual satisfies the continuing education requirement.

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education requirement for becoming a preceptor. The examination answer sheet is combined with the Preceptor Application Form.

iii. **One preceptor – one intern engaged in dispensing.**
Washington regulations specify that “The pharmacist preceptor may supervise more than one intern during a given time period; however, two interns may not dispense concurrently under the direct supervision of the same preceptor. (WAC 246-858-070(5))” If there is more than one pharmacist at the site, but only one preceptor, it is implied by the regulation that more than one intern may “dispense” at the site at the same time, but only one can count hours, and the other(s) must be supervised by a designated pharmacist. Ideally, all pharmacists working at a site that hires interns should become preceptors as soon as they are eligible.

**Comment:** This rule is obviously out of date, and reflects a focus on the distributive aspects of practice, rather than the clinical aspects. If strictly interpreted, it allows one intern to be “dispensing,” another to be “compounding,” and another to be “delivering” drugs to patients along with patient counseling, and so on. At the time the rule was written, the Board probably intended “dispensing” to encompass all the steps involved in providing medications to patients. Preceptors, who are ultimately responsible for the quality of patient care, must not oversee more interns than can be safely supervised.

iv. **“Direct supervision”** does not absolutely preclude the intern from working in areas of a pharmacy or institution without a pharmacist immediately at his or her side, nor does it preclude the supervising pharmacist from being absent for short periods of time while the intern is working. However, the supervising pharmacist must use judgment and be sure that the intern is operating under sufficient supervision for his or her ability level to assure patient safety.

1. An intern in the 4th professional year, for example, may reasonably be allowed to take telephoned prescriptions, and reduce them to writing, while the pharmacist is at the other end of the prescription department counseling patients. That same latitude might not be appropriate for an intern in the 1st professional year.
2. On the other hand, the Board has taken disciplinary action against both the intern and the pharmacist when the pharmacist allowed the intern to open the pharmacy prior to the arrival of the pharmacist and the pharmacist was a half hour late in arriving at the pharmacy.
d. **Required Hours.** The basic requirement for internship in Washington is 1,500 hours, which may be satisfied as follows (WAC 246-858-020):

i. Up to 1,200 hours is granted for completion of clinical courses as part of the PharmD program. WSU’s clerkship requirement of a minimum of 36 weeks of clinical rotations in patient care settings during the 4\(^{th}\) professional year provides 1,440 hours of patient care experience, well over the 1,200 hour maximum. UW graduates also qualify for 1,200 hours by virtue of completing the PharmD curriculum.

ii. The remaining 300 hours for graduates of Washington programs can be earned after completing the first semester of the 1\(^{st}\) professional year.

iii. Some states require more than 1,500 hours of internship credit, so the Board will allow students to document excess hours so as to be able to report the hours to other states in which they may wish to be licensed.

1. In 2008, Board staff indicated they would certify 1,680 hours for WSU students’ clerkships to other states.

iv. Graduates from other states that do not certify internship hours may submit a letter from their institution attesting that their program met the requirements for internship in Washington.\(^{30}\)

e. **License Fee.** The annual intern registration fee is $20.00 (WAC 246-907-030(14)). The registration expires on the intern’s birthday. (WAC 246-907-995).

f. **Current name and address.** As do other licensees, interns must promptly notify the DOH of any change in name or address. (See above)

g. **Discipline.** Interns are subject to discipline for the same reasons and under the same procedures as are pharmacists.

3. **Pharmacy assistants**

a. **Statutory Authority.** The authority for the use of pharmacy assistants in Washington’s pharmacies was granted by the Legislature in RCW 18.64A. This statute has several significant elements.

i. **Definitions.** It is important to note here that pharmacists are defined, but interns are not, and are not mentioned in the statute. The Board of Pharmacy has in the past interpreted this to mean that the duties of pharmacists relative to supervision of ancillary personnel are not included in the definition of the practice of pharmacy in RCW 18.64.011. Under this interpretation, interns may not supervise ancillary pharmacy personnel or fulfill any other duties required of licensed pharmacists that are specified in RCW 18.64A.

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\(^{30}\) Minutes, Board of Pharmacy Meeting, September 17, 2009.
Comment: My interpretation of this rule is that interns may not specifically supervise technicians who are preparing IV admixtures, including performing the final check on an IV admixture. Some Board staff members have made comments that seem to allow for this. However, given that interns are often novices themselves in the IV preparation area, and given the consequences to patients of an improperly prepared IV, and given further the difficulty of discovering many problems with IVs at the bedside, I do not believe that interns should be allowed to perform the final check on technician-prepared IVs in most cases. The Board indicated in 2008 that it would review this issue, but has not done so at present. (See discussion of “specialized functions” for technicians, below.)

ii. The statute defines those who assist pharmacists as “Ancillary Personnel”, and sets forth two classes:

1. Technicians, who are able to carry out certain non-discretionary functions delegated to them by pharmacists related to the practice of pharmacy.
   a. “Pharmacy technicians’ may assist in performing, under the supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the board may by rule adopt.” (RCW 18.64A.030(1))

2. Assistants, whose duties are limited to clerical and related functions: “Pharmacy assistants’ may perform, under the supervision of a licensed pharmacist, duties including but not limited to typing of prescription labels, filing, refiling [sic], bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third party reimbursements and other such duties and subject to such restrictions as the board may by rule adopt.” (RCW 18.64A.030(2). Note, “refiling” means “filing again”, not “refilling” which means to prepare a prescription order that is being refilled. Also note, that the Board interprets “typing of prescription labels” literally, to mean by use of a typewriter, and by rule (see below) has excluded entry of data into the medication record system from functions that an assistant may perform.

iii. Training programs are required for Technicians, as specified in Board Rules. According to the statute, a licensed pharmacist must supervise the training of technicians. The training shall consist of instruction and/or practical training, and the Board may include requirements for completion of specific examinations. (RCW 18.64A.020)
iv. **Technician certification.** New applicants for licensure as a pharmacy technician after January 1, 2009 must provide proof to the Board that they have passed a “board-approved national standardized pharmacy technician certification examination.” (WAC 246-901-060(2)) The Board has approved two national exams: the Pharmacy Technicians Certification Board,\(^{31}\) and the ExCPT from the Institute for Certification of Pharmacy Technicians.\(^{32}\) Completion of either examination and fulfillment of annual continuing education requirements allows the technician to use the designation CPhT. Maintaining CPhT status is not a requirement for technician licensure in Washington, and at present the Board does not have statutory authority to require continuing education for technicians.

v. **Statutory limits on pharmacist-technician ratio.** The statute sets limits on the ratio of pharmacists to technicians, but it is important to note that the statute gives the Board of Pharmacy authority to establish different ratios by rule, provided that those pharmacies wishing to use the higher ratios must submit to the Board for its approval a pharmacy services plan. (RCW 18.64A.040(3)) The statute also gives the Board authority to authorize pilot projects designed to investigate different ratios or use of technicians. Because the Board has by regulation established different ratios from the statute, see the discussion of the regulation below for the current actual ratios.

1. Without a specific technician utilization plan, retail pharmacies may utilize technicians in a 1:1 pharmacist-to-technician ratio. (RCW 18.64A.040(2))
2. Institutional pharmacies may use a 1:3 pharmacist-to-technician ratio for inpatient medications, and a 1:1 ratio for outpatient medications, unless they have a specific Board-approved utilization plan. (RCW 18.64A.040(2))
   a. The statute specifies the various institutional pharmacies covered by the higher ratio by referring to specific chapters of the RCW. The specific institutional types (and the chapters referred to in RCW 18.64A) are: Hospitals (RCW 70.41); Mental Health Institutions (RCW 71.12); Residential Habitation , unselect (RCW 71A.20); Nursing Homes (RCW 74.42).

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\(^{31}\) https://www.ptcb.org//AM/Template.cfm?Section=Home1
\(^{32}\) http://www.nationaltechexam.org/
vi. **Discipline.** Pharmacy technicians may have their registration revoked for violation of the Uniform Disciplinary Act (RCW 18.130), and for other reasons, specified in RCW 18.64A.060, that are similar to those for which pharmacists may be disciplined. Discipline of technicians is subject to the requirements and procedures of RCW 18.130, the Uniform Disciplinary Act. (RCW 18.64A.055)

vii. **Current information.** As for all licensees, ancillary personnel must maintain current address information with the Board of Pharmacy (see above).

viii. **Pharmacy must have prior approval to use ancillary personnel.** No pharmacy may use ancillary personnel unless it has applied to the Board and received approval. (RCW 18.64A.060) The Board also may assess a fee for the use of ancillary personnel, and the current original fee is $65, with an annual renewal fee of $75. (WAC 246-907-030(4))

b. **Board Rules for Ancillary Personnel.** The Board of Pharmacy’s regulations relating to pharmacy assistants are found in WAC 246-901.

i. **Key definitions.** The Board’s rule sets forth three key definitions that clarify the ability of pharmacists to delegate duties to ancillary personnel. These definitions do not apply solely to pharmacists when using technicians or assistants, however, but apply to pharmacists generally.

1. **“Consultation”** is defined to mean:
   a. “A communication or deliberation between a pharmacist and a patient, a patient’s agent, or a patient’s health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.”
   b. “A method by which the pharmacist meets patient information requirements as set forth in WAC 246-869-220.” (WAC 246-901-010(1))

2. **“Verification”** means the pharmacist has reviewed a patient drug order initiated by an authorized prescriber, has examined the patient’s drug profile, and has approved the drug order after taking into account pertinent drug and disease information to insure the correctness of a drug order for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a drug order is responsible for all reports generated by the approval of that order. The unit-dose medication fill
and check reports are an example.” (WAC 246-901-010(10))

3. “Immediate supervision’ means visual and/or physical proximity to a licensed pharmacist to ensure patient safety.” (WAC 246-901-010 (11))
   a. The Board has allowed a pharmacist to supervise a technician at a remote location under certain circumstances, for example, preparing IV admixtures while under two-way video contact, with the admixture room closed to other personnel, if the pharmacist assured that all IV admixtures were verified before distribution to patient care areas.

ii. Activities restricted to technicians, interns, or pharmacists. Only technicians, interns and pharmacists may
   1. Enter a new medication order into the pharmacy computer system
   2. Retrieve the drug product to fill a prescription (WAC 246-901-020(4)).
   3. Stocking of drugs in an automated drug distribution device (WAC 246-862-030(4)). Note, however, that the Nursing Quality Assurance Commission has stated that stocking of these devices is within the scope of practice of a registered nurse.

iii. Technician training. (WAC 246-901-030)
   1. Technicians may receive training either in a formal academic training program approved by the Board or from on-the-job training programs approved by the Board.
   2. Applicants for technician training must have a high school diploma or have received a G.E.D.
   3. Applicants for registration must submit to the Board proof of completion of an approved training program and “proof of passing a board-approved national standardized pharmacy technician certification examination.” (although the current application does not collect information regarding certification examinations, only the certification of the training director). (WAC 246-901-060)
      a. The Board currently approves the national training programs of the following national pharmacy chains: Rite-Aid, Wal-Mart, Safeway, and Sav-On.
   4. Technicians must complete 4 hours of HIV/AIDS prevention and information education. (WAC 246-901-
5. Out-of-state applicants must meet the same requirements as in-state applicants, and the Board must approve any out-of-state training programs. Out-of-state technicians must also provide proof of 8 hours of study of Washington pharmacy law under the direction of a pharmacist.

6. Additional, specialized training programs are required for technicians who wish to perform either of the following “specialized functions”
   a. Unit-dose medication checking. Such training must include proficiency testing demonstrating 99% accuracy in checking unit-dose medications.
   b. Intravenous admixture preparation. Such training must include proficiency testing demonstrating 100% accuracy in preparing a representative sample of IV admixtures using aseptic technique.

7. Foreign-trained pharmacists or physicians may apply to become technicians subject to the additional requirements in WAC 246-901-030(5).

iv. **Specialized functions.** The Board may approve utilization plans which allow technicians to perform specialized functions. (WAC 246-901-035, 246-901-100). Three functions have been approved in regulation by the Board, and others have been approved on a plan-by-plan basis.

1. **Parenteral admixtures** may be prepared by technicians who have met the special training requirements. A “licensed pharmacist” must check each parenteral product prepared by a technician (WAC 246-901-035(2)). (See discussion concerning statutory authority and implications for interns in section 3.a. above.)

2. **Tech-check-tech programs.** Technicians may check other technicians or interns who have filled unit-dose medication cassettes in institutional settings. This is often called a “tech-check-tech” program. (Note that the language of the rule does not specify that interns may check the work of technicians.) No more than a 48-hour supply may be placed in a cassette that is part of a tech-check-tech procedure. Another “licensed health professional” must again check the

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medication prior to administration to a patient. (WAC 246-901-035(2))

3. **Stocking of Automated Drug Distribution Devices** by technicians is allowed by Board rule (WAC 246-872-030(4)). This is treated as a specialized function for which the technician must be specially trained.

4. **Medication Reconciliation Activities.** The Board can approve specialized functions without requiring a pilot program or demonstration project (see below). At its January 22, 2009 meeting, the Board approved a plan by Good Samaritan Hospital in Puyallup to train pharmacy technicians for the special function of interviewing patients, under pharmacist supervision, to obtain a medication list for purposes of medication reconciliation. Under this plan, specially trained pharmacy technicians will be used in the following process:

   a. Patient is admitted through the emergency department.
   b. ED-based pharmacy technician obtains complete medication list
   c. ED-based pharmacist reviews and verifies the list.
   d. Physician reviews and reconciles pharmacist-verified medication list.34

   **Comment:** The board has not characterized this activity as a "specialized function," but its approval and review process as summarized in the Board's minutes mirrored all of the steps to authorize specialized functions: the technicians are required to take a "pharmacist taught training session" and are required in part to "shadow a current technician taking a medication list for three hours or until they are deemed ready to do this on their own by a pharmacy technician manager or responsible pharmacist [emphasis added]." This is the first instance I’ve seen in which the role of a senior technician in evaluating another technician has been the subject of a board-approved plan. The board has apparently approved applications by other hospitals to allow technicians to obtain a list of medications. It is interesting to consider how technicians in ambulatory settings could be used to assist in obtaining updated lists of drugs from patients at each pharmacy visit and improve compliance with OBRA-90 rules and Washington patient medication record requirements.

   v. **Fees.** Technicians pay a $50 application fee and a $40 annual renewal fee. The penalty fee for late renewal of a technician's certificate is also $40 (WAC 246-907-030(13)).

34 Minutes, Washington State Board of Pharmacy, 2009 Jan 22.
vi. **Pharmacy Assistants** may be utilized to perform the following (WAC 246-901-070):

1. Any duties not otherwise reserved to pharmacists or technicians
2. Prepackaging and labeling of drugs for subsequent use in prescription dispensing operations
3. Counting, pouring, and labeling for individual prescriptions. Note, however, that they may not retrieve the drug from the shelf to be used for the particular prescription, though they may replace the container on the shelf after the prescription is verified. (See WAC 246-901-020(4)) The Board received a request to allow a modification of this rule when bar code scanning was used, but declined to do so in December 2005.

vii. **No limit on number of pharmacy assistants.** There is no maximum ratio of pharmacy assistants to pharmacists, provided the pharmacy has Board approval for use of ancillary personnel.

viii. **There are no restrictions on age or educational preparation for pharmacy assistants.** (RCW 26.28 specifies rules regarding the age of majority for minors in Washington, and generally prohibits employment of minors below the age of 14.) The fee for assistants is included in the pharmacy’s fee for utilizing ancillary personnel. Pharmacy assistants must notify the Board of any change in their mailing address within 30 days, and must renew their registration every 2 years, on their birthday. (WAC 246-901-080).

ix. **ID Badges Required.** All pharmacy ancillary personnel who are in the pharmacy and who interact with patients or the general public must wear ID badges clearly indicating that they are Pharmacy Assistants or Pharmacy Technicians. (WAC 246-901-090)

c. **Utilization plans.** The pharmacy’s utilization plan must contain the following elements. (WAC 246-901-100)

i. It must describe the manner in which ancillary personnel will be utilized.
   1. A job description for each category of job.
   2. Task analysis for each job category defining duties and conditions under which they may be performed.
   3. The number of positions to be used in each category

ii. If technicians will be used for specialized functions, the plan must indicate
1. The criteria for selecting which technicians will perform the specialized functions
2. A description of how training will be performed for these technicians, and how the assessment will be made to prove proficiency as required in the rules (99% for unit-dose, 100% for IV admixtures). See comment above regarding the Board’s approval of a plan using technicians to take medication histories.
3. A copy of the pharmacy’s quality assurance plan that relates to these specialized technicians
   iii. The plan need only list the job title or function for each pharmacy assistant position.

d. Technician ratios allowed with a specific utilization plan. The Board utilized the authority granted in statute to modify the pharmacist-to-technician ratios specified in the statute. (WAC 246-901-130)
   i. All licensed pharmacies with a utilization plan may have a 1:3 technician ratio, not just institutional pharmacies.
   ii. The pharmacists who may be included in the ratio are
      1. Those pharmacists actively practicing pharmacy at the site (but not, for example, the CEO in the business office)
      2. In inpatient settings, those pharmacists practicing outside the central pharmacy may be included, if
         a. The pharmacy is not open to the public;
         b. Enough pharmacists are in the central pharmacy to safely oversee the technicians’ work;
         c. Medications are always checked by a licensed health care professional immediately prior to administration to patients; and
         d. Drug orders are not dispensed from the pharmacy unless they are checked by a licensed pharmacist or intern, or are dispensed pursuant to a tech-check-tech program.
   iii. Higher ratios of technicians to pharmacists may be approved for specific pharmacies with a well-developed plan meeting the specifications of WAC 246-901-140.
      1. As an example of a proposal for higher ratios that was not approved by the Board, at its January 22, 2009 meeting the Board rejected a request by Costco to allow a higher technician ratio at its central fill pharmacy, by a vote of 3-1, with two members recused and one member abstaining.35

35 Minutes, Washington State Board of Pharmacy, 2009 Jan 22.
iv. The Board may give conditional approval to pilot or demonstration projects.

4. Access to pharmacies restricted. Several regulations of the Board restrict access to pharmacies by non-pharmacy personnel.
   a. WAC 246-869-020 requires pharmacies with differential hours from the rest of the store to provide adequate security to assure that in the absence of a pharmacist only those individuals designated by the pharmacist, such as janitors or persons doing inventory, can have access.
   b. WAC 246-869-140 prohibits lay persons from conversing with a pharmacist while he or she is engaged in the act of “compounding a prescription,” and protects the “prescription department of every licensed pharmacy in the state of Washington from trespass by the lay public.”
   c. WAC 246-869-160(7) requires that “the prescription department shall be situated so that the public shall not have free access to the area where legend drugs, controlled substances, poisons, or other restricted items are stored, compounded, or dispensed.”
   d. May high school students “shadow” a pharmacist? The Board has interpreted these rules to prohibit employees of a pharmacy from working in the prescription department unless they are registered with the Board as pharmacy assistants or technicians, or are otherwise licensed as interns or pharmacists. Some pharmacists have interpreted this as preventing high school or other students from “job shadowing,” but it seems that the rules allow a pharmacist to permit a person, not actually engaged in practice activities, to be in the prescription department.

5. Accredited pharmacy programs. Board of Pharmacy policy recognizes as accredited those colleges and schools of pharmacy that are accredited by the Accrediting Council for Pharmaceutical Education.36
   a. Canadian graduates. Under Board Policy #30, reaffirmed in January, 2006, graduates of Canadian pharmacy programs after 1994 will be allowed to take the NAPLEX and MPJE for licensure in Washington without previously taking the FPGEE.

36 http://www.acpe-accredit.org/students/programs.asp
6. **Licensing or certifying exams.** The Board has established a policy of using examinations provided by the National Association of Boards of Pharmacy Foundation, specifically the North American Pharmacy Licensure Examination (NAPLEX) and the Multi-state Pharmacy Jurisprudence Exam (MPJE).

   a. **Registration Bulletin.** The 32-page .pdf file containing the NAPLEX/MPJE Registration Bulletin is available from NABP’s website.\(^{37}\) This describes the procedures for registering for both the NAPLEX and the MPJE in those states that use the MPJE. Registration is online for all states except NH, SD, OK, VI, and PR.

   b. **NAPLEX** is a computer-adaptive examination that is now accepted for licensure in all 50 states. Students may take the NAPLEX at any **Pearson VUE**\(^{38}\) Testing Center site and may transfer scores to other states for an additional fee of $75 per state. The basic fee for the NAPLEX is $465 ($485 after May 10, 2010). Pearson VUE has locations in Spokane Valley, Seattle, Renton, Yakima, and Portland (Beaverton). The NAPLEX is scheduled for 4 hours and 15 minutes, with a 10-minute break after 2 hours of testing.

   i. Washington accepts score transfers for NAPLEX.

   ii. Other states accepting score transfer include: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, GU, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VI, VA, WV, WI, and WY.

   iii. California accepts score transfers from applicants completing the NAPLEX after January 1, 2004. California has placed an updated bulletin\(^ {39}\) on its website concerning the NAPLEX and the California Pharmacy Jurisprudence Exam (CPJE). California allows NAPLEX score transfers.

   iv. Florida requires NAPLEX (and MPJE), and allows score transfers from participating states. (See Florida’s **Applicant Information Bulletin**\(^ {40}\) for more details.)

   v. Students may take a Pre-NAPLEX exam for $50 per attempt to help prepare for the NAPLEX. The test is on-line, and students are allowed 70 minutes to take 50 questions. The test may be taken twice. (See **NABP web page**\(^ {41}\)).

   vi. Many states limit how long a student has to complete licensure application following a score transfer – typically one to three years. Washington requires that applications for licensure must be completed within one year of the time of score transfer (WAC 246-863-020(5)).

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37 http://www.nabp.net/competency/intro.asp  
38 http://www.pearsonvue.com/nabp/  
40 http://www.doh.state.fl.us/mqa/pharmacy/ap_ph-exam.pdf  
41 http://www.nabp.net/
c. **MPJE** is a computer-adaptive examination administered at the same Pearson VUE testing sites as is the NAPLEX. You must take the MPJE once for each state in which you wish to register, since the exam is adapted to the rules of each state. The fee for each MPJE exam is $185 ($200 after May 10, 2010). Not all states use the MPJE, so it is necessary to check with each state you are interested in to determine their law exam requirements. All states require some form of law examination. The MJPE is scheduled for 2 hours, with no breaks during testing.

i. 47 states use the MPJE; other states in the west that use the MPJE include Alaska, Arizona, Hawaii, Idaho, Montana, Nevada, Oregon, and Wyoming. Jurisdictions that do NOT use the MPJE are Arkansas, California, Guam, Mississippi, Oklahoma, Puerto Rico, and Virginia.

ii. California has used the NAPLEX since January 1, 2004, and developed its own California Pharmacy Jurisprudence Exam, which is administered at Psychological Services, Inc. (PSI) Testing Centers nationwide. PSI locations include 15 centers in WA, including Spokane, Yakima, and East Wenatchee in eastern Washington. However, the PSI webpage does not show any sites in WA that offer the CPJE; the closest site is in Portland, OR. The fee for the CPJE is $33.

d. **Disability accommodations** for NAPLEX and MPJE may be requested by contacting NABP as set forth in the Registration Bulletin. However, any accommodation granted must be approved by the applicant’s Board of Pharmacy prior to testing.

e. **Retaking examinations.** Pharmacist applicants in Washington may take the NAPLEX up to 3 times within a 3-year period, after which the Board will specify additional required training before allowing further attempts (RCW 18.54.080). The Board will require additional law instruction for any applicant who has taken and failed the MPJE 3 times (WAC 246-863-020).

7. **License transfer.** Pharmacists who are already licensed by examination in another state may become licensed in Washington by transferring their licenses through the License Transfer services of the National Association of Boards of Pharmacy (www.nabp.net). In Washington regulations, this process is called “reciprocity.” (WAC 246-863-030) The NABP now uses an electronic license transfer process that takes less time than formerly. However, the transfer fees involved make license transfer somewhat more expensive than retaking the NAPLEX. A pharmacist must keep an original license by examination active in at least one state, since most states, including WA, will not allow a transfer of a license that was itself granted by the license transfer process.

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42 http://corporate.psionline.com/test-centers/test_locations.php
a. The reciprocity applicant must take the MPJE for Washington within 2 years of completing the transfer application process.

b. If the reciprocity applicant has been out of active practice for between 3 and 5 years, the Board may require additional practical exams or 300 hours of internship prior to licensing.

c. If the reciprocity applicant has been out of active practice for over 5 years, the applicant must retake the NAPLEX and serve a 300 hour internship prior to licensure.

d. WAC 246-863-035 allows for temporary permits to practice pharmacy while a transfer applicant is awaiting the next available MPJE examination.

e. California does not allow license transfer.

8. Federal installations. Pharmacists practicing in federal installations, such as the Indian Health Service, the armed forces, or the Veterans Administration, must be licensed in one of the 50 states or territories, but do not need to be licensed in the particular state in which they are stationed. However, pharmacists practicing in federal installations may not practice outside of those facilities unless they are also licensed by that state.

9. Post graduate training. Post graduate training for pharmacists includes residencies, fellowships, and graduate degree programs.

   a. **Residencies** are post-graduate training opportunities for pharmacists that are one or more years in duration. To participate in a residency, you must be licensed in the state in which the residency is located, unless it is in a federal installation. Washington allows recent graduates who are participating in residency programs to register as interns.43

   i. General institutional residencies and community practice residencies provide a broad range of experiences, and are usually required if one wishes to complete a specialty residency or a fellowship.

   ii. Specialty residencies (eg, infectious disease, pediatrics) focus on a specialty area and often require applicants to have completed a general residency.

   iii. Residencies may be accredited by national organizations, including ASHP, APhA, and ASCP.

   iv. The [ASHP Residency and Accreditation webpage](http://www.ashp.org/rtp/index.cfm?cfid=11387409&CFToken=40090822) contains information on the standards for accredited residencies, as well as information on how to apply for a residency that participates in the national matching program. Effective in 2007, accredited residencies will become to be described by terms currently used for post-graduate training of physicians:

1. PGY1, or Post Graduate Year 1, residencies are those that provide broad training, but may have a

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43 Washington Board of Pharmacy Procedure #36, approved October 30, 2008.

focus in special populations. Most current general and community residencies, and some specialty residencies such as geriatrics or pediatrics, will meet the requirements for PGY1 residencies.

2. PGY2, or Post Graduate Year 2, residencies, will be advanced residencies that require PGY1 training and will be focused in a specialty area.

v. Hospitals that incur direct costs for Graduate Medical Education (which includes pharmacy residencies) may “pass through” a proportionate share of these costs to Medicare under regulations developed by the Center for Medicare and Medicaid Services (CMS) of the Department of Human and Health Services. As of December, 2005, CMS will allow pass-through costs only for PGY1 pharmacy residencies.

b. Fellowships are one or two years in duration and focus on development of both advanced skills and the ability to research in a specific area.

c. Certain practice roles require qualification “by education, training or experience.” Included among these in Washington are directors of hospital pharmacies (WAC 246-873-040(1)), and pharmacists in charge of home IV compounding (WAC 246-871-040(1)). Residencies or fellowships can provide this training or experience.

i. Nuclear pharmacists must complete either six months of on-the-job training under the supervision of a qualified nuclear pharmacist, or must have completed a nuclear pharmacy training program in an accredited college of pharmacy. (WAC 246-903-030(3))

10. Conscientious Objection

a. Refusing to participate in abortions. No individual may be compelled to participate in an abortion.

i. Under Washington’s Reproductive Privacy Act45 (Initiative 120 -1991), “No person or private medical facility may be required by law or contract in any circumstances to participate in the performance of an abortion if such person or private medical facility objects to so doing. No person may be discriminated against in employment or professional privileges because of the person’s participation or refusal to participate in the termination of a pregnancy.” (RCW 9.02.150)

ii. Federal law similarly protects the right of individuals to refuse to participate in termination of pregnancies by any health care entity that receives federal funds. The Church Amendments (42 U.S.C. § 300a-7) prohibits discrimination against persons or entities who

45 RCW 9.02
1. Participate in health service programs funded by DHHS and who
2. Choose to participate in or refuse to participate in sterilization or abortion because of religious or moral belief.

b. **Refusing to participate in aid-in-dying.** Oregon and Washington Death with Dignity laws specify that participating in providing aid-in-dying is limited to willing health care providers, and prohibit discrimination against persons who participate in or refuse to participate in aid-in-dying. Washington’s law permits hospitals and clinics to prohibit participation in aid-in-dying on their premises, but this applies only to the acts of physicians as specified in the law. Pharmacies are not permitted to prohibit their employee pharmacists from filling prescriptions issued under the law.

c. **Refusing to participate in other health care services.** The Church Amendments further specify that “No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded … under a program administered by the Secretary of Health and Human Services if his performance or assistance in performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.” (42 U.S.C. § 300a-7(d))

i. At the close of the Bush Administration, DHHS adopted a “Right of Conscience” rule (45 CFR 88)\(^\text{46}\) which was scheduled to become effective on January 19, 2009 – one day prior to the inauguration of the new President. The rule affects upwards of 570,000 entities, including hospitals, clinics, universities, and 58,000 pharmacies. The rule proposes to implement existing statutes: the Church Amendments plus § 245 of the Public Health Service Act and the Weldon Amendment to the Consolidated Appropriations Act of 2008. It requires entities to certify to DHHS that they are in compliance with these statutes, and it specifies that pharmacies and other health care providers may not

1. Discriminate in employment or extension of privileges based on willingness or unwillingness to perform or assist in the performance of abortions or sterilizations when such willingness or unwillingness is based on an individual's religious beliefs or moral convictions.
2. Require any individual to "perform or assist in the performance of any part of a health service ... activity funded by DSHS if such service or activity would be contrary to his religious beliefs or moral convictions

\(^\text{46}\) 73 FR 78072, December 19, 2008.
3. Discriminate in employment ... because an individual performed, assisted in the performance, refused to perform or assist in the performance of "any lawful health service ... on the grounds that such [behavior] would be contrary to his religious beliefs or moral convictions, or because of the religious beliefs or moral convictions concerning such activity themselves." Note that this prohibition does not relate solely to services paid for by DHHS. “Individuals” include any person, including contractors, in the work force of the pharmacy or health care provider. The Obama administration announced its intention to rescind this rule in its entirety on March 10, 2009, with a deadline for comments of 4/9/2009.47 As of December 30, 2009, DHHS has not finalized the rescission of this rule.

ii. The Illinois Supreme Court allowed a lawsuit to go forward in December 2008 that challenges the Illinois regulation requiring that pharmacies promptly fill prescriptions for contraceptives, including emergency contraception. The plaintiffs cited contrary Illinois statutes, including the Illinois Health Care Right of Conscience Act and the Illinois Religious Freedom Restoration Act.48

iii. As noted in Chapter 3, a similar challenge to Washington’s “prompt fill” regulation is awaiting trial in federal court.49

d. Pharmacy organizations endorse the exercise of conscience by pharmacists, but they believe that pharmacists must balance their moral stance with the right of patients to receive lawful therapies.

i. **WSPA’s policy on facilitating care** reads,

> “… the WSPA supports the following statements as meeting the ‘duty to facilitate’ and the appropriate components of a standardized referral process:

1. Pharmacies have a duty to facilitate the delivery of lawfully prescribed and medically appropriate drugs or devices and those approved for restricted distribution by pharmacies, or to facilitate the delivery of therapeutically equivalent drugs or devices to patients in a timely manner, except under the following circumstances:
   a. Prescriptions containing obvious or known errors, inadequacies in the instructions, known contraindications, or incompatible prescriptions;
   b. Potentially fraudulent prescriptions; and
   c. National or state emergencies or guidelines affecting availability, usage, or supplies of drugs or devices.

2. A pharmacy fulfills the duty to facilitate the delivery of lawfully prescribed medically appropriate drugs or devices if, when

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presented with a lawful, medically appropriate prescription, or request for distribution, a pharmacy:

a. Dispenses the lawfully prescribed and medically appropriate drug or device or a therapeutically equivalent alternative drug or device;
b. Facilitates the patient's access to the lawfully prescribed and medically appropriate drug or device by referring the patient to a healthcare provider who will provide the care. To complete the referral, the referring pharmacy shall contact the provider of the patient's choice to confirm that the drug or device is available, and transfer the prescription to the new provider; or
c. If the patient or the patient's caregiver prefers to self refer, returns the patient's unfilled prescription."50

ii. The WSPA has also adopted a Position Statement on Access to Care:

WSPA believes a pharmacist’s professional responsibility is to provide optimum patient care.

WSPA opposes any pharmacist obstructing a patient’s access to care.

WSPA supports patient access to timely care in the event a pharmacist is unable to dispense a lawful prescription.51

iii. As the former executive director of the WSPA has put it, the association believes that pharmacists may stand aside from participation in activities they object to, but cannot stand in the way of patient care. The majority of WSPA members support a patient’s right to receive lawful medications, and Washington pharmacists are nationally recognized for their participation in the prescribing of emergency contraception.52

e. Moral obligations of the conscientious objector. A pharmacist or technician who intends to refuse to participate in otherwise lawful activities has two important moral obligations:

i. Authenticity.

1. The objection must be based on sincerely held, carefully considered, moral or religious convictions. It cannot be due to mere squeamishness concerning the activity.
2. The objection must be based on evidence that the activity actually offends the moral principle invoked by the objector. For example, if a pharmacist’s objection

50 http://www.wsparx.org/associations/7310/files/Pharmacist%20Duty%20to%20Facilitate.pdf
to emergency contraception is based on a moral or religious opposition to terminating a pregnancy, current pharmacological evidence does not support the conclusion that Plan B does, in fact, result in pregnancy terminations.53

3. The objection must be applied consistently. A pharmacist who objects to dispensing ECP should object to doing so regardless of which patient is seeking the drug. Conscientious objection cannot be a cover for discrimination or bias.

ii. Publicity.

1. Pharmacists enter into relationships with patients that entail expectations on the patients’ part that the pharmacist will provide care upon request. A pharmacist who provides services to women of childbearing age must be public and candid with these clients about whether he or she will dispense emergency contraception, so that the patients can decide whether to enter into a professional relationship with that pharmacist. Likewise, a pharmacist who practices hospice care in Washington or Oregon should be open about whether he or she will participate in aid-in-dying.

2. Employers have a right to know whether an employee will fill all lawful prescriptions. As with other antidiscrimination laws, employers are required to make reasonable accommodations for religious practices, but they are entitled to know in advance of the need for such accommodations. (See also Chapter 7).

11. Criminal background checks and other requirements

a. Criminal background checks. Individuals who might have unsupervised access to children, developmentally disabled persons, or vulnerable adults may not be hired by agencies or firms providing services to these individuals if they have a relevant criminal background. The Washington State Patrol is authorized to perform background checks on prospective employees or licensees at the request of employers or state agencies (RCW 43.43.832). Health care facilities that have received criminal background checks on prospective employees are permitted to share this information with other facilities under certain circumstances. The statute also authorizes the WSP to provide background checks at the request of any law enforcement agency. The Board of

Pharmacy seeks criminal background checks from the State Patrol on applicants for credentials issued by the Board.

i. Because the WSP background check is limited to records in Washington state, employers (and colleges of pharmacy) are likely to require prospective employees to permit a national background check performed by an outside firm. In certain cases, state agencies are empowered to seek an FBI background check for prospective state employees.

ii. The Department of Health now requires federal fingerprint-based background checks for out-of-state applicants (including interns). These applicants must arrange to have their fingerprints taken, pay the cost for that if any, and also pay $49.25 for the background check. The background check typically adds 5 to 10 working days to the approval process.54

b. Abuse reporting. Pharmacists are among the professionals who are required by Washington law to report suspected abuse of children or vulnerable adults.

i. Children. RCW 26.44.030 reads, in part: “(1)(a) When any practitioner, … pharmacist, … has reasonable cause to believe that a child has suffered abuse or neglect, he or she shall report such incident, or cause a report to be made, to the proper law enforcement agency or to the department as provided in RCW 26.44.040.”

ii. Vulnerable Adults. RCW 74.34.035 describes reports that are required when health providers are aware of abuse of vulnerable adults. Pharmacists are among the “mandated reporters” by virtue of being subject to the Uniform Disciplinary Act.

c. Sexual contact with clients or patients is prohibited. (See also Chapter 7) Pharmacists and other health providers are prohibited from engaging in or attempting to engage in sexual misconduct with a current patient, client, or “key party,” inside or outside the health care setting. (WAC 246-16-100). The rules also prohibit offering professional services in exchange for sexual favors, and/or using health care information to attempt to engage in sexual misconduct or to “meet the provider’s sexual needs.” A health care provider is prohibited from attempting to engage in sexual conduct during a 2-year period after the provider-patient relationship ends.

d. Mandatory Reporting of Unprofessional Conduct or Impairment (See also Chapter 7)

i. In 200655 the Legislature amended the Uniform Disciplinary Act (RCW 18.130.170) to require that all persons licensed by the Department of Health in Washington report to the

55 2006 c 99 § 1-2
appropriate disciplinary authority (e.g., the Board of Pharmacy) when

1. They are aware that another licensee has been subject to a conviction, determination, or finding that he or she has committed an act which constitutes unprofessional conduct;

2. They are aware that another licensee may not be able to practice his or her profession with reasonable skill and safety to consumers as a result of a mental or physical condition. (this information may generally be reported to an impaired practitioner or substance abuse monitoring program instead of the disciplinary authority); or

3. They themselves have been
   a. subject to any conviction, determination, or finding that he or she has committed unprofessional conduct or is unable to practice with reasonable skill or safety, or
   b. disqualified from participating in the federal Medicare or Medicaid programs. (See also Chapter 8.)

ii. Specific rules on how to make these reports to the Department of Health are contained in WAC 246-16-200 through 265. (See also Chapter 7.)

iii. The 2008 Legislature added further mandatory reporting requirements for employers. The statute now also clearly requires all employers to report termination or restriction of health care providers' privileges when due to unprofessional conduct or impairment. The current regulation specifies that “Every license holder, corporation, organization, health care facility, and state and local government agency that employs a license holder shall report to the department of health when the employed license holder’s services have been terminated or restricted based on a final determination or finding that the license holder:
   a. Has committed an act or acts that may constitute unprofessional conduct; or
   b. May not be able to practice his or her profession with reasonable skill and safety due to a mental or physical condition.” (WAC 246-16-270(1))

Reports must be submitted no later than 20 days after a final determination or finding is made. A “‘Determination or finding’ means a final decision by an entity required to report ... even if no adverse action or sanction has been imposed

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56 2008 c 134.
or if the license holder is appealing the decision.” (WAC 246-16-210(3)) Note, however, that the requirement for employers is triggered only by termination or restriction, both of which are generally considered to be adverse employment actions.

e. **Social Security Numbers.** All applicants for a license or credential must supply the agency with a Social Security number, as required in RCW 23.23.150. This statute implements a federal requirement to aid enforcement of child support decrees.

   i. Some individuals who may need a credential from the Board, such as foreign pharmacy students who wish to participate in an exchange program, cannot currently obtain a social security number. These individuals may certify to the Board their inability to obtain a social security number, using a form provided by the Board, and the Department of Health will issue the credential.

Rev. 1/13/10
1. **General considerations for establishing a business in Washington.**
   a. **Resources** for businesses are available on the Access Washington web site at the following URL: [http://access.wa.gov/business/index.aspx](http://access.wa.gov/business/index.aspx)
   b. **Form of business** – information from the Secretary of State of Washington [http://www.secstate.wa.gov/corps/registration_structures.aspx](http://www.secstate.wa.gov/corps/registration_structures.aspx)

   A **Sole Proprietorship** is one individual or married couple in business alone. Sole proprietorships are the most common form of business structure. This type of business is simple to form and operate, and may enjoy greater flexibility of management and fewer legal controls. However, the business owner is personally liable for all debts incurred by the business.

   A **General Partnership** is composed of two or more persons (usually not a married couple) who agree to contribute money, labor, and/or skill to a business. Each partner shares the profits, losses, and management of the business, and each partner is personally and equally liable for debts of the partnership. Formal terms of the partnership are usually contained in a written partnership agreement.

   A **Limited Partnership** is composed of one or more general partners and one or more limited partners. The general partners manage the business and share full in its profits and losses. Limited partners share in the profits of the business, but their losses are limited to the extent of their investment. Limited partners are usually not involved in the day-to-day operations of the business.

   A **Limited Liability Partnership** is similar to a General Partnership except that normally a partner does not have personal liability for the negligence of another partner. This business structure is used most commonly by professionals such as accountants and lawyers.

   A **Corporation** is a more complex business structure. As a chartered legal entity, a corporation has certain rights, privileges, and liabilities beyond those of an individual. Doing business as a corporation may yield tax or financial benefits, but these can be offset by other considerations, such as increased licensing fees or decreased personal control. Corporations may be formed for profit or nonprofit purposes.

   The **Limited Liability Company (LLC)** and the **Limited Liability Partnership (LLP)** are the newest forms of business structure in Washington. An LLC or LLP is formed by one or more individuals or entities through a special written agreement. The agreement details the organization of the LLC or LLP, including: provisions for management, assignability of interests, and distribution of profits or losses. Limited liability companies and limited liability partnerships are permitted to engage in any lawful, for profit business or activity other than banking or insurance.

   *Registers with the Secretary of State*
c. **Nonprofit organizations** may take the form of nonprofit corporations or nonprofit professional services corporations. The latter are formed when licensed health professionals (or other professionals) join to provide professional services as a nonprofit group (e.g., charitable clinic).

d. **Master License Application.** The state uses a Master License Application to apply for tax registration, Labor & Industries registration, corporation registration, and trade name registration.

e. **Labor and Industries registration.** Businesses that have employees are required to register with the Department of Labor and Industries, whether they are for profit or nonprofit organizations.

f. **Pharmacies, hospitals, nursing homes, shopkeepers, and others** registered by the Department of Health must also apply to the DOH and/or the appropriate board.

g. **Pharmacies and hospitals** will also need to apply to the Drug Enforcement Administration and register as dispensers. A WA Board of Pharmacy controlled substances registration number will be required by DEA.

h. **Advance inspection required.** The Department of Health and/or the Board of Pharmacy requires advanced notice and conducts an inspection of health care facilities prior to licensure.

i. **Certificate of Need.** Certain types of health care facilities (but not community pharmacies) must obtain a Certificate of Need prior to opening.

2. **Board of Pharmacy and DEA applications.**

   a. The **Board of Pharmacy** uses a single application form[^57] for all pharmacy types.

      i. Supplemental forms are needed for **differential hours**[^58] or **utilization of ancillary personnel**[^59].

      ii. Any change of ownership or location must be communicated to the Board immediately (RCW 18.64.043(2)). This includes relocating the pharmacy within the same building or facility.

      iii. Applications must be submitted 30 days prior to a regularly scheduled Board of Pharmacy meeting. (WAC 246-869-030 (1))

   b. The **Drug Enforcement Administration** now utilizes an online application[^60] procedure to submit DEA Form 224 – Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner.

[^57]: http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/690-152.pdf
[^58]: http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/690-020.pdf
[^59]: http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/690-056.pdf
[^60]: http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Individual pharmacists with prescriptive authority for controlled substances will need to register using DEA Form 224.

3. **General Requirements for Licensed Pharmacies**
   a. **Every operator of a pharmacy must place a pharmacist in charge.** (RCW 18.64.020)
   b. **Each owner of a pharmacy must pay an annual license, file a statement of ownership and location, and promptly notify the Department of any change in ownership or location.** (RCW 18.64.043)
   c. **Records of all prescriptions and dispensing of prescription drugs shall be kept for a minimum of 2 years.** (RCW 18.64.245)
      However, see Chapter 8 for the longer record requirement for Medicaid prescriptions and documentation, which is 6 years.
   d. **Controlled substances records must be maintained for 2 years.** (See also Chapter 5)

4. **Community Pharmacies (Ambulatory Care Pharmacies) – WAC 246-869**
   a. **Responsible pharmacist manager.** It is unlawful to operate a pharmacy without placing a pharmacist in charge (RCW 18.64.020). The Board requires each non-licensed proprietor of a pharmacy to appoint a responsible pharmacist manager (RPM) and to notify the Board of the name of the RPM, and when employment of that RPM has terminated (WAC 246-869-070). **Similarly, each person appointed as an RPM must notify the Board of his or her appointment, and when that appointment is terminated (WAC 246-863-060).** The RPM is responsible for compliance with all laws and regulations governing the practice of pharmacy at the pharmacy.
      i. **Overall authority of RPM.** Every portion of the establishment coming under the jurisdiction of the pharmacy laws shall be under the full and complete control of such responsible manager. (WAC 246-869-070)
         1. The Board has interpreted this rule to hold the RPM of a pharmacy responsible for problems with the labeling of OTC drugs stocked elsewhere in the pharmacy.
      ii. **Authority for ancillary personnel.** The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel. The responsible pharmacist manager shall determine the extent to which personnel may be utilized to assist the pharmacist and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities. (WAC 246-863-095).
iii. A pharmacist may be RPM for more than one location. The Board has indicated that one pharmacist may accept appointment as the RPM for more than one pharmacy location.\(^{61}\)

b. Responsibilities of pharmacies to fill all lawful prescriptions. In response to controversy concerning the refusal by some pharmacists to dispense certain drugs (e.g., emergency contraception) as a matter of moral objection, the Board adopted new requirements for pharmacies. In general, it requires all licensed pharmacies to deliver all lawfully-prescribed drugs to patients in a timely manner, while permitting pharmacies to attempt to accommodate the religious or moral beliefs of individual employee pharmacists. A pharmacy may not choose to omit particular products from its stock based on factors such as the religious objection of the pharmacy owner. This rule became effective on July 26, 2007 (WAC 246-869-010).

i. Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies (e.g., Plan B®);
   1. or provide a therapeutically equivalent drug or device in a timely manner;
   2. consistent with reasonable expectations for filling the prescription. (WAC 246-869-010(1))
      • Note the use of the term “deliver,” as opposed to “dispense.” Pharmacies do not “dispense” drugs, because to “dispense” is part of the practice of pharmacy, which only pharmacists can do. Firms, however, are licensed to distribute or deliver drugs.

ii. Exceptions to the “timely manner rule” include the following:
   1. Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or prescriptions requiring action in accordance with WAC 246-875-040 (the Drug Use Review regulation);
   2. National or state emergencies or guidelines affecting availability or supplies of drugs or devices (e.g., flu vaccine restrictions when the supply is short);
   3. Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine;

4. Potentially fraudulent prescriptions (i.e., taking time to verify a prescription); or
5. Unavailability of drug or device despite good faith compliance with WAC 246-869-150 (the minimum stock requirement – see below).
6. Failure of the patient to pay the pharmacy’s usual and customary or contracted charge.

iii. **Actions needed if the drug is not available** in a timely manner, which will provide the patient with a “timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include but are not limited to:"
   1. Contacting prescriber to address and resolve concerns with the prescription, or to obtain authorization for a therapeutically equivalent alternative;
   2. Return the prescription to the patient if requested;
   3. Transmit the information to another pharmacy of the patient’s choice if requested.
      - Note: this rule prohibits the pharmacy from transferring the prescription to another pharmacy unless the patient requests.

iv. **Engaging in or permitting the following actions will subject the pharmacy to discipline:**
   1. Destroy an unfilled lawful prescription;
   2. Refuse to return unfilled lawful prescriptions;
   3. Violate a patient’s privacy;
   4. Discriminate against patients or their agent in a manner prohibited by state or federal law; (WAC 246-863-095 (4)(d)) or
   5. Intimidate or harass a patient.

v. **Prohibition of the “transfer option” enjoined by the US District Court**
   1. A group of plaintiffs, including pharmacists who object to dispensing Plan B® for religious reasons, sued the Department of Health and Board of Pharmacy in federal court on the basis that the rule constitutes an infringement of free exercise of religion, in conflict with the First Amendment to the US Constitution.
   2. On November 8, 2007, US District Court Judge Ronald Leighton concluded that “On the issue of Free Exercise of Religion alone, the evidence before the Court convinces it that plaintiffs, individual pharmacists, have demonstrated both a likelihood of

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62 [http://www.usconstitution.net/xconst_Am1.html](http://www.usconstitution.net/xconst_Am1.html)
success on the merits and the possibility of irreparable injury. The Court cannot afford protection to individual pharmacists without including pharmacies within the ambit of the injunctive relief to be afforded,” and granted a preliminary injunction preventing the Department or Board “from enforcing WAC 246-863-095 (4)(d) and WAC 246-869-010 (4)(d) (the anti-discrimination provisions) against any pharmacy which, or pharmacist who, refuses to dispense Plan B but instead immediately refers the patient either to the nearest source of Plan B or to a nearby source for Plan B.”⁶³ (emphasis added)

vi. **Injunction Vacated by US Court of Appeals.** The State appealed this injunction to the 9th Circuit Court of Appeals. In July, 2009, the 9th Circuit vacated the injunction, holding that the plaintiffs failed to show a likelihood of success on the merits of the case at trial. In an opinion issued in October, 2009, the Court concluded that the new rules were religiously neutral and do not target practices because of religious motivation.⁶⁴ The State and the plaintiffs had previously stipulated, however, that until the trial was completed, the Department would not enforce the rule against the plaintiffs, nor would it enforce the rule against other pharmacies without a prior discussion with the Judge, regardless of the 9th Circuit’s decision.⁶⁵

1. Until further resolution occurs, all of the requirements of WAC 246-863-095 and WAC 246-869-010 remain in place and are enforceable by the Board, subject to the stipulations stated above.

2. As of January 4, 2010, the trial has not occurred and is apparently waiting rescheduling.

c. **Differential hours.** Community pharmacies in chain stores or other settings may operate with different hours than the main establishment, subject to the following requirements. (WAC 246-869-020)

i. The pharmacy must be separately secured from the rest of the establishment.

ii. All equipment, records, drugs, devices, poisons or other products that are restricted to sale by a pharmacist must be kept in the pharmacy area.

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iii. If written prescriptions are to be dropped off during non-
pharmacy hours, there must be a secure “drop box” or “mail
slot” that allows the prescription to be put into the secured
pharmacy area.
iv. No prescriptions can be dispensed or released unless the
pharmacist is present.
v. No restricted products can be sold unless the pharmacist is
present.
vi. The pharmacy must have a distinct telephone number that is
not answered by the main establishment when the pharmacy
is closed. However, if all phone calls are recorded for
playback to the pharmacist, the phone may be answered
elsewhere in the establishment when the pharmacy is
closed.
vii. Oral prescriptions may be taken on a recording device when
the pharmacist is not present, but the device must announce
the hours of the pharmacy.
viii. Pharmacy operating hours must be permanently displayed
on or adjacent to the entrance to the pharmacy. If the
pharmacy is in a larger establishment, the hours must be
posted at the pharmacy and on or adjacent to the entrance
to the larger establishment.
ix. If the larger establishment advertises the presence of the
pharmacy, or refers to products that may only be sold in a
pharmacy, the advertisement must list the operating hours of
the pharmacy.
x. A 30-day notice is required before adopting differential hours
to allow for a Board inspection.
d. **Compliance with building and fire codes.** New pharmacies
located in new or remodeled buildings must provide evidence of
being built or remodeled in accordance with local building and fire
codes. (WAC 246-868-040)
e. **Physical standards for pharmacies.**
i. **Adequate stock.** (WAC 246-869-150) “The pharmacy must
maintain at all times a representative assortment of drugs in
order to meet the pharmaceutical needs of its patients.”
Although the Board does not specify any particular products,
it is proposing a rule that emphasizes the pharmacy’s
obligation to deliver all legally-prescribed drugs to patients in
a timely manner (see discussion above; also see Poison
Control, below).
   1. No outdated drugs may be in the regular stock.
   2. Stock must be free from contamination, deterioration,
and adulteration.
   3. Stock must be properly labeled.
4. Devices not approved as fit for an ultimate consumer by the FDA may not be stocked.
5. The regulation incorporates USP standards for storage of drugs in a pharmacy, and requires that storage conditions meet USP standards.

ii. **Adequate facilities** (WAC 246-869-160)
   1. Lighting must be adequate, with 30 to 50 foot-candles of illumination
   2. Adequate ventilation with constant air flow
   3. A minimum of three linear feet of bench space (18 inch minimum depth) for each pharmacist or intern who will be working at a given time.
   4. Prescription counter must be maintained in a clean and uncluttered state.
   5. Sink with hot and cold running water.
   6. A refrigerator with a thermometer in the compounding area. Must be maintained between 2 °C and 8 °C (36 °F and 46 °F) as required by USP standards. The Board investigators usually require that food not be kept in this refrigerator.
   7. Pharmacy situated so that public does not have free access.

iii. **Sanitary conditions.** (WAC 246-869-170)
   1. Walls, ceiling in good repair, no peeling or cracked paint, etc.
   2. Adequate trash receptacles.
   3. A restroom, if provided, must have hot and cold water, soap and towels, and the toilet kept clean and sanitary.
   4. All equipment must be clean and in good repair.
   5. Professional personnel and staff working at the pharmacy shall keep themselves and their apparel neat and clean.

iv. **Adequate equipment.** (WAC 246-869-180) The Board has avoided specific equipment lists for many years, but requires that the pharmacy have the equipment needed to compound the type of prescriptions dispensed therein. In this regard, Washington differs from most other states.
   1. Specific **reference books** are required.
      a. One up-to-date copy of Washington statutes and rules governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances and medicines. Electronic or on-line versions are acceptable. (WAC 246-869-180(2))
i. The Board of Pharmacy is no longer distributing a printed version of the law book, and amended the former requirements for a bound lawbook in November, 2008. A CD-ROM version may be requested from the Board, or internet-based access to the laws is allowed.

b. Other references needed for pharmacists to furnish patients and practitioners with information concerning drugs. Most other states specify particular references or types, such as a drug interactions text, the USP-DI, etc.

v. Poison control. (WAC 246-869-200)
1. Pharmacies must have the **telephone number** of the nearest poison control center readily available. The Washington Poison Center web page: [http://www.wapc.org/](http://www.wapc.org/)
2. The **national poison center number** is **1-800-222-1222**.
   a. In Washington, this is the only number to call for immediate poison information, and it automatically connects with the Washington Poison Center.
   b. TDD services for deaf persons are available at the following number: 1-800-572-0638
3. Each pharmacy shall maintain at least one ounce bottle of **Ipecac syrup** in stock at all times. (Technically, the pharmacy must maintain 2, so that one can be sold!)
   a. In 2004, members of the WSU PharmD class of 2005 petitioned the Board to eliminate this requirement, based on current literature which recommends against use of Ipecac in childhood poisoning and on reports of abuse of Ipecac by patients with eating disorders. The Board declined to change the rule after hearing testimony in opposition to the change from the director of the Washington Poison Center.

vi. Board of Pharmacy inspections of pharmacies. (WAC 246-869-190) Investigators inspect pharmacies on a routine basis, and when a complaint has been filed with the Board. The Inspection Certificate must be “conspicuously displayed” to the public, regardless of the score on the inspection. The
following rating scale is used in Washington for all pharmacies, regardless of setting:

1. **“Class A”** – for scores of 90 to 100.
2. **“Conditional”** – for scores of 80 to 89.
   a. Pharmacies receiving a “Conditional” rating have 60 days to improve to a Class A rating, or be subject to discipline.
3. **“Unsatisfactory”** – for scores below 80.
   a. Pharmacies receiving an “Unsatisfactory” rating have 14 days to improve to a Class A rating, or be subject to discipline.
   b. Any deduction of 5 points or more for violations relating to pharmacy ancillary personnel (RCW 18.64A or WAC 246-901) results in an automatic “Unsatisfactory” rating.
   c. Any pharmacy receiving an “Unsatisfactory” rating that is due to a situation creating a “clear and present danger” to public safety, health, or welfare may be subject to summary suspension of the pharmacy’s license.
4. **Self-inspection.** Pharmacies may prepare for inspections by following self-inspection procedures, and completing an inspection report; both are available on the Board’s web site.
   a. It is highly recommended that pharmacy students seek an opportunity to complete one of these self-inspections during one or more clinical rotations.
5. The Board periodically publishes its findings of the most common violations found in inspections.

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67 http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/690-012A.pdf
a. The 5 most common violations in community pharmacies were summarized in the April 2008 Board of Pharmacy newsletter (Article No. 963):68

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<tr>
<th>Rank</th>
<th>Description</th>
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<tr>
<td>1</td>
<td>Failure to maintain minimum information in patient medication record systems</td>
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<tr>
<td>2</td>
<td>Failure to obtain written authorization to use non-child-resistant containers</td>
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<tr>
<td>3</td>
<td>Failure to properly label prescription containers and stock bottles</td>
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<tr>
<td>4</td>
<td>Failure to maintain refrigerator temperatures as required by USP</td>
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<tr>
<td>5</td>
<td>Use of pharmacy assistants and technicians beyond their scope of practice</td>
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6. **FDA inspections of pharmacies.**
   a. The FDCA (21 U.S.C. § 374(a)) allows FDA personnel to “… enter, at reasonable times, any … establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, … and to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such … establishment … and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.”
   b. The Act also allows that “in the case of any … establishment … in which prescription drugs, nonprescription drugs intended for human use … are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) …” (21 U.S.C. § 374(a)(1)). However, pharmacies are

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exempt from this additional level of inspection, which is called the "records provision," when they operate "in conformance with local laws regarding the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices ... and which do not ... manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail ..." (21 U.S.C. § 374(a)(2))

7. Other agency inspections and audits. Pharmacies are also subject to other inspections by government agencies, including local agencies such as the fire department, sanitation department, etc.
   a. The US Department of Health and Human Services is now required to conduct periodic audits of entities covered under HIPAA (see Chapter 6) to assess compliance with rules governing the security and privacy of patients' protected health information.
   b. Pharmacies are subject to audits by third party payors, including the Washington Department of Health and Human Services (for Medicaid), the Department of Labor and Industries, and Medicare Part D plans.

5. Non-Resident Pharmacies (NRPs). Pharmacies in other states that deliver medications to patients in Washington must register with the Board as Non-Resident Pharmacies. The statutory authority of the Board to conduct these registrations is contained in RCW 18.64.350 through RCW 18.64.480.
   a. NRPs must be licensed and regulated by the Board of Pharmacy in their home state or province of Canada*.
   b. A toll-free telephone number must be provided during operating hours so that Washington residents may communicate with the out-of-state pharmacy. This number must be printed on the prescription label. (Note: in-state pharmacies are not required to place their phone number on the prescription label, though almost all do.)
   c. NRPs must maintain patient profiles in compliance with Washington regulations.
   d. NRPs must provide information to patients as required by Washington law.
   e. NRPs must designate an agent in Washington for service of process (the receipt of legal claims, subpoenas, etc.).
f. NRPs must submit information when requested concerning controlled substances shipped to a Washington resident; or submit to an on-site inspection of the pharmacy’s records.

g. The Department may discipline or fine a NRP if the home state Board of Pharmacy or provincial authority* fails to initiate an investigation on a matter referred to that state or province* by Washington within 45 days.

h. **Canadian NRPs included in statute but cannot be licensed due to federal law.** The 2005 Legislature passed legislation to deal with importation of drugs from outside the US, an enacted a scheme to license Canadian pharmacies.
   i. RCW 18.64.350(3) was amended to read, “… all out-of-state pharmacies, including those located in Canada, that provide services to Washington residents shall be licensed by the department of health ...”
   ii. Because the federal Food, Drug and Cosmetic Act (see Chapter 4) preempts state law, a waiver would need to be issued by the FDA to allow this to take place. The Washington request was denied by the FDA on March 17, 2006 (see section on wholesalers, below). (See also chapter 4) Thus, any sections of the rules listed above or below that related to Canada are inoperative and are marked by an asterisk (*).

6. **General issues relating to non-ambulatory care pharmacies.**
   a. **Multiple Regulators.** Several agencies in addition to the Board of Pharmacy regulate non-ambulatory care pharmacies, which are located in institutional settings. Examples are:
      i. The Joint Commission69 (formerly known as JCAHO or “jayco”). Although The Joint Commission does accredit ambulatory care organizations, such accreditation is not currently applied to community pharmacies; however, pharmacies in certain kinds of ambulatory clinics may be involved in a Joint Commission accreditation.
      ii. The Board of Health
      iii. Medicaid (DSHS in WA)
      iv. Medicare
   b. **Types of facilities.** The state defines a wide variety of health care and medical facilities, not all of which have pharmacies, but most of which store, use, or administer drugs and devices.
      i. Health care facilities defined in RCW 70.38.025(6) include: hospices, hospice care centers, hospitals, psychiatric hospitals, nursing homes, kidney disease treatment centers, ambulatory surgical facilities, and home health agencies.
      ii. RCW 70.40.020 further defines the following:

69 http://www.jointcommission.org
1. **"Hospital"** includes public health centers and general, tuberculosis, mental, chronic disease, and other types of hospitals, and related facilities, such as laboratories, outpatient departments, nurses' home and training facilities, and central service facilities operated in connection with hospitals;

2. **"Public health center"** means a publicly owned facility for the provision of public health services, including related facilities such as laboratories, clinics, and administrative offices operated in connection with public health centers;

3. **"Medical facilities"** means diagnostic or diagnostic and treatment centers, rehabilitation facilities and nursing homes as those terms are defined in [Title VI of the Federal Public Health Service Act].

c. The regulatory scheme for institutional pharmacies differs in important ways from that applied to community pharmacies.
   
i. It is more likely to be policy driven. Institutional pharmacies establish policy and procedure manuals that govern their activities. Increasingly, however, the Board is trying to use a policy-based approach more often in community pharmacies as well, such as the Ancillary Personnel Utilization Plan requirement.
   
ii. The scheme relies on institutional checks and balances, counting on nurses and physicians, for example, to be active participants with the pharmacist in assuring the quality of the drug use process, and in setting policy regarding drug use in the institution.
   
iii. The institution often follows a medical staff model, in which the physicians who have admitting privileges in the institution participate in governing health care services.
      
      1. Hospitals have a physician who is Chief of Staff.
      2. Nursing homes have a physician who is Medical Director.
   
iv. An institutional committee is responsible for setting drug use policy. In hospitals, this is usually called the Pharmacy & Therapeutics Committee; in nursing homes it is the Pharmaceutical Services Committee. The pharmacist is often the secretary of this committee.
   
v. There are key differences in labeling requirements, distribution systems, and methods for accounting for and disposing of controlled substances.

7. **Hospitals. (WAC 246-863)**
   
a. **Director of Pharmacy.** Each hospital pharmacy must have a Director of Pharmacy, who is "qualified by education, training, and
experience." The hospital must define this position and its responsibilities in hospital policy. The rules allow small hospitals to contract with a part-time pharmacist to serve as director. (WAC 246-863-040)

i. There must be sufficient supportive personnel to assist the director.

ii. The director, or his or her pharmacist designee, must manage all the activities of the hospital pharmacy. Each decentralized unit of a hospital pharmacy must have a pharmacist supervisor.

b. **Pharmacy services must be provided on a 24-hour basis.** This requires either full-time pharmacy staffing or the availability of on-call pharmacists in accordance with a policy to provide for services.

i. If, under the policy, a pharmacist is not present after hours, a nurse may enter the pharmacy to obtain a needed drug. The nurse entitled to enter the pharmacy must be designated by the pharmacy and the hospital, and only one such nurse may be designated for a given shift. (WAC 246-873-050)

1. Written policy and procedures must be in place to guide the designated nurse.

2. The stock container from which the nurse drew the drug must be left along with the drug order for inspection by the pharmacist.

3. Only enough drug to sustain the patient until the pharmacy opens may be removed by the nurse.

c. **Important Definitions Related to Hospital Pharmacy** (WAC 246-863-010). The Board has defined several terms in ways that are consistent with hospital practice and need. Among those that are important for pharmacists to learn are the following:

i. "Authenticated" or "authentication" means authorization of a written entry in a record by means of a signature which shall include, minimally, first initial, last name, and title.

ii. "Drug administration" means an act in which a single dose of a prescribed drug or biological is given to a patient by an authorized person in accordance with all laws and regulations governing such acts. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container) reviewing it with a verified transcription, a direct copy, or the original medical practitioner's orders, giving the individual dose to the proper patient, and properly recording the time and dose given.

iii. "Protocol" means a written set of guidelines

iv. "Self-administration of drugs" means that a patient administers or takes his/her own drugs from properly labeled containers: Provided, that the facility maintains the
responsibility for seeing that the drugs are used correctly and that the patient is responding appropriately.

d. **Emergency Outpatient Medications.** The pharmacy and the hospital shall set policy and procedures to allow for the emergency outpatient dispensing of drugs when pharmacy services are not available in the community. (WAC 246-873-060) This plan uses a set of medications that have been prepackaged by the pharmacy department, and labeled in accordance with WAC 246-873-060(2). Up to a 24-hour supply may be dispensed (see rule for exceptions). The prepackaged drugs are stored in or near the emergency room.

   i. The nurse then fills in the patient name, number, directions, date, name of prescriber, and nurse’s initials prior to providing the drug to the patient.

   ii. The original order is retained for verification by the pharmacist, and must have at the time the drug is given to the patient the name and address of the patient, the date of issuance, the quantity issued, and the initials of the nurse.

   iii. This process may not be used for controlled substances, except in a group of designated rural hospitals in the Washington cities of Chelan, Chewelah, Colfax, Davenport, Dayton, Ilwaco, Newport, Port Townsend, Ritzville, and South Bend. (WAC 246-873-060(7))

e. **General standards** for physical requirements, access, drug storage, and flammable storage are specified in WAC 246-873-070. They include:

   i. Adequate space and related facilities:

      1. Appropriate transportation and communications facilities for drug distribution throughout the hospital.

      2. Space and equipment for secure, environmentally controlled storage of drugs and pharmaceutical supplies.

      3. Space for management and clinical functions.

      4. Space and equipment for the preparation of parenteral admixtures, radiopharmaceuticals, and other sterile compounding and packaging.

   ii. Controls to prevent unauthorized access to pharmacy department areas.

   iii. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. The Board, in coordination with other DOH divisions, has amplified these regulations with a position statement on “Medication Security in Hospitals.”[^70]

1. Adherence to proper storage policies and practices is a joint responsibility of the Director of Pharmacy and the Director of Nursing.
2. Locked storage units or locked medication carts must be provided on each nursing unit.
   iv. Policies and procedures for storage and disposal of flammable materials must be in place and in accordance with applicable local and state fire regulations.

f. The regulations set forth **required activities, and recommended activities** of the hospital pharmacy relating to drugs distribution and control. (WAC 246-873-080)
   i. **Musts**
      1. Control of all drugs throughout the hospital
      2. Monthly inspections of all areas where drugs are stored or used
      3. Monitoring of drug therapy (see again the definition in WAC 246-863-110, discussed in Chapter 2).
      4. Provision of drug information to patients, physicians, and others
      5. Surveillance and reporting of adverse drug reactions and drug defects.
   
   ii. **Shoulds**
      1. Obtaining and recording drug use histories and participation in discharge planning
      2. Preparation of all sterile products, except in emergencies
      3. Distribution and control of radiopharmaceuticals
      4. Administration of drugs
      5. Prescribing

   g. **Updated Policy and Procedures Manual.** The director must develop (in collaboration with the medical staff, nursing service, and the hospital) policy and procedures for the pharmacy, and must annually update these policies and procedures. As noted in the section on Board inspections of hospitals (below), failure to maintain updated manuals is one of the most common faults found in hospital pharmacy inspections.

   h. **Labeling requirements** differ for inpatient and outpatient drugs (see also Chapter 4).
      i. **Inpatient medications** must show the
         1. drug name,
         2. strength,
         3. expiration dates as appropriate,
         4. and additional cautionary labeling.
      
      ii. **Outpatient medications** must be labeled in accordance with outpatient pharmacy requirements specified in RCW 18.64.246.
iii. **Parenteral medications** must be labeled with
   1. Name and location of the patient
   2. Name and amounts of drugs added
   3. Appropriate dating
   4. Initials of the personnel who prepared and checked the solution

i. **Pharmacist review of orders.** Except in emergencies, no medication may be distributed unless the pharmacist has reviewed the original order or a direct copy of the order. (WAC 246-873-080 (6))

j. **Administration of drugs.** (WAC 246-873-090)
   i. Drugs may only be administered subject to an order from a licensed practitioner who has been granted clinical privileges in the hospital.
      1. This is a characteristic of institutional practice; before a practitioner can admit patients or issue orders, that person must be admitted to the medical staff with privileges to issue orders. This is typically the responsibility of the medical staff credentials committee.
      2. Pharmacists in hospitals with prescriptive authority must also be granted clinical privileges.
   ii. Verbal orders. Verbal orders for drugs shall only be issued in emergency or unusual circumstances and shall be accepted only by a licensed nurse, pharmacist, or physician, and shall be immediately recorded and signed by the person receiving the order. Such orders shall be authenticated by the prescribing practitioner within 48 hours.
      1. The Board of Pharmacy has traditionally interpreted this regulation to require that every order be countersigned by the prescriber within 48 hours. However, other divisions of the Department of Health (see WAC 246-330-345(5)(h)), as well as JCAHO, have allowed institutions latitude in developing policy on how authentication of orders should be accomplished.
      2. In response, in 2003 the Board issued an “interpretive guideline”\(^71\) to allow for “Passive Authentication” of certain verbal orders. Under these policies, certain orders require a countersign by the prescriber, but others can be authenticated by review and monitoring of other health professionals, including nursing specialists and pharmacists. Key elements of the guideline include:

\(^{71}\)http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/Authentication_Of_VerbalOrdersInHospitals.pdf
a. Policies and procedures must be readily available to Department of Health investigators, and must be approved by administration, medical, pharmacy, and nursing services.

b. Verbal orders must be immediately transcribed onto an order form and then read back (i.e., confirmed) by the prescriber.

c. Drugs or devices that are excluded from the policy must be listed (e.g., chemotherapy, investigational drugs)

d. Safeguards must be described, such as centralized pharmacy services or automated order entry checks

e. A specific quality improvement process must be in place to assess passively authenticated orders, identify problems, recommend changes, and assess results of improvements.

iii. Drugs may only be administered by professionals licensed to do so, and in accordance with hospital policy and procedure.

iv. Written procedures and policies must be developed for dealing with drugs brought into the hospital by or for patients. (Note: many hospitals do not allow patients’ drugs to be used.)

1. Such drugs may only be administered if properly ordered. Prior to use, a pharmacist must examine the drugs to identify them and assure they meet quality standards of the hospital pharmacy.

2. Such drugs, if stored in the hospital and not used during the patient stay, must be packaged and sealed and returned to the patient at discharge or given to the patient’s family upon discharge.

3. The hospital may develop policies to not return such drugs if it would be dangerous to the patient.

4. Policies must be developed for destruction of non-used, non-returned patient medication.

v. Self-administration of medications (SAM) may only be done in accordance with approved protocols and a formal policy and a program of self-care or rehabilitation. The policy developed by the Director of Pharmacy must be approved by the administration and by medical and nursing staff units.

Note: SAM protocols are not the same as protocols for using Patient Controlled Analgesia (PCA).

k. Records of drugs administered to patients. All medications administered to inpatients shall be recorded in the patient’s medical record. (WAC 246-873-080 (9))
l. A perpetual inventory of Schedule II drugs must be maintained, with policies established regarding the control, storage, and distribution of other controlled substances. Specific requirements are discussed later in Chapter 5.

m. Mechanical Devices. The WAC currently contains two regulations that deal with the use of automated drug dispensing devices in hospitals: Mechanical Devices in Hospitals (WAC 246-869-120), adopted in 1992, and Automated Drug Distribution Devices (WAC 246-872), adopted in 2006. The first regulation applies to hospitals only, whereas the newer regulation includes health care facilities and clinics. The newer regulation is discussed in more detail below (see section 8). It appears that hospitals may follow either set of rules. The Mechanical Devices in Hospitals rules are summarized as follows:

i. Devices authorized under these rules are to be used in hospitals only.

ii. All drugs shall be prepared by or under the supervision of a pharmacist in the employ of the hospital, from hospital stock.

iii. Devices may be stocked only by a registered pharmacist in the employ of the hospital.

iv. The pharmacist shall be responsible for the inventory and stocking of the device, and shall be the only person with access to the storage area of the device.

v. Drugs must be properly labeled.

vi. Upon removal of a drug from the device, the device shall automatically make a written record recording the drug removed, the name of the patient, and the identity of the nurse removing the drug.

vii. Only prescribers, nurses, or pharmacists may remove drugs from the device.

viii. May only be used for inpatient or emergency room dispensing.

ix. Prior approval must be obtained from the Board for the use of the device.

x. Any malfunction of the device shall cause the use of the device to be immediately discontinued until remedied.

Comment: This regulation is a vestige of earlier times and technology, and should probably be repealed now that the newer regulation has been adopted. It is unlikely that many institutions are basing their practice on this regulation. For example, most hospitals use technicians to stock dispensing machines, a practice only allowed under the newer rules. Older devices that might meet this rule would not meet the requirements of the newer rule.
n. **Handling of recalls, reporting of ADRs, and reporting of errors,** shall be according to a policy established by the Director of Pharmacy.
   i. All adverse drug reactions shall be appropriately recorded in the patient's record and reported to the prescribing practitioner and to the pharmacy. (WAC 246-873-080 (10))
   ii. All drug errors shall upon discovery be recorded in an incident report and reported to the prescribing practitioner and to the pharmacy. (WAC 246-873-080 (11))

o. The pharmacy is responsible for **investigational drugs,** **participation in appropriate hospital committees,** shall establish a quality assurance program, and should develop **clinical programs** such as
   i. Maintenance of drug histories and participating in discharge planning
   ii. Drug information service
   iii. Prescribing
   iv. Administering of drugs.

p. **Hospital Inspection Results.** The Board has recently published the [Top Hospital Inspection Violations](http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/Hospital_Pharmacy_violation.pdf) on its web site. Among the issues the Board has highlighted for hospital pharmacies are the following:

1. Policies and procedures: (1) are they in writing; (2) are they updated/reviewed annually; (3) is there documentation of the annual review; and (4) do they reflect current practice?
2. Patient medication records: (1) do they maintain allergies, idiosyncrasies and chronic conditions in the patient record that may affect drug utilization; and (2) do pharmacists use that information to conduct prospective DUR?
3. Ancillary personnel: does the pharmacy have a board approved utilization plan that reflects current practice procedures?
4. Completed prescription labels: do the labels of containers dispensed by the pharmacy comply with all requirements?
5. DEA Order Forms: (1) are DEA forms 222 filled out completely, including date(s) and quantity of drug(s) received; and (2) is a proper power-of-attorney designation available in the records when applicable?
6. Necessary equipment: is equipment appropriate and in good repair, and are appropriate references available to the pharmacist, including the law book?

72 http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/Hospital_Pharmacy_violation.pdf
7. **Long-term Care Facilities (Extended-care facilities)**

   a. **Types of senior housing**
      i. Independent living
      ii. Assisted living
      iii. Nursing care
      iv. Alzheimer’s care
      v. Continuous Care Retirement Communities (CCRC)

   b. **Considerations in living/care resources**
      i. What is the patient’s overall health?
      ii. Activities of daily living (ADL) – need for assistance
      iii. Desire for community activities (golf, social events, outings)
      iv. Community services
      v. Health services
      vi. Environment (degree of personal freedom)

   c. **Levels of care**
      i. **Basic care**
         1. Personal care
         2. Supervision
         3. Safety
         4. Can be provided by aide or family caregiver
      ii. **Skilled care**
         1. Supervised drug therapy
         2. Treatments
         3. Provided by nurses, respiratory therapists, etc.
      iii. **Sub-Acute care**
         1. Comprehensive in-patient care for a patient who is recovering from an illness
         2. Daily review and assessment

   d. Some **nomenclature** for nursing homes and other care facilities
      i. General descriptors
         1. ECF’s – extended care facilities
         2. LTCFs – long-term care facilities
      ii. Independent living
         1. Congregate care facilities
         2. Retirement communities
         3. Senior apartments
         4. Provide meals and activities
         5. Some pharmacies provide special services to these communities, such as bingo cards, but they follow all community pharmacy rules.
      iii. Assisted living
         1. Adult family homes
         2. Board and care facilities
         3. Residential care facilities
         4. Adult living facilities
5. Adult foster care
6. Adult habitation centers (WA)
7. Nurses may provide medication assistance.
   a. “Med-pack’ containers are prepared under immediate supervision of a pharmacist for a specific patient comprising a series of containers and containing one or more prescribed solid oral dosage forms including multifill blister packs” (bingo cards) (WAC 246-869-235(4))
   b. The Board allows pharmacies to provide “customized patient medication packages” by use of med-pack containers. (WAC 246-869-255)
      i. Original bulk bottle must stay in pharmacy
      ii. No more than a 31-day supply
      iii. Patient or agent requests non-child resistant container
      iv. Label must contain
         1. Pharmacy name and address
         2. Patient’s name
         3. Drug name, strength, and quantity
         4. Directions
         5. Serial prescription number, date
         6. Prescriber’s name, pharmacist’s initials
    iv. SNF’s – skilled nursing facilities. These are often also known as extended care facilities.
e. Extended-care facilities (WAC 246-865)
   i. Must have provision of timely delivery of drugs and biologicals to provide care for patients (WAC 246-865-060)
      1. Facility may operate its own licensed pharmacy; or
      2. May have written agreement(s) with one or more licensed pharmacies to provide pharmaceutical consultant services
   ii. Must have a pharmaceutical services committee
      1. Membership
         a. At least one staff or consultant pharmacist
         b. A physician
         c. Director of nursing or designee
         d. Administrator or his/her designee
      2. Develops and maintains written policies and procedures
         a. Safe and effective drug therapy
b. Distribution of drugs
c. Control of drugs
d. Use of drugs
e. Assures P&P are current and followed in practice

iii. **Written reference materials** regarding drugs must be available to staff
   1. Use of medications
   2. Adverse reactions
   3. Toxicology
   4. Poison control center information

iv. Procedures established for **recording and reporting of medication errors and adverse drug reactions**

v. **Staff pharmacist or consultant pharmacist** shall be responsible for
   1. Provision of pharmaceutical services evaluations and recommendations to the administrative staff
   2. On-site reviews to ensure that drug handling and utilization are carried out in conformance with recognized standards of practice
   3. Regularly reviewing each resident's therapy to screen for potential or existing drug therapy problems, and documenting recommendations
   4. Provision of drug information to nursing home staff and physicians as needed
   5. Planning and participating in the nursing home staff development program (“in-service training”)
   6. Consultation with other departments (nursing, housekeeping, etc)

vi. **Drug storage and security**
   1. Proper sanitation, humidity, temperature, etc.
   2. Locked cabinets, rooms, or carts, accessible only to personnel licensed to administer or dispense drugs.
   3. Schedule III drugs must be stored separately from other legend drugs, but may be stored with Schedule II drugs.
   4. External use drugs stored separately from internal use drugs
   5. Keys to drug storage areas must be carried by on duty personnel who are licensed to administer drugs
   6. May use supplemental dose kit or emergency drug kit

vii. **Labeling** (WAC 246-865-060(4))
   1. “**Traditional system**” – not unit dose
      a. Labeled as if it were an outpatient prescription, except:
         i. Directions for use need not be on label
ii. Controlled substances classification must be on label

iii. If compounded drug with controlled substances, the concentration/quantity of controlled substances must be shown.

iv. Bingo cards and modified unit dose must adhere to this rule.

2. Unit dose
   a. Require individual storage compartment for each patient clearly labeled with patient name
   b. Each individual package must contain name of drug, strength, lot number, controlled substance schedule, and expiration date

3. Non-prescription drugs
   a. Date of receipt by facility
   b. Patient’s name
   c. Manufacturer’s or pharmacy label
   d. Doesn’t apply to selected bulk drugs used by the facility

4. No label changes may be made by the facility; must be made by pharmacist.

viii. Drug control and accountability. (WAC 246-865-060(5))
   1. Written procedures must be followed for control and accountability of all drugs in the facility
   2. No drugs may be returned to the pharmacy except if in qualifying unit dose packaging
   3. No drugs released to resident on discharge unless ordered by prescriber. A receipt as specified in the regulation must be entered into the health care record
   4. Discontinued drugs (including CSA III, IV, and V) must be destroyed by a licensed nurse employee in the presence of a witness within 90 days, with accurate records maintained. Sealed unit dose packages may be returned to pharmacy for credit.
   5. Discontinued schedule II drugs be destroyed within 30 days by one of the following methods:
      a. By two of the following individuals: licensed pharmacist, director of nursing or RN designee, registered nurse employee of the facility;
      b. Destroyed at the nursing home by a Board of Pharmacy investigator if so requested.
      c. By another system if unit dose drugs are involved and specified conditions are met. (See WAC 246-865-060 (6)(g))
ix. **Emergency kits** (WAC 246-865-030)
   1. Used for emergencies in which drug therapy must be started immediately. Does not apply to routine drugs for newly admitted patients.
   2. Content list determined by pharmaceutical services committee, which is responsible for ensuring proper storage, security, and accountability
   3. Copy of contents on outside of kit
   4. Record keeping by nursing home and the supplying pharmacy
   5. Must be locked or stored in a locked area
   6. Accessible only to licensed nurses
   7. The emergency kit is considered a physical extension of the supplying pharmacy and remains owned by the supplying pharmacy (WAC 246-865-020)

x. **Supplemental dose kit.** (WAC 246-865-040)
   1. Used only in nursing homes using unit-dose drug dispensing systems.
   2. May be used for non-emergency supplemental doses.
   3. Pharmaceutical services committee determines the contents.
   4. Remains the property of the supplying pharmacy
   5. Pharmacy and PSC responsible for proper storage, security and accountability.

xi. **Continuity of drug therapy** (WAC 246-865-070)
   1. Allows for “pass meds” when a resident takes a short-term leave; not available for planned leaves that allow time for a pharmacist to prepare therapy.
   2. Nurses may prepare a 72-hour supply in accordance with protocols developed by PSC.

xii. **Federal law** regulates long-term care institutions to the extent that they provide services to Medicare or Medicaid patients. Significant involvement of pharmacists in the care of federally-funded patients in nursing homes was required by certain provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA-87). Key elements include:
   1. Development of a comprehensive care plan for each resident, which may include appropriate self-medication. (42 CFR 483.10(n))
   2. Each resident’s drug therapy must be free from unnecessary drugs: this requirement is designed to reduce excessive doses or duplicative therapy; excessive duration of therapy; inadequate monitoring; inadequate indications for use of drugs; and use of drugs in presence of adverse consequences that
suggest the dose should be reduced or the drug discontinued. (42 CFR 483.25(l)(1))

3. Special attention is given to **limit the use of psychotropic agents in residents**, and to require specific documented reasons for using psychotropic agents. Comprehensive reviews and continual efforts must be made to reduce the use of psychotropic agents in each patient receiving them. (42 CFR 483.25(l)(2)) These comprehensive reviews by a patient care team, including the pharmacist, are typically conducted every 90 days.

4. **Pharmaceutical services** must be provided or arranged for by the facility. (42 CFR 483.60)

5. **The facility must employ or obtain the services of a consultant pharmacist.** (42 CFR 483.60(b))

6. **Each resident’s drug regimen must be reviewed every 30 days by a pharmacist.** (42 CFR 483.60(d))

8. **Pharmacies in Correctional Facilities**
   a. Prisoners have a constitutional right to health care equivalent to non-jailed populations.73
      i. The 8th Amendment prohibits cruel and unusual punishment.
      ii. “Deliberate indifference to serious medical needs” contravenes the 8th Amendment.
      iii. Prisoners have 3 basic rights related to medical care74
         1. Access to care. All correctional facilities must provide for emergency care, “sick call,” and access to specialists and inpatient hospital treatment, when warranted by the inmate’s condition.
         2. Ordered care. When a health care professional has ordered care for a prisoner, jail authorities must provide that care and not interfere with it. The care must be provided in a timely manner.
         3. Professional judgment. The professional judgment of health care providers treating prisoners are given significant deference by the courts. However, prisoners have a right to demand that decisions are based on sound medical judgment.
   b. Correctional facility types.
      i. Prisons – facilities that house convicted felons, whose sentences generally exceed 1 year, and which may be operated by the federal government or states

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ii. Jails – facilities that house individuals awaiting trial or those convicted of misdemeanors with sentences less than one year. Most commonly operated at the county level. There are upwards of 1,600 jails nationwide.
   1. Federal detention centers house individuals awaiting federal trial
   2. Cities have small facilities, often called “lock-ups” which may hold persons for up to 72 business hours or 5 days while awaiting appearance before a judge
iii. Half-way houses and residential re-entry centers house individuals who have been released on parole for a period of time determined by the parole board
iv. Juvenile detention centers house minors who have been sentenced to incarceration

c. Key medical care issues in inmate populations
   i. Mental health issues afflict a large portion of jail inmates
   ii. A large proportion of prison inmates are infected with Hepatitis C
   iii. The jail population of long-term inmates is aging and thus have chronic conditions associated with this aging
   iv. Inmates (other than in re-entry centers) are not allowed to self-administer care, but may only receive medications by order of the medical staff.
   v. Medicaid and Medicare do not currently cover otherwise eligible individuals who are in jail.

d. Pharmacy services vary widely.
   i. Most jails do not have full-time pharmacies. Many jails contract with local pharmacies and drugs are often supplied in modified unit dose as they would be for assisted living centers. A growing number of jails contract with national firms that specialize in correctional health.
   ii. Most prisons and many larger county jails have full-time pharmacists. Health services – including pharmacy services – in federal prisons are provided by pharmacists in the U.S. Public Health Service.

e. Washington requirements for medication use in jails. The Washington Board of Pharmacy currently applies community-pharmacy rules to its inspection of pharmacies in jails. When the Board attempted to promulgate rules governing medication use in jails without pharmacies, the Department of Corrections and jail administrators objected. The Legislature addressed medication management in correctional facilities with revised legislation (SSB 5252) in July, 2009. Its major sections established:
   i. A Jail Medication Management Work Group, if funded, shall be developed by the Washington Association of Sheriffs and

75 2009 c 411
Police Chiefs (WASPC) to establish a model policy by December 31, 2009 regarding the management of medication in jails that do not have an on-site pharmacy or own or operate, in whole or in part, a pharmacy. The work group must include members of the WSPA, the Board of Pharmacy, and members of the nursing community. It shall consider the policies of the National Commission on Correctional Health Care and the American Jail Association. **This portion of the bill was not funded by the Legislature.**

ii. Excludes from Board of Pharmacy regulation any jail that does not operate, in whole, or in part, a pharmacy, but does allow the Board to regulate a pharmacist who has entered into an agreement with a jail for provision of pharmaceutical services. (RCW 18.64.510)

iii. New definitions related to medication administration in jails by jail staff who are not physicians, nurses, pharmacists or other practitioners: (RCW 70.48.020)

1. Nonpractitioner jail personnel (NJP) – appropriately trained jail staff who may manage, deliver, or administer medications
2. Medication assistance – assistance rendered by NJPs to an inmate to facilitate the individual’s self administration of medications
3. Administration (within a jail) – direct application of a drug by ingestion or inhalation, to the body of an inmate by a practitioner or NJPs.

iv. That jails may provide for delivery and administration of medications and medication assistance for inmates in their custody by NJPs, subject to the following actions by the jail administrator (JA) or chief law enforcement executive (CLEE): (RCW 70.48.490)

1. JA, CLEE, or designee shall enter into an agreement between the jail and a licensed pharmacist, pharmacy or other facility to ensure access to pharmaceutical services on a 24-hour basis, including consulting and dispensing services.
2. JA or CLEE shall develop policies addressing the designation and training of JNPs, and other specific issues addressed in statute. Training of JNPs in proper medication procedures must be performed by a designated physician, RN, or ARNP.
3. JA or CLEE shall consult with one or more licensed pharmacists and one or more licensed physicians or nurses in the course of developing the policies.
4. Provision of medications by a practitioner or JNP to an inmate requires a prescription or order (in the case of OTC drugs) for the drug to be administered; if the inmate is a minor, parental or guardian permission to administer medications must be obtained.

5. NJPs may assist in preparation of legend drugs or controlled substances for self-administration. Medication assistance does not include assistance with intravenous or injectable drugs.

6. NJPs may not be inmates.

v. That the DOH shall annually review the medication practices of five jails that utilize JNPs. If the reviewed jail is in noncompliance, the DOH shall provide technical assistance to help the jail resolve noncompliance.


a. Community pharmacies as well as hospital pharmacies are increasingly becoming involved in automated dispensing at sites remote from the pharmacy. In ambulatory settings, these systems include methods for counseling patients using video technology. In hospital and nursing home settings, the systems may involve shared patient record systems between the local and remote site. A current ambulatory care example is provided by a pharmacy in Bellevue, WA, that provides remote services to community health clinics in Royal City, WA and Mattawa, WA. Another consulting pharmacy in Spokane provides review and approves release of drugs from Pyxis dispensing systems in several rural hospitals in Eastern Washington. These systems are being used in hospice facilities, nursing homes, and hospitals. As noted above, these rules may apply equally well to non-remote devices used within a hospital.

b. Washington Board of Pharmacy rules related to automated dispensing are contained in WAC 246-872, which became effective on December 13, 2006. The rules apply to devices used in licensed pharmacies, health care facilities, and medical facilities as defined in state law (see 4.b. above).

i. “Automated drug distribution devices” (ADDD) means automated equipment used for remote storage and distribution of medication for use in patient care. (This would mean that automated dispensing equipment within a pharmacy is not covered by this regulation.)

ii. Approval for use of automated drug distribution devices must be obtained from the Board for each covered facility. Facilities subject to this rule include hospices, hospice care centers, hospitals, psychiatric hospitals, nursing homes,
kidney disease treatment centers, ambulatory surgical facilities, and home health agencies, as well as medical facilities.

iii. Every facility must designate a licensed pharmacist responsible for the oversight of the use of ADDD in the facility. The pharmacist is responsible to:

1. Insure that policies and procedures are in place for safe use of the ADDD.
2. Conduct quarterly audits of compliance with the policies and procedures.
3. Approve the medication inventory to be stocked in the device.
4. Assure that checking and stocking of medication in the device is reserved to a pharmacist, pharmacy intern, or pharmacy technician.
   a. The pharmacy technician must meet the “specialized functions” training and certification requirements in WAC 246-901-035, and documentation of the training must be on file.
   b. The Board may approve electronic bar code checking, or other approved technology, in lieu of manual double-checking of the medications stocked in the device.
   c. Note: The Nursing Care Quality Assurance Commission staff has determined that stocking automated drug dispensing devices is within the scope of practice of a registered nurse.76
5. Ensure security of the medications by:
   a. Limiting access to licensed health personnel operating within their scope of practice;
   b. Using safeguards to prevent unauthorized access, including terminating access when employment ceases;
   c. Monitoring controlled substance usage and taking appropriate action;
   d. Working in cooperation with nursing administration to maintain an ongoing process for monitoring medication discrepancies and resolving problems.
6. Develop and implement an ongoing training process.
7. Participate in ongoing facility ADDD system QA and Performance Improvement program.

76 Minutes, WA Board of Pharmacy, October 25, 2007
(http://www.doh.wa.gov/hsqa/Professions/Pharmacy/Documents/Documents/20071025.pdf)
iv. The facility is responsible for maintaining policies and procedures that address:

1. Equipment type, components, and locations
2. Medication and information access
   a. All removal, returns, and waste must be tracked in detail
   b. Medication records and records of access
   c. Verification that patient information in the system matches facility records
   d. Removal of patient records in the ADDD for discharged patients must be accomplished within 12 hours after discharge
3. Medication management
   a. Proper packaging and labeling

v. Quality Assurance and Performance Improvement program must include

1. Accuracy of medication filling and removal
2. Regular review of controlled substances discrepancies
3. Use of data collected to take action to improve quality and performance
4. Documentation of the outcome of QA activities

c. Remote processing of medication orders is a related activity to remote dispensing, but can also include such activities as pharmacist authorization of refills under protocol. As in other areas, the Board of Pharmacy has issued guidelines concerning remote processing of medication orders to interpret its other regulations. These guidelines allow pharmacies that are not owned by a common entity to enter into agreements for remote processing of orders.
d. Other states are enacting even more extensive rules for remote dispensing: Oregon, for example requires that the Pharmacist In Charge of a remote dispensing operation located outside of Oregon – as well as the pharmacy itself – must be licensed in Oregon (OAR 855-041-0600, “Remote Dispensing”).

10. Parenteral products for non-hospitalized patients (Home IV Therapy) – WAC 246-871

a. Operations subject to developed **policy and procedure manual** (WAC 246-871-020). The manual must be revised on an annual basis. The manual must cover the following topics:
   i. Clinical services
   ii. Parenteral product handling, preparation, dating, storage, and disposal
   iii. Major and minor spills of antineoplastic agents, if applicable
   iv. Disposal of unused supplies and medications
   v. Drug destruction and returns
   vi. Drug dispensing
   vii. Drug labeling and relabeling
   viii. Duties and qualifications for professional and nonprofessional staff
   ix. Equipment
   x. Handling of infectious waste pertaining to drug administration
   xi. Infusion devices and drug delivery systems
   xii. Dispensing of investigational medications
   xiii. Training and orientation of professional and nonprofessional staff
   xiv. Quality assurance
   xv. Recall procedures
   xvi. Infection control
   xvii. Suspected contamination of parenteral products
   xviii. Orientation of employees to sterile technique
   xix. Sanitation
   xx. Security
   xxi. Transportation
   xxii. Absence of a pharmacist

b. **Physical requirements**
   i. Adequate space, light, and restricted entry.
   ii. Capable of containing laminar flow hood
   iii. Class 100 environmental conditions
   iv. Annual certification of Class 100 environment by independent contractor
      1. Incorporates Federal Standard 209B or National Sanitation Foundation standard 49
      2. Reports maintained for 2 years
   v. Prefilters cleaned regularly and replacement date documented
   vi. Sink with hot and cold running water
   vii. Disposal containers for sharps, etc.
   viii. Refrigerator/freezer with thermometer
   ix. Temperature controlled delivery container (if appropriate)
x. Infusion devices, if appropriate
xi. Reference library related to parenteral products (eg, Trissel)
c. **Pharmacist in charge must have been trained** in specialized functions related to parenteral products
   i. Aseptic technique
   ii. Quality assurance
d. **“May use a level-A pharmacy assistant.”** This rule has not been updated since the revision of the Ancillary Personnel rules. This would correspond to a technician. The technician must have been trained in specialized functions similar to those required for hospital IV admixture technicians.
e. **Drug distribution and control.** (WAC 246-871-050)
   i. Prescriptions required. Pharmacist or intern must receive written or verbal order for any parenteral products dispensed.
      1. May be filed within the pharmacy by patient-assigned consecutive numbers.
      2. A new order is required every 12 months or upon any prescription change
      3. Elements of the prescription are the same as required for ambulatory care prescriptions
   ii. Patient profiles are required. Minimum elements required in the patient profile include several items not mandated for community pharmacies. Items required are
      1. Patient full name
      2. Age or date of birth
      3. Weight, if applicable
      4. Sex, if applicable
      5. Parenteral products dispensed
      6. Date dispensed
      7. Drug content and quantity
      8. Patient directions
      9. Prescription number
      10. ID of dispensing pharmacist and ID of technician, if applicable
      11. Other drugs the patient is receiving
      12. Known drug sensitivities and allergies to drugs and foods
      13. Primary diagnosis, chronic conditions
      14. Name of manufacturer and lot numbers of components
         a. If lot numbers not recorded, a policy must be established for return of recalled products
   iii. Required labeling is discussed in chapter 4, and Table 4-8c.
   iv. Timely delivery of parenteral products to the patient’s home must be assured.
1. Environmental controls during delivery must be maintained, and must adhere to USP standards for temperature control.
2. Proper storage facilities must be maintained in patient’s home
3. Chain of custody for controlled substances is documented, and a receipt received
   v. Must assure that patient disposal of infectious wastes does not pose a health hazard
   vi. Must provide nurse administering or starting therapy with authorized emergency kit

f. **Antineoplastic medications.** Protections are required for personnel involved in compounding antineoplastic drugs. (WAC 246-871-060)
   i. Compounding must take place in a vertical laminar flow hood
   ii. Protective apparel is required
   iii. Safety containment techniques must be used
   iv. Disposal of waste must conform to state, local, and federal requirements (i.e., OSHA and WISHA rules)
   v. Written procedures for handling major and minor spills, and provision of spill kits, must be provided
   vi. Prepared doses must be dispensed and shipped in a manner to minimize risk of container rupture
   vii. Documentation must be maintained of employee training related to antineoplastic medications

g. **Clinical services required** (WAC 246-871-070)
   i. Identify authorizing practitioner who is primary provider for the patient
   ii. Medication use review
   iii. Patient monitoring requires access to clinical and laboratory data concerning each patient
   iv. Must document ongoing drug therapy monitoring
      1. Therapeutic duplication
      2. Appropriateness of therapy
      3. Clinical laboratory or clinical monitoring
   v. Patient training must be documented to show that patient or caregiver is capable of handling home parenteral therapy
      1. Pharmacist responsible for training related to compounding, labeling, storage, stability, or incompatibility
      2. Must see that patient’s competence is reassessed regularly
   vi. Must verify that administration of a product the patient has not received before will be handled by a person trained in management of anaphylaxis.
h. **Quality assurance** (WAC 246-871-080)
   i. Documented QA program reviewed annually
   ii. Must include methods to document
      1. Medication errors
      2. ADRs
      3. Patient satisfaction
      4. Product sterility
         a. Documentation that the end product has been tested on a sampling basis for microbial contamination – at least quarterly.
         b. Nonsterile compounding rules require adhering to end product testing approaches identified in Remington.
         c. Written justification for choosing expiration dates.
   i. **USP <797> standards.** Although Washington regulations do not incorporate USP <797> standards, compliance with these standards relating to sterile compounding should be achieved, and may be required as a condition of liability insurance. (See chapter 4)

11. **Nuclear Pharmacies – WAC 246-903**
   a. Permit to operate issued only to **qualified nuclear pharmacist.** (WAC 246-903-020)
      i. All personnel must be under supervision of nuclear pharmacist
      ii. Nuclear pharmacy must be segregated from other pharmacy facilities.
      iii. May waive requirements for permits for handling non-nuclear products if nuclear pharmacy deals exclusively with nuclear pharmaceuticals
   b. **Nuclear pharmacist** is a licensed pharmacist who has submitted evidence to Board that he or she meets requirements of WAC 246-903-030
      i. Meets standards of the state radiation control agency
      ii. Licensed to practice pharmacy in WA
      iii. Submit to Board
         1. Certification of at least 6 months on the job training in a licensed nuclear pharmacy under supervision of a licensed nuclear pharmacist
         2. Completed a nuclear pharmacy training program in an accredited college of pharmacy
         3. Board may grant partial credit to non-college of pharmacy programs
      iv. Has received a letter from the Board that the person is recognized as a nuclear pharmacist
c. Minimum equipment
   i. Must submit detailed equipment list to Board and radiation control agency prior to approval of license application
   ii. May waive requirements for equipment related to compounding of non-radiopharmaceuticals if nuclear pharmacy deals exclusively with radiopharmaceuticals.

12. Closing of a Pharmacy (WAC 246-869-250)
   a. The Board must be notified prior to the closing of any licensed pharmacy, regardless of setting.
      i. The notice must be in writing and must be submitted at least 15 days prior to closure. It shall specify:
         1. The intended date of closing
         2. The names and addresses of persons who shall have custody of the pharmacy's records of: prescriptions, bulk compounding, repackaging, and controlled substances.
         3. The names and addresses of any persons who will acquire any of the legend drugs from the pharmacy, if known at the time.
   b. Within 15 days after closing, the following documents must be provided to the Board of Pharmacy:
      i. The pharmacy license
      ii. A written statement containing the following:
         1. Confirmation that legend drugs were transferred to persons authorized to receive them (along with names and addresses of the transferees), or destroyed
         2. For any transferred controlled substances, a list of drugs, quantities, date transferred, and names and addresses of transferees
         3. Confirmation that the DEA registration and all unused DEA order forms were returned to the DEA
         4. Confirmation that pharmacy labels and blank prescriptions were destroyed
         5. Confirmation that all signs and symbols indicating the presence of the pharmacy have been removed.

13. Shopkeepers and Itinerant Vendors
   a. Grocery stores, convenience stores, and other retailers who wish to be allowed to sell OTC drugs must register through the Master License System as Shopkeepers (RCW 18.64.044), if they are not already licensed as a pharmacy. Door-to-door salespersons who wish to sell OTC drugs must register with the Board as Itinerant Vendors (RCW 18.64.047). The law specifies the following restrictions on these registrants
i. They may **not sell legend drugs or OTC controlled substances.**

ii. OTC drugs may only be sold in the **manufacturer's original package.**

iii. Products containing any detectable amount of **ephedrine, pseudoephedrine, or phenylpropanolamine (EPP)** may only be purchased from a wholesaler or manufacturer licensed by the Board.

   1. If a shopkeeper or itinerant vendor has been found to have sold EPP in a “suspicious transaction” (RCW 69.43.035), then it will be subject to limits on sales of EPP, as follows:
      a. March through October – sales of EPP must be not greater than 10% of total prior monthly sales; or
      b. November through February – sales of EPP must be not greater than 20% of total prior monthly sales.

b. **Proper storage and labeling.** Shopkeepers and Itinerant Vendors must meet the storage, stability, labeling, and other requirements for drugs, and are subject to the misbranding or adulteration provisions of the FDCA and the state Legend Drug Law.

14. **Wholesalers and Manufacturers**

   a. Individuals or firms that distribute drugs at wholesale (wholesalers) or manufacture and distribute drugs (manufacturers) **must be licensed** by the Board (RCW 18.64.046, RCW 18.64.044).

   b. **The Board’s regulations** governing wholesalers are found in WAC 246-879.

      i. The Board defines the following types of wholesalers:
         1. “**Full-line**” – licensed to wholesale legend, OTC, and controlled substances (if registered) to other licensed or authorized purchasers
         2. “**OTC-only**” – licensed only for OTC wholesaling; may wholesale EPP within restrictions
         3. “**Controlled substances**” wholesaler
         4. “**Export wholesaler**” – licensed to sell legend or OTC drugs to foreign countries

      ii. **Pharmacies do not need to register as wholesalers** in order to engage in “the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.”

         1. "**Emergency medical reasons**" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such
transfers shall not exceed 5% of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

iii. **Wholesaling also does not include** the following:
   1. Sales or trades that constitute dispensing pursuant to a prescription
   2. The lawful distribution of samples by manufacturers’ representatives or their distributors’ representatives
   3. Sale, purchase, or trade of blood or blood components (regulated separately)
   4. Intracompany sales or transfers

c. **Wholesalers who distribute precursor drug products (EPP) are subject to the following restrictions:**
   i. March through October – EPP sales may not exceed 5% of the prior month’s total sales of all products
   ii. November through February – EPP sales may not exceed 10% of the prior month’s total sales of all products
   iii. The Board may exempt a wholesaler from the above limits if its sales of EPP are intracompany sales and there is no history of suspicious transactions in precursor drugs.
   iv. Sales of EPP may be only made to licensed pharmacies, a shopkeeper or itinerant vendor, a practitioner authorized to prescribe or use the particular drug, or a traditional Chinese herbal practitioner. (See also Chapter 5)

d. **Canadian Wholesalers.** The 2005 Legislature required the Board to submit by September 1, 2005, a request to the FDA for a waiver to permit the licensing in Washington of “Canadian, United Kingdom, Irish, and other nondomestic prescription drug wholesalers …” (RCW 18.64.490) The FDA denied the waiver request on March 17, 2006.
Chapter 4. Providing Drugs and Medical Devices to Patients

1. Regulation of Food, Cosmetics, Drugs, and Devices
   a. The Food and Drug Administration\(^{78}\) is responsible for regulating foods, drugs, cosmetics, and medical devices in the United States, under authority of the Food, Drug and Cosmetic Act\(^{79}\) (FDCA – 21 USC Chapter 9).
      i. The FDA web site provides several articles on the History of the FDA\(^{80}\) and the food and drug laws.
      ii. The Pure Food and Drug Act, also known as the Wiley Law, was passed in 1906, as the first comprehensive federal statute to assure purity and truthful labeling for foods and drugs.
      iii. Food, Drug and Cosmetic Act. Growing problems with modern chemicals, and limits on the applicability of the Wiley Law\(^{81}\) led to the passage in 1938 of the FDCA, which has been amended several times since then. A major impetus to the passage of the FDCA was an influential book by Ruth DeForest Lamb, “The American Chamber of Horrors.” A precipitating event was the marketing by the S.E. Massengill Company of “Sulfanilamide Elixir,”\(^{82}\) which contained diethylene glycol as the solvent –107 deaths occurred before the FDA could get the product removed from the market.
   1. New Drugs. All drugs marketed after 1938 are “new drugs.” The FDCA required that manufacturers of “new drugs”
      a. Provide proof of safety before marketing drugs. The law specified that “'new drug' means … any drug … the composition of which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe for the use under the conditions prescribed, recommended, or suggested in the labeling thereof …” Drugs “generally recognized as safe” (GRAS) were not “new drugs.” Other products required proof of safety prior to marketing.

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\(^{78}\) [http://www.fda.gov](http://www.fda.gov)
\(^{80}\) [http://www.fda.gov/oc/history/default.htm](http://www.fda.gov/oc/history/default.htm)
\(^{81}\) [http://vm.cfsan.fda.gov/~lrd/histor1a.html](http://vm.cfsan.fda.gov/~lrd/histor1a.html)
b. Obtain pre-marketing approval of “new drugs” by the FDA. Approval was to be sought by filing of a New Drug Application (NDA) with the FDA.

2. **Old Drugs.** Drugs marketed prior to 1938 are not covered by the FDCA, unless changes are made in their formulation or labeling. Examples of these “old drugs” include some dosage forms of phenobarbital and various narcotic drugs. The FDA believes that few, if any of the pre-1938 drugs now marketed are in their original formulation or labeling, and thus require submission of a NDA to allow them to be marketed legally.

3. **Identical, Related, or Similar Drugs.** After 1938 and before the subsequent passage of the Kefauver-Harris amendments in 1962, whenever FDA approved a New Drug, all existing (pre-1938) drugs that were “identical, related, or similar” (IRS) to the new drug were also considered approved, and were marketed without ever completing a specific NDA for the product.

4. **Generally Recognized As Safe.** Also between 1938 and 1962, many manufacturers introduced drug products into the market based on their own conclusion that the drugs were “generally recognized as safe” (GRAS) OR based on opinions from the FDA that the drugs were not new drugs. The FDA formally revoked all these “opinions” in 1968 (21 CFR 310.100).

iv. **Prescription Only Drugs.** Prior to 1951, pharmacists could dispense any drug – except narcotics – without a prescription. As a matter of professional ethics and courtesy, however, most pharmacists required prescriptions for many drugs, although refill procedures were somewhat lax. After 1951, however, the Durham-Humphrey Amendments created a new class of drugs that could not be dispensed without a prescription. These have become called “legend drugs,” because they were required to bear a “legend” on their label: “Caution: Federal Law prohibits dispensing without prescription.”

1. All existing drugs could be sold over the counter (OTC), without prescription.
2. New drugs that could not bear adequate labeling for safe use by the consumer would now be able to be marketed if information was provided to the physician, and these required a prescription.
3. The law allowed for oral prescriptions, and for refills.

v. **Effectiveness Required.** In 1962, additional amendments, the *Kefauver-Harris Amendments*[^83], were passed, triggered by problems with thalidomide, a drug which had not actually been marketed in the US, but which caused birth defects (phocomelia) in many babies born in Europe and Canada. The 1962 amendments required:

1. Proof of efficacy (effectiveness) as well as safety prior to marketing.
2. Established regulations called Good Manufacturing Practices (GMPs) requiring significant monitoring of manufacturers' facilities and processes
3. Moved control of advertising for Rx drugs from the Federal Trade Commission to the FDA
4. Improved procedures and requirements for obtaining informed consent during clinical trials of new drugs.
5. Generally Recognized as Safe and Effective. The GRASE status is conferred on existing products, especially for OTC use, that meet the 1962 standards.

vi. **Drug Efficacy Review.** The 1962 amendments mandated the FDA to review the *efficacy* of drugs which were previously approved on the basis of *safety*. The result of this review left three categories of drugs on the market.

1. **Approved Drug Products.** All *prescription* drugs marketed between 1938 and 1962 *for which an NDA was approved on the basis of safety only* were reviewed in a long-lasting effort by FDA known as the Drug Efficacy Study Implementation (DESI).
   a. 60 panels of experts reviewed submissions of evidence from the manufacturers, and classified each proposed indication for a product as “ineffective,” “ineffective as a fixed combination,” “possibly effective,” “probably effective,” or “effective.”
   b. Those products which were found to have at least one “effective” indication could continue to be marketed.
   c. Drugs with no “effective” indications were given a Notice of an Opportunity for Hearing (NOOH), and an opportunity to submit data to substantiate the effectiveness of their claims. Drugs without an effective indication are called “Less-than-effective” products (LTE).

[^83]: [http://vm.cfsan.fda.gov/~lrd/histor1b.html](http://vm.cfsan.fda.gov/~lrd/histor1b.html)
d. Of 3,400 products reviewed, over 1,000 were removed from the market by this process.  

2. **Nonprescription (over-the-counter or OTC) drugs** were separated from the DESI process in 1972 and potential OTC ingredients were subject to a review by groups of experts formed into OTC Review Panels. These expert panels developed monographs for therapeutic classes of drugs (e.g., antacids, cold remedies). Products comprised of ingredients listed in these monographs, and formulated in conformance with the monographs, may be used in formulating OTC products without submission of an NDA.  

3. **Drugs for which an NDA was never approved.**  
   a. Drugs still part of the DESI process. Believe it or not, over 40 years after the passage of the Kefauver-Harris amendments, some drugs are being marketed “subject to the ongoing [DESI] review” as of 2006, including Donnatal® (belladonna and phenobarbital) and Librax® (chlordiazepoxide and clidinium bromide).  
   b. Drug products which were not included in the DESI program, but which are identical, related, or similar (IRS) to a DESI product which was withdrawn.  
   c. Drug products which are IRS to a DESI product which was found effective, but for which an NDA has never been filed or approved.  
   d. “Prescription Drug Wrap Up” drugs. These drugs include those that were not approved prior to 1962 and are not IRS to DESI drugs, plus the majority of pre-1938 drugs that the FDA believes are no longer covered by the “grandfather clauses” of the 1938 and 1962 acts.  
   e. Drugs first marketed after 1962 or changed after 1962 without an NDA.  
   f. OTC products that do not comply with the OTC monographs and do not have individual approved NDAs.  

vii. **Unapproved Drugs Today.** The FDA issued a [Compliance Policy Guide on Marketing Unapproved Drugs](http://www.findarticles.com/p/articles/mi_m1370/is_v18/ai_3541522, accessed 12/17/06) (CPG Section 84 Hecht A. A long reach back to assure drug quality - Drug Efficacy Study Implementation program. FDA Consumer 1984 Dec.  

84 Hecht A. A long reach back to assure drug quality - Drug Efficacy Study Implementation program. FDA Consumer 1984 Dec.  

85 Approved Drug Products with Therapeutic Evaluations, 26th Ed. USDHHS, FDA, CDER 2006; iii.
Removing unapproved drugs from the market is a renewed initiative of the FDA, and pharmacists will be facing more issues surrounding an estimated 2% of all marketed drugs which can still be found on pharmacy shelves.

2. Enforcement Priorities. Because of limited enforcement resources, the FDA has set a priority for dealing with unapproved drugs, with highest priority assigned to:
   a. Drugs with potential safety risks
   b. Drugs that lack evidence of effectiveness
   c. Health fraud drugs
   d. Drugs that present direct challenges to the new drug approval and OTC monograph systems
   e. Unapproved drugs that specifically violate other provisions of the FDCA
   f. Drugs that are reformulated to evade FDA enforcement actions

3. When an NDA is approved for a formerly unapproved drug. The FDA, on a case-by-case basis, will take more aggressive action when an approved NDA is granted for one product in a class, when other manufacturers continue to market unapproved versions of the drug.
   a. Two recent examples of FDA action regarding pre-1938 drugs have been stimulated by manufacturers who obtained approved NDAs for older drugs:
      i. Guaifenesin extended release formulations. In 2002, the FDA approved an NDA for Mucinex® 600 mg tablets, an extended release formulation containing guaifenesin. In November 2002, the FDA sent letters to upwards of 70 manufacturers or distributors of currently marketed extended release guaifenesin products (e.g., Humibid LA, Duratuss G, and generics), informing them that their products were illegally marketed. Although the OTC cough and

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86 http://www.fda.gov/cder/guidance/6911fnl.pdf
87 http://www.accessdata.fda.gov/scripts/wlcfm/subject.cfm?FL=C
cold monograph provides for
guaifenesin to be used as an
expectorant in these products, it doesn’t
encompass single-ingredient extended-
release dosage forms of guaifenesin.

ii. Qualaquin (quinine sulfate) is currently
the only quinine sulfate product with an
approved NDA. Its manufacturer was
prompted by the Mucinex experience to
seek NDA approval, and also obtained
Orphan Drug status for its product,
which gives it “market exclusivity,” or
protection from generics, until 2012. The
FDA has previously declared that
quinine sulfate in OTC products are not
generally recognized as safe for
treatment of leg cramps or
treatment/prevention of malaria.
Qualaquin was approved as a
prescription drug only for treatment of
uncomplicated \textit{P. falciparum} malaria,
and not for leg cramps. The
manufacturer has initiated legal
proceedings against other quinine
manufacturers,\footnote{The lead case is Mutual Pharmaceutical Company, Inc., et al. v. Watson Pharmaceuticals, Inc.,
et al. Case No. ED CV-06-0757 SGL (JCx), C.D. Cal., 2006.} and, according to an
on-line article in USA Today,\footnote{Rubin R. Hundreds of unapproved drugs sold by prescription. USA Today.com,
\url{http://www.usatoday.com/news/health/2006-09-17-unapproved-drugs-cover_x.htm}, accessed
9/18/06.} all but
one agreed to discontinue their products
by November 2006.

1. The FDA issued an order in
December 2006 to discontinue
manufacturing and shipping of all
unapproved quinine products,
with no products to be shipped or
sold after June 2007.\footnote{http://www.fda.gov/bbs/topics/NEWS/2006/NEW01521.html}

\section{Federal Funds Can’t Be Used for LTE Drugs.}
Federal regulation relating to the Medicaid program
prohibits use of federal funds to pay for drugs which
have been rated LTE. If states wish to pay for any of
these drugs, they must do so with state funds only.
The Center for Medicare and Medicaid Services
(CMS) publishes a **quarterly list of LTE drugs**, which includes products such as Mycolog® (nystatin-triamcinolone), various combinations of belladonna alkaloids and phenobarbital, and hydrocortisone suppositories.

**viii. “Economic” Amendments.** Other amendments since 1976 have largely dealt with economic issues, including marketing, patent rights, and promotion of generic drugs. These include:

1. **Orphan Drug Act** of 1983, extending patent protection and giving tax relief to companies that develop needed drugs without significant market potential.

2. **Waxman-Hatch Amendment** of 1984, which streamlined processes for approval of generic drugs, and gave extended terms of patents for certain drugs.

3. **Prescription Drug Marketing Act** of 1987, which controls distribution of legend drug samples, reselling of drugs by hospitals, and requires state licensing of drug wholesalers.

**ix. FDAMA.** The Food and Drug Administration Modernization Act of 1997 created significant changes in the FDCA, predominantly affecting manufacturers. A major section dealt with pharmacy compounding, but was invalidated by the 9th Circuit in *Western States Medical Center v. Shalala*, 238 F.3d 1090 (2001), and upheld as to certain parts by the Supreme Court in *Thompson v. Western States Medical Center, 238 F.3d 1090 (2002)*. In August 2006, a federal district court in Texas relied on the Supreme Court’s specific opinion to conclude that major parts of the compounding rules specified in FDAMA remain in force. The 5th Circuit has now upheld the primary conclusion of the district court that the compounding provisions of FDAMA, absent the ban on advertising, remain in force. This decision does not affect practice in the 9th Circuit at present, which includes Washington. However, with two circuits now having ruled differently, a possible appeal again to the Supreme Court is likely. (See section on Compounding).

**x. FDAAA.** The Food and Drug Administration Amendments Act of 2007 was passed primarily to reauthorize the use of

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**Notes:**


94 Medical Center Pharmacy et al. v. Mukasey, Case No. 06-51583, 5th Cir., July 18, 2008.

95 Pub. L. 110-85.
user fees to support FDA NDA review activities, and to allow user fees related to review and approval of medical devices. However, several additional reforms were included in the Act. Among the most important for pharmacists are:

1. **FDA authority to require new safety labeling in prescription drug labeling.** The FDA can force the manufacturer to include specific “new safety information” in the prescription drug labeling, rather than “negotiate” the language to be used.

2. **FDA authority to require post-marketing clinical trials for approved drugs.** The FDA can now insist that a manufacturer conduct additional trials on marketed drugs:
   a. To assess a known serious risk related to the use of the drug involved.
   b. To assess signals of serious risk related to the use of the drug.
   c. To identify an unexpected serious risk when available data indicates the potential for a serious risk.

3. **REMS.** The FDA may require manufacturers to develop Risk Evaluation and Mitigation Strategies (REMS) as a condition of approval of a new drug, or as a post-approval requirement pursuant to new safety information. A REMS may apply to a single drug product or to an entire class (e.g., NSAIDs or long-acting opioids). A list of drugs with approved REMS is on the [FDA website](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm). Elements of a REMS plan may include any or all of the following:
   a. Assessments at 18 months, 3 years, and 7 years
   b. MedGuide or PPI development
   c. Communication plan to health professionals
   d. Access plans to insure safe use for drugs with high risk, which may include one or more of the following strategies:
      i. Limit prescribing to providers with special training
      ii. Limit dispensing to certified providers
      iii. Limit administration to patients in certain settings
      iv. Limit distribution to patients with documentation of safe-use conditions, such as laboratory tests

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v. Require monitoring for each patient receiving the drug
vi. Require each patient to be enrolled in a registry

Examples of current control programs that could be considered REMS with access plans include the controlled distribution and blood monitoring system for Clozaril®, and the iPledge® program for Accutane® prescribing and dispensing. In 2009 the FDA published a proposed REMS for long-acting opioids, including fentanyl, methadone, and long-acting forms of oxycodone and morphine. The original comment period was extended until October 2010. (See also Chapter 5)

e. REMS are enforceable against both manufacturers and practitioners
   i. The drug sponsor (manufacturer) may not introduce a product into interstate commerce if in violations of the provisions of a REMS for the drug
   ii. A dispenser who distributes the drug in violation of the REMS has created a misbranded product
   iii. FDA can impose civil penalties against manufacturers or providers who violate FDAAA; and criminal penalties may be imposed on manufacturers

4. The National Institutes of Health will expand its “clinical trials database,” and manufacturers will be required to provide information on all of their sponsored clinical trials. This information will be accessible online to the general public.

5. The FDA may require pre-broadcast review of television advertising for prescription drugs.

6. Manufacturers may submit direct-to-consumer advertising for prior review by FDA. The FDA may review DTC ads to assure that the “major statement” concerning the drug’s name, conditions of use, side effects and contraindications is presented in a “clear, conspicuous, and neutral manner.”

7. FDA required to develop a validated post-market risk identification and analysis system that will cover
   a. 25 million patients by July 1, 2010; and

97 https://www.ipledgeprogram.com/
b. 100 million patients by July 1, 2012

8. **Pharmacists must distribute to patients a “Side Effects Statement.”** (See section on prescription labeling, below.)

xi. **Rx-to-OTC Switches.** Most modern new drugs begin their marketed lives as legend drugs. However, after some time on the market, their general safety and usefulness for the lay public may become better known, and manufacturers may seek to have them moved to OTC status. This process is known as an Rx to OTC switch.

xii. **Drugs that are both Rx and OTC.** A few drugs have for many years been available without prescription, but restricted to sale in a pharmacy. Until very recently, these consisted almost exclusively of OTC products in Controlled Substance Schedule V (see Chapter 5), for which the purchaser had to sign a log book that was also signed by a pharmacist. Methamphetamine precursor products containing ephedrine, phenylpropanolamine, or pseudoephedrine have now been restricted to sale and recording in a log book, but are not specifically restricted to sale by pharmacists (see below and Chapter 5). Most recently, Plan B®, has been changed to OTC status for patients who are 17 years of age or older, but it continues to require a prescription for minors under age 17.

1. **FDA solicits comments on a class of “Behind the Counter” (BTC) drugs.** In October of 2007, the FDA issued a notice of public meeting to receive input on a proposed class of BTC drugs. BTC drugs would be available without prescription, but only from pharmacists who provide an appropriate level of patient assessment and counseling prior to delivery of the drug to the patient. The most frequently mentioned potential class of drugs for BTC status is the statin group of HMG Co-A reductase inhibitors. In general, organized medicine (e.g., the American College of Physicians) has opposed the concept, asserting, among other things, that pharmacists lack the training and time to properly supervise the distribution of BTC medications. The American Medical Association testimony at the November hearing also questioned whether FDA had statutory authority to approve such a class. Pharmacy groups

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98 [http://199.73.36.150/ChpaPortal/PressRoom/FAQs/Switch.htm](http://199.73.36.150/ChpaPortal/PressRoom/FAQs/Switch.htm)
100 ACP Statement to Commissioner Eschenbach, November 12, 2007; [http://www.acponline.org/hpp/eschenbach.pdf](http://www.acponline.org/hpp/eschenbach.pdf), accessed 12/31/07.
generally supported the concept, with recommendations that would make the distribution of BTC drugs subject to rigorous processes designed to promote patient care. The National Association of Boards of Pharmacy (NABP) has advocated a BTC class of drugs since 1993. Representatives of non-pharmacy retailers (e.g., the Food Marketing Institute) and OTC drug manufacturers were not supportive. Consumer representatives were generally supportive. The comment period was subsequently extended to December 17, 2007. As of January, 2010, the FDA is considering the input it has received.

xiii. Federal OTC drugs requiring prescriptions in Washington. Washington statute (RCW 69.41.075) gives the Board of Pharmacy to require prescriptions for some drugs that are otherwise OTC under federal law.

1. Ephedrine. The Board has classified federal OTC ephedrine-containing products as prescription-only in Washington (WAC 246-883-030). The rule exempts certain OTC combination bronchodilator products containing 25 mg or less of ephedrine (e.g., Tedral, Bronitin). Subsequently, the FDA has proposed to reclassify ephedrine combinations as not GRASE for OTC use. The FDA will continue to allow marketing of single-ingredient bronchodilator products containing ephedrine, but these products will remain prescription-only in Washington.

2. Theophylline. In 1992, the Board also classified all theophylline-containing products as prescription only, exempting OTC combination products containing 130 mg or less of theophylline per dose. These combinations were removed from federal approval in 1995.

b. State Regulation of Food, Drugs and Cosmetics. States generally have adopted a regulatory scheme that parallels the federal approach. Washington statutes implementing this scheme include

i. Intrastate Commerce in Food, Drugs and Cosmetics (formerly the Uniform Food, Drug and Cosmetic Act – RCW 69.04). This is the “FDCA” for Washington, which defines, as does the federal law, misbranding and adulteration, and requires that drugs regulated under the federal law must conform to that law.

1. Administration of the law is vested in the Director of the Washington State Department of Agriculture. The Acting Director in January 2009 is Robert W. Gore.

2. Enforcement and administration of all provisions of the statute that pertain to drugs and cosmetics, however, are placed with the Board of Pharmacy. (RCW 69.04.730)

3. Persons wishing to manufacture drugs in the state file applications with the Board of Pharmacy

ii. **Caustic Poison Act of 1929** (RCW 69.36). This statute regulates the labeling of specific caustic products sold for household use at retail.

1. “Dangerous caustic or corrosive substances” subject to the Act include
   a. HCl – in concentrations ≥ 10%
   b. H$_2$SO$_4$ – in concentrations ≥ 10%
   c. HNO$_3$ – in concentrations ≥ 5%
   d. Phenol – in concentrations ≥ 5%
   e. Oxalic acid – in concentrations ≥ 10%
   f. Acetic acid – in concentrations ≥ 20%
   g. Hypochlorous acid (chloric(l) acid – HClO) – in any preparation yielding ≥ 10% chlorine
   h. KOH – in preparations yielding ≥ 10% KOH
   i. NaOH – in concentrations ≥ 10%
   j. AgNO$_3$ – in concentrations ≥ 5%
   k. Ammonia water – in preparations yielding ≥ 5% NH$_3$

2. Misbranding of covered caustic poisons is defined as a retail parcel, package, or container of the covered substances that does not contain the following:
   a. Name of substance
   b. Name and address of manufacturer, packager, seller, or distributor
   c. The word “POISON” in contrasting color and letters of at least 24 point size
   d. Directions for treatment in case of injury

3. Labeling requirements do not apply to products
   a. sold to pharmacists for dispensing, compounding, or preparing prescriptions,
   b. for use by or under the direction of a physician, dentist, or veterinarian

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Note that dilute acids and bases are generally expressed in w/v concentrations, whereas concentrated acids, such as 38% HCl are expressed as w/w.

Anhydrous acetic acid (e.g., 100% w/w) is also commonly called “Glacial Acetic Acid”
c. for use by a chemist in the practice or teaching of his profession
d. for any industrial or professional use
e. for use in any of the arts or sciences

4. Community pharmacies (particularly in rural areas) are often sought as a source for these chemicals. The key element here is that retail packages of these products must be labeled according to the Act.

iii. Poison Sales and Manufacturing (RCW 69.38). This act requires that pharmacies or other retailers of specified poisons must maintain a poison register in which sales of specified poisons are recorded.

1. Covered poisons include
   a. Arsenic and its preparations
   b. Cyanide, hydrocyanic acid, and preparations
   c. Strychnine
   d. Other substances designated by the Board of Pharmacy – none are currently designated

2. Excluded products include those regulated under the Caustic Poisons Act of 1929 (RCW 69.04), the Legend Drug Law (RCW 69.41), the Controlled Substances Act (RCW 69.50), the Pesticide Control Act (RCW 15.58), the Pesticide Application Act (RCW 17.21), and the Drug Samples statute (RCW 69.45).

3. No sales can be made of covered products unless the seller is satisfied as to the identity of the purchaser and that the sale is for a lawful purpose.

4. The register must contain the date and time of sale, the full name and home address of the purchaser, the kind and quantity of poison sold, and the purpose for which the poison is being purchased. The name and address of the purchaser must be verified by examination of photo ID.

5. Pharmacies may dispense poisons on prescription without obtaining a poison distributors license.105

iv. Poisons and dangerous drugs (RCW 69.40). This statute prohibits placing poisons in edible products, such as crackers, biscuit, bread or other edible product (e.g., hamburger). It also prohibits distributing milk containing formaldehyde.

105 With the replacement of strychnine as a rodenticide by warfarin-based products, there are now no pharmacies in WA who have obtained a poison distributor license. When strychnine was used as a rodenticide, its sale was limited to pharmacies under RCW 16.52.193. According to Board of Pharmacy staff in January 2009, a handful of distributors are licensed and the most common purpose is for the distribution of cyanide to be used in gold mining.
v. **Poison Information Centers** (RCW 18.76). This statute established a statewide poison information center program.

vi. **Legend Drug Act** (RCW 69.41). This is the principal law governing the sale, prescribing, dispensing, and use of legend drugs. Its elements are discussed throughout this textbook where applicable.

vii. **Controlled Substances.** The laws relating to controlled substances are discussed in Chapter 5:

1. **Uniform Controlled Substances Act** (RCW 69.50). This is the state parallel to the federal CSA.
2. **Precursor Substances** (RCW 69.43). This supplements the Controlled Substances Act by regulating the sale and distribution of chemicals which are used in the production of controlled substances.
3. **Controlled Substances Therapeutic Research Act** (RCW 69.51)
4. **Medical Marijuana** (RCW 69.51A)
5. **Imitation Controlled Substances** (RCW 69.52)
6. **Use of Buildings for Unlawful Drugs** (RCW 69.53)

viii. **Over-the-Counter Medications** (RCW 69.60). This statute, now superseded by federal regulations, required that OTC solid dosage forms be imprinted with an identification symbol or code.

1. Because federal requirements (21 CFR 206.01-10) exempted certain products that were subject to the Washington Act, the Board of Pharmacy established by regulation that OTC drugs not covered by federal rules could not be marketed in Washington in the absence of a complying imprint or Board exemption. (WAC 246-885-030)

c. **Drug Development in the US.** The development of new drugs in the United States follows a multistage process.

   i. **Preclinical testing,** *in vitro* and in animals.

   ii. Filing with the FDA of a Notice of Investigational New Drug (IND)

      1. This allows the drug to shipped in interstate commerce for purposes of testing

   iii. **Clinical testing**

      1. **Phase I** – a small number of healthy volunteers to determine pharmacodynamic and pharmacokinetic properties
      2. **Phase II** – a limited number of patients who have the target disease, to determine efficacy and dose-response.
      3. **Phase III** – large-scale clinical trials in patients with the disease. At least two clinical trials must be
conducted that are double-blinded and placebo-controlled.

iv. **Filing of a New Drug Application (NDA).** This filing describes the drug, the results of preclinical and clinical trials, sets forth the proposed labeling, a Risk Management Plan, and describes manufacturing and testing processes. If the NDA is approved, the drug may be marketed.

v. **Post-marketing surveillance (also called Phase IV).** The manufacturer must maintain records and file annual reports which include summaries of adverse reactions and problems discovered after marketing. Significant problems must be reported promptly, which may lead to revisions in the labeling.

vi. **Supplemental NDAs** are filed when the manufacturer seeks additional indications or changes in the labeling or production of the drug.

vii. **Abbreviated NDAs** are filed by manufacturers who wish to market generic versions of approved drugs after patent rights expire. (See drug product selection section.)

viii. **New products are classified** by the FDA using a rating scheme, which is indicated in information announcing the drug’s approval. A number indicates the chemical type and a letter (P or S) indicates the therapeutic potential. The FDA considers 1P (New Chemical Entity that is a Therapeutic Advance) the most important kind of new drug:

1. Chemical Type (1-6)
   a. 1 = New Chemical Entity (NCE), a novel chemical agent
   b. 2 = New salt or ester of a previously approved drug
   c. 3 = New formulation of previously approved drug(s)
   d. 4 = New combination of previously approved drugs
   e. 5 = Duplicate of another product
   f. 6 = Previously marketed by the same firm
2. Therapeutic Potential (P or S)
   a. P = Therapeutic advance
      i. No other effective drugs for the indication
      ii. More effective or safe than other drugs for the indication
      iii. Other important advantages compared to other drugs
   b. S = Similar to other drugs on the market for the condition

2. Foods.
   a. Under the FDCA, “food” means
      i. articles used for food or drink for man or other animals,
      ii. chewing gum, and
      iii. articles used for components of any such article. (21 USC § 321(f))
   b. The FDA regulates labeling of foods, and has powers to seize foods that are adulterated or misbranded. Foods do not require premarketing approval, although certain food additives (colorings, preservatives, etc.) do.

3. Cosmetics.
   a. Cosmetics are defined under the FDCA to include
      i. articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
      ii. articles intended for use as a component of any such articles; except that such term shall not include soap. (21 USC § 321(i))
   b. FDA control over cosmetics is primarily restricted to assuring safety. The FDA does not regulate claims made for cosmetics.
      i. Products which make therapeutic claims are regulated as drugs, or as both cosmetics and drugs. Examples include dandruff shampoos, antiperspirant deodorants, cosmetics claiming sun-protection, and fluoride toothpaste.¹⁰⁶
   c. Cosmetic manufacturers are not required to register with FDA, but may choose to do so under the Voluntary Cosmetic Registration Program (VCRP).¹⁰⁷

4. Devices.
   a. The FDCA defines devices as follows:
      The term "device" … means an instrument, apparatus, implement,

machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is -

i. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

ii. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

iii. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. (21 USC § 321(h))

b. Medical Device Amendments. Significant authority over medical devices was granted to the FDA in 1976, with the passage of the Medical Device Amendments. The publicity concerning deaths and injuries from the Dalkon Shield\(^\text{108}\) intrauterine device is considered one of the factors leading to the passage of these amendments. The problems with the Dalkon Shield led to the bankruptcy of the A.H. Robins Co., formerly one of America’s most respected drug firms, and the outcomes of the second largest class action lawsuit (after asbestos) in American history are still unfolding. The Device Amendments modified the FDCA to provide:

i. **Classification of devices\(^\text{109}\)**
   1. **Class I** – Common and simple devices needing to conform to general standards (e.g., tongue depressors, bandages, neck braces)
   2. **Class II** – Devices needing to meet specific performance standards (e.g., thermometers)
   3. **Class III** – Devices that pose risk of injury if not properly used or produced, that require pre-market approval (e.g., defibrillators, pacemakers, IUDs)

ii. **Restricted Devices.** Some devices require a prescription or order of a prescriber to sell or dispense. These are labeled “Caution: Federal law restricts this device to sale by or on the order of a physician.”

c. **Syringes and needles.** Syringes and needles are not restricted devices under federal law. However, many states place restrictions on the sale of injection devices, and may require a prescription before a pharmacist may make a sale.

i. **Needle exchange programs are legal in Washington. Pharmacists may sell syringes and needles to adult IV drug users.** Washington law allows pharmacists to sell

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\(^{108}\) http://www1.umn.edu/scitech/dalkfina.htm  
\(^{109}\) http://www4.law.cornell.edu/uscode/html/uscode21/usc_sec_21_00000360---c000-.html
needles and syringes without prescription, subject to the requirement that “On the sale at retail of any hypodermic syringe, hypodermic needle, or any device adapted for the use of drugs by injection, the retailer shall satisfy himself or herself that the device will be used for the legal use intended.” (RCW 70.115.050) SHB 1759, passed in 2002, modified the state’s drug paraphernalia law, and added the following provisions:

- Making it lawful for “any person over the age of eighteen to possess sterile hypodermic syringes and needles for the purpose of reducing blood borne diseases” (RCW 69.50.412(5)).
- Specifying that nothing in the Drug Paraphernalia Act “prohibits legal distribution of injection syringe equipment through public health and community based HIV prevention programs, and pharmacies.” (RCW 69.50.412(3))
- Specifying that “Nothing contained in [the Drug Paraphernalia Act] shall be construed to require a retailer to sell hypodermic needles or syringes to any person.” (RCW 70.115.060)

Under these provisions, needle exchange programs are legal in Washington, and pharmacists may sell syringes and needles to persons over the age of eighteen, even if those persons are believed to be using the devices to inject illegal drugs, providing that the purpose of the sale is to prevent spread of blood borne pathogens, such as HIV, HBV, or HCV.

- A summary of state laws regulating syringe sales is available on the internet at [http://www.temple.edu/lawschool/phrhcs/otc.htm](http://www.temple.edu/lawschool/phrhcs/otc.htm)
- The *Journal of the American Pharmaceutical Association* devoted a special issue to syringe laws and access to syringes in 2002 (Nov-Dec; 42(6 Suppl 2)).
- Over 100 pharmacies in King County, WA, have agreed to participate in a syringe-access program sponsored by the King County Department of Health. A link to their “To The Point” newsletter can be found at [http://www.doh.wa.gov/hsqa/Professions/Pharmacy/documnts/Point_newsltr.pdf](http://www.doh.wa.gov/hsqa/Professions/Pharmacy/documnts/Point_newsltr.pdf)
- Possession of traces of controlled substances illegal. Although it is legal for an IV drug user to possess syringes and needles, controlled substance residue in the syringe may still be used as evidence of illegal possession of controlled drugs. Under Washington law, unlawful possession of even a trace amount of controlled substance
is punishable by up to 5 years in prison, a fine of up to $10,000, or both (RCW 69.50.140(d), State v. Malone, 864 P.2d 990 (Wash.App.Div. 1994)).

d. **Mercury-containing devices.** Concerns with the buildup of mercury in the environment led the Legislature in 2006 to prohibit the sale of thermostats and other devices containing mercury, including medical thermometers and manometers. Exceptions are:
   i. Prescribed thermometers, such as low-temperature reading devices or basal temperature thermometers;
   ii. Electronic thermometers with mercury-containing batteries;
   iii. Thermometers or manometers used to calibrate other devices;
   iv. Devices sold to hospitals or hospital-controlled health care facilities that have adopted a plan for mercury reduction in accordance with state law. (RCW 70.95M.050)

5. **Animal Drugs.** This textbook, unless otherwise specified, discusses drugs for use in humans. The FDA also regulates drugs used to treat other animal species, and shares with the Department of Agriculture responsibility for drugs and other chemicals used in animal feed or in the production of foods. The FDCA makes a distinction between a “new drug” and a “new animal drug” and enforces specific regulations for both types of drugs. In general, veterinarians may prescribe human drugs for animals, and pharmacies may fill them. It should be noted that many human drugs are toxic to specific species, such as lincomycin’s gastrointestinal toxicity in horses, and other drugs are less toxic in other animal species than in humans, such as chloramphenicol in dogs. Animal drugs may not be used in humans, and there are species-specific restrictions on their use in other animals. Also, animal drugs used in feed may pose environmental and other dangers, and there are a number of animal drugs that may not be administered in feed. The regulations also treat non-food animals (e.g., cats and dogs) differently from animals intended for human food (e.g., cattle, pigs, chickens, etc.). Veterinarians increasingly refer to “pets” as companion animals, whose proper care is worthwhile in itself, but frequently important to the health of their human companions as well.

   a. The FDA’s [Center for Veterinary Medicine](http://www.fda.gov/cvm/default.html) administers the FDCA as it pertains to drugs used in animals and in animal feed.
   b. The veterinary equivalent to the “Orange Book” is the “Green Book” ([FDA Approved Animal Drug Products](http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm042847.htm)).
   c. Two recent laws are of interest to pharmacists involved in veterinary pharmacy or in supplying drugs to veterinarians.
      i. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), which provides for veterinarian prescribing of extra-label drug use (ELDU) for non-food animals.

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110 http://www.fda.gov/cvm/default.html
111 http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm042847.htm
ii. The Minor Uses and Minor Species Health Act of 2004 (MUMS), which provides for legal use of non-approved drugs in minor animal species such as ornamental fish and uncommon diseases in major species.

d. Many pharmacists are involved in compounding drugs for use in animals, with creating flavored dosage forms for companion cats being a particularly significant activity. (See compounding)

6. **Non-prescription (OTC) drugs.** The FDCA defines a drug in 21 USC § 321 (g) as follows:

<table>
<thead>
<tr>
<th>21 USC § 321 (g) (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The term &quot;drug&quot; means</td>
</tr>
<tr>
<td>(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and</td>
</tr>
<tr>
<td>(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and</td>
</tr>
<tr>
<td>(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and</td>
</tr>
<tr>
<td>(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.</td>
</tr>
</tbody>
</table>

a. A drug is **adulterated** if it contains any added deleterious substances, has been stored improperly, or is packaged in such a way as to allow deterioration. *(21 USC § 351)*

i. Any article listed in the official compendium (i.e., the USP/NF) must conform to compendial standards for purity, quality, strength, and appropriate assays.

ii. Drugs must be stored in accordance with USP standards, and any special requirements specified on the manufacturer’s label.

iii. The USP defines the following temperature ranges for storing drugs:

1. Controlled room temperature
2. Cool place
3. Cold place

iv. Pharmacies must maintain their drug storage areas within a controlled range, which requires air conditioning in most areas of the US.

v. Refrigerators or freezers used to store drugs may not be used to store food or non-drug products.
b. A drug is **misbranded** if its labeling is incomplete or misleading. Repackaging an OTC drug without supplying all the information contained on the original bottle is a form of misbranding. *(21 USC § 352)*

i. The “label” of a drug is the actual label affixed to the bottle or box containing the medication. The “labeling” includes the label, and any other printed or written material accompanying the drug. Labeling also includes statements made by the manufacture or seller in promotional materials, advertisements, or other communications to patients or health professionals.

ii. OTC drugs must bear adequate directions so that lay persons can use the product safely and effectively. If a product cannot be labeled in such a way that the consumer can use it just by reading the label, it will be restricted to sale by prescription.

iii. Specific elements are required by the FDCA on the labels of OTC drugs. The “7-point label” must contain:

   1. Name of Product
   2. Name and address of manufacturer, packager, distributor
   3. Net contents
   4. Active ingredients and quantity of certain other ingredients
   5. Name of any habit forming drug
   6. Cautions and warnings
   7. Adequate directions for use

iv. **Imprints required on solid oral dosage forms.**
Washington requires that all OTC solid oral dosage forms sold in the state must be imprinted with a distinctive symbol or code. *(RCW 69.60)* Subsequent FDA regulations require imprints on virtually all US OTC products.

v. **Standardized “Drug Facts” OTC Labels.** The FDA developed new regulations\(^ {112} \) in 1999 that have changed the look of OTC drug labels and require the same format for all labels. Information about the OTC product must be in plain language and provide the following in the order shown:

   1. The product's active ingredients, including the amount in each dosage unit.
   2. The purpose of the product.
   3. The uses (indications) for the product.
   4. Specific warnings, including when the product should not be used under any circumstances, and when it is appropriate to consult with a doctor or pharmacist.

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\(^{112}\) [http://www.fda.gov/cder/consumerinfo/OTClabel.htm](http://www.fda.gov/cder/consumerinfo/OTClabel.htm)
This section also describes side effects that could occur and substances or activities to avoid.

5. Dosage instructions—when, how, and how often to take the product.

6. The product's inactive ingredients, important information to help consumers avoid ingredients that may cause an allergic reaction.

vi. **English Language Required.** All required label elements must be in English (CFR 21.15(c)(1)). This requirement is implemented in WA regulations in WAC 246-869-150(4).

1. **Spanish-speaking US Territories.** However, drugs distributed in Puerto Rico, or a US Territory where the predominant language is other than English, the label elements may be in the predominant language. (CFR 21.15(c)(1))

2. Drugs labeled in English that include any representations in the label or labeling in a foreign language (e.g., Spanish or French) must also include all the other required information in the same foreign language (CFR 21.15(c)(2,3)).

3. The Washington Board of Pharmacy has previously charged a pharmacist with violating these requirements when a European herbal product, “Doktor Mom,” which is labeled in Ukrainian but with ingredients described using Linnaean nomenclature, was sold to a Russian-speaking consumer allegedly without any supplemental labeling in English.

vii. **Poison-prevention packaging.** Selected OTC products must be packaged in “special packaging,” otherwise known as child-resistant containers (CRCs), as required by the Poison Prevention Packaging Act (15 USC §§ 1471-1474). Regulations implementing the act are developed by the Consumer Product Safety Commission, which publishes “Poison Prevention Packaging: A Guide for Healthcare Professionals.” Rules for non-prescription drugs are contained in 16 CFR § 1700.14. **OTC drugs requiring child-resistant containers** include:

1. **Aspirin or acetaminophen:** any formulation containing ASA in any amount or containing APAP > 1 g/pkg. Exceptions:
   a. Effervescent tablets/granules ≤ 15% ASA or APAP, if the oral LD_{50} of the granules ≥ 5 g/Kg

b. Unflavored APAP or ASA-containing powders (not intended for pediatric use) packaged in unit doses providing ≤13 grains APAP or ≤15.4 grains ASA per unit dose.

2. NSAIDs
   a. Ibuprofen > 1 g/pkg
   b. Naproxen > 250 mg/pkg
   c. Ketoprofen > 50 mg/pkg

3. Iron preparations (including dietary supplements) > 250 mg elemental iron per package

4. Diphenhydramine > 66 mg per package

5. Fluoride > 50 mg F-/pkg or > 0.5% w/v

6. Lidoaine > 5 mg/pkg or Dibuaine > 0.5 mg/pkg

7. Loperamide > 0.045 mg/pkg

8. Minoxidil > 14 mg/pkg

9. Methacrylic acid (in liquid bandage) > 5% w/v

10. Methyl salicylate

11. Ethylene glycol

12. Methyl alcohol

13. Mouthwash containing 3 g or more ethanol/package.
   a. Pump container with non-removable pump, containing 7% w/w or more cinnamon or mint flavoring, and < 15 g of ethanol per container, and dispensing < 0.03 g of ethanol per pump is exempt.

14. Hydrocarbons, solvents, household fuels; drugs and cosmetics containing low-viscosity hydrocarbons (e.g., certain light mineral oil, NF)

15. NaOH, KOH

16. H₂SO₄

17. Permanent wave neutralizers (> 600 mg NaBrO₃ or >50 mg KBrO₃)

18. Other OTCs containing any active ingredient that was previously available for oral administration only by prescription (e.g., omeprazole, ranitidine) (This rule became effective in 2001.)

19. All OTC controlled substances

viii. Packages for Households without Small Children. For OTC drugs, each manufacturer must make at least one package size with a CRC. A manufacturer may make one size only that is intended for households without small children. It must bear the caution “This Package for Households without Young Children.” For small packages, the manufacturer may substitute the wording, “Package Not Child-Resistant.”
ix. **Dispensing covered OTCs by prescription.** Washington law requires pharmacists who dispense any of the above-listed OTC drugs on prescription to use a CRC. (RCW 18.64.246 and WAC 246-869-230) These regulations can be read to require CRCs on all prescriptions in which OTC drugs are dispensed, even if the CPSC has not listed the product, but in at least one state court case the judge ruled to the contrary.

c. **Preventing Product Tampering.** Problems with product tampering have led to requirements in the Federal Anti-Tampering Act. Most OTC drugs, devices, and cosmetics require the following elements (dentifrices, dermatologicals, lozenges, and insulin are exempted):
   i. An indicator of tampering or barrier to entry, that
   ii. If breached or missing provides visible evidence of tampering
   iii. A label statement must describe the barrier or indicator

d. **Recalls of OTC products** are handled in the same manner as for legend drugs (see below).

e. **Unlabeled uses of OTC drugs.** Sellers are responsible for any false, misleading, or unapproved claims they or their employees make concerning OTC products that are not consistent with the approved labeling.
   i. Pharmacists are allowed to make recommendations to customers about the hazards and benefits of medications, consistent with their knowledge, training, experience, and good judgment.
   ii. Specific assurances (“this is perfectly safe for your baby”) may create a warranty of fitness for a particular purchase that can lead to liability to the consumer if the product does not perform as stated or is harmful.

f. **Controlled OTC substances** (see also Chapter 5).
   i. The Controlled Substances Act permits the sale of certain products without a prescription. However, unlike most other OTC products, these products may only be sold by pharmacists pursuant to state and federal laws.

g. **Methamphetamine precursor-containing products**
   i. At various times it has been permissible to sell cough-and-cold or diet-control preparations containing ephedrine, phenylpropanolamine (PPA), or pseudoephedrine as OTC formulations. Each of these ingredients has been a source of illegal production of methamphetamine.
      1. **PPA** was found to be associated in OTC doses of 75 mg or greater with increased risk of hemorrhagic stroke, and the FDA requested all manufacturers to voluntarily recall PPA-containing OTC products in November, 2000. On December 22, 2005, the FDA
published a proposed final rule that would permanently place OTC formulations of PPA in Category II, i.e., not approved for use OTC, and has established a 90-day comment period. (70 FR 75988-98, December 22, 2005.)

2. Drug products containing ephedra or its alkaloids may not be promoted for weight loss, enhancement of athletic performance, or as stimulants.
   a. The FDA proposed in 1995 to remove ephedrine alkaloids from OTC monograph approval status for use in bronchodilator products. In July 2005, the FDA withdrew this proposal and published a proposed final rule allowing the continued use of these ingredients with enhanced warnings and label requirements (70 FR 40237-49, July 13, 2005) Subsequently, the FDA has proposed to reclassify ephedrine combinations as not GRASE for OTC use, \(^{114}\) but will continue to allow single-ingredient products.
   b. Certain ephedrine salts may be used in ophthalmic preparations or nasal sprays and in rectal products used to treat hemorrhoids; in all cases as topical vasoconstrictor.
   c. Single-ingredient ephedrine/ephedra products are further restricted to sale behind the counter by DEA rules (see Chapter 5).
   d. Washington law classifies all ephedrine containing products, except certain combinations which will soon be taken off the market, as prescription-only drugs.

3. Pseudoephedrine containing products are now restricted by both federal and state laws which limit the quantity that can be sold at any one time and/or require the product to be kept behind the counter. (See also Chapter 5) Manufacturers are reformulating many nasal decongestant products with phenylephrine to allow their brand to be continued to be sold without restriction (e.g., Sudafed $\rightarrow$ Sudafed P.S.E.).

h. Non-pharmacy Sales of OTC Drugs. At various stages in the 20\(^{th}\) century, the requirement that pharmacies must be owned by pharmacists gained acceptance and was later abandoned in most states. A US Supreme Court decision in 1928 (Liggett v Baldridge, 278 US 105 (1928)) overturned state laws restricting ownership of

\(^{114}\) 70 Fed Reg 40232, July 13, 2005.
pharmacies and was seen as binding until 1973, when the Supreme Court reversed its decision in Liggett and allowed state legislatures the right to pass such laws (North Dakota Board of Pharmacy v Snyder’s Drug Stores, Inc., 414 US 156 (1973)). Few state legislatures have chosen to restrict ownership of pharmacies to pharmacists, instead to require that a registered pharmacist be placed in charge of every pharmacy. At the same time, states allow OTCs to be sold in non-pharmacy outlets. Most states require registration of these sellers, as does Washington. Non-pharmacy sellers of OTCs in Washington must be registered as Shopkeepers or Itinerant Vendors (see Chapter 3).

7. **Dietary Supplements.** Dietary supplements are regulated by the Dietary Supplement Health and Education Act of 1994 (DSHEA). The Act was passed to allow certain health-related claims to be made for dietary supplements without violating the FDCA or causing the supplements to be regulated as if they were drugs.
   a. **Dietary supplements** are defined under the DSHEA as articles containing one or more of the following
      i. Vitamin
      ii. Mineral
      iii. Herb or other botanical
      iv. Amino acid
   b. To be considered dietary supplements, a product must be
      i. **Intended to supplement the diet** by increasing total dietary intake, or
      ii. A concentrate, extract, metabolite, constituent or combination of the above.
   c. The dietary supplement must also be
      i. **Intended for ingestion**
      ii. Not represented for use as a conventional food or sole item of a meal or diet
      iii. **Labeled as a dietary supplement**
   d. If the article meets all of the above requirements, it is deemed to be a food, and is regulated by the FDA as a food, subject to some specific labeling requirements.
   e. **Allowable labeling** for a dietary supplement can
      i. Claim benefit related to a **classic nutritional deficiency disease** (e.g., scurvy, beri-beri)
      ii. **Describe the role** of a nutrient intended to affect the structure or function of the body
      iii. Characterize the **mechanism of action**
      iv. Describe **general well-being** gained from consuming a nutrient
      v. **Must state that the FDA has not evaluated any labeling claims**
f. The FDA can take action against false statements, adulterated or misbranded products, or remove from market products that are shown to be harmful
   i. Dietary supplements containing ephedra or ephedrine alkaloids (ephedrine, ephedrine HCl, ephedrine sulfate, and ratshephedrine HCl) were banned in the US by FDA rule making in February 2004 (69 FR 6788-6853) that declared such products adulterated (21 CFR 119).

g. Sellers May Not Add Promotional Information that is not allowed in Labeling. Sellers of dietary supplements may not juxtapose non-complying material (books, advertisements, etc.) with dietary supplements in such a way as to make health claims not allowed in the labeling
   i. Sellers may sell or display articles, books, and abstracts of peer-reviewed scientific publications.
      1. These must be reprinted in their entirety
      2. Must be presented with other publications to present a balanced view
      3. Must be physically separate from the product
   ii. Sellers may not apply information to the product by sticker, shelf-talker, etc., that would make claims not allowed in labeling.

8. Legend Drugs (Prescription Only Drugs)
   a. FDA determines a drug’s status on a case-by-case basis. Unless the drug can be marketed as an OTC product in accordance with the various approved monographs, a new entity will be evaluated on a case-by-case basis to determine whether it can be marketed OTC or must be prescription only.
      i. Washington designation of prescription only drugs. For the purposes of the state Legend Drug Act, the Board of Pharmacy is charged with determining by regulation the drugs covered by the Act. (RCW 69.41.010(12)). The Board has traditionally done this by specifying a nationally-recognized list of drugs requiring a prescription under federal law, i.e., the Drug Topics Red Book.
         1. For the period from May 31, 2008 through June 1, 2009, the Board has adopted the 2008 edition of the Drug Topics Red Book (WAC 246-883-020, filed 10/1/08). In November 2009, the Board published its intent to adopt the 2009 edition of the Red Book.  
         2. Marketed products that are in fact legend drugs under federal law, but not listed in the Red Book, may or

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115 WSR 08-20-127. The Board had not updated this regulation for some time; the prior official list was the 2002 Red Book.
116 WSR 09-22-083.
may not constitute legend drugs under Washington law. This is usually a technical issue when a person is charged with a violation of RCW 69.41. For pharmacists, however, dispensing such a product without prescription would violate federal law, in any case, which is a basis for discipline.

b. **“Rx” Symbol on Label.** Regulated under §502 of the US Food, Drug, and Cosmetic Act (FDCA – 21 USC Subpart 9). Formerly, prescription drugs were required to bear the *legend*, “Caution: Federal Law prohibits dispensing without a prescription.” Now they may merely bear the “Rx” symbol.

c. **Bar coding requirements for institutional use drugs.** Although most bulk packages of prescription drugs have a bar code on the label, unit-dose items often do not. The lack of bar coding on individual packages of prescription drugs has hampered the implementation of bar code scanning systems in hospitals, which are seen as an essential element for improving patient safety. The FDA adopted regulations in 2004, which became effective in April 2006, requiring certain human drug and biological product labels to contain a bar code consisting of the NDC number in a readily scanned format. (21 CFR 201.25) Exemptions can be sought for selected products. Covered products include:

i. Versions of prescription drug products that are sold to or used in hospitals, except:
   1. Prescription drug samples
   2. Allergenic extracts
   3. IUDs treated as drugs
   4. Medical gases
   5. Radiopharmaceuticals
   6. Low-density polyethylene (LDPE) form fill and seal containers not packaged with an overwrap

ii. Biological products

iii. OTC products that are dispensed pursuant to an order and are commonly used in hospitals

d. **Pharmacist labeling of dispensed prescription drugs.** As with OTC drugs, a legend drug is *misbranded* if its labeling is incomplete or misleading. Dispensing a legend drug pursuant to a prescription without a prescription label is a form of misbranding.

i. The “*label*” of a legend drug is the actual label affixed to the bottle or box containing the medication. The “*labeling*” includes the label, and any other printed or written material accompanying the drug. Labeling also includes statements made by the manufacture in promotional materials, advertisements, or other communications to patients or health professionals.
ii. **Labels on ambulatory prescriptions.** The FDCA and state law requires the following on the label of a prescription dispensed by a pharmacist to a patient:

<table>
<thead>
<tr>
<th>Table 4-8a. Elements required on a prescription label dispensed to a patient (Ambulatory Pharmacy, Hospital Outpatient)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Elements required on a prescription label dispensed to a patient</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Name and address of the pharmacy</td>
</tr>
<tr>
<td>A serial number</td>
</tr>
<tr>
<td>Name of prescriber</td>
</tr>
<tr>
<td>Name of patient, if on the prescription</td>
</tr>
<tr>
<td>Name of patient</td>
</tr>
<tr>
<td>Directions for use, if on the prescription</td>
</tr>
<tr>
<td>Complete directions for use</td>
</tr>
<tr>
<td>“As directed” prohibited. (WAC 246-875-020(1)(h))</td>
</tr>
<tr>
<td>Date of filling or refilling</td>
</tr>
<tr>
<td>Name and strength of drug</td>
</tr>
<tr>
<td>Quantity dispensed</td>
</tr>
<tr>
<td>Max. 31 day supply</td>
</tr>
<tr>
<td>An expiration date. Often called a “use before” or “discard after” date</td>
</tr>
<tr>
<td>A Transfer Caution Label containing the statement, “Warning: State or Federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed”</td>
</tr>
<tr>
<td>Identity of pharmacist responsible for dispensing.</td>
</tr>
<tr>
<td>Supplemented by additional oral or written information as required by regulation. Includes auxiliary labels.</td>
</tr>
<tr>
<td>A Side Effects Statement: “Contact your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.”</td>
</tr>
</tbody>
</table>

* May be omitted if prescriber requests.

** May be omitted if tracked in the patient record system.

*** May be omitted if present on container cap, a MedGuide, PIL, or other printed matter presented to patient with each prescription.

e. **Labeling Requirements for Non-ambulatory Prescription Medications.** Drugs supplied to hospitals, nursing homes, and physician offices must meet the general labeling requirements of the FDCA. How those drugs are labeled in these settings when they are being prepared for administration to patients is left primarily to state law or, for Medicare and Medicaid patients, to
regulations issued by CMS. The Board of Pharmacy in Washington has developed specific regulations for several settings (see also Chapter 3), which is summarized in the following table:

| Table 4-8b. Elements Required on Non-Ambulatory Prescription Drug Labels in Washington |
|-----------------------------------------------------|------------------|-----------------|-----------------|-----------------|
| Hospital, Parenteral                               | Hospital, Inpatient | Non-hospital, Parenteral | ECF, Non-unit Dose | ECF, Unit Dose   |
| WAC                                                 | 246-873-080(5)c   | 246-873-080(5)a | 246-871-050      | 246-865-060(4)a | 246-865-040(4)b |
| Phcy Name                                           | ✓                 | ✓               | ✓               |                 |
| Phcy Address                                        | ✓                 | ✓               | ✓               |                 |
| Phcy Phone                                          | ✓                 | ✓               | ✓               |                 |
| Rx Number                                           | ✓                 | ✓               | ✓               |                 |
| 24-hr Phone                                         | ✓                 | ✓               | ✓               |                 |
| Pt Name                                              | ✓                 | ✓               | ✓               | On cassette     |
| Pt Location                                         | ✓                 | ✓               | ✓               | On cassette     |
| Prescriber                                          | ✓                 | ✓               | ✓               |                 |
| Drug Name                                           | ✓                 | ✓               | ✓               | ✓               |
| Drug Conc. or Strength                              | ✓                 | ✓               | ✓               | ✓               |
| Dosage                                               | ✓                 |                 |                 |                 |
| Lot No.                                             |                  |                 |                 | In profile     |
| Directions for use                                  | ✓                 |                 |                 |                 |
| Infusion rate                                        | ✓                 |                 |                 |                 |
| CSA Sched.                                          | ✓                 | ✓               | ✓               |                 |
| Quantity                                             | ✓                 |                 |                 |                 |
| Date Prepared or Dispensed                          | ✓                 | ✓               | ✓               |                 |
| Exp. Date                                           | ✓ (“appropriate dating”) | ✓ | ✓ | ✓ |
| Expiration Time                                     | ✓ (“appropriate dating”) | | | ✓ |
| Storage instructions                                | ✓                 | (“appropriate”) | ✓               |                 |
| RPh Initials                                        | ✓ (“appropriate”) | | |                 |
| Preparer Initials                                   | ✓ (“appropriate”) | | | In Profile |
| Auxiliary Labels                                    | ✓ (“appropriate”) | (“appropriate”) | (see WAC) |                 |
| Transfer Caution Label                               | ✓                 |                 |                 |                 |

f. **Professional Labeling and Prescribing Information.** Labeling of a prescription drug includes **prescribing information**, which is often called the **package insert**. The law does not prohibit the patient from receiving the package insert.
i. **Structured Product Labeling.** The FDA has recently issued revised regulations to standardize the package insert and make it more useable by prescribers and pharmacists. A tutorial on the new product labeling is available at CDERLearn\(^{117}\). The rule became effective in 2006, and is applicable to:
   1. All new legend drugs approved on or after the effective date
   2. Drugs approved within 5 years prior to the effective date
   3. Older drugs when there is a major change in the prescribing information

ii. **“Highlights of Prescribing Information”** will be the first section of the insert. It will summarize the following:
   1. Recent Major Changes
   2. The Drug Approval Date
   3. Adverse Event Reports
   4. Table of Contents

iii. **The major sections are now numbered, and referred to in the Highlights and Table of Contents.** The new regulations put information on use, dosage, and precautionary statements first, whereas the descriptive information was first in older inserts.
   1. Indications and usage
   2. Dosage and administration
   3. Dosage forms and strength
   4. Contraindications
   5. Warnings and precautions
   6. Adverse reactions
   7. Drug interactions
   8. Use in specific populations
   9. Drug use and dependence
   10. Overdosage
   11. Description
   12. Clinical pharmacology
   13. Nonclinical toxicology
   14. Clinical studies
   15. References
   16. How supplied, storage, and handling
   17. Patient counseling information

\(^{117}\) [http://www.fda.gov/cder/learn/CDERLearn/default.htm](http://www.fda.gov/cder/learn/CDERLearn/default.htm)
iv. “Contraindication” clarified. In a draft guidance document, the FDA makes it clear that a “contraindication” is a reason not to use the drug: “A drug should be contraindicated only in those clinical situations for which the risk from use clearly outweighs any possible therapeutic benefit. Only known hazards, and not theoretical possibilities, must be listed. If there are no known contraindications for a drug, this section must state ‘None’” [emphasis added].

118

g. “DailyMed.” The FDA has instituted a service in cooperation with the National Library of Medicine to electronically disseminate up-to-date and comprehensive information for use with information systems that support patient care. This site (http://dailymed.nlm.nih.gov) is a source of the most current labeling for the drugs that are listed. Not all drugs are listed, but as of January 2009, over 4,200 product labels were available.

h. Patient Patient Inserts, PILs, and MedGuides.
   i. Many products also contain additional patient package inserts (PPIs), which are intended to be included with the dispensed prescription. Failure to dispense a patient package insert or MedGuide, unless specifically directed to withhold it by the prescriber, is considered misbranding. However, if a patient requests a PPI or MedGuide, it must be provided, even if the prescriber has directed otherwise (21 CFR 208.26(b))
      1. Two specific parts of the CFR deal with patient package inserts for oral contraceptives and with estrogens.
         a. Oral contraceptive inserts consist of a complete insert and a brief insert. Both must be dispensed to ambulatory patients each time the drug is dispensed. In hospitals, these must be provided to the patient at the first dispensing, and once every 30 days.
         b. Estrogens also require a single patient information leaflet be dispensed with each prescription and each refill. In hospitals, these must be provided to the patient with first use of the drug, and every 30 days.
   ii. Patient Information Leaflets (PILs). PILs are supplementary information sheets provided by pharmacies

as part of the prescription process. These are generally written by 3rd party providers, of which FirstDataBank and MediSpan are among the largest. Washington requires that written information accompany prescriptions that are delivered outside the confines of the pharmacy, and it is a national standard of practice to provide written material to patients that expands and reinforces the information they need to properly use their drugs, which should also be communicated during patient counseling.

iii. **MedGuides** The FDA has authority under 21 CFR 208 to require a “MedGuide” in a specific format to accompany a particular drug product. The FDA has become active in requiring MedGuides, which replace PILs when they are required. Numerous difficulties for pharmacies have arisen in obtaining adequate quantities of MedGuides from manufacturers, and in incorporating MedGuide distribution into pharmacy workflows. The FDA held a public hearing on MedGuide Reform in June, 2007. The National Community Pharmacists Association (NCPA) estimated that the additional cost of printing the currently-required MedGuides exceeds $89 million per year, and presented several recommendations to FDA in concerning changes to the MedGuide program. The National Association of Chain Drug Stores (NACDS) summarized the following issues with the MedGuide Program:

1. FDA is not implementing MedGuides in a manner consistent with its own regulations
2. Major reforms are needed to make MedGuides effective for patients
3. Little evidence exists that MedGuide distribution improves patient understanding of medications
4. Patients may be overwhelmed with too much information from multiple sources
5. Long-term solution is a single document, of no more than 2 pages, that combines MedGuides with Consumer Medicine Information (CMI)

The American Society of Health-System Pharmacists summarized the following concerns, as well:
- FDA’s reliance on outmoded preprinted leaflets & cumbersome distribution mechanisms
- FDA’s unwillingness to permit use of well-established electronic means for generation
- Resultant low levels of distribution

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• Gross underestimates of burden relative to original (1998) estimates
• Consumer confusion from wide array of documents (CMI, MedGuides, PPIs PISs)
• Lack of research concerning the role, scope, and effects on patient understanding and behavior\textsuperscript{121}

Nevertheless, the FDA continues to rely heavily on MedGuides as key elements of newly-developed REMS plans.

iv. \textbf{Antidepressant labeling and packaging}. Following criticisms that the FDA encouraged manufacturers of antidepressants to withhold information or otherwise suppressed evidence\textsuperscript{122} from clinical trials that suggested that antidepressants were associated with increased risk of suicide in children and adolescents, the FDA has (2005) requested all manufacturers of antidepressants to modify their labeling and packaging to include specific information for patients regarding the use of antidepressants in children and adolescents, following the MedGuide format. In addition, manufacturers were asked to discontinue distributing antidepressants to pharmacies in packaging that is not a unit-of-use package with an enclosed patient package insert.

1. This mandate affects manufacturers’ packaging, but it is not clear that it prevents physicians from prescribing, nor pharmacists from dispensing, quantities smaller or different than are available in the unit-of-use packaging provided by manufacturers. I believe that, when dictated by patient needs or safety, pharmacists should consider it professionally appropriate to dispense in smaller quantities than standard unit-of-use packaging; being sure to provide a copy of the patient information insert to the patient.

v. \textbf{FDA Index to Drug-Specific Information}. The FDA provides an index to currently marketed drugs for which specific FDA information materials have been published. These include HealthCare Professional, Patient, or Consumer Information Sheets, MedGuides, or Information Pages. The index can be accessed at \url{http://www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm}.

i. \textbf{Expiration Dates}. Manufacturers must place an expiration date on the containers of legend drugs, as well as a lot number. As pharmacists know from their education in pharmaceutics, these dates generally reflect a time when at least 95% of the drug’s

\textsuperscript{121} \url{http://www.fda.gov/downloads/Drugs/DrugSafety/UCM173475.pdf}
labeled potency is still available, and no undesirable degradation has taken place. These dates are usually assigned very conservatively by manufacturers. If the expiration date is specified in the form of a month, day, and year, the drug may not be dispensed after that date. If the date is specified as a month and year only, then the drug is considered expired after the last day of the month indicated. Pharmacists should not dispense a quantity of drug that cannot be used by the patient prior to the expiration date.

i. **“Use Before” or “Discard After” Dates.** Washington regulations (WAC 246-869-210(1)) specify that in determining a Use Before (or “Discard After”) date to place on a dispensed prescription, the pharmacist must consider several factors, including (a) **the nature of the drug**; (b) **the container in which it was packaged by the manufacturer and the expiration date thereon**; (c) **the characteristics of the patient’s container**, if the drug is repackaged for dispensing; (d) **the expected conditions to which the article may be exposed**; (e) **the expected length of time of the course of therapy**; and (f) **other relevant factors**. It is permissible to dispense medications in the manufacturer’s original container, and the expiration date and lot number may be left visible to the patient. Many states impose a one-year limit on the Use Before date, but there is no such limit in Washington. **Many computer systems used by retail pharmacies default to a one-year “Use Before” date.** Care should be taken to override this default if the actual manufacturer’s date is earlier than one year from the date dispensed.

ii. **Regular Inspection of Drug Stocks Required.** Pharmacists are required by regulation in WA to regularly inspect drugs in the pharmacy and remove products from their stock when the merchandise has exceeded its expiration date. (WAC 246-869-150(2)) Outdated drugs are considered adulterated.

j. **Prescribers who dispense drugs** must label the prescriptions in accordance with the same standards that are required for pharmacists. (RCW 69.41.050)

i. The **label** must contain the **name of the patient, name, strength of the drug, the date, the name of the prescriber, and complete directions for use.** The drug name and directions may be omitted on the basis of a considered judgment by the prescriber.

ii. **Sample packages** need to contain the **name of the prescriber and the name of the patient** (very seldom actually done, however).
iii. **Nurses may not dispense**, so if a prescriber dispenses a drug he or she must do it personally. Prescribers may not dispense drugs for other prescribers. (Except that PAs may dispense drugs ordered by their supervising physician.)

iv. **Veterinarians** are required by their disciplinary board to include complete directions for use, the name of the client or identification of the animal, the name of the drug and strength, and name of prescribing veterinarian. No exception is made for samples in this rule. (WAC 246-933-340(5)(b))

v. Prescribers are equally subject to the **USP requirements** for storage and **dispensing containers**, for to store or dispense drugs in violation of compendial standards is to subject the drugs to adulteration under the FDCA.

vi. Prescribers must also adhere to the **Poison Prevention Packaging rules**, except that they may specify non-CRC containers on a case-by-case basis for individual patients.

9. **Elements of a Prescription.** All of the following conditions must be present to authorize a pharmacist to dispense a legend drug in WA. (RCW 69.41.040)

   a. **Written for a specific patient.** Each prescription should be written for a specific, named patient. In order to fulfill the obligations to prevent adverse drug reactions and conduct drug use review, the pharmacist must be able to match the prescription order with a particular patient’s profile. Some patients have requested that they be allowed to use a code name to shield their identity (e.g., HIV-positive patients), but the Board of Pharmacy rejected the request. HIPAA requirements should be sufficient to assure confidentiality to those patients. Sometimes prescriptions are written for all the members of a family, or are written for one spouse who has insurance to provide drug for the uninsured spouse. These are challenges for the pharmacist, and these prescriptions are technically invalid.

   b. **Written by Authorized Prescribers** (RCW 69.41.030)
      
      i. All states allow physicians, podiatrists, dentists, and veterinarians to prescribe legend and controlled substances. Other practitioners may or may not have prescriptive authority for one or more classes of drugs
      
      ii. All states honor prescriptions from out of state physicians, podiatrists, dentists, and veterinarians.
      
      iii. Washington allows full or partial prescriptive authority to a variety of practitioners. Table 4-8-b summarizes prescriptive authority and scope of practice in WA. This table also includes academic and other abbreviations commonly used by professionals who practice in health care settings.
1. **Practitioners** – out of state prescriptions are acceptable. WA allows the following prescribers who are licensed in any state or US territory, or in British Columbia, to issue prescriptions for legend drugs that are valid in WA. (Note: Canadian prescribers cannot issue prescriptions for controlled substances unless they are also licensed in the US and registered with the DEA.)
   a. Physicians (MD) and Osteopathic Physicians (DO)
   b. Dentists (DMD, DDS)
   c. Podiatrists (PodD, DPM)
   d. Veterinarians (DVM)

2. **Mid-level practitioners** – out of state prescriptions are **not allowed** from these practitioners.
   a. Physician’s Assistants (PA, PA-C)
   b. Nurse Practitioners (ARNP) (includes Nurse Midwives)
   c. Nurse Anesthetists (CRNA)
   d. Optometrists (OD)
   e. Naturopaths (ND)
   f. Midwives (very limited)
   g. Pharmacists (R.Ph., Pharm.D.) under collaborative practice agreements
   h. Physical therapists (R.P.T., Dr.P.T.) and Occupational Therapists (O.T., Dr.O.T.) – may not prescribe, but may order and use certain legend drugs.

3. **Prescribing by Pharmacists.** The Board of Pharmacy has limited authority to review or approve collaborative practice agreements for pharmacists. The statute (RCW 18.64.011(11)) defines the practice of pharmacy to include “initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs.” The phrase, “initiating or modifying drug therapy” is tantamount to saying “prescribing.” Since this authority is inherent in the license to practice pharmacy, the does not authorize restriction of prescriptive authority to pharmacists with particular levels of training or experience. As long as the protocol or guideline is in writing, and approved by an authorized prescriber, the pharmacist may proceed. The Board has developed rules that establish
appropriate elements be contained in a collaborative practice agreement (WAC 246-863-100):

a. A written copy of the **approved protocol** must be on file in the pharmacy and on file with the Board of Pharmacy. The protocol must contain:

   i. The **identity of the authorizing practitioner and the pharmacist(s) authorized** must be stated. The guideline may authorize a pharmacist or a group of pharmacists.

   **Comment.** The Board has at times allowed a group to be described collectively, e.g., “all pharmacists practicing at Modern Pharmacy.” I believe this is inconsistent with the language of the statute which requires the protocol be approved for “his or her practice.” I believe **each pharmacist should be named in the protocol** specifically, and should have his or her own copy of the protocol.

   ii. A **time period**, not to exceed 2 years, during which the protocol will be in effect.

   iii. A statement of the **type of prescriptive authority authorized**, that includes:

   1. Types of diseases, drugs, or drug categories included, and the type of authority (i.e., initiating or modifying) allowed for each type.

   2. A general statement of the procedures, decision criteria or plan the pharmacist will follow when making therapy decisions.

   iv. A statement of the **activities the pharmacist is to follow** when exercising prescriptive authority, including documentation of decisions made, and a **plan for communication or feedback to the authorizing prescriber** concerning decisions made. The regulation allows documentation on the prescription, in a patient chart, patient medication profile, or separate logbook.

b. A pharmacist who exercises prescriptive authority is **responsible for obtaining informed consent** to the prescribed therapy, as are all other prescribers – see Chapter 7.
Table 4-9a. Practitioner and professional designations and prescribing limits in Washington.
(Revised January 6, 2010 — ©2002-2010, William E. Fassett)

This table provides descriptions of common academic degrees and/or professional designations commonly encountered in the health care environment. It also discusses drug-related dispensing, use, or prescribing authority issued to credentialed health care providers in Washington.

<table>
<thead>
<tr>
<th>Designation*</th>
<th>Indicates</th>
<th>Law Ref.**</th>
<th>Prescribing Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.R.N.P.</td>
<td>Advanced Registered Nurse Practitioner</td>
<td>RCW 18.79.250; WAC 246-840-410 et seq.</td>
<td>Drugs necessary for treatment of patients within specialty; C-5 controlled substances. May prescribe C-2, 3, and 4 if within scope of specialty. If has C-2 to 4 authority, may dispense up to a 72 hr supply, in addition to prescribing. Must place initials, “ARNP” on Rx. Example specialty areas: family practice (children and adults); psychiatric; pediatric; women’s health; nurse midwife. Nurses have sought legislative removal of the 72-hour dispensing limit for CSA drugs, citing need to be able to dispense samples of certain drugs, but action was not taken on this request in the 2008 Legislature.</td>
</tr>
<tr>
<td>C.Ph.T.</td>
<td>Certified Pharmacy Technician</td>
<td>RCW 18.64A; WAC 246-869-060</td>
<td>A pharmacy technician who has passed a certifying examination provided by the Pharmacy Technicians Certification Board (the PTCE) or the Institute for Certification of Pharmacy Technicians (the ExCPT). As with other pharmacy technicians, may assist pharmacists by performing non-discretionary tasks related to dispensing. All new applicants for pharmacy technician registration in Washington must have completed one of these examinations, but do not need to maintain certification.</td>
</tr>
<tr>
<td>C.R.N.A.</td>
<td>Certified Registered Nurse Anesthetist</td>
<td>RCW 18.79.240(r)</td>
<td>Drugs used in anesthesia practice; scope of practice established by American Association of Nurse Anesthetists. May prescribe drugs, including C-2 to C-5 for anesthesia in accordance with protocols approved within the facility. Is a specialty area practiced by ARNPs in WA.</td>
</tr>
<tr>
<td>D.C.</td>
<td>Doctor of Chiropractic</td>
<td>RCW 18.25</td>
<td>No prescriptive authority</td>
</tr>
<tr>
<td>D.D.S., D.M.D.</td>
<td>Doctor of Dental Surgery, Doctor of Dental Medicine</td>
<td>RCW 18.32</td>
<td>Same scope as MD as long as treating diseases of the head and neck.</td>
</tr>
<tr>
<td>D.N.P.</td>
<td>Doctor of Nursing Practice; see R.N.</td>
<td>A clinical doctorate awarded to nurses; it is intended to become the primary credential for nurse clinicians and nurse practitioners. Same scope as A.R.N.P.</td>
<td></td>
</tr>
<tr>
<td>D.O.</td>
<td>Doctor of Osteopathy;</td>
<td>RCW 18.57</td>
<td>Osteopathic Physician and Surgeon; same scope as MD</td>
</tr>
<tr>
<td>D.P.M</td>
<td>Doctor of Podiatric Medicine, see also Pod.D.</td>
<td>RCW 18.22</td>
<td>Podiatry is the diagnosis and treatment of diseases of the foot. Podiatrists may not amputate feet, administer spinal or general anesthesia, or treat systemic conditions. May prescribe all drugs and controlled substances necessary in the practice of podiatry.</td>
</tr>
<tr>
<td>Designation*</td>
<td>Indicates</td>
<td>Law Ref.**</td>
<td>Prescribing Limits</td>
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<tr>
<td>Dr.O.T., O.T.</td>
<td>Doctor of Occupational Therapy, Occupational Therapist</td>
<td>RCW 18.59.160</td>
<td>&quot;may purchase, store, and administer topical and transdermal medications such as hydrocortisone, dexamethasone, fluocinonide, topical anesthetics, lidocaine, magnesium sulfate, and other similar medications for the practice of occupational therapy as prescribed by a health care provider with prescribing authority … Administration of medication must be documented in the patient's medical record. Some medications may be applied by the use of iontophoresis and phonophoresis. An occupational therapist may not purchase, store, or administer controlled substances. A pharmacist who dispenses such drugs to a licensed physical therapist is not liable for any adverse reactions caused by any method of use by the occupational therapist.&quot;</td>
</tr>
<tr>
<td>Dr.P.T., R.P.T.</td>
<td>Doctor of Physical Therapy, Registered Physical Therapist</td>
<td>RCW 18.74.160</td>
<td>&quot;May purchase, store, and administer medications such as hydrocortisone, fluocinonide, topical anesthetics, silver sulfadiazine, lidocaine, magnesium sulfate, and other similar medications, and may administer such other drugs or medications as prescribed by an authorized health care practitioner for the practice of physical therapy. A pharmacist who dispenses such drugs to a licensed physical therapist is not liable for any adverse reactions caused by any method of use by the physical therapist.&quot;</td>
</tr>
<tr>
<td>D.V.M.</td>
<td>Doctor of Veterinary Medicine</td>
<td>RCW 18.92; WAC 246-933-340(5)b</td>
<td>Unlimited scope as long as treating animals. May prescribe for animals and prescriptions may be filled by pharmacists. May dispense drugs for prescribed by other veterinarians, subject to certain limits.</td>
</tr>
<tr>
<td>J.D.</td>
<td>Juris Doctor (doctor of law)</td>
<td></td>
<td>Attorney. No prescriptive authority. By convention, within legal circles attorneys who hold the J.D. do not use the title &quot;doctor,&quot; but are referred to as &quot;Mr.,&quot; &quot;Ms.,&quot; etc.</td>
</tr>
<tr>
<td>L.P.N.</td>
<td>Licensed Practical Nurse</td>
<td>RCW 18.79</td>
<td>May administer prescribed drugs.</td>
</tr>
<tr>
<td>M.D.</td>
<td>Doctor of Medicine, Physician and Surgeon</td>
<td>RCW 18.71</td>
<td>All drugs needed for his or her patients. No limits on controlled substances unless restricted for a given practitioner by the board of medical examiners.</td>
</tr>
<tr>
<td>Midwife</td>
<td>Licensed Midwife (not a nurse midwife)</td>
<td>WAC 246-834-250</td>
<td>May order and use drugs needed in delivery and immediately post-partum. May prescribe a limited list of products, and pharmacists may fill their orders for diaphragms issued for post-partum women.</td>
</tr>
<tr>
<td>Nurse Midwife</td>
<td>ARNP</td>
<td></td>
<td>A specialty area of practice for ARNPs, same authority as ARNPs.</td>
</tr>
<tr>
<td>N.D.</td>
<td>Doctor of Naturopathy</td>
<td>RCW 18.36A; WAC 246-836-210</td>
<td>All legend drugs with the exception of Botulinum toxin (e.g., Botox®) and inert substances used for cosmetic purposes. Non-drug contraceptive devices. Controlled substances are limited to codeine and testosterone products that are contained in Schedules III, IV, and V in chapter 69.50 RCW. May not treat malignancies except in collaboration with a physician (MD or DO).</td>
</tr>
<tr>
<td>O.D.</td>
<td>Doctor of Optometry</td>
<td>RCW 18.53; WAC 246-851-580, 590</td>
<td>Prescribes eye glasses and contact lenses, and treats minor eye conditions. Currently there are 4 levels of authority: (a) May order and use topical ophthalmic products for diagnosis and refraction. (b) May also prescribe topical ophthalmic drugs in WA. (c) May also prescribe certain oral drugs including C-3, 4, and 5 drugs, (d) may also administer epinephrine injection for anaphylactic shock. Levels (b), (c) and (d) must show &quot;TX&quot; on prescription after license number. Under revised legislation, all optometrists will need to qualify for all 4 levels of prescriptive authority by 2011. Allowed drugs are listed in WAC 246-851-580 and -590. Limits: Benzodiazepines for anti-anxiety associated with procedures – single doses per Rx; CSA not more than 7 days; C-3 or C-4, not more than 30 dosage units/Rx.</td>
</tr>
<tr>
<td>Designation*</td>
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<tr>
<td>PA</td>
<td>Physician’s Assistant&lt;br&gt;Physician Assistant-&lt;br&gt;Certified Osteopathic Physician’s Assistant&lt;br&gt;Osteopathic PA -Certified</td>
<td>RCW 18.57A; 18.71A; WAC 246-854-030; WAC 246-918-030, 035.</td>
<td>PA: May prescribe legend drugs and controlled substances if specifically designated by licensing authority. Osteopathic PA may not prescribe C-2s, and must have CSA prescriptions countersigned.&lt;br&gt;PA-C: May prescribe legend drugs and controlled substances. Osteopathic PA may not prescribe C-2s.&lt;br&gt;Both PA and PA-C: Limited to a list of drugs approved by supervising physician. Must write on supervising physician’s prescription blank. Needs own DEA number if prescribing CSAs. May dispense drugs from office when prescribed by supervising physician. Indicates “PA” or “PA-C” after name.</td>
</tr>
<tr>
<td>Ph.D.</td>
<td>Doctor of Philosophy</td>
<td>RCW 18.64; WAC 246-863-100</td>
<td>Research degree in many fields, including pharmacy, nursing, psychology, pathology, etc. Has prescriptive authority only related to a prior professional degree. May be addressed as “doctor,” but should not use the title to imply expertise outside their training.</td>
</tr>
<tr>
<td>Pharm.D., B.S. Pharm., B.Pharm., R.Ph.</td>
<td>Doctor of Pharmacy; Bachelor of Science in Pharmacy; Bachelor of Pharmacy; Registered Pharmacist</td>
<td></td>
<td>May prescribe (“initiate or modify therapy”) in accordance with approved protocol as part of collaborative practice agreement. Same limits for his or her protocol as the authorizing prescriber. Must have DEA number to prescribe CSAs. May administer prescribed drugs.</td>
</tr>
<tr>
<td>Pod.D.</td>
<td>Doctor of Podiatry – see also D.P.M.</td>
<td>RCW 18.22</td>
<td>Same scope as M.D. if treating or performing surgery on feet or ankles.</td>
</tr>
<tr>
<td>R.N., B.S.N., M.N., M.S.N., D.N.P.</td>
<td>Registered Nurse; Bachelor of Science in Nursing, Master of Nursing; Master of Science in Nursing; Doctor of Nursing Practice</td>
<td>RCW 18.79</td>
<td>No prescriptive authority unless also an ARNP. May administer drugs ordered for his or her patients. The Nursing Care Quality Assurance Commission has determined that nurses may restock remote drug dispensing devices. Many ARNPs hold either the M.N. or M.S.N. degrees, and the D.N.P. (Doctor of Nursing Practice) degree is intended to become the primary graduate degree for nurse practitioners and nurse clinicians. Nurses who are not ARNPs or CRNAs may convey a prescriber’s order but cannot be delegated to prescribe or authorize refills.</td>
</tr>
<tr>
<td>R.T., R.R.T., Respiratory Care Practitioner</td>
<td>Respiratory Therapist; Registered Respiratory Therapist</td>
<td>RCW 18.89</td>
<td>Now licensed as Respiratory Care Practitioners in Washington. May administer prescribed respiratory drugs.</td>
</tr>
<tr>
<td>R.V.M.C.; R.V.T.</td>
<td>Registered Veterinary Medication Clerk; Registered Veterinary Technician</td>
<td>RCW 19.92.30; WAC 246-935, 937</td>
<td>R.V.M.C. may perform dispensing tasks under direct supervision of a veterinarian, and may deliver verified drugs to a client. R.V.T. may administer veterinary drugs under direct or indirect supervision of veterinarian.</td>
</tr>
</tbody>
</table>

*Academic degrees are in **BOLD ITALIC.**  ** See also RCW 69.41.030 and RCW 69.50.101(w)

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123 This degree was offered in the US only for the 5-year baccalaureate program at Washington State University. It was formerly the entry-level degree for pharmacists offered in Australia, India, Ireland, and the United Kingdom.
124 Board of Pharmacy meeting minutes, October 25, 2007, p. 5.
iv. **Prescribing authority may not be “delegated,” unless specifically provided in statute.** As the Board of Pharmacy has recently noted, “Valid prescriptions must be ‘signed,’ either manually or electronically, by a practitioner with prescriptive authority. … the act of ‘signing’ a prescription cannot be delegated. A registered nurse may ‘prepare' a prescription for manual or electronic signature, but the prescribing practitioner is always responsible for ensuring that the prescription conforms in all the essential elements to the law and regulations.”\(^{125}\)

1. Where otherwise allowed by law, a nurse or staff member may “communicate” a prescription to the pharmacist at the prescriber’s request. When a telephoned prescription or refill reauthorization is allowed, a nurse or designated staff member may communicate the order to the pharmacist at the direction of the prescriber.

v. **Deceased or Disciplined Prescriber.** What becomes of his or her prescriptions when a prescriber loses his or her license or dies? Obviously, no prescriptions written after the loss of a license could be valid, and prescribers cannot issue prescriptions from the grave (there have been cases where a deceased physician’s widow continued to try to operate his practice after his death). In Washington, however, it appears that prescriptions, when written by an authorized prescriber, are valid until they legally expire, even if the prescriber subsequently loses his or her license to practice (State v. Clausing, 147 Wn.2d 620 (2002) – see below). Because a patient can no longer obtain care from a practitioner when that practitioner is not licensed, but a prescription previously-written by that practitioner is still valid, then, by extension, there is also no basis to invalidate the previously-issued prescriptions of a practitioner who dies.

1. A former executive director of Washington’s Board of Pharmacy was publicly on record that “prescriptions die with the prescriber,” and that when a prescriber loses his or her license, the prescriptions she or he previously wrote now become invalid. However, when the executive director provided testimony in a state court criminal trial that a physician’s previously-written prescriptions become invalid when that physician loses his or her license, the Washington Appeals Court subsequently opined that “The State concedes that this opinion 'does not appear to be explicitly

supported in statutory law,’ and indeed, there is no Washington authority for [the executive director’s] statement." (State v. Clausing, 104 Wn. App. 75, 86, 15 P.3d 203 (2001)) The Washington Supreme Court subsequently declared that the executive director’s opinion “was an erroneous one ...” (State v. Clausing, 149 Wn.2d 620, 629, 56 P.3d 550 (2002)).

2. However, if a patient presents a new or refill prescription, and there are problems with the prescription that preclude dispensing the medication until they are resolved, the pharmacist cannot consult with a dead or unlicensed prescriber, and will need to locate a licensed practitioner currently caring for the patient to resolve them.

3. If a patient has a new or refillable prescription that is not expired under Washington law, and there are no problems related to the prescription that need to be resolved in order to provide the patient with pharmaceutical care, the pharmacist may consider the prescription valid.

4. In every case, the best practice for a pharmacist to follow is one that assures continuity of patient care; making sure that patients remain in appropriate relationships with currently-licensed practitioners, but at the same time not causing the patient to go without necessary medication.

c. Issued in the Due Course of Medical Practice (RCW 69.41.040)
   i. Must be prescribed in the context of a bona fide prescriber-patient relationship. Prior to issuing a prescription, for example, the prescriber must have conducted an appropriate examination and maintained proper records, and made a professional judgment.

   1. Prescriptions that are “sold” to patients are not valid. For example, Internet prescribing seldom involves a bona fide patient-prescriber encounter. Likewise, prescription “mills” where patients pay to have prescriptions written (often for CSAs) do not produce valid prescriptions that a pharmacist can lawfully dispense.

   2. Internet prescriptions are generally invalid. Prescriptions written by physicians on the basis of a Internet questionnaire filled out by the patient are generally invalid, because there is no actual examination of the patient involved.
Congress passed Public Law 110-425, named after Ryan Haight, a high school senior in La Mesa, CA, who died in 2001 following ingestion of Vicodin obtained from an online pharmacy in Oklahoma. The act prohibits the delivery dispensing or distribution of a controlled substance via the Internet unless it is pursuant to a prescription issued by a practitioner who has conducted at least one in person physical examination and evaluation of the patient within the prior 24 months. It also requires Internet pharmacies to register with the DEA prior to engaging in Internet pharmacy involving controlled substances (see chapter 5).

3. Treatment of partners for sexually-transmitted diseases. A physician may prescribe antibiotics to treat a patient with Chlamydia or gonorrhea, and issue a prescription for the patient’s partner, even though the partner has not been examined. This activity is known as “Expedited Partner Therapy (EPT)”, and is considered acceptable and ethical medical practice, because without treatment of the partner, the patient is likely to become reinfected. The benefits of treating the partner may be seen to outweigh the risk of adverse effects arising from a less-than-ideal prescribing and dispensing situation. The Washington Medical Quality Assurance Commission has issued a policy statement acknowledging the appropriateness of such prescribing under certain circumstances. Under this policy, the bona fide physician-patient relationship is considered established, so the prescriptions are valid.

In accordance with this policy, public health clinics in Washington distribute “partner packs” which may or may not contain the partner’s name on the label. Quite a few counties distribute these partner packs free through participating community pharmacies. Not all county health departments provide these services, however. The Board of Pharmacy has provided input to the Department of Health on this

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126 [http://www.cdc.gov/std/ept/default.htm](http://www.cdc.gov/std/ept/default.htm)
program and has encouraged pharmacist to contact their local public health clinic for more specific information on the special prescribing protocol for partner packs.\textsuperscript{129}

Even when prescriptions are written for EPT outside of such a protocol, the pharmacist is justified in dispensing these prescriptions in outpatient pharmacies if certain steps are taken.

1. Importantly, unless the patient’s 3\textsuperscript{rd} party payer specifically allows it, do not charge a 3\textsuperscript{rd} party for the partner’s medication.

2. Determine as best as possible whether the partner has any conditions or allergies which would preclude use of the drug.

3. Advise the patient to tell the partner to confer with a pharmacist or physician before taking the drug if the partner has drug allergies or is on any medication.

4. In many cases, the prescriber does not know or indicate the partner’s name on the prescription. This creates a problem under Washington law, which requires that the name of the person receiving the drug must be on the prescription. However, the Board of Pharmacy has given tacit approval to the Department of Health’s protocol using partner packs. Other states do allow processing of these kinds of prescriptions. For example, when the physician does not provide, and the patient refuses to name, the partner, on an outpatient prescription for EPT, the following approach has been suggested and approved by the Colorado Board of Pharmacy:\textsuperscript{130}

i. Prepare a separate container for the partner’s medication.

ii. Label the patient’s prescription with the patient’s name

iii. Label the partner’s prescription with the partner’s name, if known, or with the patient’s name followed by “Partner” (e.g., Jordan Smith’s Partner).

iv. Issue a separate prescription number for each prescription.


\textsuperscript{130} http://www.dora.state.co.us/pharmacy/policies/40-4.pdf
ii. Must be within the **scope and authority of the prescriber**. A podiatrist cannot prescribe medications for congestive heart failure, even though ankle edema is a result of CHF. A dentist cannot normally prescribe birth control pills. Likewise, some practitioners, such as optometrists, are not able to prescribe Schedule II drugs in most states. Veterinarians cannot prescribe drugs for humans, and MDs cannot prescribe drugs for cats or dogs. A pharmacist who knows, or should know, that a particular prescription is not within the scope or authority of the issuing prescriber has a corresponding responsibility not to fill the prescription. The pharmacist must be aware, however, of current trends in use of drugs by the various practitioners who normally prescribe for his or her clients. If in doubt, ask the prescriber to fill you in on how they intend the drug to be used, so you can help the client understand its use better.

d. **Issued for a Legitimate Medical Purpose**

i. Drugs used for non-medical purposes include stimulants for "recreational use" or androgens for weight training. This could include Ipecac used by persons with eating disorders. Non-legitimate drug use is a greater problem with controlled substances than with legend drugs. Nevertheless, if a pharmacist knows or should know that the drug is being used for a non-medical purpose, he or she is not authorized to dispense the product.

ii. Specific statutory prohibitions exist against prescribing, administering, or dispensing "steroids," or any form of autotransfusion, for the purpose of manipulating hormones to increase muscle mass, strength, or weight, or to enhance athletic ability unless medically necessary (e.g., runner’s anemia). Steroids include

1. “Anabolic steroids”
2. “Androgens”
3. “Human growth hormone” (RCW 69.41.300-310)
4. The Board of Pharmacy has listed by regulation particular drugs that constitute steroids (WAC 246-863-040).

iii. **Off-label uses.** Drugs may be prescribed for uses not included in their package insert; this is not the same as issuing a prescription for other than a legitimate medical purpose. The FDCA prohibits manufacturers from promoting drugs for off label use, but does not restrict the practice of medicine under state law. When dispensing a prescription written for a non-FDA approved indication, the pharmacist should be aware of the intended use, and the literature supporting it. The pharmacist must distinguish between use
of the drug for a condition not listed in the package insert and prescribing of doses that are outside the normal range for the drug. Resources available to evaluate off label uses include the American Hospital Formulary Service (AHFS) and the USP-DI. (See chapter 8 regarding off label uses and Medicaid or Medicare prescriptions.)

e. **Legible.** Written prescriptions in Washington must be “legible”
   i. RCW 69.41.120 requires written prescriptions to be legible.
   ii. RCW 69.41.010(13) defines a “legible prescription” as “capable of being read and understood by the pharmacist filling the prescription or the nurse or other practitioner implementing the medication order. A prescription must be hand printed, typewritten, or electronically generated.” This statute is interpreted to declare prescriptions or drug orders written in cursive to be legally “illegible.”
   iii. Pharmacists who fill illegible prescriptions without verifying the prescription are liable for damages caused to their patients.
   iv. The best strategy for dealing with a prescription in cursive handwriting is to call the prescriber to verify it, and indicate on the prescription the verified order.

f. **Tamper-Resistant Prescription Pads.**
   i. **For Medicaid recipients.** A provision in an omnibus Iraq War and Katrina Recovery appropriations bill requires written prescriptions issued for Medicaid recipients to be executed on tamper-resistant prescription pads. CMS has published a fact sheet for pharmacists.
      1. A qualifying prescription pad contains the following elements:
         a. One or more industry-recognized features designed to prevent copying;
         b. One or more industry-recognized features designed to prevent erasure or modification; and
         c. One or more industry-recognized features designed to prevent use of counterfeit forms.
   2. The rule does not apply to oral prescriptions, faxed prescriptions, or electronic prescriptions, or to refills of prescriptions which were issued prior to the effective date (June 2006).
   3. When receiving transferred prescriptions for Medicaid patients, the receiving pharmacist must confirm from

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131 U.S. Troop Readiness, Veteran’s Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, § 7002(b).
the transferring pharmacist that the prescription was written on tamper-resistant pad or was exempt.

4. Pharmacists may fill non-complying prescriptions in emergencies as long as confirmation from the prescriber is received by fax, phone, or e-mail within 72 hours. Pharmacist should document the time of day dispensed in the time of day that confirmation is received.

5. Pharmacists may confirm noncomplying prescriptions with the prescriber, either verbally or by fax, if the confirmation is received before the product is dispensed to the patient. The exact time of day that the confirmation is received, and that the product is dispensed, should be documented.

6. Pharmacies that dispense Medicaid prescriptions pursuant to non-qualifying prescriptions are subject to rejection of the related Medicaid claim and sanctions imposed under federal law.

ii. All Washington State prescriptions issued after July 1, 2010 must conform to the same tamper-resistant prescription pad (TRPP) requirements as Medicaid prescriptions. However, the pads must also be purchased from an approved vendor and must bear a Board of Pharmacy "seal of approval." (RCW 18.64.500(7)) The Board announced in January 2010 that the seal will consist of a map of the State of Washington with a mortar and pestle in the center. To the right of the graphic, the text will read “Paper Approved by the Washington State Board of Pharmacy.”

1. Approved vendors are listed on the Board’s website.

2. TRPPs are required for all prescriptions that are hand written by the prescriber (for both legend drugs and controlled substances) for delivery to a pharmacy, except for:
   a. Prescriptions that are transmitted to the pharmacy by telephone, fax, or e-prescribed; or
   b. Prescriptions written for patients in hospitals (inpatient or outpatient), residents of nursing homes, inpatients or residents of mental health facilities, or incarcerated individuals, where:

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133 2009 c 328 §1; RCW 18.64.500  
134 [http://www.doh.wa.gov/hsqa/Professions/Pharmacy/documents/ApprovedVendors.pdf](http://www.doh.wa.gov/hsqa/Professions/Pharmacy/documents/ApprovedVendors.pdf)
i. The order is written by the prescriber into the patient’s medical or clinical record,
ii. The order is given directly to the pharmacy, and
iii. The patient never has the opportunity to handle the written order. (RCW 18.64.500(9))

3. The statute specifies that “All acts related to the prescribing, dispensing, and records maintenance of all prescriptions shall be in compliance with applicable federal and state laws, rules, and regulations.” (RCW 18.64.500(10)). The Board has interpreted this in its FAQ to mean that “A pharmacist may provide emergency medications in compliance with federal and state laws and rules, and any applicable health care plan restrictions and procedures.”

4. The statute gives the Board authority to issue regulations to implement its requirements.

g. **Time Limits on Prescriptions.** Prescriptions must have been written no more than one year prior to the date of filling or refilling, and no more than six months prior in the case of prescriptions for controlled substances in schedules III or IV. The general one-year limit on legend drugs found in Board of Pharmacy regulations that specify that no prescription in Washington may be refilled beyond one year from the date written. (WAC 246-869-100(2)(d)) This rule necessarily means that a prescription may not be initially filled more than one year after the date it was written. A specific rule placing a “12-month” limit on prescriptions applies to home IV therapy drugs. (WAC 246-871-050(1)) The limit on controlled substances is found in the federal Controlled Substances Act and in RCW 69.50.308(d) (see Chapter 5). The Board published proposed rule-making that would extend the time limit on prescriptions and refills to two years, but has not enacted such a regulation change. There was significant opposition to the change expressed to the Board.

h. **Other Required Elements.** Other elements that must be on the prescription or available to the pharmacist include
   i. **Date written**
   ii. The **patient’s address** must be on the prescription or available in patient medication record, a record book, or hospital or clinic record. (WAC 246-869-100(2)(a)) The definition of “address” as it applies to the patient is not clear under federal law. And, frankly, some patients don’t have a home. The only description under federal law of an “address”

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135 [http://www.doh.wa.gov/hsqa/Professions/Pharmacy/TamperResFAQs.htm#?IsTheWaStateLawDiff](http://www.doh.wa.gov/hsqa/Professions/Pharmacy/TamperResFAQs.htm#?IsTheWaStateLawDiff)
is contained in the US Postal Service Domestic Mail Manual, which indicates that “the delivery address specifies the location to which the USPS is to deliver a mailpiece.” The DMM indicates that for “street and number” the sender shall “Include the apartment number, or use the post office box number, or general delivery, or rural route or highway contract route designation and box number, as applicable.” Thus, it appears that under federal law the patient may provide any location to which the USPS could deliver mail. It is a common practice for the Medicaid program to use a physician’s office address as the address for a homeless Medicaid recipient. The WA patient medication record regulations define the “address” to be used in the medication profile as “the place of residence of the patient,” but a similar definition is not set forth for WAC 246-869. (WAC 246-876-010)

iii. Directions for use. WAC 246-875-020(h) requires that the pharmacist record in an automated patient medication record system, “The complete directions for use of the drug. The term “as directed” is prohibited pursuant to RCW 18.64.246 and 69.41.050.” Thus, Washington does not allow a pharmacist to record “UD” (ut dictum – as directed) instructions as the directions for a prescription in an automated patient medication record system. (Note, however, that this requirement is not specified for manual record systems in WAC 246-875-030). Thus, for the pharmacist to satisfy this rule, the prescription must contain complete directions. If not, the pharmacist must ascertain the directions from the prescriber.

Comment. In my opinion, the Board’s reliance on the cited statutes is misplaced. RCW 18.64.246 refers to the requirements for information on the label of a dispensed prescription, and requires the pharmacist to place “the prescriber’s directions,” on the label, without limiting what directions the prescriber may specify. So, under RCW 18.64.246, the Legislature did not seem to prohibit the prescriber from specifying “As directed” as his or her instructions in the prescription. RCW 69.41.050 describes the information that a prescriber must place on a container he or she dispenses directly to the patient, and does specify that the prescriber shall place “complete directions for use” on the container. However, the Legislature does not define “complete directions,” and, furthermore, allows them to be omitted from any sample package that is “labeled in accordance with federal law.” HOWEVER, IT IS POOR PRACTICE TO DISPENSE MEDICATIONS TO PATIENTS WITH INCOMPLETE, AMBIGUOUS, OR MISLEADING DIRECTIONS, AND I ENDORSE THE BOARD’S POSITION THAT MOST OF THE TIME THE PHARMACIST MUST OBTAIN COMPLETE INSTRUCTIONS FOR HIS OR HER RECORDS.
1. **Dealing with Specific Labeling Situations:**
   a. **Products with Consumer Labeling.** Some products are clearly labeled on the container, such as birth control pills. In these cases, "UD" should be interpreted to read "as directed on the container."
   b. **Complicated Dosage Regimens.** Some directions are for complicated doses. The prescriber may have given a written schedule to the patient, such as in step-down dosing of prednisone. In such a case, the pharmacist needs to know what those instructions were, to determine compliance. The pharmacist should make a copy of the instructions and attach them to the original prescription, and use them to estimate a days' supply. The directions would then be interpreted as "Take according to written sheet provided by physician." If appropriate, a "not to exceed" limit should be specified on the label.
   c. **Drug Requiring Dosage Adjustment.** Sometimes the patient is given the drug, and told to confirm the dosage with the prescriber, or will take differing doses in accordance with monitoring of therapy, as in treatment with Coumadin®. In such cases, the directions should be interpreted as "take on a [daily] basis in accordance with consultation with [physician]." Maximum dosing should be specified if appropriate.

iv. **Instructions regarding **generic substitution**. This is automatic with two-line prescription blanks, but the information needs to be gathered specifically on telephoned orders, and recorded on the face of the prescription by the pharmacist. (RCW 69.41.120).

   1. Prescriptions written by generic name (or telephoned by generic name) do not come under the requirements of the substitution law.

v. **Rx number, date of filling, pharmacist ID.** The pharmacist must place a serial number, the date of dispensing, and the initials of the responsible pharmacist on the face of the prescription. (WAC 246-869-100(2)(c)).

vi. **NDC of drug product dispensed.** In all cases where product interchange has occurred (see below), the pharmacist must record the identity of the actual drug dispensed on the prescription and in the patient record.
This is most easily and clearly done by recording the National Drug Code (NDC) of the product dispensed.

i. Telephoned or oral prescriptions. Pharmacists may receive oral or telephoned prescriptions for legend drugs. It is a long-standing practice for pharmacists to reduce the oral prescription to written form, and to store the file copy with other written prescriptions. This practice is not specifically mentioned in rules for legend drugs, but it is explicitly required for controlled substances. (RCW 69.50.308(2)(d), 21 CFR § 1306.21(a)) It is important for the pharmacist to record the full name of the person communicating the prescription, with enough detail to unambiguously identify the person in case of later inquiry. (See also Chapter 7 section on risk-management).

   i. Voice message systems. Board rules allow for recording of prescribers’ verbal prescriptions in pharmacies with approval for differential hours (see Chapter 3), subject to the requirement that the pharmacist must be the one to play back the message, and the voice message system must inform the caller of the pharmacy’s hours of operation. The FDA has published a compliance policy guide that considers a recorded oral prescription as meeting the requirements in the FDCA of an “oral prescription,” “if the pharmacist plays back the recording and concludes that the voice he or she hears is that of a physician known to the pharmacist, and there is no obvious reason for suspecting the authenticity of the recorded prescription.” This CPG, issued in 1980, seems based on an archaic model of community pharmacy practice.

   ii. Best Practices for Verbal Prescriptions. Board of Pharmacy and other Department of Health staff have developed the following guidelines for transmission of verbal prescriptions to a pharmacist.

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136 WAC 246-869-020(7),(8)
137 FDA. CPG § 460.425, Prescription Status when Telephoned to Recording Machine (CPG 7132b.08), October 1, 1980.
BEST PRACTICE GUIDELINES FOR VERBAL PRESCRIPTIONS

When calling in a prescription to a pharmacist, the following information should be provided:

Patient Information
- Name, including middle initial (spell last name if unusual)
- Date of birth
- Phone number

Drug Information
- Drug name
- Strength
- Dosage
- Directions (dose & frequency of administration)
- Route of administration
- Quantity
- Refills, if any
- Notation of purpose, if appropriate
- If generic substitution is permitted

Prescriber Information
- Name (whole name, with identifier, if a common name)
- Name of clinic or practice
- DEA number if appropriate
- Name and role of caller, if other than practitioner
- Phone number where pharmacist can check back with the prescriber if there are any questions about the prescription

iii. **2ID National Patient Safety Goal.** National patient safety standards now advocate that key patient care record elements use at least 2 unique means of identifying (“2ID”) the patient, such as the patient name, telephone number, date of birth, and/or medical record number. This is included in The Joint Commission’s National Patient Safety Goals for 2010 (NPSG 01.01.01).139 As the Board suggests, obtaining at least 2 identifiers when receiving verbal orders should be standard of practice for pharmacists.

j. **Facsimile transmission (FAX).** In general, FAXes of legend drugs are treated as if they were telephoned orders. The Board of Pharmacy has specified the following requirements for FAXes for legend drugs as part of the regulation of electronic transmission of prescriptions *directly from the prescriber* to the pharmacy. (WAC 246-870-050):
   
i. Must contain the *date, time, and telephone* number and location of the transmitting FAX machine.

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ii. The pharmacist is responsible for assuring that the FAX will be **legible for two years** (i.e., not printed on thermal paper).

iii. The **pharmacist is responsible for verifying** that each FAX is valid and shall verify the authenticity of the prescription with the prescriber if there is a question.

iv. There cannot be an exclusive agreement concerning FAXed orders between the pharmacy and the prescriber.

v. FAXed orders for **C-2 drugs** are permitted if
   1. The order is for an injectable C-2 narcotic substance that is to be compounded by the pharmacist for patient use; or
   2. The prescription is written for patients in a long-term care facility or a hospice program;
   3. The prescription is signed by the prescriber;
   4. In a non-emergent situation the pharmacist may rely on the FAX to prepare the order for delivery to the patient, but may not deliver the prescription until the hard copy of the FAX has been presented;
   5. In an emergent situation, a FAX may serve as the “AUTHORIZATION FOR AN EMERGENCY SUPPLY” of a C-2 drug;
   6. The order is FAXed to a hospital for a patient being admitted to or discharged from the hospital.

k. **Electronic prescriptions.**
   i. The law allows for electronic transmission of prescriptions, (RCW 69.41.055) and permits the Board to adopt specific rules (WAC 246-870). The law requires the following:
      1. Transmission is directly from the prescriber to a pharmacy of the patient’s choice, with no intervening person having access to the information. (This prohibits orders being transmitted through an insurance company.)
      2. The Board must approve the systems for sending and receiving the information.
      3. The information must include an “explicit opportunity” for prescribers to communicate preferences regarding generic substitution.
      4. Confidentiality and security of the information must be
         a. The pharmacist in charge (responsible pharmacy manager) shall establish or verify procedures and policies to ensure integrity and confidentiality of the prescription information.
         b. All managers, employees, and agents of the pharmacy must read, sign, and comply with the established procedures.
5. The pharmacist must exercise professional judgment regarding the accuracy, validity and authenticity of the drug orders transmitted electronically.

ii. The Board publishes a list of approved systems on its website.

iii. The Board has adopted additional rules in WAC 246-870. An electronically-transmitted prescription must include the following elements. Electronic prescriptions lacking these should be verified with the prescriber and treated as telephoned prescriptions after verification.
   1. Prescriber’s name and address
   2. Prescriber’s DEA number for CSA prescriptions
   3. Date of issuance
   4. Patient’s name and address
   5. Drug name, dose, route, form, directions for use, quantity
   6. Electronic, digital, or manual signature of the prescriber
   7. Refills or renewals authorized, if any
   8. A place to note allergies and a notation of purpose for the drug
   9. Indication of a preference for generic substitution.
   10. Other requirements of the law
   11. Identification of the electronic system readily retrievable for Board of Pharmacy inspection.

iv. Currently, prescriptions C-2 drugs may not be transmitted electronically, except by FAX where allowed (see Chapter 5).

10. Drug Product Selection. The policy issues related to the selection of a drug product to meet a physician’s prescription are almost entirely economic, and related to balancing the need for new drugs, and hence the need for incentives for innovation, with the goal of making drug therapy affordable. However, modern policy has emerged from earlier policy that was concerned with protecting the public against pharmacists’ mistakes in compounding, as well as the possibility that a pharmacist would substitute an inferior ingredient instead of the one intended by the prescriber.

   a. Accurate Dispensing. The pharmacist is required to dispense the product and strength called for in the prescription. The Board may discipline a pharmacist or intern who has “compounded, dispensed, or caused the compounding or dispensing of any drug or device which contains more or less than the equivalent quantity of ingredient or ingredients specified by the person who prescribed such drug or device.” (RCW 18.64.160(5))

http://www.doh.wa.gov/hsqa/professions/Pharmacy/RxElectronicSystems.htm
i. When a drug is prescribed by its official or “generic” name (e.g., Ibuprofen tablets 800 mg), the prescriber has left it to the pharmacist to determine the particular manufacturer or source of the product, *secundum artem* (“according to the art [of the apothecary]”).

ii. When a drug is prescribed by brand name (e.g., Motrin tablets 800 mg), it is understood that the prescriber intends a particular product from a particular manufacturer.

b. Most states allow generic substitution, and many provide for therapeutic substitution. These two activities fall in the category of drug product selection, sometimes called product interchange. When allowed, product interchange does not expose pharmacists to charges of misfilling prescriptions when they use a different manufacturer’s product.

c. **Brand versus Generic Drugs.**

i. **The Innovator Product.** All “new drugs” marketed in the US must be subject to an approved New Drug Application (NDA) approved by the FDA. The manufacturer who is first granted an NDA is said to be the “innovator” of the drug, and generally has patent rights granting it exclusive privileges to sell the drug for a defined period of time (typically 17 years from the date the patent is filed). Since it may take seven to ten years to develop a patented “New Chemical Entity” (NCE) after a patent is obtained, the marketing exclusivity may last for as little as seven years after the NDA is approved. Certain provisions of the Prescription Drug Marketing Act (PDMA) and the Orphan Drug and Patent Right Extension Act allow for extension of market exclusivity.

ii. When, as a result of Phase IV experience, a manufacturer wishes to change information in the package insert (e.g., new indications, changed directions, additional warnings, etc.), a Supplemental New Drug Application (SNDA) is filed with the FDA. To the extent that these changes result from patentable innovations, the innovator may gain additional market exclusivity for the new claims.

iii. **Official Name.** All approved new drugs are given a non-proprietary name, which in the US is officially called the United States Adopted Name (USAN), approved by the USAN Commission, a division of the Department of Commerce. The manufacturer’s label of all approved drugs must include the USAN, and the manufacturer may also market the drug under a proprietary, or trade name.

iv. **Trade names** are the property of the manufacturer who coins them, subject to filing with the Patent Office. The trade name may be either “registered” as indicated by the ® symbol, or “trademarked,” as indicated by the ™ symbol.
The manufacturer’s label must present the non-proprietary name in letters at least half as high as the trade name. Pharmacists labeling prescription containers may always use the nonproprietary name, and may also use the trade name as long as the product in the container is made by the manufacturer who owns the trade name.

v. **Enforcement of Copyright.** The manufacturer is required by copyright law to enforce its rights to a trade name by challenging in court any inappropriate use of the trade name by others. From time to time, drug companies have filed lawsuits against pharmacists who used their trade names on packages of drugs containing a generic product, challenging phrases such as “Ibuprofen – same as Motrin” or “Ibuprofen – generic Motrin.” Some pharmacy law experts recommend the following language on prescription labels to avoid trademark infringement suits: “Ibuprofen – substituted for Motrin.”

vi. **Patent Expiration.** After the patent rights expire on a particular drug product, other manufacturers may market generic products that are the same chemical entity as indicated in the NDA, provided they meet requirements for bioavailability and bioequivalence. Primarily, the generic equivalent must provide the same pharmacokinetic parameters, Cp, Tp and AUC, as the innovator’s product, as demonstrated by *in vivo* testing. The generic manufacturer does not need to repeat the innovator’s Phase I through Phase III testing, but only the more limited proof of bioavailability and bioequivalence. These are documented in an Abbreviated New Drug Application (ANDA). After the FDA approves the ANDA, the generic manufacturer may distribute the product under its non-proprietary (“generic”) name, and/or may develop a brand name of its own for the product.

vii. **Hatch-Waxman Act.** In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act\(^\text{141}\) with the intention of speeding the adoption and approval of generic drugs. It is commonly called the Hatch-Waxman Act, after its congressional sponsors, Sen. Orrin Hatch (R-Utah) and Rep. Henry Waxman (D-Cal). The title of the Act suggests it was a matter of compromise: it hoped to increase competition yet at the same time extended patent protections to certain drugs. Two major sections of the Act deal with these goals:

\(^{141}\) Pub. L. 98-417; 21 USC 355(j)
1. **ANDAs.** The Act clarified and standardized the process by which a generic manufacturer may seek to market a generic drug, by filing an ANDA.

2. **Patent issues.**
   
a. The Act provides for up to 5 years of patent extension for certain categories of new drugs to cover time spent in drug development after the patent was issued.

b. The Act also provided a means by which a generic manufacturer could challenge the patent status of the innovator's product without running the risk of lengthy post-marketing patent infringement lawsuits.
   
i. Each innovator must file with the FDA a list of the patents it claims protect its right to market the product. These patents are listed by the FDA in *The Orange Book* (see below).

ii. The first generic competitor to file an ANDA may, under section 505(j)(5)(B)(IV) of the Act, file a so-called Paragraph IV notice that it is contesting the innovator's patent. This triggers two provisions:
   
   1. If the innovator files a suit within 45 days to challenge the generic application, then the innovator is awarded a 30-month extension of its patent.

   2. The first generic manufacturer to file a successful ANDA gains a 180-day exclusive right to market the drug, and the FDA will not approve another ANDA for the same product during that period of exclusivity.

c. **Alleged abuse of Hatch-Waxman provisions.** By the early 2000s it became apparent to many that innovators were taking advantage of the Paragraph IV provisions to unduly extend their marketing exclusivity, largely by protecting their drugs with "extra patents of poor quality, filing lawsuits to protect the patents even when the lawsuit will be lost, but getting the extra market exclusivity
anyway.” In addition, manufacturers have begun to enter into a variety of schemes with potential generic competitors. Strategies used to avoid generic competition have included:

i. Filing of additional patents based on such things changes in the crystalline structure of the active pharmaceutical ingredient.

ii. Filing last-minute changes to the innovator’s product labeling.

iii. Entering into agreements for “authorized generics” and/or “pay for delay” contracts where the generic manufacturer agrees to delay bringing its product to market in return for “reverse payments” from the innovator.

d. Proposed Legislative actions. Proposed legislation to eliminate the abuses was included in the Senate version of the “healthcare reform bill,” formally titled the Patient Protection and Affordable Care Act, passed in December 2009. Several proposed amendments would have addressed the “pay for delay” and “reverse payments” issues, but these were not included in the final bill. However, the bill did include provisions that would allow the FDA to approve a generic version of a drug notwithstanding last minute labeling changes. As of January 2010, the health care reform bill awaits reconciliation of House and Senate versions.

e. Antitrust litigation. The Department of Justice filed a brief in July 2009 in an antitrust case in the 2nd Circuit Court of Appeals, in which it took the position – in agreement with the Federal Trade Commission – that “pay for delay” agreements presumptively violate antitrust laws.

f. Impact on pharmacies. In general, these issues affect manufacturers only, and do not affect pharmacists who dispense or distribute generic drugs that are subject to an ANDA.

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The major exception is when pharmacists attempt to prepare by extemporaneous compounding a product that is subject to an existing patent. (See section on compounding)

d. **Generic Substitution**
Virtually all states provide for “generic substitution,” whereby the pharmacist may or must dispense the generic drug, even when the prescriber prescribes the product by its trade name. The purpose of all these laws is to provide savings to consumers, or to third party payers (such as state Medicaid programs). Many states, including Washington, require that all or a significant part of the savings arising from generic substitution be passed on to the purchaser. Generally, the pharmacist must have some evidence that the generic product is an approved drug product that has been found bioequivalent to the innovator’s product. In Washington (RCW 69.41.100-180), the pharmacist may use any information he or she considers reliable. Other states specify one or more of several resources or lists that the pharmacist can or must consult.

i. **Pharmacist’s Reference Sources**
In all states, a prescription written by generic (nonproprietary) name permits the pharmacist to choose the source of the product, whether it is bioequivalent to a brand name drug or not.

1. **Orange Book**
The “Orange Book” is officially entitled “Approved Drug Products with Therapeutic Equivalents” and is published by the FDA. The only products listed are drugs with NDAs and/or ANDAs. None of the unapproved drugs discussed above are listed.

a. **Equivalency Determinations.** Drugs are considered equivalent if they are approved drugs with the same ingredient and dosage form, and generally produce the statistically equivalent AUC and $C_{\text{max}}$ when compared to the reference drug. If for various reasons a comparison between a generic and the reference product cannot be done, the products cannot be rated. Thus, an Orange Book rating of AB can be taken as evidence of therapeutic equivalence, but other ratings do not prove inequivalence.

b. **Equivalency Ratings.** Drugs that are considered therapeutically equivalent are given an “A” rating; those that are not are rated “B.” A second letter is appended to indicate the basis

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144 [http://www.fda.gov/cder/orange/default.htm](http://www.fda.gov/cder/orange/default.htm)
for the rating, and all generically equivalent products are rated “AB.” In every case, the rating of a generic drug is related to a specific innovator’s product. In some cases, two innovator’s products have the same chemical ingredient, but are not, themselves, bioequivalent. This is most often the case with sustained-release preparations that use different formulations to achieve their release characteristics. For example, Adalat CC™ and Procardia XL™ each contain nifedipine HCl. However, they use different formulations, and are not interchangeable as generics. Adalat CC is rated AB1 and Procardia XL is rated AB2. Generic nifedipine formulations that are interchangeable with Adalat CC are rated AB1, and those that can be substituted for Procardia XL are rated AB2.

c. **Levothyroxine** products have posed a special problem, and the FDA uses four ratings AB1, AB2, AB3, and AB4. Some products are rated in more than one category. For example, here are the November 2009 ratings for 25 mcg levothyroxine products:

   i. Synthroid® is rated AB1 and AB2
   ii. Levoxyl® is rated AB1 and AB3
   iii. Levo-T® is rated AB2 and AB3
   iv. Levothroid® is rated AB4
   v. Unithroid® is rated AB1, AB2, and AB3
   vi. Levothyroxine (Merck KGAA) is rated AB2, AB3
   vii. Levothyroxine (Mylan) is rated AB1, AB2, AB3, and AB4
   viii. Currently, Mylan’s levothyroxine in 25 mcg strength may be substituted for any of the other named products, and careful matching of the remaining products shows that they may all be interchanged for one another, with the exception of Levothroid®.

2. **Positive Formularies.** Some states do not allow the pharmacist to substitute any equivalent generic, but require the pharmacist to choose from drugs on a specific list. This list is often called a “positive formulary.” Some states specify the Orange Book as their positive formulary, while others have a special
commission that develops the list. Washington allows the pharmacist to choose from sources in addition to the Orange Book, so Washington does not require a positive formulary. However, the Orange Book is referred to in WAC 246-899-030(b) as a “board approved reference for a positive formulary of therapeutically equivalent products within the limits stated in that publication.”

3. **Negative Formularies.** A few states have lists of drugs that cannot be substituted. Many of these lists include so-called “narrow therapeutic index drugs,” such as levothyroxine, warfarin, digoxin, and furosemide. The drugs placed on these lists are often placed there as a result of a political process in which manufacturers and physicians have lobbied to limit generic substitution. Washington does not specifically preclude generic substitution by use of a negative formulary.145

ii. **“DAW” instructions and special prescription blanks.** Most states allow prescribers to prevent generic substitution on a per-prescription basis. Some will allow the prescriber to indicate “Dispense As Written” or “DAW” in writing on the prescription. Others allow a check-box ( DAW). Washington, like several other states, requires a two-line prescription blank, with one signature line indicating “Substitution Permitted” and the other indicating “Dispense As Written.” In Washington, manufacturer’s successfully lobbied to have the DAW line be on the right hand side of the blank, reasoning that many right-handed physicians would, by force of habit, preferentially sign that line. Under Washington law, a prescription that is written by a Washington prescriber is not valid unless it is written on a two-line prescription blank. In Washington, pharmacists are required to obtain and record specific instructions regarding substitution when receiving telephoned prescriptions, and to indicate this on the permanent record (WAC 246-899-020 (a)).

1. **Dealing with out-of-state prescriptions.** According to the statute, Washington pharmacists may substitute the generic product on an out-of-state prescription written by brand name unless “otherwise instructed by the prescriber through the use of the words ‘dispense as written’, words of similar meaning, or some other indication.” However, the Board has

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qualified this requirement in WAC 246-899-050. If the practitioner has not clearly provided instructions regarding substitution, the pharmacist may substitute a generic only if the pharmacist has determined substitution is permitted by one of the following means:

a. The pharmacist has personal knowledge of the rules in the state of origin; or
b. The pharmacist has obtained authorization from the prescriber; or
c. The pharmacist obtains current information on the rules in the other state from
   i. The Washington Board of Pharmacy
   ii. The Board of Pharmacy in the other state
   iii. Some other reliable professional means.

iii. **Generic substitution is required in Washington.**
Washington does not allow the pharmacist to dispense a brand name if substitution is permitted except when:

1. The pharmacy does not have a generic product in stock which is, in the pharmacist's professional judgment, bioequivalent to the drug prescribed; or
2. The patient or the patient’s agent requests the branded product, and the product is not being paid for by public funds.

iv. **Savings must be passed on to purchaser in Washington.**
Washington law requires that 60% of savings resulting from generic substitution be passed on to the consumer. The calculation should be made as follows:

\[
\text{Savings} = \frac{\text{Actual Acquisition Cost of Brand Name Drug}}{\text{Actual Acquisition Cost of Generic Drug}}
\]

\[
\text{Maximum Price} = \frac{\text{Normal Price of Brand Name Drug}}{0.4} - (\text{Savings} \times 0.6)
\]

Example: Your pharmacy’s normal cash price for a brand-name drug is $85.00 for 90 tablets. The Average Wholesale Price (AWP) for this product is $83.00 per 100. Your Actual Acquisition Price (AAC) from the wholesaler is AWP less 18% for this drug. Your AAC for the generic equivalent is $41.00 per 100. What is the maximum price you can charge the patient for 90 tablets under WA law?

\[
\text{Savings} = (\$83 \times 90/100 \times 0.82) - (\$41 \times 90/100) = \$24.35
\]
\[
\text{Max. Price} = \$85.00 - (\$24.35 \times 0.6) = \$70.39
\]
For this example, the margin on brand name drug: $23.75 ÷ $85.00 × 100% = 27.9%, and the margin on generic drug: $33.49 ÷ $70.39 × 100% = 47.5% (assuming competition will allow you to charge the maximum allowed price).

**Comment:** I am not aware of any enforcement of this rule by the Board or any other group. However, attorneys for consumers in other states have filed class action suits for consumer fraud when pharmacists have failed to follow specific regulations and they can show economic damages.

v. **Notice to Public.** RCW 69.41.160 requires the following notice to be displayed to the public in every pharmacy:

“Under Washington law, an equivalent but less expensive drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.”

vi. **Pharmacist judgment protected.** Pharmacists are protected by RCW 69.41.170 from being coerced by employers to dispense a particular generic drug or to substitute a generic drug for another drug.

e. **Therapeutic Substitution**

Therapeutic substitution involves dispensing a drug in the same therapeutic class as the brand prescribed, but not of the same chemical entity. A common example would be use of atorvastatin (Lipitor™) when the prescription was issued for simvastatin (Zocor™) Therapeutic substitution could also include dispensing of a generic equivalent that is not of the same dosage form or delivery system as the drug prescribed, such as using Adalat CC™ in place of Procardia XL™. The key element is that the control of the patient’s symptoms is equivalent once adjustments have been made for dosage and/or dosing intervals. It is normally assumed that therapeutic interchanges are made in such a way as to avoid additional adverse effects. Therapeutic interchange is often performed to provide the “drug of choice,” as in dispensing amoxicillin when ampicillin has been prescribed (to improve absorption and avoid GI effects). The driving force behind most therapeutic interchange, however, is to achieve drug cost savings. Washington law allows therapeutic substitution whenever the pharmacist has obtained “prior authorization” from the prescriber, and is not explicit about how this authorization must be obtained, in
contrast to the rules regarding generic substitution. The pharmacist may exercise therapeutic substitution under the following circumstances:

i. **With prior authorization** (Washington requires documentation to be available in the pharmacy records – WAC 246-899-030(3).)

ii. **Specific authorization on an individual prescription**

iii. **Via Collaborative Practice Agreement** (in this case, the pharmacist is not performing therapeutic interchange as much as is prescribing a different drug.)

iv. In accordance with the **Therapeutic Interchange Program and Preferred Drug List** (RCW 69.41.190; WAC 182-50-200.)

1. A Therapeutic Interchange Program (TIP) is required, using a Preferred Drug List (PDL), in all state-funded drug programs, including Medicaid, Labor and Industries, and the Uniform Medical Plan (UMP) for state employees. The Washington Health Care Authority (HCA) administers the program, which is entitled **Rx Washington**. The current **Preferred Drug List** is updated frequently on the Rx Washington web site.

2. The Pharmacy & Therapeutics Committee that determines the PDL is composed of 10 members (4 physicians, 4 pharmacists, 1 PA, 1 ARNP). Currently (12/06), two of the members are on the WSU faculty: Angelo Ballasiotes, PharmD and Jason Iltz, PharmD.

3. A Therapeutic Interchange Program (TIP) is established by the legislation. This program went into effect in mid-2004, and pharmacists dispensing prescriptions that are paid for by a state program are authorized and required to perform therapeutic substitution using drugs on the PDL, where a non-preferred drug has been ordered. The statute was last revised in 2009.

a. Eligible prescriptions must be have been written by an “endorsing practitioner.”

i. HCA maintains a **database** to identify endorsing practitioners

ii. Prescriptions written by non-endorsing practitioners are treated as follows by each state-funded program:

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146 [www.rx.wa.gov](http://www.rx.wa.gov)


148 2009 c 575

149 [http://wa-bcm.com/search.aspx](http://wa-bcm.com/search.aspx)
1. Uniform Medical Plan (PPO): The pharmacist cannot make a substitution, even for a generic equivalent. The patient would receive the non preferred drug as prescribed, at a higher cost.

2. L&I: A non-endorsing practitioner does not qualify for the "dispense as written" exemption and the non preferred drug would not be payable unless the pharmacist or practitioner calls with medical justification.

3. Medicaid: The pharmacist is required to contact ACS to request the non preferred drug and show medical justification.

   iii. The endorsing practitioner may indicate "DAW" – the drug will NOT be subject to him prior authorization, but will be subject to Tier-3 pricing for UMP recipients.

   1. This “DAW” does not relate to generic substitution, which is indicated by a signature on a two-line blank, but must be specifically written on the prescription.

   iv. A UMP recipient may request DAW, and pay the Tier-3 price, if the drug is covered.

b. Substitutions are to be made from within the same therapeutic class.

c. Refills of certain types of drugs are not subject to substitution

   i. Antipsychotics
   ii. Antidepressants
   iii. Antiepileptics
   iv. Chemotherapy
   v. Antiretrovirals
   vi. Immunosuppressives
   vii. immunomodulator/antiviral treatment for hepatitis C for which an established, fixed duration of therapy is prescribed for at least twenty-four weeks but no more than forty-eight weeks.
d. When a substitution is made, the pharmacist shall notify the prescriber of the specific drug and dose dispensed (can be by FAX, etc.)

4. Pharmacist liability is limited when substituting in accordance with the PDL, in RCW 69.41.150: “(3) A pharmacist who substitutes a preferred drug for a nonpreferred drug pursuant to section 5 of this act assumes no greater liability for substituting the preferred drug than would be incurred in filling a prescription for the preferred drug when prescribed by name.”

5. The 2009 amendments\(^{150}\) provided state purchased healthcare programs with increased ability to restrict use of “DAW” and to enforce use of generics, OTCs, and to limit use of brand name drugs for off-label uses:

a. Programs may impose limited restrictions on endorsing prescribers’ authority to write DAW prescriptions, under the following conditions:
   i. There is clear data or statistical evidence that the prescriber’s pattern of use of DAW differs from his or her peers;
   ii. The program director has
      1. Presented data to the endorsing practitioner indicating his or her deviation from peer norms,
      2. Provided the endorsing practitioner with an opportunity to explain the variation, and
      3. If the variation has not been explained, has given the practitioner sufficient time to change his or her prescribing patterns.
   iii. The restrictions must be limited to the extent necessary to reduce variation, and only until the practitioner can demonstrate a reduction in variation in line with his or her peers.
   iv. Refills of antipsychotics and other listed drugs may not be restricted.

\(^{150}\) 2009 c 575
b. Agencies may immediately designate an available generic as the preferred drug in a previously reviewed therapeutic class without P&T committee review.

c. Programs may designate an available equally effective OTC alternative as a preferred drug.

d. Limited restrictions may be imposed on endorsing practitioners’ options to specify DAW for a patient’s first course of therapy within a therapeutic class, when:
   i. There is a less expensive equally effective therapeutic alternative generic product available to treat the condition;
   ii. The DUR board has reviewed and provided recommendations as to the appropriateness of the limitation;
   iii. The endorsing practitioner retains the opportunity to request the brand drug as a medically necessary first-course treatment;
   iv. The program may provide available prescription, emergency room, diagnosis and hospitalization history to the endorsing practitioner; and
   v. For any antipsychotic restrictions, the program shall effectively guide good practice without interfering with the timeliness of clinical decision making. DSHS prior authorization programs must provide for responses within 24 hours and at least a 72-hour emergency supply of the requested drug.

e. **Off-label use of brand name drugs** may be subject to restrictions on use of DAW by endorsing practitioners when:
   i. There is a less-expensive, equally effective on-label product available to treat the condition;
   ii. The DUR board has reviewed and provided recommendations to the appropriateness of the limitation;
   iii. The endorsing practitioner shall retain the ability to request the off-label drug as medically necessary.
11. Refilling and partial filling of prescriptions, and other deviations from quantity requirements.
   a. **How Prescribers Indicate Refills.** Refills may be authorized by the prescriber at the time the prescription is written. The prescriber may indicate refills in a number of ways:
      i. **May be refilled X times.** In this case, the pharmacist may refill the drug up to X times, in the same quantity as the original.
      ii. **May be refilled through a certain date.** In this case the pharmacist may refill the drug as often as needed in an appropriate quantity until the date shown.
      iii. **May be refilled “PRN.”** In Washington, PRN is defined by the Board to indicate authorization for up to one year from the date the prescription was written. No prescription in Washington may be refilled beyond one year from the date written. (WAC 246-869-100(2)(d))
         1. This rule necessarily means that a prescription may not be initially filled more than one year after the date it was written.
      iv. **Refills may be authorized by the prescriber after the prescription is written,** typically upon a call from the pharmacist. The Board requires pharmacies to treat a refill authorization occurring more than a year after the prescription is written as a new prescription, with a new prescription number.
   b. **Refills must be consistent with directions.** In all cases of refills, the pharmacist must issue refills and quantities that are consistent with the directions on the prescription. The pharmacist is responsible for noting and dealing with both overuse and under use. An early refill at one point must be considered when reviewing the appropriate time for refill at a later date. It is good practice to communicate to the prescriber unusual circumstances such as when a patient reports the loss of drug so that both the pharmacist and prescriber may become aware of patterns potential of misuse.
   c. **Effect of time limit on refills.** When a refill is time-limited, the pharmacist may dispense the full original quantity at any time prior to the expiration date of the authorization.
   d. **Emergency Supply.** In Washington, a pharmacist may dispense an “emergency supply” of legend drugs: “if the prescriber is not available and in the professional judgment of the pharmacist an emergency need for the medication has been demonstrated, the pharmacist may dispense enough medication to last until a prescriber can be contacted but not to exceed 72 hours’ supply. The prescriber shall be promptly notified of the emergency refill.” (WAC 246-869-100(f)).
i. Note that this regulation applies to all legend drugs in Washington, but because there is no equivalent provision under federal rules for controlled substances, this provision does not apply to prescriptions for controlled substances.

ii. In determining how many doses to give the patient, the pharmacist must estimate how soon the prescriber will be available, and dispense enough to last until the prescriber is available, but not more than a 72 hours’ supply.

iii. The pharmacist, when finally contacting the prescriber, does not need to obtain the prescriber’s permission to have dispensed the emergency supply – the pharmacist needs merely to inform the prescriber that the supply was given. However, the prescriber must authorize any additional refills.

iv. In some cases, an emergency supply of a unit-of-use package may involve dispensing more than 72-hours’ worth of drug, such as with a bronchodilator inhaler. If clearly needed by the patient on an emergency basis, it is unlikely that the Board will discipline the pharmacist. However, in the event that the physician determines that continued use of the drug dispensed would be not in the patient’s interest, the pharmacist must be prepared to recover the excess supply from the patient or to take other steps to minimize the risk to the patient. A better solution: develop a prescriptive authority protocol with local physicians to allow the pharmacist to prescribe these emergency supplies to patients of the pharmacy.

e. **Prescribers cannot delegate refill authority to staff.** Sometimes a local physician may be planning a vacation and wishes to tell his or her office staff to “okay all refills till I come back.” This is an unlawful delegation of authority to his or her staff, and prescriptions or refills authorized based on this delegation are not valid. A pharmacist who knows or should know of the situation may be disciplined for dispensing pursuant to these authorizations. The physician is responsible to provide alternative physician coverage for his or her patients. However, it is possible for the physician to establish a collaborative practice agreement with a pharmacist to allow the pharmacist to review requests for refills and to authorize them in accordance with a protocol. This protocol could allow the pharmacist to review requests from pharmacies other than his or her own site.

i. The Washington Nursing Quality Assurance Commission received a request in 2007 to allow registered nurses at a clinic to approve refill requests in accordance with a protocol approved by the clinic physicians. The Commission denied
the request, recognizing the inability of prescribers to delegate such authority to nurses.\textsuperscript{151}

f. **Partial filling.** Generally, when the patient’s interests require, pharmacists are allowed to dispense less than the prescribed quantity of medication, as long as each dosage form is of the correct strength. There are special requirements for partial filling of controlled substances, but for legend drugs, it is generally sufficient for pharmacists merely to track the quantities dispensed. Partial filling often occurs when

- **For financial reasons** (including insurance coverage) the patient doesn’t want to purchase the full amount. A prescription written for levothyroxine 100 mcg, #90, can be filled for any quantity less than 90, e.g., 30 tablets. It may be refilled in quantities of 30 until a total of 90 have been dispensed.

- **When the patient has not received the drug before** and is unsure whether he or she will tolerate it or if it will meet the patient’s needs.

- **When the pharmacy does not have sufficient medication in stock.**
  1. **Billing to 3rd Party Payers for Partial Filling.**
     Handling of out-of-stock creates problems when third parties (especially government payers) are to be billed for the drug. These parties do not want to pay for unused drug or drug that is not delivered to patients. When partial fills have been made with the expectation that patients will pick up the remainder, and the third party is billed for the full amount due to transaction requirements, the third party will feel defrauded if the patient forgets to pick up the drug. The US government sued a major chain over this issue and the settlement was in the millions of dollars. (See also Chapter 8)
     a. **If possible, 3rd parties should not be billed until the full quantity has been dispensed.**
  2. The pharmacy cannot legally reuse drugs that have been sold to a patient, even if the patient “abandons” the drug by not returning. Most states, including Washington, have “abandoned property” statutes that require that the abandoned property belong to the state.
  3. If the pharmacy wants to deliver or mail the remainder of the product to the patient, that may raise problems of making drugs available to children or others without

\textsuperscript{151} Article No. 997, Washington State Board of Pharmacy Newsletter 2009 Apr; 30(4):4.
the knowledge of the patient that the drug was to be mailed.

a. If possible, **obtain the patient’s written permission to mail the remainder of the drug to their home** in the event that they have not picked up the drug in a certain length of time.

iv. **Combining refills to dispense a larger quantity.** It is a long-standing standard of practice that the pharmacist may dispense more than the amount specified in the prescription when refills have been allowed, and the patient’s interests warrant it. For example, the physician prescribes Lipitor 10 mg, #30, and labels the prescription “Refill PRN.” It is known and obvious that if the patient tolerates the initial prescription, he or she will be continuing to take the drug chronically. If the insurance allows a 90-day supply, the patient will want to obtain the drug in the larger quantities on refills. Using good judgment, the pharmacist may reasonably refill the Lipitor in quantities of 90, without consulting the physician. If no refills were allowed, however, this would not be possible. Generally, controlled substance prescriptions cannot be refilled in larger amounts than specified on the original prescription.

1. **Judgment is important.** Just because a drug is not a controlled substance does not justify refilling in larger quantities than originally specified. For example, a patient with a history of attempted suicide may be placed on tricyclic antidepressants in quantities of 10 to 30 tablets per refill. Even if additional refills are allowed, the pharmacist must be cognizant of the reality that dispensing 100 tablets at a single time provides the patient with the opportunity of taking a fatal overdose. Excessive early refills of carisoprodol have led the Board of Pharmacy to discipline a pharmacist,152 and, in at least one case, to the death of the patient.

2. It is important to note, however, that nothing in law **requires** a pharmacist to refill in larger quantities than originally ordered without confirming it with the prescriber.

   g. **Dispensing different strengths to achieve the prescribed dose.** Pharmacists may also reasonably deviate from the prescription by providing alternate strengths if the patient’s interests require.

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i. A prescription written for prednisone 10 mg tablets #50, ½ tablet daily, may be filled with prednisone 5 mg #100, provided the label directions correctly specify 1 tablet instead of ½ tablet as the dose. The patient must clearly understand what has been done, and it is best practice to notify the prescriber.

ii. A prescription written for levothyroxine 225 mcg cannot be dispensed as such because no manufacturer makes a 225-mcg tablet. The pharmacist may wish to verify the dose to be sure an error was not made, but otherwise has the choice of dispensing the prescription as follows:
   1. Levothryoxine 113 mcg, with directions of 2 tablets per dose.
   2. Levothyroxine 200 mcg, 1 tablet per dose, plus Levothryoxine 25 mcg, 1 tablet per dose, as two separate prescriptions.

In either situation, the best practice is to notify the prescriber what was actually dispensed.

iii. Tablet splitting programs. Many insurers or third party payers encourage patients to split tablets to achieve cost savings. For example, Lipitor® 20 mg tablets were available at DrugStore.Com in January 2010 for $415.95 for 100 tablets, while the 40-mg tablets were also $415.95 for 100, or exactly half as expensive per mg. Many pharmacists consider a request by a patient to adjust the dose on the prescription to be within the general reasonable deviation from the prescription discussed here. Not all patients are good candidates for tablet-splitting programs, however. Because the primary interest served here is cost savings, not patient care issues, the pharmacist should probably proceed with tablet splitting programs only when based on prior consultation with or approval of the prescriber.

- It is important that the prescriber’s records of what is dispensed are consistent with the pharmacist’s actions to avoid confusion and possible overdose. Confusion over a tablet splitting program led to a recent federal lawsuit when a patient suffered rhabdomyolysis after he was instructed by a nurse practitioner to increase his simvastatin dose to “1 whole tablet.” The nurse practitioner believed he was inappropriately taking only 20 mg per day, when in fact he was taking half of an 80-mg tablet as part of a tablet splitting program.
h. Transfers of prescriptions between pharmacies. There are many times when a patient requests that his or her prescription be filled at a different pharmacy, or wishes to take a copy of the prescription to another prescriber or pharmacy.

i. **Copies.** The original of every prescription must be retained in the pharmacy. Sometimes patients will request a “copy” of their prescription for informational purposes. Such copies may be made, but must be clearly labeled as such. (WAC 246-869-100(e)).

1. Prescriptions may be photocopied and provided to the patient or others to whom the patient has authorized, stamped with “COPY”.
2. Pharmacists may hand copy the prescription on the pharmacy’s prescription form, indicating a COPY.
   a. **Coding prices on copies no longer acceptable.** It was the practice of pharmacists in past years to include pricing information on the prescription, often in coded fashion. One popular code was called the NARD Code, developed by the National Association of Retail Druggists, now known as NCPA. This code used the word “PHARMOCIST” where each letter represented the digits, 1-2-3-4-5-6-7-8-9-0, respectively. The letters NA preceded the code and it was followed by RD. For example, “NA-PHM-RD” would indicate a price of $1.25. This practice is uncommon now, in part because of challenges to its use as a means of price fixing among competitors.
3. These copies are not valid for filling, so the pharmacist receiving such a copy must contact the prescriber and obtain a new oral prescription.

ii. **Transfer of Refill Information.** Pharmacies are allowed under WAC 246-869-090 to transfer prescriptions, along with available refills, to another pharmacy. It is important for the pharmacist or intern involved in the process to follow the steps listed in the regulation. In Washington, pharmacists or interns may transfer and receive transferred prescriptions.

1. **The originating pharmacist** (“transferor pharmacist”) must perform the following steps:
   a. Record that the prescription has been transferred in the medication record system.
b. Record in the medication record system the
   i. Name and address of the pharmacy to which it has been transferred
   ii. The name of the pharmacist (or intern) that received the information. Note: it is usage that a person’s “name” for legal purposes is the full name that the person normally would use to conduct business. Thus, simply recording the first name of the other pharmacist is not generally appropriate. A Board of Pharmacy consultant pharmacist has stated that “Neither WAC 246-869 nor CFR 1306.25 define the word ‘name’ as it is used in each respective passage. However, both the law and rule require both transferring pharmacists to be identified when transferring a prescription. This may (or may not) be achieved by recording the first name only. The extent of required information depends on … your ability to unequivocally identify the other pharmacist if required to do so at a later time.”

c. In addition, for controlled substances (schedule III, IV, and V), the originating pharmacist must follow the procedures specified in 21 C E. FR § 1306.25, which include the following:
   i. Locate the original hard copy of the transferred prescription.
   ii. Write the word “VOID” on the face of the prescription
   iii. Record the name, address, and DEA number of the pharmacy receiving the information on the reverse of the original prescription, along with the name of the pharmacist receiving the information.

2. The receiving pharmacist treats the prescription as an oral prescription, and must perform the following steps:
   a. Reduce the prescription to writing on a prescription blank, including patient name, address, prescriber’s name and address, and

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other information required to be on the prescription.
b. Write the word “TRANSFER” on the face of the prescription.
c. Also record the following:
   i. The date the prescription was originally written (cannot be refilled for a year after that.)
      1. When processing a transferred prescription, it is important to override the current date in the computer, and record the original date written
   ii. Number of refills remaining
   iii. Date of last refill
   iv. The name and address of the transferring pharmacy, and the serial number of the original prescription at that pharmacy
   v. The name of the transferring (transferor) pharmacist. As noted above, this should normally be the full legal name of the individual.
d. For controlled substances, the receiving pharmacist must also record the following:
   i. Number of original refills allowed on the prescription
   ii. Dates (and locations) of all previous refills
   iii. Number of valid refills remaining
   iv. DEA number of transferring pharmacy
   v. Name, address, serial number and DEA number of pharmacy at which prescription was originally filled (if different from transferring pharmacy).
e. For Medicare or Medicaid prescriptions originally issued in writing after April 1, 2008, the receiving pharmacist must
   i. Obtain and record from the transferring pharmacist verification that the original prescription, if a written prescription, was issued on a tamper-resistant pad, or that the transferring pharmacy had obtained verification of the prescription by fax, phone, or e-mail.
3. Refill information and prescriptions for legend drugs may be transferred, and re-transferred as often as needed until all refills are used. If a patient has had a prescription transferred to another pharmacy, and now wants to have it refilled at the original pharmacy, the original pharmacy must contact the other pharmacy and receive the prescription back as a transferred prescription. At this point, it should be given a new prescription number.

4. According to DEA rules, controlled substances may be transferred on a “one-time” basis, unless the transferring pharmacies share a common electronic database. My interpretation of this rule is that it is intended that all refills be transferred to the receiving pharmacy, as opposed to one refill at a time. (See further discussion in Chapter 5.)

5. Pharmacies with a common electronic database may track refills for non-controlled substances at any outlet in this common database, without going through the prescription transfer process. Many chains (e.g., Rite-Aid and Walgreens) have these databases.

iii. May a pharmacist “transfer” a new prescription? It is not clear that the rules as written permit transfer of a prescription that has not been actually filled at the transferring pharmacy. However, it is hard to see why this would be much different than transferring information on an already filled prescription. Unless the pharmacy merely refers the patient to another pharmacy, and returns a written prescription to the patient to take to the other pharmacy, in order to conform with the letter of the rule, the transferring pharmacy should enter the prescription into the patient medication record, indicate that it was never filled, then record the transfer as indicated above, keeping the original prescription on file.

12. Packaging

a. **USP containers.** All drugs that are repackaged for dispensing to patients must meet USP requirements. Multi-dose containers of solid dosage forms must meet USP requirements for “tight” containers that are sealed to be air- and water-resistant, and must be either opaque or light-resistant. The USP also provides recommendations for materials used in unit-dose or “Bingo Card” packaging.

b. **Child-resistant containers required for prescription drugs.** Washington law requires that the cap of every prescription container meet safety standards adopted by the board of pharmacy (RCW 18.64.246). The Board, in turn, has incorporated by
reference Chapter 16, part 1700 of the CFR (WAC 246-869-230). Prescription drugs are included among “household substances” that must be packaged in “special packaging” as specified in the Poison Prevention Packaging Act (PPPA, 15 USC 1471). These containers are commonly-called Child-Resistant Containers (CRCs). The PPPA is implemented by rules promulgated by the Consumer Products Safety Commission (CPSC). The CPSC has published a guide for pharmacists and other health professionals.  

i. **Unit of use packaging for retail pharmacies.** Products packaged by manufacturers in unit-of-use retail units (e.g., Z-packs, OTC omeprazole 20 mg) are in packages that have been designed and tested to meet the requirements for child-resistant containers.

ii. **All prescriptions for ORAL dosage forms of legend drugs in WA must be dispensed in CRCs, except for drug products exempted by the CPSC.** Exempted products are listed in 16 CFR § 1700.14, and include:
   1. Nitroglycerine sublingual tablets
   2. Sublingual and chewable isosorbide tablets ≤ 10 mg
   3. NaF ≤ 110 mg per package (tablets and liquids, must be ≤ 0.5% elemental fluoride w/w or w/v)
      a. Exercise: how many tablets of Chewable Vitamins with Flouride containing 0.5 mg of fluoride ion per tablet may be dispensed in a non-CRC? (Hint: 1 mg F⁻ is contained in 2.21 mg of NaF.)
   4. Cholestyramine and colestinol powder
   5. Oral cortisteroids
      a. Prednisone containing ≤ 105 mg per package
      b. Betamethasone containing ≤ 12.6 mg per package
      c. Methylprednisolone containing ≤ 84 mg per package
   6. Mebendazole ≤ 600 mg per package
   7. K⁺ supplements ≤ 50 mEq/dose in unit dose packaging
   8. Erythromycin ethylsucinate, measured as erythromycin equivalent
      a. Granules for suspension and suspensions containing ≤ 8 g
      b. Tablets containing ≤ 16 g per package
   9. Aerosols for inhalation
   10. Pancrelipase

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11. Hormone products
   a. Oral contraceptives in memory aid packages
   b. Medroxyprogesterone acetate tablets
   c. Conjugated estrogens in mnemonic packages containing \( \leq 32 \text{ mg per package} \)
   d. Norethindrone acetate in mnemonic packages containing \( \leq 50 \text{ mg per package} \)
   e. Hormone Replacement Therapy Products relying solely on one or more estrogens or progestogens for activity.

12. Sacrosidase (sucrase) in glycerol and water.

iii. **Use of Non-CRC Containers.** Pharmacists may dispense legend drugs in non-CRCs if:
   1. **The patient or the patient’s agent requests.** Such a request may be a “blanket” request that all drugs dispensed to the patient be in non-CRCs.
   2. **The prescriber requests it on the prescription at the time it is written.** Prescribers may not issue “blanket” requests, either for all drugs dispensed to a particular patient, or for all of his or her patients.

iv. **Requests for non-CRCs must be in writing in Washington.** Under federal law, requests for non-CRC containers may be oral or in writing. Washington incorporates the federal rules into its pharmacy regulations, but requires in addition:
   1. That requests for non--CRC containers are in writing, by the patient or the patient’s agent, or in writing by the prescriber. Authorization by the patient or agent shall be verified in one of the following ways:
      a. A statement on the back of the prescription signed by the patient or agent;
      b. A statement on the medication record requesting non-child resistant containers, or;
      c. A signed statement on any other permanent record requesting non-CRC containers. (WAC 246-869-230(2))

The date of the request should be included in the documentation kept in the pharmacy. At various times, Washington Board of Pharmacy investigators have insisted that such requests be renewed after some “reasonable” length of time, such as one year. This is a good practice, but it is NOT required by current Washington pharmacy regulations.

2. An indication that a non-CRC has been requested must be made in the **patient medication record system.** (WAC 246-875-020(1)(j))
v. **Legal liability for use of non-CRCs.**

If a pharmacist dispenses a covered drug in a non-CRC, and a child is injured as a result of gaining access to the drug, the child, his or her guardian, or the child’s estate (in case the child dies), may file a lawsuit against the pharmacist for damages. In an Iowa case\(^{155}\) the pharmacist was found liable for the death of a child who ingested Tedral SA (containing theophylline) prescribed for her father that was dispensed in a non-CRC. The pharmacy argued that the father had requested a non-CRC on the prescription, but didn’t have a written record to substantiate this, and the parents claimed otherwise. Normally, being able to document that the parent or guardian of the child authorized the use of the non-CRC will serve as a defense against liability. However, most childhood poisonings from legend drugs now occur as a result of children obtaining access to grandparents’ drugs. Because grandparents are not normally the legal guardians of their grandchildren, their request for non-CRCs may not provide an adequate defense. Pharmacists should consider including statements covering the following elements in the form used by patients to request a non-CRC.

1. CRCs are required by law unless specifically requested otherwise by the patient.
2. The purpose of these regulations is to prevent childhood poisoning from prescription drugs.
3. As few as one or two tablets of some drugs may be fatal to young children.
4. Of the oral prescription drugs ingested by children ages 4 and under, 23 percent belong to someone who does not live with the child; 17 percent belong to a grandparent or great-grandparent. (Source: [Safe Kids, USA](http://www.usa.safekids.org/tier3_cd.cfm?folder_id=540&content_item_id=1152)\(^{156}\))
5. Over 90% of elderly persons can successfully open CRCs if shown how. The pharmacy is willing to provide demonstrations and instructions to the patient on how to open a CRC. There are alternative CRCs that can be used by patients with arthritis or lack of hand strength, and the pharmacy is willing to obtain and provide these at cost to the patient.
6. The patient agrees that it is his or her responsibility to keep medications out of children’s reach, especially when using a non-CRC container.

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\(^{155}\) Baas v. Hoye, 766 F.2d 1190 (8th Cir., 1985)

\(^{156}\) [http://www.usa.safekids.org/tier3_cd.cfm?folder_id=540&content_item_id=1152](http://www.usa.safekids.org/tier3_cd.cfm?folder_id=540&content_item_id=1152)
7. Having read and understood the above, the patient nevertheless requests that non-CRCs be used on his or her prescription, and agrees to indemnify and hold harmless the pharmacy for any injuries that might occur to a child as a result of the patient’s request to use non-CRCs.

c. **Fixed Container Size for Sublingual Nitroglycerine.** Sublingual nitroglycerin tablets (e.g., Nitrostat®) are now only available for dispensing in bottles of 25 tablets, to preserve stability. FDA rules indicate that these products may not be repackaged, so pharmacists should not undertake to do so.

d. **Medisets and Compliance Packaging.** Medisets, pharmacy-packaged blister cards (“Bingo Cards”), and similar packages have not met federal standards for CRCs, thus, pharmacists must obtain requests from the patients to use non-CRC packaging.

13. **Pharmacist Administration of Drugs to Patients**

   a. **Is certification required to administer drugs?** No. Pharmacists may administer drugs ordered for a patient by an authorized prescriber, by any route, by virtue of their license to practice. Certification programs for immunizations are part of the process by which pharmacists in Washington may easily gain documented competence and adhere to the terms of a prescriptive authority protocol developed by WSPA and endorsed by the Board in order to prescribe vaccines. However, a pharmacist may develop a prescriptive authority protocol to prescribe and inject drugs without certification, as long as an authorized prescriber agrees to the protocol. Clearly, pharmacists should not undertake procedures unless they are adequately skilled in them.

   b. The Board of Pharmacy has alerted pharmacists involved in flu shot clinics that the Centers for Disease Control strongly recommends that providers do not pre-fill individual syringes because of risks of administration and dosing errors and concerns over stability.\(^\text{157}\)

   c. **Mercury-containing Vaccines and Injectables.** Washington law prohibits injection of a vaccine (or other product) containing greater than 0.5 mcg of mercury (present in thimerosol) per 0.5 mL dose into a person **known to be pregnant** or a child **under 3 years** of age. (RCW 70.95M.115).

      i. **Exception for flu vaccines.** Influenza vaccines (seasonal and H1N1) may contain up to 1 mcg of mercury per 0.5 mL dose.

         1. The CDC has published a [fact sheet on thimerosal-free]\(^\text{158}\) and thimerosol-reduced flu vaccines for use during the 2008-09 flu season.

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\(^{158}\) [http://www.cdc.gov/flu/about/qa/thimerosal.htm](http://www.cdc.gov/flu/about/qa/thimerosal.htm)
ii. **Exception for emergency.** The secretary of the DOH may suspend these restrictions upon declaration of a public health emergency (i.e., an outbreak or vaccine shortage), for the duration of the emergency. A woman known to be pregnant or lactating, and the parent or guardian of any minor who be vaccinated with a product containing mercury above the limits, must be informed of the fact.

1. The Secretary of DOH invoked this provision on September 23, 2009 and exempted H1N1 vaccines for a 6-month period ending March 23, 2010.\(^{159}\)

14. **Administration of Drugs to Patients by Other Persons**

a. **Other Health Professionals Who May Administer Drugs**

i. Anyone who may prescribe drugs may administer drugs.

ii. Nurses, both RNs and LPNs

iii. Nursing Technicians, under direct supervision of nurse

1. May not administer chemotherapy, blood or blood products, iv meds, scheduled drugs, or carry out procedures on central lines

iv. Respiratory Care Practitioners may administer prescribed or ordered respiratory drugs

v. Health Care Assistants. Under regulations of the Department of Health, practitioners may delegate certain tasks to health care assistants under their supervision:

1. Administer skin tests and subcutaneous, intradermal, intramuscular, and intravenous injections;

2. Perform minor invasive procedures to withdraw blood;

3. Administer vaccines licensed by the FDA by oral, topical, nasal, or injectable routes;

4. Health Care Assistants were given additional authority in 2009 to administer drugs via oral, topical, rectal, otic, ophthalmic, or inhaled routes, in accordance with a written order by the supervising practitioner. The Legislature mandated the Department of Health to conduct a review of the regulation and scope of practice of medical assistants, and approved the following drugs for administration by health care assistants for a 4-year period (through July 1, 2013).\(^{160}\)

   a. OTC drugs while in the care of a practitioner:

   "Benadryl, acetaminophen, ibuprofen, aspirin, neosporin, polysporin, normal saline, colace, kenalog, and hydrocortisone cream;"

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\(^{160}\) 2009 c 43; RCW 18.135.130
b. Legend drugs while in the care of a practitioner: “Kenalog, hydrocortisone cream, reglan, compazine, zofran, bactroban, albuterol, xopenex, silvadene, gastrointestinal cocktail, fluoride, lmx cream, emla, lat, optic dyes, oral contrast, and oxygen;”

c. Only HCAs certified in category C or E by the DOH may administer these drugs.

5. The supervising practitioner must be physically present in the facility when the HCA administers injections, vaccines, or drugs, but need not be present during procedures to withdraw blood.

6. Note: none of these rules allow HCAs to dispense drugs. For example, an HCA may not give the patient a sample package or a bottle of ibuprofen to take later.

vi. Licensed Midwives may purchase and administer certain drugs, and administer prescribed drugs

vii. Occupational therapists and Physical therapists may purchase, use, and administer modalities and certain other drugs used in physical therapy.

viii. Dental hygienists may administer local anesthetics and topical fluorides for dental patients

ix. EMTs may administer prescribed drugs per verbal or written orders of MD or DO

b. Non-health care professionals who may administer drugs

i. School personnel – including trained paraeducators – may administer drugs to students in accordance with school district policies and state regulations. 161

ii. Nonpractitioner Jail Personnel may provide medication assistance to inmates and administer drugs via oral route or inhalation. (See Chapter 3, Correctional Facilities)

iii. Ship captains on ocean-going vessels, when a health care practitioner is not stationed on the ship (e.g., large fishing vessels), may stock and administer drugs in case of emergencies. (See below)

15. Return or Exchange of Drugs from Consumers. Generally, pharmacies may not accept returns or exchanges of drugs, items of personal hygiene, or sick room supplies, after the items have left the pharmacy. (WAC 246-869-130) (The FDA issued a compliance policy guide in 1980 in which it stated that "a pharmacist should not return drug products to his stock once they have been out of his possession. … The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he mix returned portions of drugs to his

161 http://www.k12.wa.us/HealthServices/pubdocs/b034-01.pdf
shelf stocks.”162 Consumers may not return recalled drugs to pharmacies, but may only send them directly to the recalling manufacturer or a reverse distributor authorized to receive them. Exceptions to this rule are:

a. unit dose packages or full or partial multiple dose medication cards may be accepted from hospitals or long-term care facilities, if.
   i. The pharmacist can determine that the package is intact;
   ii. the pharmacist determines that the unit dose package or a multiple dose medication card meets USP standards for storage including temperature, light sensitivity chemical and physical stability;
   iii. the drug has been stored in such a manner as to prevent contamination by means that would affect the efficacy or and toxicity of the drug;
   iv. the pharmacist knows that the drug has always been under the control of a third party trained and knowledgeable in the storage and administration of drugs;
   v. the labeling or packaging has not been altered or defaced so that the identity of the drug, it is potency, lot number, and expiration date is retrievable;
   vi. if the drug had been prepackaged, it was not mixed with drugs of different lot numbers and/or expiration dates, unless the specific lot numbers were retrievable and expiration dates accompany the drug. If the drug is extemporaneously package, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label.

b. Durable medical equipment, including mobility aids and wheelchairs, may generally be returned.

16. Recalls. The FDA may seize actual packages of drugs that are adulterated or misbranded. To preclude seizure, manufacturers may “voluntarily” recall adulterated or misbranded drugs. (Note: the FDA may initiate a recall of non-complying infant formulas or for medical devices.)

a. **Recalled Drugs Cannot Be Dispensed.** Any drug for which a recall is announced must be assumed to be either misbranded or adulterated, and thus may not be sold or dispensed without violating the FDCA.

b. **Levels of Recalls.** Recalls may extend to one of the following levels (in increasing order of severity):
   i. Wholesaler level
   ii. Retail level
   iii. Consumer level – most serious

162 FDA, CPG Section 460.300, Return of Unused Prescription Drugs to Pharmacy Stock (CPG 7132.09), October 1, 1980.
c. **Classes of Recalls.** When the FDA approves a voluntary recall, it determines and publishes a classification of the recall to indicate its severity.

i. **Class I – most serious** – there likelihood of injury or death from the use of the product; may include a public warning

   1. The FDA’s compliance policy guide on Class I Recalls of Drugs[^163] requires that pharmacies, hospitals and nursing home pharmacists review their prescription files to determine which patients may have received the specific lot numbers involved in any Class I recall, and must then notify the patients’ physicians of the specific problem, and keep a record of the notification. If the pharmacy cannot separate out lot numbers to identify patients who received the specific product involved in the recall, they must notify the physicians of all customers who received the drug. The FDA will also under most circumstances issue a warning to the general public.

   **Comment:** I can find no record of any pharmacy being subject to discipline or prosecution for failing to comply with this guidance. However, it is conceivable that an injured patient could use this guidance to support a standard of care when maintaining a lawsuit against a pharmacy who failed to issue a warning following a Class I recall.

ii. **Class II** – health problems, if any, are expected to be temporary or reversible

iii. **Class III** – use of the product is NOT likely to cause health problems

iv. **Market withdrawal** – minor health risk or minor FDA violation

17. **Disposal of Outdated Drugs or other Dangerous Waste**

Pharmaceutical wastes have been regulated for many years, but recent publicity in the national press in 2008 has increased attention on the issue. The Associated Press reported in March 2008 that drugs had been detected in the drinking water supplies of 24 major metropolitan areas. In September, the AP reported that an EPA survey revealed that the majority of 5,700 hospitals and 45,000 long-term care facilities flush unwanted drugs down the drain and do not document amounts. Data from 14 facilities in Minnesota extrapolates to over 250 million pounds of drug waste annually, including packaging. Congressional hearings were held in 2008 as well.

a. **Waste Management Companies.** Under state and federal laws, each non-household waste generator (such as a pharmacy, clinic, or hospital) is required to handle its waste to assure that dangerous and hazardous wastes are disposed appropriately. Several national companies now provide a suite of programs combining reverse distribution with waste management to help pharmacies comply with the law. Some, like Waste Management, primarily handle non-viable pharmaceutical waste. Others are primarily reverse distributors, such as Guaranteed Returns and National Pharmaceutical Returns, and some, like Stericycle, offer both waste management and reverse distribution.

b. **Waste categories.** The four major categories of waste are liquid, gaseous, radioactive, and solid waste. Waste may be hazardous or non-hazardous. Most pharmacies (other than nuclear pharmacies) produce primarily liquid and solid waste, and most pharmaceutical waste is a form of solid waste.

c. **Waste streams.** At one time, pharmacies dumped all their waste in a single trash receptacle, which was then picked up by the garbage collector and most commonly trucked to a land fill (or dump). The operations of a pharmacy create, however, several distinct streams of unwanted materials. Each facility must have a plan and process for dealing with each of these streams, and must train staff to handle waste safely and appropriately. Protections for individual workers handling dangerous or hazardous products and materials are subject to regulations issued by the Occupational Safety and Health Administration (OSHA) or its state counterpart (WISHA in Washington).

   i. **Returnable products.** Depending on the nature of the sales contract between the pharmacy and its suppliers, unsold, overstocked, defective, recalled, or outdated products may be returned for credit. In many instances, these products cannot be resold or reused, and the manufacturer will need to determine how to dispose of them. Most pharmacies now utilize the services of **reverse distributors** who collect returnable products, separate them by manufacturer, obtain available credits, and return credit payments to the pharmacy, less the service fee. Reverse distributors who handle returns of controlled substances must be registered with the DEA, and these firms can handle controlled substances that are intended for destruction.

   ii. **Recyclables.** A significant portion of the waste generated by pharmacies can be recycled. Paper packaging, cardboard, paper records, labels, glass and metal packages, batteries, electric lighting elements, and many other items need to be separated into a recycling stream at the source in most municipalities.
iii. **Medical biohazard waste** needs to be segregated and stored to avoid human exposure prior to its destruction, and most of it is ultimately incinerated. Sharps disposal is a part of medical waste management.

iv. **Dangerous and hazardous solid waste** produced by pharmacies differs from biohazard waste in that it consists primarily of chemical compounds that must be kept out of air and water.

v. **Non-hazardous solid waste that cannot be readily recycled** includes food items and materials for which a recycling market doesn’t currently exist.

d. **Federal regulation of pharmaceutical waste** is governed by the Resource Conservation and Recovery Act of 1976 (RCRA), the principal federal statute dealing with solid waste disposal. The statute is enforced by the Environmental Protection Agency (EPA), with regulations in 40 C.F.R. parts 238-282. Congress amended the RCRA by the Hazardous and Solid Wastes Amendments of 1984, which added small quantity generators (e.g., pharmacies) and established requirements for hazardous waste incinerators. The federal Clean Water Act (CWA) also has implications for pharmaceutical waste, because it sets goals for elimination of toxic substances from drinking water. The CWA is also enforced by the EPA.

i. **Listed chemicals.** The EPA currently maintains lists of specific chemical substances, some of which are pharmaceuticals. In particular there are “P-listed” and “U-listed” chemicals.

   1. Example P-list pharmaceuticals
      a. Arsenic trioxide – P012
      b. Epinephrine base – P042 (salts exempted federally, but not in WA)
      c. Nicotine – P075
      d. Phentermine (C-4) – P046
      e. Physostigmine – P204
      f. Physostigmine salicylate – P188
      g. Warfarin > 0.3% - P001

   2. Example U-list pharmaceuticals
      a. Chloral hydrate (C-4) – U034
      b. Chlorambucil – U035
      c. Cyclophosphamide – U058
      d. Daunomycin (daunorubicin) – U059
      e. Melphanal – U150
      f. Lindane – U129

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165 Pub. L. 98-616
166 33 U.S.C. § 1251 et seq.
g. Warfarin < 0.3% - U248

3. Containers that have held listed chemicals are treated as hazardous waste. P-list containers are not considered “empty” unless they have been triple washed and the washing solution treated as hazardous waste. U-list containers are considered empty if all contents are removed that can be removed through normal means, and no more than 3% by weight remains.

ii. **Characteristics of hazardousness.** A waste is hazardous if it has one or more of the following characteristics

1. **Ignitability**
   a. Solutions with flashpoints < 140° F
      i. Aqueous with > 24% alcohol
      ii. Nonaqueous
   b. Oxidizers
   c. Flammable aerosols
   d. Rubbing Alcohol
   e. Topical preparations (e.g., clindamycin phosphate topical solution)
   f. Injections (e.g., paclitaxel injection)

2. **Corrosivity - Aqueous solution with pH ≤ 2 or ≥ 12.5**
   a. Glacial acetic acid
   b. Sodium hydroxide

3. **Toxicity – 40 chemicals included in P or U lists**
   a. Heavy metals – selenium, chromium, and silver
      i. Selenium injection
      ii. Chromium injection
      iii. Silver sulfadiazine cream
   b. Preservatives – thimerosol and m-cresol
      i. Influenza vaccines
      ii. Insulin injections

4. **Reactivity – explosive and water reactive wastes**
   a. Nitroglycerin formulations are excluded federally and in most states unless they exhibit ignitability

iii. **Chemotherapy agents** are not fully regulated by EPA. About 100 agents are not federally regulated under the RCRA, but most are state-regulated. Chemotherapy wastes that are regulated fall into three categories:

1. Trace waste (yellow label/container), including empty vials, syringes, iv’s, gowns, gloves, ziplock bags. These are treated as infectious medical waste and incinerated as medical waste.
2. “Bulk” chemo waste (black container) – if not empty, should be placed into RCRA hazardous waste container

3. Spill clean up (black container) – managed as RCRA hazardous waste

iv. Universal Waste. “Universal waste” is a general category of RCRA waste that allows combining into a single waste stream. P-listed and U-listed waste must be “designated” (segregated and labeled separately) by the waste designator, whereas universal waste does not. The EPA published a proposed rule that would place pharmaceutical waste generated by health care entities into the Universal Waste category.\textsuperscript{167,168} The comment period closed on March 4, 2009. It is expected that final rule making will occur in mid-2010. The goal of the rule is to streamline pharmaceutical waste management and encourage the development of consumer take-back programs. It will also remove current concerns about using reverse distributors as a national take-back model.

e. Washington State regulation of pharmaceutical waste. The Department of Ecology regulates disposal of dangerous wastes. Solid waste (such as drugs or medical devices) may be designated as dangerous, and if so, it must be disposed of in accordance with the Department’s regulations and/or federal regulations. The Department has established a 4-step process by which a “waste generator” can determine if a solid waste is designated as a dangerous waste:

(a) To determine whether or not a solid waste is designated as a dangerous waste a person must:

(i) First, determine if the waste is a listed discarded chemical product, WAC 173-303-081;

(ii) Second, determine if the waste is a listed dangerous waste source, WAC 173-303-082;

(iii) Third, if the waste is not listed in WAC 173-303-081 or 173-303-082, or for the purposes of compliance with the federal land disposal restrictions as adopted by reference in WAC 173-303-140, determine if the waste exhibits any dangerous waste characteristics, WAC 173-303-090; and

(iv) Fourth, if the waste is not listed in WAC 173-303-081 or 173-303-082, and does not exhibit a characteristic in WAC 173-303-090, determine if the waste meets any dangerous waste criteria, WAC 173-303-100.

(b) A person must check each section, in the order set forth, until they

\textsuperscript{167} 73 Fed. Reg. 73520, December 2, 2008

\textsuperscript{168} http://www.epa.gov/waste/hazard/wastetypes/universal/pharm.htm
determine whether the waste is designated as a dangerous waste. Once the waste is determined to be a dangerous waste, further designation is not required except as required by subsection (4) or (5) of this section. If a person has checked the waste against each section and the waste is not designated, then the waste is not subject to the requirements of chapter 173-303 WAC.

Any person who wishes to seek an exemption for a waste which has been designated DW or EHW must comply with the requirements of WAC 173-303-072.

f. Generally, drugs are now considered to be dangerous waste, and in Washington may not be disposed of in sewers (e.g., by flushing down the toilet) or in sanitary landfills or other waste disposal sites. Upon input from the Board of Pharmacy, the DOE has exempted controlled substances, legend drugs, and OTC drugs from most of its regulations when they are disposed of by a person or entity licensed to possess them, provided they are disposed of in an approved incinerator or a facility approved to incinerate municipal waste. WAC 173-303-071(3)(nn)(i)

i. State-only hazardous waste. These regulations affect only “state-only” hazardous substances. Some drugs are classified under federal law as hazardous waste and the state cannot exempt these drugs from federal requirements. (See above).

ii. Incinerators. Hospitals may operate approved incinerators, and hospital pharmacists may be able to use these facilities.

iii. Reverse Distributors. Pharmacies are increasingly relying on “reverse distributors” to handle pharmaceutical returns. Any product that can be returned to the manufacturer for credit is called a “viable pharmaceutical.” A product disposed of without receiving credit is “non-viable.” The DOE rules indicate that pharmacies may return viable pharmaceuticals using a reverse distributor, and may also use a DEA-registered reverse distributor to dispose of non-viable controlled substances. (See also chapter 5) Other pharmaceutical waste must be sent to a properly-registered incinerator. The Board has advised pharmacists to make sure that they obtain confirmation from their “reverse distributor” that it will dispose of drugs in accordance with WA law, since the person who “arranges” for the disposal of hazardous waste is ultimately responsible if the waste is not disposed of properly.

iv. Conditional Exclusion – The DOE considers “special wastes” to be those wastes that pose a relatively low hazard. Under DOE guidelines, certain pharmaceuticals are considered “special wastes” that can be handled under the Conditional Exclusion...
v. **Interim Enforcement Policy** – In April 2008, the DOE published an “Interim Enforcement Policy for Pharmaceutical Waste in Healthcare”\(^{169}\) under which it will “refrain from enforcing portions of the *Dangerous Waste Regulations* … at facilities meeting the conditions of this policy.” The policy is to remain in effect until EPA finalizes its proposed Universal Waste Rule for Pharmaceuticals. Eligible facilities include patient care facilities and retail pharmacies. Steps in using the policy include:

1. Create a waste profile by characterizing waste accumulated over a minimum of 90 days. List each waste type (e.g., warfarin, silver nitrate, cyclophosphamide, etc.) by its waste code and estimate its minimum and maximum percentage by weight of the total waste. Include “conditionally excluded state-only pharmaceutical waste” (i.e., all other non-listed pharmaceutical waste) as a single total. The waste profile must be updated every 3 years.

2. Notify DOE that your facility is managing waste under the policy, including a copy of your completed profile.

3. Train staff in proper handling of pharmaceutical waste.

4. Accumulate waste in accordance with DOE guidelines. Waste may be accumulated for up to 180 days.

5. Dispose of Waste by following DOE guidelines.
   a. Viable waste and non-viable controlled substances may be returned using a reverse distributor
   b. Non-viable non-controlled substances may be submitted to a registered waste transporter.

vi. **HIPAA regulations** apply to any PHI contained within the waste stream. Waste that contains patient information on labels must be stored and handled so as not to breach a patient’s privacy. (See also Chapter 6)

vii. The Department of Ecology has established a **“Pharmaceuticals” website** to assist medical facilities in management of dangerous wastes, including pharmaceuticals, iv admixtures, and sharps. It can be found at [http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html](http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html). Specific “Best Management Practices” are listed for various categories of pharmaceutical waste at

g. **Patient Disposal of Drugs.** The hazardous substances rules applying to drugs in the possession of waste generators (e.g., pharmacies and hospitals) do not apply to private citizens. However, The Board of Pharmacy and the Department of Ecology have approved a pilot program involving Group Health, Bartell’s and others, whereby collection bins are provided for patients to discard unwanted drugs. A recent article in the Seattle P-I described the program:

http://seattlepi.nwsource.com/health/301869_hcenter01.html

i. Residents of Spokane, WA may discard drugs and syringes in their residential garbage, because Spokane incinerates all its municipal waste in its unique Waste-to-Energy Facility.

ii. Residents of most other communities may normally take medications to the hazardous-waste area of their local landfill or transfer station. They should be advised to call their local waste management authority for instructions.

h. **Pending legislation** in Congress in 2009 included HR 1191 – the Safe Drug Disposal Act, sponsored by Rep. Jay Inslee of Washington State, which would allow for ultimate users to return controlled substances to a state take-back disposal program, and would also amend the FDCA to prohibit instructions on labels to dispose pharmaceuticals by flushing. The 2009 Washington Legislature also considered, but did not pass, HB 1165, which would establish a pharmaceutical product stewardship program (i.e., a consumer take-back program) funded and provided by drug producers. As of January 8, 2010, the State Senate is considering its companion bill, SB 5279, and had scheduled a public hearing on the bill for January 14, 2010.

18. **Extemporaneous Compounding of Drug Products by Pharmacists**

a. **Pharmacies Exempt from Registration with FDA.** Extemporaneous compounding of medications is a long-standing aspect of the practice of pharmacy. When the FDCA was adopted in 1938, manufacturers were required to register with the FDA.

i. § 510(b) requires annual registration by every person engaging in the “manufacture, preparation, propagation, compounding, or processing of drug[s] ...”

ii. However, § 510(g) exempts from registration “pharmacies ... regularly engaged in dispensing drugs and devices ... and which do not ... compound ... drugs other than in the regular course of their dispensing or selling drugs at retail ...”

b. **Compounding pharmacies may still be viewed as manufacturers under state product liability laws.** Although compounding pharmacies are not treated as manufacturers under
the FDCA, they remain liable for defects in the products they produce. Unlike laws regarding suits for professional negligence, product liability laws may impose liability on the entity that introduces the product into the stream of commerce for any product defect, whether it was foreseeable or not. (See also Chapter 7)

c. **Pharmacies must be engaged in bona fide pharmacy operations.** Until the 1980s, the FDA and most commentators believed that pharmacists could compound any medication ordered by a physician without violating the FDCA. Some pharmacies began to expand their compounding business greatly, and a few used the excuse that they were compounding drugs to shield them from regulation for some potentially or actually harmful practices.

i. For example, the Seven Freedoms Pharmacy in Florida compounded a product called “GH-8,” and shipped the product around the United States via the mail. GH-8 consisted of a formulation of procaine, and it was alleged to retard aging reduce or eliminate many of the symptoms of aging. GH-8 was the only product compounded or sold by Seven Freedoms Pharmacy, and the “patients” joined Club Sene-X to receive prescriptions for GH-8, or to receive instructions for their own physician to prescribe GH-8. In a landmark lawsuit, the US Court of Appeals ruled that Seven Freedoms Pharmacy was not engaged in the bona fide practice of pharmacy, that GH-8 was a new drug that had not been approved by the FDA, and that its distribution violated the FDCA.

ii. Injuries from poorly compounded prescriptions included overdoses of pediatric medications, blindness from non-sterile compounded eye drops, and deaths due to meningitis caused by non-sterile betamethasone injection. FDA surveys in 2001 discovered several problems in a random selection of compounded products.

d. **Changes in FDA’s View of Compounding.** In response to these events, the FDA reexamined its position that compounding was exempt from FDA oversight. It determined that, although pharmacies do not need to register, §510(g) does not exempt pharmacies from the new drug requirements of the Act, which include the following three sections:

i. § 501(a)(2)(b) – A drug is adulterated if it is not manufactured in accordance with Current Good Manufacturing Practices (GMPs).

ii. § 502(f)(1) – A drug is misbranded if it lacks adequate directions for use.

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170 United States v Sene-X Eleemosynary Corp., 479 F.Supp. 970 (S.D. Fla. 1979), aff’d, 697 F.2d 1093 (11th Cir. 1983)

171 [www.findarticles.com/p/articles/mi_m0CYD/is_22_37/ai_94817352](http://www.findarticles.com/p/articles/mi_m0CYD/is_22_37/ai_94817352)
iii. § 505 – An approved New Drug Application is required before a new drug can be marketed or introduced into the stream of commerce. Thus, the FDA determined, compounded products are new drugs, which come under its jurisdiction.

e. The 1992 Compliance Policy Guide. The FDA indicated that it had long recognized the role of compounding, and would exercise discretion in enforcing the FDCA against compounding pharmacists. Agencies, and prosecuting attorneys, are generally allowed discretion in enforcing laws and rules under their jurisdiction, if for no other reason that most agencies lack the resources to enforce every minor (de minimis) violation. Thus, they are allowed to prioritize their use of resources. With regard to compounding by pharmacists, the FDA issued a Compliance Policy Guide (CPG 7132.16), which would be followed by FDA and its agents in determining when to act against pharmacies who are compounding medications. The Compliance Policy Guide indicated that pharmacies would not be charged with a violation of the FDCA if they met all of the following criteria.

i. The pharmacies compounded products only upon receipt of prescriptions for individual patients, issued by an authorized prescriber, in the context of a bona fide (“good faith”) physician-pharmacist-patient relationship.

ii. Pharmacists did not compound an inordinate supply of the product in advance of receiving prescriptions for the product.

iii. Pharmacists did not use large-scale or commercial equipment.

iv. Pharmacists did not use commercial-grade testing equipment.

v. Products were prepared only from FDA-approved drug products.

vi. Pharmacists did not compound products that were essentially copies of existing marketed dosage forms.

vii. Pharmacists did not compound for resale to other practitioners, but only for sale to the end user of the product.

viii. Pharmacists did not advertise or promote specific drugs, classes of drugs, or dosage forms, but could advise practitioners that they were capable of compounding drugs.

f. The “P2C2” lawsuit. A group of pharmacists and consumers (“Professionals and Patients for Customized Care” or “P2C2”) filed a federal suit in the Southern District of Texas challenging the FDA’s development and use of the Compliance Guide. They argued, among other things, that the FDA failed to hold proper hearings before making what was, in essence, a rule regulating compounding. The federal court ruled that the FDA’s use of Compliance Guides was a legitimate internal policy making activity that did not require a formal rule-making process as is required to modify the Code of Federal Regulations.172

g. The FDAMA Amendment – Section 503A. Several national pharmacy organizations joined to persuade Congress to amend the FDCA to clearly indicate that compounding by pharmacists does not create a new drug covered by the FDCA. Congress enacted such a provision as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA added a new section,

172 Professionals and Patients for Customized Care v. Shalala, 56 F. 3d 592 (5th Cir. 1995)
§503A, which excluded compounded products from the definition of new drugs. The amendment stated that

i. §§ 501(a)(2)(b), 502(f)(1), and 505 do not apply to drugs that are compounded … for an individual identified patient, based on the unsolicited receipt of a valid prescription by a licensed pharmacist or physician

ii. Limited quantities may be compounded prior to receiving a prescription, based on a history of the pharmacist receiving valid orders within an established relationship between the pharmacist, physician, and patient.

iii. Components and methods used to compound the product
   1. Must comply with USP or NF monographs, if they exist, and the USP Chapter on Pharmacy Compounding.
   2. If no monographs exist, the products must be made from components of approved drugs, or
   3. Must be components that appear on a bulk ingredients list developed by FDA [Proposed rule published 1/7/99].
   4. Must be manufactured in an FDA registered facility

iv. Pharmacists are prohibited from compounding certain products:
   1. May not compound products that are listed by FDA as having been removed from market due to lack of safety or efficacy [Final Rule published 3/8/99].
   2. May not compound “regularly or in an inordinate amount” products that are essentially copies of commercially available drug products.
   3. May not compound products that are listed by FDA as having demonstrable difficulties in compounding [list to be developed].

v. As with the Compliance Guide, the new section prohibited pharmacists from promoting a particular drug, a particular class of drugs, or a particular type of drug. Pharmacists were allowed to promote the fact that they had a compounding service.

h. The Western States Lawsuit. Pharmacists in Nevada filed suit in federal court that challenged the prohibition of promotion of compounded products, arguing that the Act violated the free speech rights guaranteed under the First Amendment of the US Constitution.

i. In general, speech may not be restricted by the government unless it meets the following three tests:
   1. The restriction of commercial speech must fulfill a compelling government interest.
2. The restriction must be reasonably related to the achievement of the government interest.
3. The restriction must be the least intrusive option available to achieve the government interest.

ii. **Political speech**, in which individuals express their opinions to others, can only be restricted in extreme conditions, such as when the speech presents a “clear and present danger” to the safety of others. For example, in a 1919 landmark case, the Supreme Court said that a person does not have a right to falsely shout “Fire” in a crowded theater and cause a panic.\(^\text{173}\)

iii. **Commercial speech**, although still protected, may be more easily restricted, since the government has a compelling interest under the Commerce Clause of the Constitution to regulate interstate commerce, in part, by preventing false speech, among other things. The tests for regulating commercial speech were specified by the US Supreme Court in the 1980 case of *Central Hudson Gas & Electric v. Public Service Commission* (447 US 557, 1980). Under these “Central Hudson Tests,” government restriction of commercial speech is subject to a “four-prong test”:

1. Is the speech false or related to unlawful activity?
2. Does the government assert a “substantial interest” in restricting the speech?
3. Does the restriction directly advance the government interest?
4. Is the restriction not more extensive than necessary to achieve the asserted government interest?

iv. The **US District Court** found that FDAMA was an unconstitutional restriction on commercial speech, in that it sought to prohibit promotion of a legal product, and commercial speech that was not demonstrated to be false. The court ruled that the government failed to demonstrate a substantial interest in preventing the spread of compounding, which would be the basis for restricting advertising. The court also ruled that the anti-promotion provisions of the Act could be invalidated without affecting the status of the other portions of §503A, or, in other words, that the offending provisions were “severable” from the rest of the Act.\(^\text{174}\)

v. The government appealed, arguing in part that the anti-promotion provisions were a condition that Congress placed into the Act as part of an overall scheme, and were not severable. The government also argued again that the

\(^{173}\) Schenck v United States, 249 US 47 (1919)
\(^{174}\) Western States Medical Center v. Shalala, 69 F. Supp. 2d 1288 (D. Nev. 1999)
restrictions met a compelling government interest and met the Central Hudson tests. The 9th Circuit Court of Appeals affirmed the district court’s ruling that §503A’s prohibition of promotion of compounded drugs was unconstitutional, but reversed the district court’s ruling that these provisions were severable from the rest of §503A, and invalidated all of §503A. (Western States Medical Center v. Shalala, 238 F.3d 1090, 9th Cir. 2001).  

vi. Upon appeal to the Supreme Court, the 9th Circuit’s affirmation of the invalidation of §503A was allowed to stand, and the Supreme Court did not take up the issue of severability. ¹⁷⁶ Thus, §503A was declared invalid, and has no current force in law in the 9th Circuit.  

vii. Courts outside the 9th Circuit have, however, taken notice of the specifics of the Supreme Court decision. Because the Supreme Court only specifically affirmed the unconstitutionality of the prohibitions against promotion of compounded drugs, these other courts have held that the remaining provisions of the Act remain valid. (See below.) 

i. The Current CPG (CPG 460.200) The FDA has subsequently reissued its Compliance Policy Guide, absent the restrictions on promotion.  

   i. The current provisions of the Guide are as follows:  

   ...when the scope and nature of a pharmacy’s activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:  

   1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.  

   2. Compounding drugs that were withdrawn or removed from the market for safety reasons. ... 

   3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312. 

   4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of ...  

¹⁷⁵ Western States Medical Center v. Shalala, 238 F. 3d 1090 (9th Cir. 2001)  
¹⁷⁶ Thompson v. Western States Medical Center, 535 U.S. 357 (2002)
the drug substance has been made in an FDA-registered facility.

5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.

6. Using commercial scale manufacturing or testing equipment for compounding drug products.

7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.

8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

ii. The full text of the Compliance Policy Guide on Pharmacy Compounding is available on the [FDA webpage].

iii. The FDA has also developed CPG 608.400, regarding compounding of drugs for non-food animals, and has asserted that compounding of drugs for non-food animals from bulk ingredients is a violation of the FDCA.

j. **The Medical Center Pharmacy lawsuit.** The latest turn in this saga is another lawsuit in Texas, in which 10 pharmacies sued for declaratory judgment that pharmacy compounding of drug products human and non-food animals is not a violation of the FDCA, and an injunction against certain FDA inspection practices and enforcement of CPG 608.400 on compounding of drugs for non-food animals. The District Court found generally in favor of the plaintiffs, and granted summary judgment on the following major issues:

i. The Supreme Court decision in *Western States* did not invalidate all of the FDAMA section on pharmacy

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compounding, but only those elements that unconstitutionally restricted commercial speech.

ii. Pharmacy compounding in accordance with state laws in pharmacies that adhere to those laws, and regularly engage in the practice of pharmacy, does not create new drugs within the meaning of the FDCA.

iii. The CPG is an internal enforcement policy that cannot be enjoined prior to improper acts by the FDA. However, the FDA is enjoined from engaging in certain inspection procedures that are applicable only to firms required to register with the FDA. (See Chapter 3, FDA inspections of pharmacies.)

In July 2008, the 5th Circuit Court of Appeals essentially affirmed this decision, holding that compounded drugs are exempted from the new drug provisions of the FDCA if they are prepared in accordance with §503A.\(^\text{180}\)

k. **Current legal status of §503A and the FDA Compliance Policy Guide.**

i. Within the 5\(^\text{th}\) Circuit (Texas and surrounding states), the FDA is subject to the order of the District Court of the Western District of Texas, and §503A, absent its prohibitions on advertising, is in force.\(^\text{181}\)

ii. Within the 9\(^\text{th}\) Circuit, which includes Washington, the FDAMA compounding provisions do not operate, and the CPG is current FDA policy.

iii. It is likely that the Supreme Court will need to revisit its decision in *Western States* to resolve the conflict between the circuits.

l. **Challenges to “bio-identical” hormone replacement therapy.**

i. In early 2008, Wyeth filed a citizen's petition asking the FDA to take enforcement actions, including seizures, injunctions and/or warning letters, against pharmacies engaged in compounding of so-called bio-identical hormone replacement therapy (BHRT). Among the requested actions were that pharmacies compounding BHRT must provide a patient package insert, noting that BHRT is not FDA approved, is not manufactured according to good manufacturing practices, and that the BHRT has not been demonstrated to be safe for effective for any use. Wyeth also requested that the FDA issue an alert or talk paper directed

\(^\text{180}\) Medical Center Pharmacy v. Mukasey, No. 06-51583, 5\(^\text{th}\) Cir., July 18, 2008. Her

\(^\text{181}\) As of January 2010, “the FDA and the Department of Justice are … evaluating the Fifth Circuit’s opinion …” FDA states it will abide by the decision “in the Fifth Circuit and with respects to the plaintiffs covered by the decision. Elsewhere, the agency will continue to follow the enforcement approach reflected in the … CPG …”

*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm134919.htm*
to consumers, health care providers and the compounding industry. FDA limited its actions in response to the citizen’s petition to developing a consumer awareness campaign, publishing an article on its web site, issuing a press release, and arranging calls with media and stakeholders to discuss the issues.\textsuperscript{182}

ii. At the same time, the FDA independently sent warning letters to 7 compounding pharmacies that were promoting BHRT on their web sites. In general the FDA raised three types of issues relating to the pharmacies’ website claims:

1. unsubstantiated therapeutic claims, such as "bio-identical estrogen replacement therapy can benefit a woman by … reducing risk of heart disease, reducing the risk of Alzheimer's …";

2. unsubstantiated superiority claims, such as "bio-identical hormones differ from synthetic hormones in that synthetics are not identical in either structure or function to the natural hormones they emulate …";

3. unsubstantiated “bio-identical claims”, which suggests that compounded hormone therapy drugs are natural or identical to the hormones made by the body.

It seems clear that the pharmacies came to the FDA's attention primarily because of their websites, and the claims made therein. The FDA was careful to note that this action did “not target pharmacist who practice traditional pharmacy compounding and do not make false or misleading claims about compounded products.”\textsuperscript{183}

m. FDA Guidance on possible melamine contamination. The presence of melamine contamination in Chinese-produced components used in animal food gained significant publicity in 2008. In August 2009, the FDA issued a guidance\textsuperscript{184} to alert pharmaceutical manufacturers and pharmacy compounders to the possible contamination by melamine of pharmaceutical components. It suggests that compounders should independently test components for possible melamine contamination, or purchase such components only from reliable suppliers who have performed such testing. Because the testing involves liquid or gas chromatography combined with mass spectrometry (LC-MS/MS and/or GC-MS), the most practical response of pharmacy compounders is to purchase only components that are certified melamine free by a reputable supplier. Example at-risk components

\textsuperscript{182} www.fda.gov/ohrms/dockets/dockets/05p0411/BHRTletter.html
\textsuperscript{183} http://www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html
listed by the FDA include certain amino acids, gelatin, guar gum, and lactose, among other items. The advice in the guidance is generally non-binding. Failure of a compounding pharmacy to act in response to this announcement, however, could be seen as evidence of negligence if a patient were injured.

n. **USP Chapter Revisions.** The USP has developed two chapters related to compounding. The first, chapter <795> of USP 27, relates to compounding of nonsterile products, and covers most compounding activities of community pharmacies. The second monograph, chapter <797> of USP 27, details good practices for compounding of sterile products, which includes home IV admixtures, eye drops, and similar products. The standards in these chapters were incorporated by reference in §503A prior to its invalidation, and remain as elements of the FDA’s Enforcement Compliance Guide. **The USP 27 chapter <795> provides the following standards for compounding of non-sterile formulations.**

i. “Appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.” (27 USP 2346)

ii. “… Beyond-use dates are to be assigned conservatively.” (27 USP 2347)

iii. “In the absence of stability information that is applicable to a specific drug and preparation, the following maximum beyond-use dates are recommended for nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated:

1. For **Water-Containing Formulations** (prepared from ingredients in solid form) – The beyond-use date is not later than 14 days for liquid preparations when stored at cold temperatures between 2º and 8º (36º to 46º F).” (27 USP 2347)

2. For **nonaqueous liquids and solid formulations** –
   a. Where the **manufactured drug product is the source of the active ingredient** – the beyond-use date is not later than 25% of the time remaining until the product’s expiration date or 6 months, whichever is earlier.
   b. **Where a USP or NF substance is the source** of the active ingredient – the beyond-use-date is not later than 6 months.

3. For **all other formulations** – the beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.
iv. **Labeling.** The USP specifies that, as part of the compounding process, the compounder should “label the prescription containers to include the following items: a) the name of the preparation; b) the internal identification number; c) the beyond-use date …; d) the initials of the compounder who prepared the label; e) any storage requirements; and f) any other statements required by law.” (27 USP 2349)

o. **The International Association of Compounding Pharmacists (IACP)** has issued labeling guidelines for its members for medications compounded for human use,\(^\text{185}\) and for products compounded for office use in human patients.\(^\text{186}\) These are recommendations only, and are not legally binding, but represent a published standard of practice.

i. **Each guideline recommends a statement on the label that the product was specially compounded.**

   1. “This medicine was specially compounded in our pharmacy for you at the direction of your prescriber;” 
   or
   2. “This medicine was compounded in our pharmacy for use by a licensed professional only.”

ii. The guideline for non-office use medications recommends specific language be used in a package insert for the patient, conveying:

   1. The special compounded nature of the product.
   2. The lack of standardized information or literature.
   3. Instructions to specifically discuss the product usage with the prescriber.
   4. Instructions to contact the prescriber or pharmacy if questions or side effects arise, and to share any other medications, allergies or medical conditions with the prescriber.

iii. **All labels should include:**

   1. Name of patient and prescriber, if dispensed to patient
   2. Name, address, and phone number of pharmacy
   3. Prescription number or lot number
   4. Medication’s established or distinct common name
   5. Strength
   6. Statement of quantity
   7. Directions for use if dispensed to patient
   8. Date filled
   9. Beyond use date


10. Storage instructions
11. Other required labeling

p. Pharmacy Compounding Accreditation Board. In 2006, 8 national organizations (ACA, APhA, IACP, NABP, NCPA, NASPA, NHIA, and USP) established the Pharmacy Compounding Accreditation Board (PCAB). In a manner similar to the Joint Commission’s review of hospitals, PCAB evaluates compounding pharmacies’ compliance with over 35 standards and certifies qualified pharmacies as meeting its standards. In particular, pharmacies that undertake any forms of sterile compounding will likely need to become accredited in order to obtain liability insurance in the future. The PCAB has adopted labeling guidelines that are essentially the same as those suggested by IACP.

q. Washington Compounding Rules. Washington Board of Pharmacy regulations regarding compounding generally follow the NABP Model Act, and specify that pharmacists may extemporaneously compound products ordered for a patient in the context of a physician-pharmacist-patient relationship. (WAC 246-878-020)

i. Documentation of Physician and Patient Acceptance of Compounded Alternative. If a commercially available product is being replaced by a compounded equivalent, records must indicate that the patient and physician agree to the use of the compounded product, and this shall be documented on the prescription or in the prescription records.

ii. Source of Ingredients. The first choice for compounded products is to use ingredients meeting USP or NF requirements; however, pharmacists may use judgment if compendial products are not available.

iii. Limited Quantities. Products should be compounded in limited quantities, based on a history of receiving prescriptions for the product, or upon anticipated need for refills of existing products. Compounding of excessively large amounts is considered manufacturing.

iv. Wholesaling Prohibited. The regulation prohibits sale of compounded products to other licensed persons or commercial entities. However, it is permitted in WA to sell compounded products to a prescriber for administration to a patient.

v. Promotion Restricted, but this restriction not enforceable. The regulation allows promotion of the compounding service, but states that they “they shall not solicit business (e.g., promote, advertise, or use

187 http://www.pcab.info/standards.shtml
salespersons) to compound specific drug products.” (WAC 246-878-020(4)). Given the Supreme Court and 9th Circuit Court of Appeals decisions in *Western States*, this provision would be unenforceable and the Board will likely repeal it eventually.

vi. **Personnel Requirements.** The regulation specifies requirements for pharmacists and ancillary personnel involved in compounding (WAC 246-878-030):
   1. The pharmacist is responsible for inspecting all supplies, processes, and equipment, and for making sure of the accuracy of the compounding process.
   2. Pharmacists and ancillary personnel involved in compounding must keep up to date with training and continuing education, and be aware of the requirements of WAC 246-878.
   3. Clean clothing and appropriate protective apparel are required.
   4. Compounding areas are limited to personnel involved in compounding, and the pharmacist shall exclude persons with lesions or other illnesses that may compromise the product.

vii. **Facilities.** Requirements for facilities used in compounding are specified in WAC 246-878-040:
   1. There shall be adequate space and facilities, and non-sterile compounding shall be separate from sterile compounding facilities.
   2. Bulk containers shall be properly stored, including under refrigeration if necessary.
   3. Adequate water and other supplies must be available for compounding and cleaning.
   4. Facilities must be maintained in clean and sanitary condition.

viii. **Sterile Products.** Compounding of sterile products must conform with WAC 246-871.

ix. **Applicability of USP Standards.** The Washington regulation does NOT incorporate by reference the standards of USP chapters <795> or <797>. However, these standards are widely regarded as best practices, and should be followed wherever applicable.

r. **Compounding and prepackaging or repackaging by hospitals.** The FDA has indicated in a compliance policy guide\(^{189}\) that it does not regard hospitals as being required to register under section 510 if it compounds drugs for inpatients or outpatients, but it must register as a manufacturer if it resells a unit of compounded

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\(^{189}\) CPG § 460.100 Hospital Pharmacies – Status as Drug Manufacturer (CPG 7132.06), October 1, 1980.
medication to another hospital or pharmacy. It does not believe that the Current Good Manufacturing Practices (CGMPs) apply to hospitals not registered as manufacturers. The CPG also deals with investigational drugs, compounding of individual prescriptions, and prepackaging.

19. Prescription Drug Samples. The Prescription Drug Marketing Act (PDMA) placed restrictions on the distribution of drug samples by manufacturers. In essence, the law requires that samples of legend drugs be distributed only to authorized prescribers pursuant to a request by the receiving prescriber. Written records must be retained by manufacturers’ representatives of the samples they have distributed.

a. Distribution of samples by hospital pharmacies or at direction of prescriber. Section 503(d)(1) of the act states that, for purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a practitioner licensed to prescribe such drug, by a health care professional acting at the direction and under the supervision of such a practitioner, or the pharmacy of a hospital or of another health care entity acting at the direction of such a practitioner who received the drug sample in accordance with the act and regulations.

b. FDA Guidance for Industry on distribution of samples to “free clinics.” The FDA adopted regulations in 1999 to allow samples to be distributed to a charitable organization, which is defined as “a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation” which has received exemption under section 501(c)(3) of the Internal Revenue Code. Included in these proposed regulations were the requirements that such samples must be inspected by a licensed practitioner or registered pharmacist, and drug sample receipt and distribution records must be kept by the institution for a minimum of 3 years. (21 CFR 203.39) Numerous free clinics asserted that these regulations were overly burdensome, and a study of the matter commissioned by the FDA found that clinics with total revenues under $200,000 per year were, in fact, over burdened by the rules. While awaiting rule making to revise the regulations, the FDA adopted a “Guidance for Industry” on samples in free clinics in March 2006. The guidance indicates that the FDA will exercise enforcement discretion when free clinics are not in full compliance with sections of the regulations related to receipt, disposal, and record keeping. However, the clinics are expected to comply with certain requirements, including

i. The sample must be received in its original unopened container with intact labeling.

ii. The sample may not be distributed or administered to a patient unless it has been inspected by a licensed practitioner or registered pharmacist to assure it is not adulterated or misbranded. The FDA will allow registered pharmacist or licensed practitioner to designate a staff member of the clinic to perform the inspection.

iii. The clinic must store samples properly to assure they do not become adulterated or misbranded.

iv. The clinic shall notify the FDA within 5 days if it becomes aware of known theft or significant loss of drug samples from the clinic.

c. **Washington restrictions on samples.** The Washington statute corresponding to federal law is RCW 69.45.050:
   1. Drug samples may be distributed only to authorized prescribers, or, at their request, to a hospital pharmacy or health care facility.
   2. The written request shall contain:
      a. The name and address of the receiving practitioner, and professional designation.
      b. Name, strength, and quantity of samples delivered.
      c. Name of manufacturer and individual delivering the samples.
      d. Dated signature of practitioner requesting the sample.
   3. No fee or charge may be imposed for distribution of samples within this state.
   4. Manufacturers’ representatives may only possess sample drugs distributed by the manufacturer they represent. This does not preclude any individual from possessing drug samples that have been prescribed for that individual.

ii. **The parallel regulation** is WAC 246-877-020:
   1. The possession, distribution, or dispensing of legend drug samples by a pharmacy is prohibited.
   2. This does not apply to any pharmacy of a licensed hospital or health care entity which has received samples by the direction of an authorized prescriber as specified in RCW 69.045.050.
   3. A health care entity under this rule is one that does not include a retail pharmacy licensed under state law.
Comment: I interpret the statute to allow pharmacists in Washington who have prescriptive authority to request and receive samples of any drugs they are allowed to prescribe. However, the regulation does not allow those pharmacists who practice in a retail pharmacy to store those samples in that pharmacy or dispense the samples from the pharmacy. There are licensed pharmacies associated with community health centers who currently are distributing samples which are stored in the clinic’s facilities. Whether the regulation would withstand a challenge by a community pharmacist with prescriptive authority is an open question.

20. Accommodation Sales and Transfers to Other Practitioners.
   a. Accommodation Sales. There is a long tradition of pharmacists loaning or borrowing drugs – or purchasing them outright – from other pharmacists to meet urgent needs. These exchanges are often called “accommodation sales,” and are generally excluded from the definitions of either wholesale or retail sales. As a result, these sales or trades are not subject to wholesale or retail sales taxes, or to business and occupation taxes.
   b. Transfers to Other Practitioners. Pharmacists may also sell legend drugs directly to authorized practitioners (see Table 4-9a) for use in their practices, but those sales are subject to applicable taxes. In addition, sales to pharmacists or other practitioners do not require the pharmacist who is providing the drug to register as a wholesaler if they do not constitute more than 5% of total sales as measured during any 12 consecutive months (WAC 246-879-010(10)(e)). Pharmacies may also sell legend drugs to certain other individuals for use in their practice or occupation. The following is a partial list, and other individuals may assert a right to purchase legend drugs, subject to verification (e.g., with the Board of Pharmacy).
   i. Acupuncturists may use certain legend drugs including sterile water for injection in procedures such as point-injection therapy (e.g., aquapressure).  
   ii. Animal control agencies and humane societies may purchase drugs in accordance with Board of Pharmacy rules.  
   iii. Masters of Ocean-going Vessels (i.e., ship captains and/or first officers) may purchase legend drugs and controlled substances to be used in case of an emergency. To purchase controlled substances, the master must appear in person at the pharmacy, and the pharmacy must maintain a record of “Sale of Controlled Substances to Vessels.”

191 RCW 18.64.010(1)(j).
192 RCW 69.41.080; WAC 246-886
that “the pharmacist … supplying prescription drugs for use on ships should exercise reasonable care and assure themselves that the prescription drugs are in fact going to a ship’s medicine chest and are not being diverted to improper channels.”

iv. Teaching institutions may register with the DEA to order and use controlled substances in research and/or instruction. A separate application is used for teaching and for research. Individual teachers do not need to register, but use the institution’s DEA number when ordering products, which may be supplied by a community pharmacy in accordance with the rules for distribution to other registrants. The educational institution and individual researchers must also register with the Board of Pharmacy. (See Chapter 5).

c. However, the long-accepted practice of pharmacists repackaging or relabeling drugs that are loaned, borrowed, or sold to other practitioners is unacceptable under the FDCA or most state laws unless the repackaged product has all of the required labeling. Incomplete relabeling renders the product misbranded.

d. In order to avoid creating a misbranded product, pharmacists should loan, borrow, sell, or trade products with other pharmacies or practitioners only in the manufacturer’s original package with all of the accompanying labeling, including the package insert.

e. Distribution of legend drugs to other pharmacists or practitioners must be documented in the pharmacy’s records; this is done by preparing an invoice and retaining a copy. (See Chapter 5 for requirements related to sales of controlled substances to other registrants.)

f. When the drugs in question are purchased at a special price (e.g., by hospitals, or pharmacies eligible for 340B pricing), they may not be resold to any entity that is not eligible for the same pricing. To do so places the seller in possible violation of federal antitrust laws, or, in the case of 340B drugs, federal fraud statutes. In emergencies, these drugs may only be loaned, and the borrower must repay with the same quantity of the same drug product.

21. Importation of Drugs from outside the US.

a. No drug may be imported into the US except by a firm registered with the FDA, and the particular drug product must be an approved drug with a current NDA.

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195 WAC 246-887-200(2)
b. **Only US licensed drug firms may reimport US-made FDA-approved drugs** into the US for marketing and distribution within the US (21 U.S.C. § 381(d)(1)).

c. **Drugs imported from outside the US may also violate the FDCA for other reasons.** They may be:
   i. Unapproved (21 U.S.C. § 355)
   ii. Labeled incorrectly (21 U.S.C. § 353(b)(2)), and/or
   iii. Dispensed without a valid prescription (21 U.S.C. § 353(b)(1))

d. The FDA has adopted as a regulatory policy that it will not generally take action against individuals who bring small amounts of drugs (generally not more than a 3-month supply) into the US from abroad (especially Canada) for **their personal use as prescribed by their personal physician.** This does not mean that such actions are legal, only that the FDA will use discretion in enforcing the Act under the circumstances set forth in its policy.
   i. Neither the FDA nor the DEA will knowingly permit importation of **controlled substances** by individuals for their own use.

e. Congress passed legislation in 2002 (the Medicine Equity and Drug Safety (MEDS) Act), which was revised in 2003 by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) that modified the FDCA to potentially allow for reimportation of US-made FDA-approved drugs from Canada by pharmacists, wholesalers, and individuals. This **only becomes effective following a certification** from the Secretary of Health and Human Services that implementation of these programs would (1) pose no additional risk to public health and safety, and (2) result in a significant reduction in the cost of drugs to the American consumer (21 USC § 384). An HHS Task Force on Drug Importation issued a report to Congress (required by the MMA) in December 2004 that essentially concluded that reimportation would pose significant risks and would not result in a correspondingly significant reduction in drug costs to American consumers. Two HHS Secretaries have declined to provide the certification provided for by either the MEDS Act or the MMA.

f. **Department of Homeland Security prohibited from preventing individuals from bringing in 90-day personal supplies of drugs from Canada.** Congress in 2006 adopted §535 of the Homeland Security Appropriations Act (PL 109-295) which provides that US Customs and Border Protection may not use appropriated funds for the purpose of preventing individual patients from bringing up to a 90-day personal supply of FDA-approved drugs into the US from Canada.
Canada. This provision does not apply to biological products or controlled substances.

g. **State waiver requests.** Numerous state and local governments have requested waivers from the FDA to allow various schemes for importing drugs from Canada. The FDA has routinely denied these waiver requests from a wide variety of states including Oregon, California, Nevada, Texas, Minnesota, Illinois, New Hampshire, and Wisconsin. Of particular interest is the denial of the request for a waiver from Montgomery County, Maryland, the county in which the FDA’s Headquarters is located.

i. A 2004 request from Vermont was denied by the FDA, and Vermont filed suit to compel approval of their request. In September 2005, the federal district court for the District of Vermont dismissed the Vermont lawsuit and affirmed the FDA’s position that, as a matter of law, granting the waiver is prohibited by the FDCA. (*State of Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt., 2005)).

h. **Washington importation waiver request.** The Washington request for a waiver to allow for the licensing of Canadian pharmacies as Non-resident Pharmacies in Washington, and for the licensing of Canadian wholesalers, was denied by FDA on March 17, 2006.
Chapter 5. Controlled Substances

Note: This chapter is to be read in conjunction with the Pharmacist’s Manual, US Department of Justice, Drug Enforcement Administration, April 2004.197

1. Statutory schemes for controlling substances of abuse.
   a. Early federal interest in regulating narcotics arose primarily from American dealings abroad. As a result of the Spanish-American War, the US acquired possession of the Philippines, which had a pre-existing system of licensing opium addicts. At the same time, Great Britain was attempting to deal with significant problems with opium trade from China. A US commission established to propose an alternative to the licensing system in the Philippines recommended that international control of opium trafficking was essential. In 1906 – the year of the passage of the US Pure Food and Drug Law – President Roosevelt called for an international conference on opium, which was held in Shanghai in 1909. A second conference in 1911 was held at The Hague, Netherlands, and the resulting Hague Convention became the first international compact governing narcotics. Congress passed the Harrison Narcotic Act in 1914 as a means of controlling narcotic distribution, and limiting its possession and use to medical purposes.
   b. The scheme of the Harrison Act was similar to the scheme for controlling alcohol, and, later, marijuana – a federal tax was imposed on sales of narcotics, and each sold package had to bear a narcotics tax stamp. Dealing in narcotics which were not under this scheme became a tax law violation. As with alcohol, the “revenuers” (Department of Treasury agents) became the enforcers of narcotic control law. The Act remained the principal US controlled drug law until the 1960s.

i. In the 1960s, the law identified 4 categories of “narcotics”: A, B, X, and M. Class A narcotics required a written prescription that was not refillable. Class B narcotics could be telephoned. Classes X and M were “exempt narcotics” because no tax was collected on them. They could be dispensed pursuant to a telephoned prescription, and some forms could be sold OTC by pharmacists if the sales were recorded in a register.

1. The statute required the pharmacist who filled a prescription for a Class A narcotic to sign his name across the face of the filled prescription and indicate the date filled. Pharmacists often called this “cancelling” the prescription. Many pharmacists continue to sign their name on Schedule II drugs, but this is NOT a requirement of federal or Washington law, and very few states still require this.

ii. New drugs of abuse. The Harrison Act defined “narcotics” to include opiates and certain stimulants, including cocaine. However, the 60s saw the development of newer drugs, not controlled by the Act, which were subject to abuse. Barbiturates, amphetamines, carbamates, and benzodiazepines were not covered. Non-medical agents, such as LSD, phencyclidine, and psilocybin, were likewise not controlled, except that their distribution was a violation of the FDCA.

iii. With the repeal of Prohibition in 1933, many of the agents formerly in the Bureau of Prohibition were moved to the new Federal Bureau of Narcotics, which was created in 1930 and placed under the direction of Harry Anslinger, former assistant director of the Bureau of Prohibition. Anslinger undertook a sustained campaign against marijuana, which previously had not been seen as a significant problem to the US government. In 1937, the Marihuana Tax Act was passed, classifying marijuana as a narcotic, and bringing it within the ambit of the FBN. The medical product, cannabis, became subject to federal narcotic control, at a tax rate of $1 per ounce for persons registered under the Act who would pay a special tax of $24 per year; largely removing it from the medical armamentarium because of cost, in spite of over 100 years of use by physicians in the US.

1. The average income of a US physician in 1933 was $3,600 (Paul Starr, The Social Transformation
of American Medicine, New York: Basic Books, 1982, p. 270). In today’s terms, an equivalent registration fee for a family physician to prescribe marijuana (distinct from the general narcotics registration) would be over $850.

c. The growth of substance misuse in the late 1950s and early 1960s led to adoption of a new international compact, the Single Convention on Narcotic Drugs, in 1964, which incorporated controls on all psychoactive drugs of abuse, including narcotics, marijuana, stimulants, and psychedelic drugs.

d. Congress passed the Drug Abuse Control Amendments of 1965 which added “stimulant, depressant, or hallucinogenic” agents to federal control as if they were narcotics. A Bureau of Narcotics and Dangerous Drugs (BNDD) was created in 1968 as a successor to the Narcotics Bureau, and placed, for the first time, in the Department of Justice. The DACA continued to use a tax scheme to control substances.

e. In 1970, Congress passed a completely revised scheme, the Controlled Substances Act, to replace previous controlled substances law. Rather than a tax act, the CSA is a criminal statute, establishing criminal penalties for unlawful possession, manufacturer, distribution or diversion of controlled substances. The new scheme is described more fully below. In 1973, the Drug Enforcement Administration, a division of the Justice Department, was created to administer the CSA.

f. The CSA is found in the US Code in Title 21, starting at section 801, and the corresponding DEA regulations implementing the Act are found in 21 CFR § 1301 et seq.

2. Prescribing and Dispensing Controlled Substances. The CSA (21 USC § 801 et seq.) serves as a model for Washington’s laws and regulations regarding controlled substances, which closely follow federal rules. The Washington Controlled Substances Act, RCW 69.50, is the principal law dealing with controlled substances, and, like the federal CSA, requires registration of prescribers, dispensers, manufacturers, and wholesalers of controlled substances.

i. It sets forth five schedules of controlled substances based on likelihood of abuse and/or medical use. Only substances in schedule II through V are available for medical use. Table 5-2a summarizes the requirements of these schedules.
Table 5-2a Controlled substances requirements

<table>
<thead>
<tr>
<th>Sched.</th>
<th>Basis for Inclusion</th>
<th>Examples</th>
<th>How Prescribed</th>
<th>Prescriptions Expire</th>
<th>Refill Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Federal Law</td>
<td>WA</td>
</tr>
<tr>
<td>I</td>
<td>No medical use, high potential for abuse</td>
<td>Heroin, LSD, psilocybin, marihuana</td>
<td>May not be prescribed</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>II</td>
<td>High potential for abuse</td>
<td>Meperidine, oxycodone, methylenidate, amphetamines, propoxyphene powder, codeine, hydrocodone</td>
<td>Requires written prescription</td>
<td>Never</td>
<td>1 year</td>
</tr>
<tr>
<td>III</td>
<td>Moderate potential for abuse; mostly narcotic combinations</td>
<td>Codeine with APAP or ibuprofen; Hydrocodone with APAP</td>
<td>Written or oral</td>
<td>6 months from date written</td>
<td>6 months from date written</td>
</tr>
<tr>
<td>IV</td>
<td>Moderate potential for abuse; Non-narcotics mostly</td>
<td>Benzodiazepines, Testosterone, phenobarbital, meprobamate, <strong>carisoprodol</strong> (*15 states, incl. WA)</td>
<td>Written or oral</td>
<td>6 months from date written</td>
<td>6 months from date written</td>
</tr>
<tr>
<td>V</td>
<td>Codeine ≤10 mg/dose plus other ingredients; antidiarrheals</td>
<td>Lomotil®; Tylenol® with Codeine Elixir; codeine cough syrups</td>
<td>Written or oral</td>
<td>Never</td>
<td>1 year</td>
</tr>
</tbody>
</table>

ii. It requires that prescriptions be **issued in good faith for a legitimate medical purpose**, by a **practitioner authorized to prescribe** in Washington, in the **due course** of that prescriber’s practice.

1. The due course of practice requires that the prescription be issued in the context of a **bona fide prescriber-patient relationship**, and within the **scope of practice** of the prescriber.

2. **Legitimate medical purposes** are those which are consistent with the generally recognized standards of the prescriber’s profession, with due consideration of the prescriber’s specialty. Prescriptions for legitimate medical purposes do **not** include the following:
   
a. **Prescriptions issued “for office use,”** i.e., as a means of obtaining controlled
substances for the prescriber to use in his or her office, without specifying a specific patient. Purchases of controlled substances by a practitioner for office use are accomplished by order forms or purchase orders.

b. **Fraudulent or forged** prescriptions

c. **Prescriptions issued solely to maintain an addiction** (other than issued in office-based narcotic maintenance programs – see below). Prescriptions issued to an addicted person to treat pain, for example, are permissible.

d. In Washington, **practitioners may not prescribe or dispense controlled substances for themselves** – it is considered unprofessional conduct to prescribe controlled substances for oneself in RCW 18.130.180(6). This does not prohibit practitioners from prescribing controlled substances for a family member. It is also a violation of the WA Controlled Substances Act for practitioners (this does not include pharmacists who lack prescriptive authority) to dispense Schedule II, III, or IV substances for oneself (RCW 69.50.308(i)). This, again, does not prohibit a practitioner from dispensing controlled substances for family members.

e. **Prescriptions for controlled substances that are for uses not within the approved indications** (or those that are contraindicated) in the package insert. The DEA takes the somewhat controversial position that non-approved uses cannot normally be legitimate, but generally does not rest a decision to prosecute on this factor alone.

f. **Use of Controlled Substances for aid-in-dying.** The DEA in 2001 issued an “interpretive rule” that use of controlled substances in accordance with Oregon’s Death with Dignity Law would violate the CSA since using these drugs to cause death would not be for a “legitimate medical purpose” within the normal course of a practitioner’s practice, and physicians who wrote – or
pharmacists who filled prescriptions for this use could lose their DEA number.

i. This rule was challenged in court, and in January 2006 the US Supreme Court ruled in Gonzales v. Oregon that “The CSA does not allow the Attorney General to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide under state law permitting the procedure.” The Court ruled that Congress has not given the Attorney General authority to promulgate rules other than those to register or deregister individual registrants, and to determine which schedule into which a controlled substance will be placed.

ii. The Court’s opinion is consistent with the notion that Congress has not yet chosen to regulate the practice of medicine or pharmacy, but has deferred that role to the states.

g. Washington’s Death with Dignity Act was presented to Washington voters as Initiative 1000 in November 2008. A 58% majority approved the law, which took effect on March 4, 2009. It closely parallels the Oregon Death with Dignity Act, and the fundamental effect of the law is to exclude from the definition of “assisted suicide” (which remains a crime) the prescribing and dispensing of a drug that will aid a qualified patient in dying.

i. Qualified patients are mentally competent adults who reside in Washington who have been certified by two independent physicians as being terminally ill with a life expectancy of six months or less. If either physician believes that the patient’s judgment may be affected by depression or other mental conditions, he or she is required to seek a psychological evaluation.

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199 2009 c 1 (Initiative Measure No. 1000, Approved November 4, 2008); RCW 70.245
before issuing the request of prescription.

ii. The law requires the patient to make a written and oral request to the physician, and then must make a second oral request for the prescription. A minimum of 15 days must elapse between the first and second oral requests. The written request must be witnessed by two individuals, and at least one witness must not be related to the patient, entitled to share in the patient's estate, or employed by an institution in which the patient is receiving care. At least 48 hours must elapse following the second oral request and issuance of the prescription.

iii. The physician may dispense the medication directly to the patient, or, with the patient's permission contact a willing pharmacist and inform the pharmacist of the prescription and then deliver the prescription to the pharmacist personally by mail or by fax.

iv. The pharmacist, upon agreeing to participate, must prepare the prescription and dispensing directly to the patient, the attending physician, or an agent of the patient specifically named in the prescription. Within 30 days, the pharmacist must mail a copy of the "dispensing record and such other administratively required documentation" to the Department of Health in accordance with DOH regulations. The Department proposed these regulations in January 2009 as WAC 246-978.

v. Prescriptions must be written for medications that the patient may self administer by ingestion, i.e., orally, without help from another person. The most common oral prescriptions
written in Oregon consist of 24 hours of pre-medication with metoclopramide (20 mg Q8H) to minimize vomiting, followed by 9 g of secobarbital or pentobarbital in 100 mL of oral suspension.200

vi. No pharmacist is required to participate in dispensing prescriptions written under this act.

vii. A pharmacy may not discipline, suspend, or otherwise penalize a pharmacist for "participating or refusing to participate in good faith compliance" with the law. The law does not permit a pharmacy to prohibit its employee pharmacists from dispensing prescriptions issued under the act.

viii. The Board of Pharmacy’s regulation on Pharmacies’ Professional Responsibilities (WAC 246-869-010) is not applicable to prescriptions written under the act, primarily because of the law’s requirement that only willing providers shall participate in the provision of medication to the qualified patient, but also because the regulation only mandates prompt dispensing of FDA-approved products. The compounded barbiturate prescriptions will not meet this test.

Comment: The law is explicit that only licensed physicians (MD or DO) may be involved in the process of issuing prescriptions to aid in dying, and that only licensed pharmacists may be involved in the dispensing of those prescriptions. My interpretation of this specificity is that pharmacy technicians or interns should not participate in dispensing prescriptions issued under the law. Also, note that the need to compound a palatable formulation of the barbiturate – a bitter drug – will probably limit involvement to compounding pharmacies.

h. **Specific prohibitions** exist under the law for the use of certain substances. For example:
   i. Anabolic steroids for weight training.
   ii. Specified CNS stimulants for weight control.

3. **Corresponding responsibility of the pharmacist.**
   While the prescriber bears the primary responsibility for the legitimacy of his or her prescriptions, the law holds the pharmacist to a "corresponding responsibility" for recognizing invalid prescriptions, when the pharmacist “knew or should have known” from the circumstances that the prescription was suspect. (RCW 69.50.308(e); 21 CFR §1306.04(a))
   (See Reporting of Violations, below)

4. **Excessive issuance of otherwise appropriate prescriptions.** It is not uncommon for a pharmacist to receive prescriptions for a controlled substance that, on their face, are appropriate. However, what should the pharmacist do when the patient brings in a subsequent prescription, written by the same prescriber, which is prescribed exceedingly early given the quantity and directions on the prior prescription? It is my opinion that anything prescribed in excess of the prescriber’s own dosage instructions is no longer for a legitimate purpose. Certainly when early prescribing becomes a pattern, the DEA and/or the Board could hold the pharmacist responsible for recognizing the situation.

   iii. **Prescribers and firms must register with the DEA.** The federal law requires registration of practitioners, and defines practitioners as a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is authorized by the jurisdiction in which he or she is licensed to practice to prescribe controlled substances.

   1. **Internet pharmacies.** Special registration requirements were established by the **Ryan Haight Online Pharmacy Consumer Protection Act of 2008**\(^{201}\) for pharmacies that distribute or dispense controlled substances via the Internet.
      a. An “online pharmacy” is defined as “a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver,

distribute, or dispense, a controlled substance by means of the Internet.”

b. Exempted from the definition of “online pharmacy” are

i. Manufacturers or distributors registered with the DEA;

ii. Nonpharmacy practitioners registered with the DEA;

iii. Hospitals or other medical facilities operated by an agency of the United States that are registered with the DEA;

iv. Health care facilities owned or operated by an Indian tribe or tribal organization which is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

v. Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

vi. Pharmacies registered with the DEA whose dispensing of controlled substances via the Internet consist solely of

1. Refilling prescriptions for controlled substances in schedule III, IV, or V; or

2. Filling new prescriptions in schedule III, IV, or V where the pharmacy had previously filled a non-Internet prescription for the same patient and at the patient’s request contacts the prescriber for a new prescription which is issued in the due course of that prescriber’s practice for a legitimate medical purpose.

vii. Note that any dispensing of schedule II controlled substances via the Internet appears to make a pharmacy an online pharmacy.

c. Online pharmacies must register with the DEA 30 days prior to engaging in Internet pharmacy involving controlled substances.
d. Monthly reports must be made to the DEA of the quantity of each controlled substance dispensed by the pharmacy, if, during the month in question, the pharmacy has dispensed at least 100 prescriptions or at least 5,000 dosage units.

e. A statement must be placed on the pharmacy’s home page that includes:
   i. A statement that the pharmacy complies with the Act;
   ii. The name, address, e-mail address, and telephone number of the pharmacy;
   iii. The name, professional degree, and states of licensure for the pharmacist-in-charge, and a telephone number at which the PIC may be contacted;
   iv. A list of states in which the pharmacy is licensed;
   v. A certification that the pharmacy is registered with the DEA as an Internet pharmacy; and
   vi. The name, address, telephone number, professional degree, and states of licensure of any practitioner who has a contractual relationship with the pharmacy.

f. The following statement must also be posted: “This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of Section 309 of the Controlled Substances Act.”

g. The Act gives states authority to bring complaints against Internet pharmacies seeking injunctions or damages for violations of the law.
h. The Attorney General is authorized to issue a special registration for prescribers of controlled substances engaged in telemedicine.

iv. **Authorized prescribers** are specified in RCW 69.50.101(w)(1) to include the following. The various authorizing statutes specify the levels of authority shown. [Also see Table 4-8-b in Chapter 4]

1. A **physician** [MD] under chapter 18.71 RCW – all schedules
2. A **physician assistant** [PA, PA-C] under chapter 18.71A RCW
   a. Allopathic PA (under supervision of MD) – all schedules as permitted by the supervising physician
   b. Osteopathic PA (under supervision of DO) – schedules III, IV, and V as permitted by the supervising physician
3. An **osteopathic physician and surgeon** [DO] under chapter 18.57 RCW – all schedules
4. An **optometrist** [OD] licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010 subject to any limitations in RCW 18.53.010 – Rules for optometrists are found in WAC 246-851-580 through -610.
   a. Drug list is limited to specific products or classes of products
   b. May only prescribe allowed controlled substances in Schedule III, IV, and V
   c. Benzodiazepines are limited to single doses per prescription for anti-anxiety related to procedures.
   d. No more than a 7-day supply of controlled substances may be prescribed.
   e. Schedule III and IV have a maximum prescribed quantity of 30 dosage units per prescription.
5. A **dentist** [DDS, DMD] under chapter 18.32 RCW – all schedules
6. A **podiatric physician and surgeon** [DPM, Pod.D.] under chapter 18.22 RCW – all schedules
7. A **veterinarian** [DVM] under chapter 18.92 RCW – all schedules (for non-human animals)
8. A **naturopathic physician** [ND] under chapter 18.36A RCW – codeine and testosterone products in schedules III through V.
9. An **advanced registered nurse practitioner** [ARNP] under chapter 18.79 RCW – Schedule V; Schedule II, III, and IV within scope of specialty. If has C-II through C-IV authority, may dispense up to a 72 hour supply to a patient.

10. A **pharmacist** [R.Ph., Pharm.D.] under chapter 18.64 RCW – all schedules if authorized by a protocol approved for his or her practice by a practitioner authorized to prescribe, consistent with the scope of that authorizing practitioner.

v. **Mid-level prescribing authority in other states.** The DEA maintains an interactive guide to CSA prescribing authority of midlevel practitioners in each state on its website at [http://www.deadiversion.usdoj.gov/drugreg/practioners/index.html](http://www.deadiversion.usdoj.gov/drugreg/practioners/index.html).

vi. **Out-of-state prescriptions allowed.** Controlled substances prescriptions may be also be filled in Washington when prescribed by “A physician licensed to practice medicine and surgery, a physician licensed to practice osteopathic medicine and surgery, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, or a veterinarian licensed to practice veterinary medicine in any state of the United States.” (RCW 69.50.101(w)(3)) Note: “State” includes DC, Puerto Rico, or territory of US (RCW 69.50.101(aa)). Prescriptions from mid-level practitioners in other states are not valid in Washington.

vii. **Registration procedures.** Registration with the DEA is required in order to exercise prescribing authority for controlled substances. The Drug Enforcement Administration now utilizes an online application ([http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm)) procedure to submit DEA Form 224 – Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner.

1. **How to validate a DEA number.** Registered practitioners (or pharmacies) are issued a DEA Number, in the form, AA1234567

   a. The first letter is usually “A,” “B,” or “F” for physicians, dentists, etc., and “M” for mid-level practitioners (MLPs, e.g., P.A.s, ARNPs, and pharmacists).

      i. The DEA began using “F” as the first letter for “Type A” practitioners in
2006, having exhausted the available numbers for “A” or “B” registration numbers.

b. The second letter is usually the first letter of the registrant’s last name. (May be a former last name, or may be a number, under certain circumstances).

c. The numbers consist of a 6-digit registration number and a “check digit.” The check digit is calculated as follows:
   i. Add the 1st, 3rd, and 5th digits of the registration number.
   ii. Add the 2nd, 4th, and 6th digits of the registration number and multiply that sum by 2.
   iii. Add the sum of (i) to the product of (ii); the check digit is the right most digit in the resulting sum.
   iv. Example: MJ2034685:
       \[
       2 + 3 + 6 = 11 \\
       (0 + 4 + 8) \times 2 = 24 \\
       35 \leftarrow \text{Chk digit} = 5
       \]

2. **Hospital-based prescribers.** Any practitioner who works in a hospital may use the hospital’s DEA number, plus a hospital-assigned internal code, when **prescribing only for hospital patients**, without registering with the DEA (see *Pharmacist’s Manual* for additional requirements). The prescriptions issued for hospital patients may be filled at community pharmacies.

3. **Federal employees exempt.**
   a. Public Health Service or Bureau of Prisons employees do not need to register – use Social Security number as DEA number.
   b. Military practitioners do not need to register. They indicate their branch of service plus their service identification number; however, DEA will issue DEA numbers to military personnel, so they can use a DEA number as well. Military MLPs must be specifically licensed or authorized to prescribe in the state where they are stationed to receive a DEA number. To prescribe “off base,” they need a separate DEA registration.
4. **A separate registration** is required for each location at which controlled substances are stored. Practitioners who prescribe in multiple locations, but store or administer controlled substances at only one location, do not need a separate registration number for locations where they only prescribe.

5. **Registrants practicing in more than one state** must obtain a separate DEA registration number for each state.\(^{202}\)

viii. **Loss or theft of controlled substances must be reported.** Any “significant loss” or theft must be reported immediately to the DEA, by telephone, fax, or brief written message to the local DEA office. The DEA encourages an immediate notification to the local police.

   1. **What is “significant?”** It is up to the pharmacy to determine whether a loss or shortage is significant. The DEA cites the following factors to be considered:
      a. The type of pharmacy and the total volume of controlled substances dispensed by the pharmacy.
      b. Small losses, but repeated over time.
      c. Signs of break-in, physical entry, or armed robbery.
      d. Other factors listed in the Pharmacist’s Manual.

   2. **Losses in-transit.** Suppliers are responsible for reporting in-transit losses. Pharmacies are responsible for reporting items missing from a shipment they have signed for.

   3. **Breakage or spillage is not “loss,”** and can be accounted for as breakage or spillage in the pharmacy’s CS records.

   4. **Pharmacies must follow up initial report of loss with DEA Form 106.** Following an investigation, pharmacies must file a DEA Form 106 with the DEA. The DEA now has an on-line version of DEA Form 106, available at https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp

   5. **A copy of Form 106 must be provided to the Board of Pharmacy.** (WAC 246-887-020 (3)(c))

   6. **If loss is not confirmed.** If, after further investigation, it is found that the loss did not occur, no Form 106 needs to be filed, but the DEA (and the

\(^{202}\) 71 FR 69478, Dec. 1, 2006
Board of Pharmacy) must be informed that the investigation was conducted and that no Form 106 is forthcoming.

ix. **Required Records.** All pharmacies must maintain in their files for inspection by the DEA or Board of Pharmacy the following controlled substances records.

1. **DEA Registration Certificate.**
2. **Official Order Forms (Form 222)**
3. **Power of Attorney authorization to sign order forms.**
4. **Initial inventory upon opening of pharmacy.**
5. **Biennial inventory records.**
6. **Reports of Theft or Loss (DEA Form 106)**
7. **Inventory of Drugs Submitted for DEA Disposal (Form 41)**
8. **Records of transfers between pharmacies**
9. **Inventory Transaction Records.** A pharmacy must maintain records of receipt, dispensing, and destruction of controlled substances.

   a. **Schedule II records** must include copies of Form 222, copies of requisitions for order forms, and copies of powers of attorney documents related to order forms, plus invoices and filled prescriptions. Invoices and Forms 222 are stored separately from other controlled substances records.

   b. **Schedule III, IV, and V records** include copies of invoices and filled prescriptions. These are stored separately from records of purchase of non-controlled substances (see below for prescription filing requirements), or may be stored in such a way as to make them readily retrievable from non-controlled substance records.

   c. **Threshold amounts of List 1 Chemicals.** These are precursor chemicals. Few pharmacies are involved in threshold level sales, except as otherwise provided by rules for sales of EPP OTC products (see below).

x. **Pharmacies must conduct periodic physical inventories (counts) of controlled substances.** These include an initial inventory upon opening of a pharmacy, or upon transfer of ownership, and a biennial inventory thereafter. Many wholesalers provide pharmacies with pre-printed forms for completing these inventories.
1. **Required elements of these inventories include:**
   a. The inventory date
   b. Time of inventory (i.e., opening or closing of business)
   c. Drug name
   d. Drug strength
   e. Drug form
   f. Number of units/volume
   g. Total quantity

2. **Recommended elements** include:
   a. Name, address, and DEA number of registrant
   b. Signature of person or persons responsible for taking the inventory.

3. **An actual physical count must be made for Schedule II drugs.**

4. **An estimated count may be made for Schedule III, IV, and V drugs.**
   a. An **actual count** must be made for Schedule III, IV, or V drugs if the container contains more than 1,000 dosage units and has been opened.

5. A **biennial inventory** must be completed at least every 2 years after the initial inventory. If a drug changes its status, as carisprodol changed in Washington to Schedule IV on February 5, 2010, stocks of the drug must be added to the inventory on that day.

   xi. **Records must be maintained for 2 years.**

   xii. **Requirements for prescriptions** are essentially identical between RCW 69.50 and the federal CSA. The major difference is that all prescriptions for legend drugs, including Schedule II drugs, expire after 1 year, whereas the federal CSA does not place an expiration date on Schedule II prescriptions.

1. **Schedule II**
   a. C-II drugs are exchanged between registrants (manufacturers, wholesalers, pharmacies, prescribers) by use of Order Forms (DEA form 222). See the *Pharmacist’s Manual* for more information.
      i. The DEA has recently announced standards by which registrants may order CSA drugs electronically, using the Controlled Substances Ordering System (CSOS). Registrants must
apply for a CSOS Certificate, and adapt their computer system to work within the specifications of the DEA. Currently, this is voluntary, but it is the DEA’s intention to eliminate paper order forms over time.

b. The individual who signed the original registration application for the pharmacy is the person who can sign DEA form 222, or sign the requisition to obtain additional DEA 222 forms. To allow other employees of the pharmacy to sign order forms or requisitions, the applicant must execute a **limited power of attorney**, which is kept on file in the pharmacy. (See the *Pharmacist’s Manual* for further information.) A person does not have to be a pharmacist to have authority to order controlled substances or order forms. A person authorized by a power of attorney must obtain his or her own digital signature certificate from the CSOS to participate in electronic ordering.

c. **Written prescriptions.** C-II prescriptions must be in writing, signed by the prescriber in his or her hand. Currently, **electronic prescribing** of C-II prescriptions is not allowed by DEA rules.

d. **Faxes** are allowed for C-II drugs for LTC facilities, hospice patients, and for home IV products for injectable C-IIs.

i. Faxes may serve as the “Authorization for an Emergency Supply” of a C-II drug.

ii. Faxes may be a reference for filling a C-II prior to the patient’s arrival, if compared to the original before dispensing.

iii. Under WA law, “LTC facilities” include nursing homes, boarding homes, and adult family homes. (RCW 69.50.308(ii)) Federal regulations define LTC facilities to mean a nursing home, retirement care, mental care or other facility or institution which provides extended health care to
resident patients. (21 CFR § 1300.01(b)(25))

e. **Authorization for emergency supply.** If an urgent need exists and the prescriber cannot supply a written prescription to the pharmacy in sufficient time to meet the patient’s needs, the pharmacy may accept a telephoned or FAXed “Order for an Emergency Supply” of C-II meds, provided the prescriber delivers a written prescription to the pharmacy within 7 days (or postmarks it within 7 days). Note: the relevant WA regulation still says “72 hours,” but the Board is not enforcing that rule. (WAC 246-887-020(6))

i. There is no actual limit on the quantity that can be prescribed, except that it should be “sufficient … to last until a written Rx can be supplied”

ii. The pharmacist must place “Authorization for an Emergency Supply” on the face of the prescription, and the same wording must be on the original written Rx

iii. The quantity authorized on the two orders must be identical.

iv. If the written prescription is not delivered within 7 days, the pharmacy must notify the Board and the DEA.

v. The pharmacist staples the written prescription to the telephoned or FAXed order.

f. **C-II Prescriptions are not refillable.**

g. **Prescriptions are invalid if they are “post-dated,” i.e., dated on a date later than the day actually written.** However, nothing in the law prohibits a prescriber from indicating in the directions to the pharmacist a date before which the prescription should not be filled.

h. **Multiple prescriptions for the same patient may be written on one date to be filled at later dates.** The DEA adopted a final rule that became effective on December 19, 2007 allowing, where otherwise permitted

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203 72 Fed Reg 64921
by state law (21 CFR §1306.12 and 21 CFR §1306.14):

i. Multiple prescriptions for a single substance and patient, written and signed on the same day when
   1. No more than a 90-day supply is authorized;
   2. Each prescription after the first includes instructions indicating the earliest date on which the pharmacy may fill the prescription; and
   3. The prescriber concludes that this does not create an undue risk of diversion or abuse.

ii. Pharmacists may not fill prescriptions prior to the date indicated in the prescriber’s instructions.

iii. This rule does not create a 90-day limit on the amount of a schedule II drug that can be prescribed on a single prescription.

The Washington Board of Pharmacy has indicated that Washington laws allow this procedure. This is not available to prescribers in states, such as Idaho, which place a 30-day expiration date on Schedule II prescriptions.

i. Washington and Federal law (21 CFR §1306.13) allow for partial filling of C-II prescriptions.

   i. If the pharmacy is unable to supply enough drug to fill the prescription; the remainder must be delivered within 72 hours or not at all. (This is the statutory specification.)

   ii. If the patient initially doesn’t want or can’t pay for the full quantity; the remainder must be delivered within 72 hours or not at all.204

   iii. If the pharmacy is attempting to confirm the validity of the prescription, may fill a small amount to start the patient’s therapy, then, if

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204 Letter from DEA to Prof. David Brushwood in 2001
the prescription is verified, supply the rest within 72 hours.205

iv. If the pharmacist is informed by the prescriber that the patient is terminally ill, may partially fill for up to 60 days from date written.

v. If the patient is in a nursing home (see definition, above), may partially fill for up to 60 days from date written.

j. Transfer Label Required. Federal law requires C-II Rx containers to bear the label: “Warning: Federal law prohibits transfer of this medication to any person other than the person for whom it was prescribed.”

Washington regulation requires ALL prescription containers, including those containing CSA drugs, to bear, instead, the label: “Warning: State or federal law prohibits transfer of this medication to any person other than the person for whom it was prescribed.” (WAC 246-869-010(3))

k. Federal law does not impose a time limit on the filling of C-II prescriptions; once written, they do not expire under federal law. UNLIKE UNDER FEDERAL LAW, C-II prescriptions are invalid after 1 year in WA, as are all legend drugs (WAC 246-869-100(2)(d)).

l. A completed C-II prescription must bear all of the following elements:
   i. Patient name
   ii. Patient address
   iii. Date written
   iv. Drug, quantity, directions
   v. Prescriber address
   vi. Prescriber DEA number
   vii. Prescriber Written Signature
   viii. Indication in Washington of substitution status, using a 2-line Rx blank

m. What may a pharmacist change or edit on a C-II prescription? The DEA has amended its policy on edits to a C-II prescription several times in recent years. Its current statement on its website says that no

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205 Personal communication, V. Seeger, R.Ph., DEA, 4/4/05
elements on a C-II may be changed orally, based on a preamble to a final rule issued regarding multiple prescriptions written on the same day. The Washington Board of Pharmacy has reiterated its policy that a pharmacist may make the following changes to a controlled substance prescription:

i. Add or change the patient’s address after verification

ii. After consultation with the prescriber, may change or add
   1. Dosage form
   2. Drug strength
   3. Drug quantity
   4. Directions for use
   5. Issue date

iii. Brand-generic changes

iv. Pharmacists may not change the patient’s name or the controlled substance prescribed (other than brand/generic).

Comment: Following the US Supreme Court decision in Gonzales v. Oregon, it seems likely that the DEA does not have authority to overrule state regulations interpreting what the nature of a valid prescription is or whether changes may be made to written prescriptions once issued. Given the DEA’s wavering position on this issue, however, pharmacists should make changes to C-IIs based on verbal instructions only when clearly needed in the patient’s best interest, and document the changes carefully, adhering to state rules. Under such circumstances, it is unlikely that the Board or the DEA will take action.

n. Electronic prescribing. The DEA has proposed but yet adopted rules to allow for electronic prescribing of C-II drugs. The prescriber using an electronic system must print a copy of the prescription and sign it in his or her own hand.

o. Filing of Prescription Records.
Prescriptions for C-II prescriptions may not be filed by the pharmacist in the same file as prescriptions for legend drugs. The federal law allows 3 options:

206 http://www.deadiversion.usdoj.gov/faq/general.htm#changes_rx_ii
i. Option 1 – Three separate files (one for C-II, one for C-III, C-IV, and C-V, and one for legend drugs)

ii. Option 2 – Two separate files (one for C-II, and one for all other drugs)

iii. Option 3 – Two separate files (one for Controlled Substances and one for legend drugs)

iv. “Option 3” not allowed in WA.
   UNLIKE FEDERAL LAW, Washington regulations (WAC 246-887-020(4)) do NOT permit filing of C-II prescriptions in the same file as non-schedule II drugs.

p. Amphetamine salts and other schedule II non-narcotic stimulants are restricted in WA to use for only limited medical indications.

i. The Board of Pharmacy has identified the following substances as subject to these limitations (WAC 246-887-040)
   1. Amphetamine and its salts or combinations
   2. Dextroamphetamine and its salts or combinations
   3. Phenmetrazine (Preludin®)
   4. Methylphenidate (Ritalin®, etc.)

ii. RCW 69.50.402 specifies these indications by statute as follows:
   1. Narcolepsy
   2. Hyperkinesis
   3. Epilepsy
   4. Differential diagnostic psychiatric evaluation of depression
   5. Depression refractory to other modalities

iii. The Board of Pharmacy, in consultation with medicine and osteopathic boards, may designate additional medical uses by rule, and has added multiple sclerosis to the list of approved indications for the designated non-narcotic stimulants. (WAC 246-887-045 – effective 2/28/03)
2. **Schedule III, IV, and Schedule V Legend Drugs** are treated in Washington identically to federal law.

   a. **Products are exchanged between registrants using an invoice** with the address and DEA# of each registrant contained on the invoice.

   b. **Oral or FAXed prescriptions are allowed.**

   c. **Electronic prescriptions should be treated as if they were telephonic; a printed copy should be placed in the files.** According to Board of Pharmacy policy (4/11/05), in response to DEA advisories, the pharmacist must “ensure the validity of these prescriptions.” The Board did not mandate the method by which a pharmacist should validate these orders, but does expect the pharmacist “to contact the prescriber if there is any suspicion that the prescription is not valid.” It is not considered necessary for the pharmacist to call each prescriber on each electronic schedule III-V prescription.

   d. Prescribers may authorize **up to 5 refills for C-III or C-IV drugs.** There is no refill limit for C-V legend drugs.

   e. Prescriptions for **C-III or C-IV drugs** may be **filled or refilled up to 6 months** after the date written. There is no time limit under federal law for filling or refilling C-V legend drugs, but, like all other legend drugs, prescriptions for C-V drugs are limited to 1 year in Washington.

   f. **May transfer prescriptions and refill information on a one-time basis to another pharmacy.**

      i. Information to be recorded on the **hard copy of** original prescription by the **transferring** pharmacist:

         1. The word “VOID”
         2. Name, address, and DEA number of receiving pharmacy
         3. Date of transfer
         4. Name of receiving pharmacist (should be full name!)
         5. Name or ID of transferring pharmacist.
ii. Information to be transferred and recorded on the hard copy by the receiving pharmacist:
1. Name, address, and DEA number of the transferring pharmacy.
2. Prescription number of the prescription at the transferring pharmacy.
3. Name of the transferring pharmacist (should be full name!)
4. Date the prescription was originally written.
5. Complete dispensing history:
   1. Date of original dispensing
   2. Date of each refill dispensed
   3. Prescription number and pharmacy name of each dispensing
6. Original number of refills ordered.
7. Number of refills remaining.

iii. The following illustrates the information needed on the original and transferred controlled substances prescription.

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"VOID"
Transferred to
Jones’s Pharmacy
301 Miller St
Ankeny
DEA #PM1314567
11/15/97
To: Bob Jones, RPh
By: Bill Fassett

"Transferred" from:
Fassett Phcy
1210 Ingersoll, DSM
DEA #PF1021156
Rx # 101255
By: Bill Fassett RPh
Date Written: 10/1/97
Dispensing History
(*)=Original
Date  Rx #  Pharmacy
*10/1/97 101255 Fassett Phcy
10/15/97  “  “
11/1/97  “  “

Orig # Refills: 5
Refills Remaining: 3
```
Comment: Many states interpret the DEA phrase “one time basis” to mean that once a prescription is transferred to another pharmacy, it may not be retransferred to a third pharmacy. However, the language of the DEA’s rule suggests a different interpretation:

1. Pharmacies sharing a database may transfer “up to the maximum refills allowed,” i.e., could transfer one refill at a time to other locations;
2. The rule for pharmacies without shared databases requires tracking “each location” at which a prescription was previously dispensed, implying that a transferred prescription could have been originally dispensed, and then refilled, at several different pharmacies.
My interpretation is that “one time basis” means that all remaining refills must be transferred to the new pharmacy, and then all remaining refills may be subsequently retransferred to another pharmacy.
HOWEVER, the DEA’s Chief, Liaison and Policy Section, has written to me that he disagrees with my interpretation.

3. Computer records for C-III or C-IV must be kept on-line for 24 months after the last possible refill of a given prescription. In practice, this means that 2½ years worth of data must be available on line for refillable prescriptions.
4. Pharmacist using computer records must sign a daily log sheet, or a bound book, at the end of each shift or day, indicating the correctness of the computer records.
5. The State transfer warning label must be affixed.
6. Pharmacists may partially fill C-III or C-IV prescriptions in quantities less than the original prescription, and these partial fills do not count as “refills” within the 5-refill limit, provided that:
   a. No partial fills are dispensed after 6 months
   b. The total quantity dispensed by the original and all partial fills does not exceed the total quantity authorized on the prescription.
7. Carisoprodol is now a C-IV product in WA and at least 15 other states. The Board added carisoprodol to Schedule IV (WAC 246-887-170)

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http://www.deadiversion.usdoj.gov/faq/general.htm#prescrip
in a notice filed on January 5, 2010.\textsuperscript{210} The change takes effect on February 5, 2010. Prescriptions for carisoprodol written prior to February 5, 2010 should be treated as if they are expired when they have been refilled 5 times or are over 6 months old.

a. The DEA published a notice of Proposed Rulemaking on November 17, 2010 to announce its intention to place carisoprodol in Schedule IV federally.\textsuperscript{211}

xiii. **Schedule V legend drugs are treated under both federal and state law the same as legend drugs generally**, except:

1. Records of purchases must be kept with other controlled substance records.
2. The purchaser’s DEA number must be recorded on transfers to other registrants.
3. A prescriber must be registered with the DEA to prescribe schedule V, and the DEA number must be on the prescription.
4. Some states place a 6-month limit on Schedule V prescriptions, but Washington does not.

xiv. **Schedule V OTC drugs are NOT treated the same in Washington as under federal law.**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Federal Law</th>
<th>WAC 246-887-030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opium containing antidiarrheal products</td>
<td>Not more than 240 mL or 48 solid doses in 48 hrs.</td>
<td>Not more than 240 mL (solid forms not allowed) in 96 hours, not more than 480 mL in 60 days.</td>
</tr>
<tr>
<td>Codeine containing cough syrups</td>
<td>Not more than 120 mL in 48 hours</td>
<td>Not more than 120 mL in 96 hours, not more than 240 mL in 60 days.</td>
</tr>
<tr>
<td>Codeine containing pain relievers</td>
<td>Not more than 24 solid doses in 48 hours.</td>
<td>Not allowed OTC in WA</td>
</tr>
<tr>
<td>Minimum age to purchase</td>
<td>18</td>
<td>21</td>
</tr>
</tbody>
</table>

1. WA rules require a specific style of C-V registry book, containing a non-carbon required copy.

\textsuperscript{210} WSR 10-02-080, January 5, 2010.

These are purchased through the WSPA or wholesalers. The duplicate page must be sent to the Board of Pharmacy when (a) the page is full, or (b) the last day of the month, whichever is sooner.

2. The pharmacist or pharmacy intern selling the C-V substance must
   a. Examine and record the number of photo ID provided by the customer (Driver’s License, Passport, etc.)
   b. Place his or her initials, the date sold, and the name of the pharmacy on the container.
   c. Enter his name or initials, the quantity, and name of substance sold in the register book.
   d. Obtain the name, address, and signature of the customer in the register book.
   e. Show the patient a copy of the rules contained in WAC 246-887-030(3) and (4).

xv. The DEA issues clarifications of its rules in response to inquiries from pharmacists or other registrants at http://www.deadiversion.usdoj.gov/faq/

xvi. **Compounding products with controlled substances.** Pharmacists may use controlled substances to compound lawfully-issued prescriptions. The schedule into which a compounded product is placed depends on the composition of the finished product, not the schedule of ingredients used. For example, codeine powder (schedule II) mixed with other active non-narcotic ingredients to make a cough syrup, will produce a product in schedule III if the codeine content is 90 mg or less per 5 mL dose, or a product in schedule V if the codeine content is 10 mg or less per 5 mL dose. It is wise to place a copy of the prescription in the schedule II prescription files, however. (See the Pharmacist's Manual for specific requirements for each schedule.)

3. **Controlled Substances in Institutional Practice**
   a. **Hospitals.** The Director of Pharmacy is responsible for developing policies and procedures to assure accountability and compliance with state and federal laws.
      i. **Written orders rather than prescriptions.** Controlled substances (and other drugs) are administered to patients based on written orders in the patient charts, rather than by individual prescriptions, except for outpatient distribution.
ii. **Hospital Outpatient Pharmacies** are treated just like community pharmacies.

iii. **Specific Schedule II requirements in WA include** (WAC 246-873-080 (7)):

1. Maintenance of a perpetual inventory of Schedule II drugs in the pharmacy.
2. Maintain a record of drugs distributed to other units (e.g., nursing unit) which includes:
   a. Date
   b. Name of the drug
   c. Amount of drug issued
   d. Name and/or initials of pharmacist who dispensed the drug
   e. Name of the patient and/or unit to whom the drug was issued.
3. Hospital units must maintain records of administration and disposition of Schedule II drugs. These are usually maintained in the MAR or patient chart, and must include:
   a. Date
   b. Time of administration
   c. Name of the drug (if not already indicated on the records)
   d. Dosage of the drug which was used which shall include both the amount administered and any amount destroyed.
   e. Name of the patient to whom the drug was administered
   f. Name of the practitioner who authorized the drug
   g. Signature of the licensed individual who administered the drug.

iv. **“Wastage” must be witnessed.** When nurses must “waste” small amounts of controlled substances in any schedule, the destruction shall be noted and witnessed by a second nurse, who must sign the record.

v. **Policies for destruction of controlled substances** that conform to state and federal law must be developed by the Director of Pharmacy. (See Chapter 4 on environmental rules for drug waste.) A copy of the policies must be provided to DEA and the Board of Pharmacy. At a minimum, the policies must assure that:

   1. Destruction renders the drugs unrecoverable.
   2. Destruction is by a pharmacist and one other licensed health professional.
3. Records of destruction are maintained in the pharmacy, and quarterly summary reports are mailed to the DEA with copies to the Board of Pharmacy.

vi. **Periodic monitoring** by a nurse or a pharmacist is performed to assure that chart records are accurate.

vii. **Use of multiple dose vials** of controlled substances is discouraged.

viii. **Physical counts at change of shift are required** for floor stocked Schedule II or III drugs. These counts must be made by two individuals licensed to administer drugs.

ix. **Controlled substances records must be kept for 2 years**; this includes records of destruction.

x. **Hospital pharmacies may apply for approval to use innovative record keeping systems**.

xi. **Significant losses or disappearances of controlled substances must be reported** to the pharmacy department, the DEA, the Board of Pharmacy, the hospital CEO, and other appropriate officials.

b. **Long-term Care.** (WAC 246-865-060) Extended care facilities are subject to specific requirements for storage and administration of controlled substances. These differ in many instances depending on whether the facility uses unit-dose distribution or stores patients’ drugs in “traditional” outpatient containers.

i. **Pharmacies must include the CSA Schedule number on labels** of drugs dispensed to LTC patients. (WAC 246-865-060 (4))
   1. **Compounded drugs** containing Schedule II or III substances must show the quantity of drug per mL or teaspoonful on the label.

ii. **Non-unit dose systems** must handle controlled substances as follows:
   1. **Schedule II drugs must be stored separately** in an individually keyed and locked area or cabinet.
   2. **Schedule III drugs must be stored separately** from other drugs, but may be stored with Schedule II drugs.
   3. **A bound log book must be maintained for Schedule II and III drugs**, which records all receipts and withdrawals of these drugs.
   4. **Physical counts by two individuals licensed to administer drugs must be made** at least every 24 hours for Schedule II drugs, and at least weekly for Schedule III substances.
5. **Upon discharge** of a resident, a record of release of Schedule II or III drugs shall be kept in the log book.

6. **Discontinued or remaining Schedule II drugs** must be destroyed, with proper documentation, within 30 days of discontinuance or discharge by
   a. A pharmacist or the director of nursing services (DNS) or a RN-designee, plus an RN employee of the facility; or
   b. By a representative of the Board of Pharmacy.

7. **Discontinued Schedule III, IV, and V drugs** (as well as legend drugs) remaining after discontinuance or discharge must be destroyed within 90 days.

   iii. **Unit dose distribution systems** may follow the rules for non-unit dose systems, or may develop an alternative system which maintains equivalent records of the receipt and disposition of Schedule II and III drugs.
   1. Schedule III drugs may be stored with other unit dose medications.
   2. Discontinued unit dose drugs other than Schedule II may be returned to the pharmacy.

   iv. **Challenges for destruction/return of scheduled drugs.** Because nursing homes are not registered with the DEA, current rules do not allow them to transfer drugs to other registrants. The DEA is currently reviewing input on proposed rule making that would allow consumers and other non-registrants to return or cause the destruction of controlled substances by using the services of reverse distributors.212

4. **Washington Prescription Monitoring Program (PMP).** As of November 2008, 38 states had adopted legislation establishing programs to track prescriptions, generally limited to controlled substances.213 The goals of these programs vary among the states, but in general, these programs seek to monitor prescribing of controlled substances and/or legend drugs for purposes of education and information, public health initiatives, early intervention and prevention, and/or investigation and enforcement, and all seek to protect the confidentiality of the data collected.214 Washington has had a PMP in place for a number of years by which disciplined prescribers have been required to use triplicate prescription forms. In 2007, the Legislature enacted a statute

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213 http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#1
214 http://www.nascsa.org/Alliance/PDF/Goals.PDF
authorized the Department of Health to expand this program statewide, subject to available funding. (RCW 70.225.020)

a. The core elements of the PMP include the following:
   i. The program is to monitor the prescribing and dispensing of covered drugs by “all professionals licensed to prescribe or dispense such substances in this state.”
   ii. Drugs to subject to monitoring include Schedule II, III, IV, and V substances and “any additional drugs identified by the board of pharmacy as demonstrating a potential for abuse.”
   iii. Program goals include improving health care quality and effectiveness by reducing abuse of controlled substances, reducing duplicative prescribing and overprescribing of controlled substances, and improving controlled substance prescribing practices.

b. Dispensers (pharmacists and dispensing prescribers) are required to electronically submit the following information for each prescription dispensed for more than immediate one day use:
   i. Patient identifier
   ii. Drug dispensed
   iii. Date of dispensing
   iv. Quantity dispensed
   v. Prescriber ID
   vi. Dispenser ID

c. These requirements do not apply to
   i. inpatient hospitals and related settings
   ii. pharmacies operated by the Department of Corrections for prescriptions dispensed to inmates, except for the offender’s current prescriptions for controlled substances issued upon release from a correctional facility

d. The 2008 Legislature provided funding to begin the implementation of the PMP, but in response to the state’s budget difficulties, the Department suspended program implementation in December 2008.215

5. Methamphetamine Precursor Drugs. RCW 69.43 deals with precursors to controlled substances. Sections relevant for retail pharmacies are aimed at limiting the availability of OTC products containing ephedrine, phenylpropanolamine, and pseudoephedrine, or their salts or isomers (EPP), which are used to make methamphetamine. This law was significantly revised by the 2005 Legislature, with changes taking place in October 2005 and January 2006.

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a. Pharmacies, shopkeepers, itinerant vendors, and Chinese herbal practitioners may sell lawful EPP-containing products only under the following restrictions (RCW 69.43.105):
   i. They must obtain photo ID of the purchaser showing date of birth, and the purchaser is required to provide such ID.
   ii. EPP products must be kept in a central location in the licensed premises that is not accessible by customers without assistance of an employee of the seller.
   iii. The purchaser must be at least 18 years of age.
   iv. Exceptions: These restrictions do not apply to the following:
       1. Combination products (i.e., EPP plus non-EPP ingredients) in liquid, liquid capsule, or gel capsule form.
       2. Legend drugs sold pursuant to a prescription.
       3. Sale by a traditional Chinese herbal practitioner to a patient.
       4. When the details of the transaction are recorded in a pharmacy profile individually identified with the recipient and maintained by a licensed pharmacy.

Comment: It appears this allows pharmacies to sell to persons under age 18 if the transaction is recorded in the pharmacy computer system as a patient record!

v. Police Organizations May Petition to Add Drugs. The law allows for a petition from the Washington Association of Police Chiefs, or the Washington State Patrol, asking the Board to place particular combination products within the ambit of the log requirements based upon a showing that EPP within the product can be effectively converted into meth and evidence that the product is being converted into meth or other controlled substance.

vi. Limits are specified in RCW 69.43.110 through .130. Individuals may not
   1. Purchase more than 2 packages, each containing 3 g or less of EPP, at any one time within 24 hours;
   2. Possess more than 15 g of EPP, except in their home as consistent with typical household use.
   3. A pediatric formulation containing EPP is exempted if its label indicates it is intended for administration to persons less than 12 years of age and if each dose is less than 15 mg; or if it is a liquid intended for children less than 2 years of age.
age, for which the dose does not exceed 2 mL and the total quantity in the package is not more than 1 fl oz.

b. Effective January 2006 sellers must maintain a Retail Transaction Log of sales of covered products, as part of a pilot project to collect data on these sales. The Board of Pharmacy was authorized to promulgate regulations regarding the content and maintenance of these logs. These regulations are in WAC 246-889-070.

i. A record under this rule is required for all EPP sales, except:
   1. For combination products in liquid, liquid capsule, or gel capsule formulation.
   2. Sales pursuant to a prescription.
   3. Sales recorded in a pharmacy profile and the profile is maintained by the pharmacy. The record must contain at least the name, address, date of purchase, purchaser’s date of birth, and the product description.

ii. Unless exempted, the retailer must
   1. Review the purchaser’s photo ID, which must include the date of birth. The purchaser must be 18 or older.
   2. Record specific information in a record of the transaction.

iii. Photo IDs must be issued by a government agency and include a photograph, patient’s name, address, date of birth, and signature. Acceptable forms of ID include:
   1. State or Canadian province-issued driver’s license or instruction permit. (If the photo ID is expired, must be accompanied by a temporary license.)
   2. US Armed Forces ID card
   3. US Coast Guard Merchant Marine ID Card
   4. State liquor control ID card, or official age identification card issued by liquor control authority of any state or province of Canada.
   5. State ID card issued by any state or province of Canada.
   6. Official passport issued by any nation. (Note: US passports contain a place for the bearer to add his or her address)
   7. Enrollment card issued by federally-recognized Indian tribe located in Washington, if the card would be recognized by the Washington Liquor Control Board.

iv. The seller must record the following items in the log:
1. Date of purchase
2. Name of purchaser
3. Date of birth
4. Type of identification
5. Number of packages and number of tablets per package

v. A seller may apply to the Board for permission to record sales by means other than electronically or in written form (e.g., photographically?)

vi. Records must be maintained for 2 years; when destroyed must be done so in a manner that leaves the record unidentifiable and nonretrievable.

vii. The records are confidential and only open to inspection to the Board and law enforcement agencies. No copies of the records will be required to be sent to the Board or a law enforcement agency, but the records may be required in a court.

c. Retailers must do either or both of the following:
   i. Post signs in the establishment stating the restrictions in RCW 69.43.110;
   ii. Program scanners, cash registers or other POS devices to record sales in a manner that will alert clerks to potential violations.
   iii. The Board of Pharmacy has posted an example sign on their website:

   Washington State law restricts the sale & possession of drug products containing the substances ephedrine, pseudoephedrine, or phenylpropanolamine.

   It is illegal to:

   - Sell more than 2 packages in a single transaction;
   - Purchase more than 2 packages in 24 hours;
   - Possess more than a total of 15 grams of these substances.

   These restrictions do not apply to products intended for pediatric use.

d. Federal Limits. Subsequent to the revision in WA law, Congress passed more stringent legislation – The Combat Methamphetamine Epidemic Act of 2005 – as part of the
extension of the USA PATRIOT Act (PL 109-177). These apply to non-liquid dosage forms of EPP sold OTC. Key differences between the federal requirements and WA are:

i. The maximum quantity of EPP is 3.6 g/day and 9 g/month, with a maximum of 7.5 g/month if ordered via the mail or common carrier.

ii. EPP must be sold only in blister packs containing 2 or fewer doses per blister.

iii. The log book must include the address and signature of the purchaser, and the time as well as the date of the sale, which must be filled in by the purchaser. (The seller checks the ID and fills in name and quantity of drug sold.)

1. Until October, 2008, federal law did not permit electronic tracking of EPP retail sales. A new federal statute, the Methamphetamine Production Improvement Act of 2008, now allows retailers to use one of the following options:

   a. A written logbook
   b. An electronic logbook by which the purchaser’s signature is captured
      i. By a device that captures signatures in an electronic format. The device must display the required notice of penalties, and clearly links the signature to other electronically captured required information relating to the sale.

      ii. Signing a bound paper book to which the seller affixes a printed sticker displaying the required information regarding the sale or a unique identifier linked to that information, or in which the seller writes the unique identifier and the purchaser signs an adjacent line. The bound book must display the required penalty notices.

      iii. Signing a printed document produced by the seller at the time of sale that displays the required penalty notices and the required information related to the sale. The signed page is immediately placed into a binder or other secure means of document storage.
c. Product information may be captured through electronic means including barcode reader technology.

iv. The log book must contain "a notice to purchasers that entering false statements or misrepresentations in the logbook, or supplying false information or identification that results in the entry of false statements or misrepresentations, may subject the purchaser to criminal penalties under section 1001 of title 18, United States Code, which notice specifies the maximum fine and term of imprisonment under such section."

v. The federal law does not specify an age minimum.

vi. Each seller must train all employees in the law and procedures, must maintain records of this training, and must certify to the DEA on a website,\(^{216}\) that it has met these requirements.

e. Summary of requirements: Sales Limits

<table>
<thead>
<tr>
<th></th>
<th>WA</th>
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</tr>
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<tr>
<td>Sales/day</td>
<td>6 g</td>
<td>3.6 g</td>
</tr>
<tr>
<td>Sales/month</td>
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<td>9 g (7.5 g for Internet or mail order)</td>
</tr>
<tr>
<td>Possession</td>
<td>15 g</td>
<td>n/s</td>
</tr>
<tr>
<td>Pkg size</td>
<td>3 g</td>
<td>3.6 g</td>
</tr>
<tr>
<td>Pkg type</td>
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f. Summary of requirements: Log Book

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<tr>
<td>Notice of penalties</td>
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<td>Yes</td>
</tr>
</tbody>
</table>

\(^{216}\) http://www.deadiversion.usdoj.gov/meth/index.html
g. An updated Retail Transaction Log that meets both federal and state requirements is available from the Washington State Pharmacy Association.

h. The Board has authority to exempt certain products or packages from the statutory sales limits upon application from the manufacture in accordance with specific guidelines in the statute. A list of exempted products is maintained on the Washington Board of Pharmacy web site.

i. **Wholesalers must report suspicious transactions.**
   Methamphetamine precursors are called “regulated products” in RCW 69.43.010(1), and the statute requires reports of sales by wholesalers, and gives the Board of Pharmacy authority to regulate these products and sales. Any person who sells or transfers precursor chemicals (which could include pharmacies selling regulated product in bulk form rather than prepared dosage forms) must make certain reports under this statute. In particular, any manufacturer or wholesaler that sells a regulated product to any licensee must report to the Board in writing any suspicious transactions. The Board has adopted by rule the following definitions of suspicious transactions:
   i. Sales that would lead a reasonable person to believe that the substance would be used for illegal manufacture of controlled substances, based on such factors as
      1. The amount of the substance involved
      2. The method of payment
      3. The method of delivery
      4. Past dealings with the participant
   ii. Sales of regulated product paid for by cash or money orders in a total amount of more than $200
   iii. Sales meeting criteria for suspicious transactions set by the DEA
   iv. Where the dollar value of regulated products exceeds 10% of the dollar value of the total order of non-prescription products.
   v. An order containing only regulated products and no other non-prescription products.

   Required wholesaler reporting of suspicious transactions extends to controlled substances generally, not just to precursor chemicals. In November, 2007, the DEA registration of a Cardinal Health Drug Supply wholesale branch in Auburn, WA was suspended by the DEA for allegedly selling and failing to report excessive quantities of controlled substances to Horen’s Drug Store in Burlington, WA, which was allegedly operating an Internet pharmacy operation selling hydrocodone without valid prescriptions.
The DEA reported\textsuperscript{217} that Cardinal sold 605,000 hydrocodone doses to Horen’s Drug Store between March and October, 2007, and that Horen’s was the branch’s largest single purchaser of hydrocodone. In December, 2007, Cardinal’s Lakeland, FL distribution center’s DEA license was also suspended.\textsuperscript{218} Amerisource-Bergen’s Orlando distribution center’s DEA license was similarly suspended by the DEA in June, 2007, for excessive hydrocodone sales to Internet pharmacies.\textsuperscript{219}

6. Treatment Programs for Opioid Addiction.
   a. Narcotic Treatment Programs. The Narcotic Addict Treatment Act of 1974 allows for the establishment of NTPs which may administer certain controlled substances, particularly methadone and levomethadyl (LAAM), to narcotic addicts being treated in the programs. No prescribing of methadone or LAAM can be done by NTPs, and community pharmacies may not fill prescriptions for methadone used to prevent withdrawal (levomethadyl is not available in the US outside of NTPs). These rules do not affect the use of methadone for treatment of pain.
      i. A practitioner who is not part of an NTP may administer methadone to an addict to relieve acute withdrawal symptoms while that practitioner is making arrangements to refer the addict to an NTP. No more than one day’s drug may be administered at a time, and no more than three days’ treatment may be provided.
      ii. A hospital which does not have an NTP may administer methadone to prevent withdrawal symptoms while the hospital is treating the patient for a medical condition other than narcotic addiction.
      iii. Pharmacists receiving prescriptions for methadone should generally question prescriptions that are prescribed for obvious maintenance doses (e.g., once daily), rather than multiple daily doses which would be appropriate for treatment of actual pain.
         1. Effective January 1, 2008, Methadone 40 mg dispersible (Methadone Disket\textsuperscript{®}) tabs will no longer be available to community pharmacies, but

\textsuperscript{217} “DEA Suspends Seattle Branch Of Cardinal Health Drug Company And Rogue Internet Pharmacy From Distributing Controlled Substances” http://www.usdoj.gov/dea/pubs/states/newsrel/seattle112907.html
\textsuperscript{218} http://tampabay.bizjournals.com/tampabay/stories/2007/12/03/daily52.html?jst=b_in_hl
\textsuperscript{219} http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-newsArticle&ID=1018680&highlight=
will be restricted for distribution to SAMHSA-certified opioid treatment programs.\textsuperscript{220}

2. Pharmacists should be alert when patients present with initial prescriptions for methadone. In opiate-naïve patients, starting doses are typically 2.5 mg every 8 to 12 hours, and as low as 2.5 mg daily in frail elderly. Methadone dosed at 10 mg q 8 h is roughly equivalent to 120 mg of morphine per day or greater. Conversions from other opiates to methadone are not straightforward, and at higher chronic doses methadone is progressively more potent.\textsuperscript{221} Failure to consult with prescribers concerning obviously high methadone conversion doses is a growing source of negligence lawsuits against pharmacists.

b. **Office-based narcotic maintenance programs.** Congress passed the Drug Addiction Treatment Act of 2000 (DATA) (21 USC 823(g)), which allows for office-based narcotic maintenance programs using buprenorphine as an alternative to Methadone Maintenance Programs. Physicians wishing to prescribe outpatient buprenorphine for maintenance must apply for a waiver with the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA’s buprenorphine web page can be found at \texttt{http://buprenorphine.samhsa.gov/}.

i. Pharmacists may fill prescriptions for buprenorphine issued by physicians who have DATA waivers.

ii. Federal rules governing privacy in treatment programs require that any party disclosing information about the treatment must obtain a signed release from the patient before the information is transmitted. Prescriptions transmitted from the prescriber to the pharmacist would fall under this requirement. Thus, pharmacists filling prescriptions for buprenorphine written by a physician with a DATA waiver are advised to require the patient to bring a written prescription to the pharmacy, since information released directly by the patient is not subject to the need for a release.

iii. Only Subutex\textsuperscript{®} (buprenorphine) 2 mg or 8 mg SL tablets (or an AB rated generic\textsuperscript{222}) and Suboxone\textsuperscript{®} (buprenorphine and naloxone 4:1 ratio) 2 mg or 8 mg SL

\textsuperscript{220} \url{http://www.deadiversion.usdoj.gov/pubs/pressrel/methadone_advisory.htm}, accessed 1/10/10.
\textsuperscript{221} Toombs JD, Kral LA. Methadone treatment for pain states. Amer Fam Phys. 2005 Apr 1; 71(7):1353-8; \url{http://www.aafp.org/afp/2005/0401/p1353.html}
\textsuperscript{222} The ANDA for Buprenorphine HCl SL tablets, Roxane Laboratories, was announced on October 8, 2009.
tablets are FDA-approved for narcotic maintenance or withdrawal treatment. The DEA could consider dispensing of buprenorphine injection for maintenance as diversion, since it would not serve a “legitimate medical purpose.”


v. Prescribers are encouraged to include their DATA Waiver Number on prescriptions for buprenorphine, and SAMHSA has proposed rules that will require this in the future. Pharmacists may use the Buprenorphine Physician Locator page on the SAMHSA web site (http://buprenorphine.samhsa.gov/bwns_locator/index.html), which includes a link to information on how to verify a waiver for a physician who is not listed in the locator. The DEA issues qualified prescribers an additional DEA number with “X” as the first letter.

vi. Although the use of Subutex or Suboxone for treatment of pain is an off-label use, these products may be prescribed for treatment of pain, typically in doses given 3 or 4 times a day, by prescribers authorized to prescribe Schedule III drugs. No DATA waiver is required to prescribe Subutex or Suboxone for treatment of pain.223

7. Impaired Health Professionals The current trend in health profession regulation is to treat impairment due to alcohol or substance abuse as an illness, and to encourage treatment that will return the impaired professional to practice. Some states, such as Michigan, have developed recovery assistance programs that deal with all or most health professions in the state. Others have tended to deal with each profession individually. The Uniform Disciplinary Act (RCW 18.130) authorizes disciplinary boards to establish programs for monitoring professionals whose practice has been restricted, and to contract with organizations and licensees to undertake such monitoring. Washington has adopted rules to allow for referral of impaired pharmacists (and students and other licensees) to an approved recovery network. In Washington, this recovery program is called the Washington Recovery Assistance Program for Pharmacy (WRAPP).

a. WRAPP was established in 1983 by the Washington State Pharmacists Association and the Washington State Society of Hospital Pharmacists (now merged into the Washington State

223 http://buprenorphine.samhsa.gov/faq.html#A21
Pharmacy Association). It is supported by the Board of Pharmacy, WSU, UW, and WSPA.

i. **Goals.**
   1. Protect the health and safety of the public.
   2. Provide a health resource and rehabilitation support for the impaired pharmacist.

ii. **No fee** for WRAPP services.

iii. **Cost of assessment and treatment** (including drug screens) borne by the participant.

b. **Referral can be by self, with intervention by a concerned individual, or by Board.**

i. **Self-referral.**
   1. **Details are confidential.** No notification is made to the Board as long as participant is compliant with monitored treatment program.
   2. **Practice restrictions** may be required by program during early phases of treatment.
   3. **Self Referral Contact:** 800-446-7220.

ii. **Involuntary, due to intervention** by a concerned individual.
   1. **Notification will not be made to Board** as long as participant is compliant with monitored treatment program.
   2. **If drug theft is linked to discovery of impairment,** Board may be notified.

iii. **Board referral.**
   1. **Board may refer licensee to WRAPP as an alternative to discipline**
   2. **Contract developed with licensee**
   3. **If contract completed, no discipline** is taken, and participation is kept confidential
   4. **Board may refer disciplined licensee** to WRAPP for monitoring of compliance with Board order.

c. **Board rules** are found in WAC 246-871.

i. **Recovery program rules apply to any licensee** of the Board: pharmacists, interns, and ancillary personnel.

ii. **Licensees are required to report known or suspected impairment** of another licensee, and may choose to report to WRAPP or to the Board.
   1. Reporting to WRAPP satisfies the reporting requirement.
   2. A licensee who is required to report known or suspected impairment, and who makes good faith reporting of known or suspected impairment to WRAPP or the Board, is immune from civil liability. This is specified in WAC 246-867-030, but stems
from the statutory protection afforded by RCW 4.24.500-510 (see next section).

8. Pharmacists’ reporting of suspected violations of the CSA. The corresponding responsibility of the pharmacist that is imposed by the CSA, requires that the pharmacist independently determine for each controlled substance prescription whether the prescription is legitimate. Because the pharmacist is first a primary care provider, and not a law enforcement officer, these determinations must always be made with the needs of the patient in mind.

a. "Red flags" are characteristics that should alert a pharmacist to the possibility of a problem with the prescription. The DEA has suggested that the following are red flags, and that the more of these characteristics found in a given prescription, the greater is the possibility that the prescription is not legitimate or there is need for caution in dispensing addicting drugs to a particular patient:

   i. The prescription looks "too good."
   ii. The directions, quantity, or dosage differs from usual medical usage.
   iii. Abbreviations used differ from standard medical abbreviations.
   iv. Directions are written in full with no abbreviations. (This is actually a desirable practice, to minimize error, but it is unusual.)
   v. Different handwriting, and/or different colored inks are used in the prescription.
   vi. The patient appears to be "doctor shopping" by visiting multiple prescribers to obtain multiple prescriptions for the same or similar drugs.
   vii. The patient appears to be altering elements on the prescription, such as the quantity or the date written.
   viii. The pharmacist has evidence that the patient is selling or sharing his or her controlled substances.
   ix. The patient insists on specific brand-name narcotics and refuses generics in situations where the use of generics is appropriate.
   x. The patient insists on paying cash for controlled substances, which could be covered under insurance.
   xi. The patient has a history of frequent reports of "lost," "stolen" or accidentally destroyed prescriptions and/or drugs.

b. "White flags" may be thought of as signals to the pharmacist that he or she needs to assure patient care. When a pharmacist, delays or refuses to dispense a prescription in response to a red flag, patient care is delayed or denied. If the pharmacist's
judgment is in error, the patient suffers unnecessarily. Sometimes this leads to a lawsuit. Before deciding to delay, refused to fill, or report the patient to the police, the pharmacist should engage in direct conversation with the prescriber about his or her concerns. The following are questions a pharmacist should ask when deciding about the legitimacy of a prescription:

i. Did the pharmacist’s information about the validity of the prescription come directly from the prescriber? If not, did the party providing the information state unequivocally that the prescription was a fraud, and that his or her information is not based solely on a lack of information in the patient record?

ii. Did the pharmacist discuss with the prescriber that he or she was intending to call the police? If yes, did the prescriber agree that action was appropriate?

iii. Does the patient have a pre-existing relationship with the pharmacist or the pharmacy? If so, has the pharmacist carefully reviewed the patient profile to see if this prescription represents a pattern of reasonable treatment?

iv. Did the pharmacist ask the patient specifically about his or her concerns? If so, did the patient have a reasonable explanation for any discrepancies?

v. Does the pharmacist expect the police to further investigate before deciding to arrest or charge the patient with a crime? If no, as the pharmacists believe the police can rely on his or her information to conclude that the prescription is fraudulent?

vi. Is the pharmacist prepared to defend his or her actions in court?

c. When pharmacists exercise their duties as citizens to report crimes or apparent crimes to the police, the Board of Pharmacy, or the DEA, in Washington they may be protected against civil suits arising from these reports by a Washington statute, RCW 4.24.510:224

Communication to government agency or self-regulatory organization -- Immunity from civil liability. A person who communicates a complaint or information to any branch or agency of federal, state, or local government, or to any self-regulatory organization that regulates persons involved in the securities or futures business and that has been delegated authority by a federal, state, or local government agency and is subject to oversight by the delegating agency, is immune from civil liability for claims based upon the

224 Note, however, that this protection does not extend to civil actions against the person who was the subject of the report, when the plaintiff is the person who engaged in the protected communication with the agency. See Saldivar v. Momah, No. 34891-8, Wa App Div II, June 24, 2008.
communication to the agency or organization regarding any matter reasonably of concern to that agency or organization. A person prevailing upon the defense provided for in this section is entitled to recover expenses and reasonable attorneys' fees incurred in establishing the defense and in addition shall receive statutory damages of ten thousand dollars. Statutory damages may be denied if the court finds that the complaint or information was communicated in bad faith.

d. To avoid common law liability for libel, defamation, or false arrest, pharmacists should follow these guidelines:
   i. In making reports to police of suspicious prescriptions, pharmacists must take reasonable care to be sure of their facts
      1. Follow the DEA's guidelines for identifying a forged or suspicious prescription
      2. Remember that reports from medical offices based on lack of records or absence of the prescriber may be unreliable
      3. Record the specific names and contact information of any individuals who have provided information used in the pharmacist’s decision. If possible have them FAX you any documentation.
   ii. Do not communicate suspicions to anyone other than the police or another person who has a need to know the information (e.g., the prescriber, store management, other pharmacy staff)
   iii. Do not unreasonably detain the patient. If you have obtained an address, the police can follow up on your report even if the patient has left the pharmacy.
      1. Do not restrict the patient from leaving
      2. Do not threaten or intimidate the patient
      3. Do not physically restrain the patient

9. Other controlled substances laws in WA include the following related to cannabis and marijuana, and to products sold on the street which are imitations of controlled substances. These laws are rarely of importance to pharmacy practice.
   a. RCW 69.43 – Precursor Substances
   b. RCW 69.51 – Controlled Substances Therapeutic Research Act
   c. RCW 69.51A – Medical Marijuana
   d. RCW 69.52 – Imitation Controlled Substances
   e. RCW 69.53 – Use of Buildings for Unlawful Drugs

Rev. 1/10/10
Chapter 6. Patient Information: Collection, Use, Quality Assurance, and Confidentiality

1. **Informational responsibilities of pharmacists.** In general, pharmacists have six major responsibilities regarding patient information, under both federal and state laws and regulations.
   a. They must **maintain patient records for every patient** which will aid them in documenting the distribution of drugs and devices to the patients and in providing pharmaceutical care services to their patients.
   b. They must **use these records to review therapy prior to dispensing**; this is known as Prospective Drug Use Review (P-DUR).
   c. They must **act to correct any problems** that are discovered as a result of this review.
   d. They must **provide information to their patients necessary to insure appropriate use of their medications** and promote the attainment of desired therapeutic outcomes.
   e. They must **assure the confidentiality of protected health information** (PHI) under their control.
   f. They must use information concerning patient outcomes and adverse events to **continuously improve the quality** of their patient care.

Table 6-1a summarizes the legal sources for these requirements:

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>State Law or Regulation</th>
<th>Federal Law or Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintain patient records</td>
<td>RCW 18.64.245, 69.41.042; WAC 246-875-020</td>
<td>Omnibus Budget Reconciliation Act of 1990 (OBRA-90)</td>
</tr>
<tr>
<td>Conduct P-DUR</td>
<td>WAC 246-875-040</td>
<td>OBRA-90</td>
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<tr>
<td>Act on P-DUR findings</td>
<td>WAC 246-875-040; WA case law (McKee v American Home Products, 782 P2d 1045, 1989)</td>
<td>OBRA-90</td>
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<tr>
<td>Provide information to patients</td>
<td>WAC 246-869-220</td>
<td>OBRA-90; Title VI Civil Rights Act</td>
</tr>
<tr>
<td>Assure confidentiality of PHI</td>
<td>RCW 70.02; RCW 18.64.245; 69.41.044, 69.41.055; WAC 246-875-070(2)</td>
<td>Health Information Portability and Accountability Act of 1996 (HIPAA); Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH)</td>
</tr>
<tr>
<td>Engage in Quality Improvement Activities</td>
<td>RCW 43.70.510; WAC 246-50-001 thru 990; Joint Commission standards</td>
<td>Patient Safety and Quality Improvement Act of 2005 (PSQIA)</td>
</tr>
</tbody>
</table>
2. **Maintaining Patient Records.**

a. **Historical development of the patient records requirement.** The requirement to maintain a record of all prescriptions dispensed has been in WA law since at least 1939. However, maintenance of individual prescription records for each patient was not a standard of practice nationally well into the 1980s. The first state to actually require pharmacists to maintain patient profiles was New Jersey, whose administrative rule was sustained by the New Jersey Supreme Court in 1973.²²⁵ The Washington Board, at about the same time, adopted a regulation requiring the pharmacist to maintain such records as would enable him or her to “attempt” to detect drug-drug interactions, multiple prescribing of similar drug classes by different physicians, and the like. The Board adopted more specific regulations setting forth the requirements of patient records systems in 1984. Among the changes in practice needed to bring about patient record systems were the following, which were reflected in the 1984 regulations:

i. Allowing refill information to be recorded on the patient record, rather than on the back of hardcopy of the prescription.

ii. Allowing (prior to computerization) pharmacists to refill prescriptions without going back to the original prescription each time, if the patient record contained a correct copy of the original.

iii. Recognition that a system of records could be used to meet needs for patient information as well as records of distribution of drugs. This included understanding that in some facilities, the patient’s chart or medical records could be used as part of a system accessible to the pharmacist to fulfill the needs of a patient medication record system.

b. **Washington’s regulations require every pharmacy and other place where dispensing of drugs takes place to maintain a “patient medical record system.”** It must assure the pharmacist the means to retrieve all new and refill prescription information relevant to patients of the pharmacy. (WAC 246-875-001) The purpose of the system is to “insure that the information it contains will be reviewed by the pharmacist in a manner consistent with sound professional practice when each prescription is filled.”

i. **Individual records required.** The regulation does not explicitly require that an individual record is maintained for each patient. However, the same chapter (WAC 246-875-070) sets forth a requirement that information in the patient medication record which identifies the patient shall be deemed confidential. Thus, the Board has held for many

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years that a “family medication record” cannot be maintained, because it creates a record that, when shared with any patient in the record, reveals protected information about other patients. Standards under newer state and federal laws (RCW 70.02 and HIPAA/HITECH) clearly preclude non-individual patient records.

Table 6-2a. Required Elements in Patient Medication Record Systems in WA

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<td>WAC 246-875-020(1)</td>
<td>WAC 246-875-030(1)</td>
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<td>Name of mfr and lot numbers of components used</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Refill instructions</td>
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</tr>
<tr>
<td>Start and stop dates and time when appropriate</td>
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<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Prescriber (name, address, DEA number if required)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Complete directions for use (&quot;as directed&quot; not allowed)</td>
<td>✓</td>
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<tr>
<td>Patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If no allergy data, indicate &quot;none&quot; or &quot;NKA&quot;</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Authorization for non-CRC use</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td>Special status (on hold, dc’d, self-administration, etc.)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Other drugs used by patient</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Any cautionary alerts to be placed on labeling</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Required by OBRA-90 (see below)</td>
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<td>✓</td>
<td>✓</td>
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</tr>
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<td>Patient’s age or DOB</td>
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<td>✓</td>
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<tr>
<td>Patient’s gender</td>
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</tr>
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<td>✓</td>
</tr>
<tr>
<td>Other drugs and devices used by patient</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Pharmacist’s comments regarding therapy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
ii. **Minimum required information.** The regulation sets forth minimum information that must be maintained in the patient medication record. It specifies this slightly differently depending upon whether a manual or computer system is used for ambulatory patients. The requirements for an automated system are specified in WAC 246-875-020. The manual system requirements are set forth in WAC 246-875-030. The requirements are the same for institutional patients whether a manual or automated system is used, and are repeated for each section.

As seen from Table 6-2a above, it is assumed that refill instructions in a manual system may be maintained on the original prescription, but they may be maintained in the manual system/card itself. Likewise, although information on use of non-CRCs does not need to be on the manual patient medication record, it may be, or it may be maintained in a separate file or on the original prescription. Note that OBRA-90 also requires outpatient pharmacies to maintain the patient’s age or date of birth, the patient’s gender, and telephone number in medication record systems. **Some believe that the WA regulation does require gender as a “chronic condition” that may relate to drug utilization;** in any case, recording age and gender can be considered a standard of practice, or at least a practical necessity in an age of third party payers. OBRA-90 also requires “pharmacist’s comments relevant to an individual’s therapy.”

c. **Omnibus Budget Reconciliation Act of 1990 (OBRA-90) Patient Record Requirements**

i. The sections of OBRA-90 that relate to Medicaid prescription drug programs were enacted by Congress primarily to take advantage of certain pharmaceutical care services that were expected to result in more appropriate utilization of outpatient prescription drugs by Medicaid patients, and that, in turn was expected to produce savings in the federal government’s share of the cost of these drugs. The Act mandated that federal and state Medicaid programs perform or require the following activities:

1. **Establish a system of mandatory rebates** from manufacturers of prescription drugs purchased for use by Medicaid recipients.

2. **Fund demonstration projects** among one or more states to establish the value of
   a. On-line Prospective Drug Use Review (OPDUR). These systems involve use of centralized computer systems to screen for
patient drug related problems prior to authorization of payment for a proposed claim. A project was conducted in Iowa. These systems are commonly used in all states and by almost all third-party payors and pharmaceutical benefits managers (PBMs).

b. Payment for pharmacist’s cognitive services. This project was funded and conducted in Washington. Overall, it showed that in the mid-1990s, for an average payment of around $5, each cognitive service provided by participating pharmacists saved approximately $13.

3. **Mandate states to conduct Retrospective Drug Use Review**, whereby overall utilization of various drugs or classes of drugs is reviewed by the Medicaid agency to determine population-based approaches to improving drug use.

4. **Require pharmacists in community pharmacies to conduct Prospective Drug Use Review prior to filling prescriptions for Medicaid recipients**

5. **Require pharmacists to offer counseling to Medicaid recipients**.

ii. The **patient record requirements** arose because without an adequate patient medication record, pharmacists cannot conduct prospective drug use review. OBRA-90 calls these records “Patient Drug Use Histories,” and requires that the pharmacist make a “reasonable effort to obtain” the following information for each patient:

1. Name, address, phone, age/DOB, and gender of each patient
2. Significant disease states that the patient has that may affect drug therapy
3. Known allergies or drug reactions
4. A list of all drugs and devices previously used by the patient (from ANY source, not just the dispensing pharmacy)
5. Pharmacist comments relevant to an individual’s therapy.

iii. **States were required to modify their own regulations as they related to Medicaid patients to comply with OBRA-90**. Washington had both patient record system and patient counseling requirements in place that applied to ALL patients well before OBRA-90, so the federal government deemed our state to be in substantial compliance without further rule changes.
1. Pharmacies that provide services to Medicaid patients agree to abide by OBRA-90 as part of their contract with the Department of Social and Health Services, which is Washington’s Medicaid agency. Technically, these pharmacies do not need to maintain OBRA-90-only data elements for all patients, since the Board has not amended its regulations, but they do need to maintain them for Medicaid patients. Obviously, they must perform a review of the record and provide counseling to ALL patients in Washington.

d. May the patient refuse to provide certain information? Those elements that are only required by OBRA-90 are subject to the “reasonable effort” qualification of OBRA-90, so it seems that a patient may decline to provide them, which would include age/DOB, gender, and telephone number. Washington’s rule is not so qualified, however, it is clear that a pharmacist can’t collect information that is inapplicable or unavailable from a given patient. If a pharmacist requests that the patient inform him or her of other medications he or she is taking, and the patient omits some drugs, the pharmacist will only be held responsible for knowing what the patient revealed.

e. Data Security.

   i. Washington’s pharmacy regulations require that information in patient records be maintained for a minimum of two years, and that security codes must be imposed in automated systems to prevent unauthorized modification of data. (WAC 246-875-0070)

   ii. Each pharmacy must have an auxiliary record system for use when the automated system is inoperative due to system interruption, with provisions for prompt entry of information into the system – within two working days – after the system is again functioning. (WAC 246-875-050)

   iii. Pharmacies are also subject to the requirements of Washington’s Health Care Information Act, RCW 70.02, which specifies in RCW 70.02.150 that:

       A health care provider shall effect reasonable safeguards for the security of all health care information it maintains. Reasonable safeguards shall include affirmative action to delete outdated and incorrect facsimile transmission or other telephone transmittal numbers from computer, facsimile, or other data bases. When health care information is transmitted electronically to a recipient who is not regularly transmitted health care information from the health care provider, the health care provider shall verify that the number is accurate prior to transmission.
iv. **Federal rules governing security** of patient information have been promulgated under authority of the Health Information Portability and Accountability Act of 1996 (HIPAA).\(^{226}\)

1. **The Security Standards require pharmacies to provide basic safeguards** that will "protect electronic PHI from unauthorized access, alteration, deletion, and transmission.” Much of the summary in this section is based on Bell’s presentation to the NACDS Foundation HIPAA Security Conference, available on the Internet.\(^{227}\)

   a. The standards apply to **electronic PHI only**, or PHI that is maintained or transmitted using electronic media. These systems include

   1. Computers and computer networks;
   2. Optical and magnetic storage;
   3. Telephone voice response and “faxback” systems; and
   4. The Internet

   b. Information transmitted via telephone is **NOT** included in these standards.

2. It is the purpose of the standards to protect the **integrity, confidentiality, and availability** of electronic PHI

   1. **Integrity** – the data has not been altered or destroyed in an unauthorized manner

   2. **Confidentiality** – data or PHI is not disclosed to unauthorized persons or processes

   3. **Availability** – data is accessible on demand by an authorized requestor

   c. The standards allow for each entity to develop approaches appropriate to their own systems, scope of operations, and capabilities

   1. This does mean that each entity needs to assess its own system, size, and capabilities, and identify specific risks applicable to its systems as it develops its safeguards


2. They require each covered entity (e.g., pharmacy) to establish the following **Organizational Practices**:
   a. Establishment of information security officer
   b. Establishing security policies
   c. Providing for education and training for each employee in security practices
   d. Sanctions for violation of policies

3. They require that each covered entity have in place **Technical Practices and Procedures** that encompass the following elements:
   a. Individual authentication of users of health information systems
   b. Access controls
   c. Audit trails
   d. Physical security and disaster recovery
   e. Protection of remote access points
   f. Protection of external electronic communications
   g. Software discipline
   h. System assessment

4. The federal rule sets forth **“Implementation Specifications”** that describe how the entity is to undertake to fulfill the standard in specific areas. These specifications may be “addressable” or “required.”
   a. Addressable standards -- The entity needs to assess whether an addressable specification is reasonable and appropriate for its situation, and
      1. Implement the specification if it is reasonable and appropriate, or
      2. If the specification is not reasonable and appropriate to the entity’s situation,  
         1. Document in its plan why the specification is inappropriate and  
         2. Implement an equivalent alternative measure if appropriate.
   b. Required standards -- The entity must implement the specification as written in the rules. For example, according to Bell, all pharmacies must adhere to the “Security Management Process” specified in the rules.

5. Ultimately, each pharmacy will need to take advantage of resources provided by various professional organizations, such as the National
Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), or their state pharmacy association, all of whom provide access to implementation manuals or guides. Larger pharmacy firms may well have in-house expertise, but smaller firms may need to work with their system vendors or other experts to help develop their implementation plan.

6. The major impact of the security standards on individual practicing pharmacists will likely be

a. the implementation of more stringent authentication processes, such as requiring re-logging on to the terminal after a minimum timeout and use of positive ID requirements, such as thumb print, retinal scan, or key card access to terminals;

b. creation of a hierarchy of system users, such that, for example, Pharmacy Assistants will not be able to access prescription entry or editing functions of the computer system;

c. Pharmacists and pharmacy department managers will be more responsible for overseeing security issues and knowing how to report and respond to security incidents

v. Required notification to patients and customers of security breaches. The HITECH Act of 2009 was contained in the American Recovery and Reinvestment Act of 2009228 (ARRA – the “stimulus package”). A major subtitle of the Act amends HIPAA to strengthen its privacy and security requirements. The Act sets forth requirements for covered entities to notify their customers or patients if the security of their protected health information has been breached. The Act also strengthens enforcement provisions and restricts sales of certain information for marketing purposes.

3. Use of Patient Information in Providing Pharmaceutical Care: Reviewing the information and taking action if problems are found

a. Minimum Procedures for Use of Patient Information. Washington pharmacy regulations have required prospective drug use review since at least 1984. WAC 246-875-040 sets forth the “Minimum procedures for utilization of a patient medication record system:”

i. On receipt of a prescription or drug order, a dispenser must

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228 Pub. L. 111-5.
1. **Examine the patient’s medication record**, visually or via an automated data processing system to determine the possibility of
   a. A clinically significant **drug interaction**;
   b. A clinically significant **drug reaction**;
   c. A clinically significant **therapeutic duplication**;
   or
   d. Improper utilization of the drug

2. **Consult with the prescriber** if needed
   
   ii. **Orders modified in the system** must carry in the audit trail the unique identifier of the person who modified the order.

   iii. **Any change in drug name, dose, route, dose form or directions** which occurs after an initial dose has been given must
       1. result in a new order entered into the system and the old order discontinued; or
       2. accurately document changes in the system in such a manner that the original record or its audit trail is not destroyed.

b. Note that Washington’s rule

   i. **Does NOT distinguish between new and refill requests.**
      1. Although it requires the review “on receipt of” an order, which might imply only when the order is first received, it also requires that the review must consider improper utilization of the drug, which involves looking at the patient’s history of use as revealed by prior dispensing of the drug; thus, one should consider the receipt of an order to include the patient’s request for a refill of that order

   ii. **Requires the dispenser to examine the medication record each time** (for new and refill requests) an order or prescription is processed
      1. **This involves “interpretation of the data in a patient medication record system”** which is a professional responsibility that cannot be delegated to ancillary personnel (WAC 246-863-095(e)).
      2. **This is part of the “verification” defined in WAC 246-901-010(10).** “Verification’ means the pharmacist has … examined the patient’s drug profile …”

   iii. **Requires evaluation of the patient’s “utilization of the drug”** – this includes early and late refills or other evidence that the drug is not being utilized properly

   iv. **Uses the phrase “prescription or drug order”** so that this rule covers inpatient and ambulatory care settings.
c. The Supreme Court of Washington has concluded that a
“pharmacist has a duty to take corrective measures when
confronted with a prescription containing an obvious or
known error, such as an obviously lethal dosage,
inadequacies in the instructions, known contraindications, or
incompatible prescriptions.”

d. **OBRA-90’s prospective drug use review rules** closely parallel
Washington’s regulation.
   
   i. They require that all prescriptions are “screened against the
   patient’s drug use history” to identify
      1. Therapeutic duplication
      2. Drug-disease contraindications
      3. Drug-drug interactions (including interactions with
         OTC drugs)
      4. Incorrect dosage or duration of treatment
      5. Drug allergies
      6. Clinical abuse or misuse
   
   ii. They specify that the review be manual and/or computer-
   assisted, and may take advantage of “on-line” PDUR
   
   iii. OBRA-90 rules impose at **least three additional
   requirements** on pharmacists beyond those that are
   imposed by Washington regulation
      1. They explicitly require the PDUR to **consider
         interactions with OTC drugs** the patient is taking
      2. They are **based on the assumption that the
         patient’s drug use history is current** and contains
         information concerning all the drugs that the patient is
         taking, whether or not they have been dispensed by
         the pharmacy conducting the review
      3. They anticipate that **pharmacists will record their
         observations concerning therapy** and the decisions
         they have made in the patient record

e. **The pharmacist is not required to contact the prescriber in
   every case where a potential problem is identified.** WAC 246-
875-040 only requires contacting the prescriber “if needed.”
However, it is clear that the pharmacist must “take corrective
measures” when problems are discovered. A couple of obvious
possibilities include
   
   i. **Consulting with the patient** to gain more information that
   helps resolve the problem.
      1. Example: a prescription is written for Tylenol with
         Codeine 30 mg tablets, with directions to “Take 1-2
         tabs q4-6h prn infection.” This suggests a possible
         error in the product that is specified, or at least
         “inadequacies in the directions.” However, the

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229 McKee v American Home Products, 113 Wn.2d 701, 782 P.2d 1045 (1989)
pharmacist notes that the patient also has a prescription for an antibiotic, which is also labeled “for infection.” She asks the patient what the physician told her the Tylenol with Codeine was for, and the patient responds, “The pain of my sinus infection.” This clarifies the order, and the pharmacist may resolve the problem by augmenting the directions to read, “Take 1 or 2 tablets every 4 to 6 hours if needed for pain of sinus infection.”

ii. **Exercising his or her judgment** and subsequently informing the prescriber of the decision

1. Example: a prescription is received for a 3-year old for 30 Amoxicillin 250 mg capsules, to be taken q8h. The dose is appropriate for the child’s weight, but the child cannot swallow capsules. The prescriber is not immediately available for consultation. The pharmacist discusses with the mother the choice of liquid or chewables, which the child can ingest, and they agree on the use of chewables. This is not technically allowed by the generic substitution rules, but it is arguably a form of "secundum artem" that effectively solves the problem. This will allow the resolution of the problem promptly and get the mother and sick child on their way. The pharmacist can notify the prescriber of the decision, which will normally be acknowledged without any problems.

4. **Providing Information to Patients**

   a. **Washington was the first state in the US to require all pharmacists to provide patient consultation.** The original rule (WAC 360-16-250), promulgated in 1973, specified that "With each new prescription dispensed after January 1, 1974, the pharmacist, in addition to labeling the prescription in accordance with preexisting requirements, must orally explain to the patient or the patient’s agent the directions for use and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation shall be by telephone or in writing. PROVIDED, that this shall not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications, or to those prescriptions for patients who are to be discharged from a hospital or institution."

   i. This regulation, although it set a national precedent, was limited to requiring information on new prescriptions only. In addition, in its actual application, pharmacists tended to limit
their “counseling” to fairly superficial issues. Also, the Board has, over the years, been disappointed with the extent of compliance with this requirement by pharmacists.

b. In 2001, the Board promulgated a revised patient counseling regulation, WAC 246-869-220, which sets forth its purpose as “educate the public in the use of drugs and devices dispensed upon a prescription.”

i. The pharmacist shall directly counsel the patient or the patient’s agent on the use of drugs or devices.

ii. For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist.

iii. For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance

1. to promote safe and effective administration of the medication, and
2. to facilitate an appropriate therapeutic outcome for that patient from the prescription.

iv. This rule applies to all prescriptions except where a medication is to be administered by a licensed health professional authorized to administer medications.

c. Note that the current WAC 246-869-220 differs from the old rule in several significant ways

i. It is not limited to new prescriptions only

ii. It requires an offer to counsel, not just written information, on drugs dispensed outside of the pharmacy

iii. It requires the pharmacist to evaluate what is needed to promote safe and effective use of the drug and facilitate an appropriate therapeutic outcome and to tailor the counseling to the specific patient

iv. It no longer specifically exempts hospital or institutional discharge medications from its requirements

d. OBRA-90 requires that pharmacists

i. Make an “offer to counsel” Medicaid patients; and

ii. If the offer is accepted, OBRA-90 sets forth the following “significant items” that the pharmacist should be prepared to discuss with patients:

1. Name and description of the medication
2. Dosage form, dose, route, and duration of therapy
3. Special directions for preparation, administration, or use by the patient
4. Common severe side effects, adverse effects, interactions, or contraindications that the patient can detect and deal with
5. Self-monitoring techniques
6. Storage and refill information
7. What to do if a dose is missed

iii. Pharmacists may allow the patient to refuse to be counseled. “Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual … or caregiver of such individual refuses such consultation.” (42 USC § 1396r-8(g)(2)(A)(ii)(II)) Nor does OBRA-90 require that refusal be documented, although some states have placed such a requirement in their rules.

e. Currently, there is no requirement in Washington that counseling must be documented or that refusal to be counseled must be documented. Given the continued concern by the Board that pharmacists are not as fully compliant with these rules as they should be, the Board at its October, 2004, meeting voted to establish a stakeholders group to advise the Board on a rule to require documentation of counseling.

i. Voluntary Sign in Pharmacy. After much deliberation, the Board decided not to proceed with further rule making, but in January 2006 developed a notice to patients that could be voluntarily placed in the pharmacy. The figure below is similar to the one developed by the Board; the original is available on the Board website.

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Ask questions. It’s your health.

Take an active part in your health care. Talk with your pharmacist about your medicines.

Pharmacists have a duty to counsel you on your medicines. Questions? Contact the Washington State Board of Pharmacy at 800-896-0522.

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230 http://www.doh.wa.gov/hsqa/Professions/Pharmacy/documents/Patient_Counseling_Sign.pdf
f. Legal impact of OBRA-90
   i. States have implemented OBRA-90 patient counseling requirements in different ways. Some allow an offer to counsel to be made by other than the pharmacist; some, like Washington, simply require counseling and make no provision for an "offer." (Washington requires an "offer" only when the drug is delivered outside the pharmacy.) In a few states, these rules apply only to Medicaid patients, but most states chose to apply the requirements to all patients.
   ii. OBRA-90 rules, however, do establish an objective standard for the structure needed to support patient counseling and prospective drug use review (ie, patient drug use histories, on-line or pharmacy-based computer systems)
   iii. OBRA-90 rules also establish an objective standard for the process of patient counseling and prospective drug use review.
   iv. Finally, OBRA-90 rules establish an objective standard for the content of patient counseling
   v. In a state with a rule like Washington's, OBRA-90 rules provide evidence of a minimum, objective standard of how the pharmacist should have implemented patient counseling in his or her practice.
   vi. To the extent that pharmacists can document their compliance with OBRA-90 standards, they are providing evidence of proper professional practice.

g. Patients with Limited English Proficiency (LEP) Title VI of the Civil Rights Act of 1964 prohibits discrimination against persons based on national origin. Recipients of federal financial assistance, which includes pharmacies receiving federal funds under Medicaid or Medicare, are covered by this prohibition. The U.S. Supreme Court in 1974 held that Title VI prohibits conduct that has a disproportionate effect on LEP persons because such conduct constitutes national-origin discrimination.
   i. Executive Order 13166 was signed by President Clinton on August 11, 2000; its title is “Improving Access to Services for Persons with Limited English Proficiency.” The order requires every federal agency that provides financial assistance to non-federal entities publish guidance on how their recipients can provide meaningful access to LEP persons.

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231 42 U.S.C. 2000d: No person shall “on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.”
233 65 FR 50121 (August 16, 2000).
ii. **HHS LEP Guidance.** The Department of Health and Human Services published its current guidance document affecting Medicaid and Medicare providers in 2003.\(^{234}\)

iii. **Are pharmacists and pharmacies covered?** Yes, if they participate in Medicare, Medicaid, or other federally funded programs (e.g., SCHIP).

iv. **Who is an LEP individual protected by Title VI?** LEP persons are individuals who “do not speak English as their primary language and who have a limited ability to read, write, speak or understand English.” LEP persons seeking health care services are eligible to receive “language assistance” during health care encounters.

v. **Language Assistance** may be either oral assistance (by use of interpreters or by providers who are multilingual) or written assistance (printing materials in the LEP person’s primary language).

vi. **Amount of assistance required of a pharmacy varies** according to a four-factor test:

1. The number or proportion of LEP persons served or encountered in the pharmacy’s patient population.
2. The frequency with which LEP persons come into contact with the pharmacy.
3. The nature and importance of the care provided.
4. The resources available to the pharmacy and the cost of adaptation.

vii. **Each covered entity is required to assess** its compliance in light of the four-factor test and develop a written compliance plan. Pharmacies that serve “very few” LEP persons are exempt from this requirement.

viii. **Enforcement of these rules against pharmacies** has been limited, but it is expected to increase. In 2008, the state of New York entered into a consent agreement with Rite Aid and CVS by which these chains will provide language assistance to LEP persons.

ix. **At a minimum, pharmacies should develop** dual language labeling for prescriptions for commonly encountered LEP patients. For example, many pharmacies in Eastern Washington regularly provide prescriptions to Spanish-speaking patients. Computer software readily exists to print Spanish-language prescription labels and should be used by these pharmacies.

x. **Resources and additional information can be found at** a federal government interagency web site: [www.lep.gov](http://www.lep.gov)

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5. **Improving use and availability of patient care data** – the Health Information Portability and Accountability Act of 1996 (HIPAA) – provisions to improve use and availability of patient care data. Passed by Congress with three major goals:

   i. **Portability**
   1. **Improve the ability of employees to take insurance coverage with them when they change jobs**
   2. These portability provisions **add to those that are generally known as “COBRA” provisions**
      a. COBRA (Consolidated Omnibus Budget Reconciliation Act of 1986) provided that employees who leave one employer may keep their health care benefits in force for up to 18 months by paying premiums
      b. A problem arose with the ability of COBRA beneficiaries to convert their old coverage to new coverage with a new employer, since the new employer's plan would often not cover “preexisting conditions.”
      c. HIPAA establishes that the maximum time period during which a new employer’s plan can refuse coverage for preexisting conditions is 12 months, after which these conditions must be covered, unless the condition is not covered for any employee

   ii. **Accountability**
   1. **Integrity** of health care information
   2. **Confidentiality** of health care information
   3. **Availability** of health care information

   iii. **Administrative Simplification.** The Act recognized considerable health care costs in the US associated with administrative complexity – some estimates are that over 20% of the health care dollar is spent on claims processing costs. Thus HIPAA dealt with “Administrative Simplification” involving electronic transmission of health care data among providers and payers. It established five major areas of new federal regulation:
   1. **Transaction standards** – creating a common set of standards for sharing claims among providers and payers
      a. For pharmacies, the regulations have adopted the NCPDP 5.1 standards for claims transactions
1. Developed by the National Council on Prescription Drug Programs
2. All Medicare claims must be submitted electronically.
   b. NCPDP’s SCRIPT 8.1 standard applies to e-prescribing transactions.

2. **Standard identifiers** – establishing a single set of identifiers for health care providers
   a. Rules (45 CFR 162.402-414) established a National Provider System which assigns a unique **National Provider Identifier (NPI)** to each health care provider and covered entity.
      1. 10-digit number, which for some uses will be expressed in conjunction with an international prefix of 80840 (80 = health care, 840 = United States)
   b. The NPI replaces all other provider identifiers (CHAMPUS, UPIN, Blue Cross/Blue Shield, etc.)
   c. The NPI is assigned for the provider’s lifetime
      1. Address, name, and other changes will be made on-line, and must be made within 30 days.
   d. Each individual provider – including pharmacists – is eligible to receive an NPI
   e. The application is online, through the **National Plan & Provider Enumeration System (NPPES) website**.  
   f. All health care providers who are covered entities under HIPAA must obtain an NPI whenever they first become a covered entity.
   g. No charge to individuals to apply
   h. Pharmacists will need to know NPI of the prescriber to submit prescription claims
      1. The NPPES website has a search option to find the NPI for any individual provider
   i. Will allow systems to track contributions and productivity of individual pharmacists

3. **Code sets for data elements** – establishing a common data set to simplify communications among providers and payers

4. **Security Standards** – providing for integrity and security of health care information (see discussion above)

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235 https://nppes.cms.hhs.gov/NPPES/Welcome.do
5. **Electronic signatures** – allowing for a paperless health care information system

iv. **Covered Entities** – with regards to the accountability requirements, HIPAA applies to all entities that

1. Render care to individuals
2. Collect and maintain Protected Health Information (PHI)
3. Exchange electronic records
4. Virtually all pharmacies fit these requirements and are “covered entities”

6. **Assuring the confidentiality of patient information**

a. HIPAA has been the center of recent national attention regarding protection of the privacy of patient information. However, **Washington has required confidentiality of patient records in pharmacy regulations at least since the inception of mandatory patient records, and the Washington Legislature passed a comprehensive Health Care Information Act in 1994 (RCW 70.02), prior to HIPAA.** Other state rules affecting privacy of medical records include the AIDS Omnibus Act of 1988 (RCW 70.24) and various statutes and regulations regarding mental health (RCW 71.05.390). Federal laws (PL 104-193 § 407) also govern confidentiality in substance abuse treatment programs. The privacy rules of each state are important for practitioners to understand, since HIPAA does not preempt any state or other federal privacy rules which are more stringent than the HIPAA requirements. Thus, in each state, what is actually required will be a combination of federal and state rules. HIPAA was amended in 2009 by the HITECH Act, and important changes will be occurring between 2009 and 2017.

b. The **HIPAA Privacy Rule is encoded at 45 CFR 160 and 45 CFR 164.** It’s principal features are:

   i. **Protected Health Information (PHI)** is that which
      1. Relates to a health condition (past, present, or future); and
      2. Identifies the patient (45 CFR 164.501)

   ii. **Covered entities may use PHI for TPHCO:**
      1. Treatment;
      2. Payment; or
      3. Health care operations

   iii. **Consent from the patient is not required to use information for TPHCO**

   iv. **All other disclosures or dissemination of PHI requires consent**

   v. **Use of PHI for marketing, research, and other non TPHCO functions requires permission**
1. Data may be shared for marketing or research if it is “de-identified”

vi. **Stricter provisions of any state law** must be followed

vii. **Business associates** must assure compliance with the rules and are subject to the same penalties.

1. Business associates include firms who perform payment or health care operations functions on the entity’s behalf

viii. **Consent from minors is subject to state law**

ix. **Each patient must be provided with a Notice of Privacy Practices (NOPP)** at first point of contact; receipt of the NOPP must be documented

c. **Use of PHI for Treatment.** Pharmacies may use PHI to provide treatment to patients. The NOPP of the pharmacy must include a description of how it will use PHI for treatment, which would typically include the following activities:

i. Processing prescriptions and dispensing drugs

ii. Maintaining and reviewing patient profiles

iii. Consulting with prescribers relative to the patient’s care

iv. Providing emergency information necessary for the patient’s care

v. Consulting with the patient or caregiver regarding the patient’s medications

vi. Transferring refill information to or from other pharmacies

d. **Use of PHI for Payment.** Typical pharmacy activities involving payment would include:

i. Determining eligibility or coverage

ii. Preauthorization of prescriptions and on-line prospective drug use review

iii. Billing 3rd party payers, justifying charges

iv. Collecting payment from the patient, or collecting past-due charge accounts

v. Providing certain information to consumer reporting agencies

vi. Transmitting credit card charges

vii. Refunding charges or payments

e. **Use of PHI for Health Care Operations.** Typical pharmacy HCO activities would include:

i. Quality assurance within the pharmacy

ii. Quality assurance activities with external organizations

iii. Contacting providers or patients with information on treatment alternatives and related functions that do not include treatment

iv. Medical review, legal services, auditing, and fraud and abuse detection

v. Employee training and development
vi. Complying with regulatory agencies and complying with other provisions of HIPAA

vii. Inventory control and planning

f. **Minimum Necessary Data Set.** Disclosures of PHI between covered entities for TPHCO are now limited to the minimum information necessary to accomplish the intended purpose of the request or release. It does not apply to requests from the patient for his or her own information, nor to releases to another provider for treatment. Under the rule, the requesting party is to determine the needed elements, and specify those to the entity releasing the information. For example, a request to a pharmacy for certain information from a payer may indicate that only the prescription number, NDC, and patient’s date of birth are to be supplied. If the pharmacy sends more information than requested, it may be in violation of the rule.

g. **Deidentified data.** If a covered entity deidentifies an individual’s PHI by removing the following identifiers, the information is no longer individually identifiable health information: Identifiers of individuals or of relatives, employers, or household members of the individual must all be removed, including but not limited to, name, address, zip code, city, birth date, admission date, discharge date, age, telephone number, fax number, electronic mail address, social security number, medical record numbers, vehicle identifiers, and pictures. (45 CFR § 164.502).

   Such deidentified data is not subject to the privacy rule and may be used for research or studies, and can be electronically transmitted.

h. **Notice of Privacy Practices**
   i. Advises patients that you will use their PHI for TPHCO
      1. Spells out what that means for your pharmacy
   ii. Advises patients of their rights
   iii. Advises patients that you do need written permission to release PHI for non-TPHCO purposes
   iv. Identifies the pharmacy’s Privacy Officer and how to contact that person
   v. Describes business associate relationships
   vi. Describes applicable state laws and regulations
   vii. Describes how you will notify of changes
       1. Most pharmacies will take advantage of the option to notify of changes to the NOPP by posting them in the pharmacy
   viii. Requires patient to acknowledge receipt of the NOPP
       1. May use a signature log
       2. Should place an indication in the computer record that notice was provided
   ix. The title of the notice must be printed exactly as stated in the regulation:
       1. “This Notice Describes How Medical Information About You May Be Used And Disclosed And How You Can Get Access To This Information”
x. The pharmacy must post a notice announcing the availability of this information
xi. Must provide a copy of the NOPP to any person who requests it
xii. Must track changes to the NOPP
xiii. Because of changes prompted by the HITECH Act, pharmacies will need to amend their NOPPs in February 2010.

i. Patients have a right to see a copy of their record
   i. Patient may see records, and may request changes in the record to correct any errors
      1. The pharmacy must respond to the request in a timely manner. This is treated differently under Washington law than under HIPAA, so the shorter time limits apply in Washington.

<table>
<thead>
<tr>
<th>Type of Request</th>
<th>Limits under HIPAA</th>
<th>Limits under Washington law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to records</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time for Initial Response</td>
<td>If information is available on site</td>
<td>30 days</td>
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<tr>
<td></td>
<td>If information is off-site</td>
<td>60 days</td>
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<tr>
<td>One time extension</td>
<td>30 days (total of 60 or 90 days)</td>
<td>6 days (total of 21 days)</td>
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<tr>
<td>Corrections to Records</td>
<td></td>
<td></td>
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<tr>
<td>Initial response</td>
<td>60 days</td>
<td>10 days</td>
</tr>
<tr>
<td>One time extension</td>
<td>30 days (total of 90 days)</td>
<td>11 days (total of 21 days)</td>
</tr>
</tbody>
</table>

ii. When a patient requests copies of his or her records, the pharmacy must either deliver the copies within the time limit for an initial response, or provide the patient with an explanation that it will take additional time to provide the records; the pharmacy then can take advantage of a one-time extension as specified in the law. In Washington, the maximum time if 21 days, including the extension, and the initial response must be made within 15 days. Washington law, unlike HIPAA, does not distinguish between on-site and off-site records.

iii. When a patient requests changes to his or her records, the pharmacy must respond within 10 days in Washington,
which may include a notice that additional time is needed, which will provide an extra 11 days in which to
1. Amend the record as requested by the patient; or
2. Deny the request to amend the record.
   a. If the pharmacy denies the requested change, the patient may provide a statement to be inserted into the record.

iv. **HIPAA and Washington law allow providers to charge a reasonable fee for searching and copying records.** (If there is a fee to be charged, it should probably be set forth in the NOPP.) Washington law sets forth maximum amounts that can be charged in WAC 246-08-400:
   1. Copying charges
      a. 1st 30 pages, not more than $1.02 per page.
      b. Beyond 30 pages, not more than $0.78 per page
   2. Other charges
      a. Up to a $23 clerical fee for searching and handling records
      b. If the provider personally edits confidential information, may charge his or her usual and customary fee for a basic office visit. (Pharmacists may be able to establish a UAC office visit fee based on charges for disease management services, such as diabetic counseling, etc.)
   3. These fees are updated each biennium; the current fees are approved through June 30, 2011.
   4. HIPAA Restrictions. If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information as part of a formal HIPAA request then the following federal rule applies: the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:
      a. Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;
      b. Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
      c. Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.\(^{236}\)

\(^{236}\) 45 CFR § 164.524(c)(4)
The pharmacy will need to determine its actual costs, and may charge the lesser of its actual costs or the Washington maximum fee. The “office visit fee” probably cannot be assessed for formal HIPAA disclosures.

j. **Patients may request an accounting of disclosures.** The patient may request that the provider provide a listing of all disclosures of PHI made during the six years prior to the request.
   i. The provider is not required to account for disclosures
      1. Made directly to the patient
      2. Made to carry out TPHCO
      3. Made pursuant to an authorization granted by the patient
      4. Made to persons involved in the patient’s care
      5. Made prior to April 14, 2003 (the effective date of the HIPAA privacy rule)
   ii. If the provider maintains a qualifying Electronic Health Record (EHR) as provided in the HITECH Act, then the patient may request a listing, in electronic form, of all disclosures made during the prior 3 years. The exceptions above do not apply. The effective date will begin based on when the provider first adopts an EHR. If the EHR was adopted prior to January 2009, then the system must become capable of reporting all transactions by January 1, 2014. EHR systems adopted after January 1, 2009 must be capable of reporting all transactions from the date of adoption.
      1. It is not clear whether current retail pharmacy medication record systems constitute EHR systems under the HITECH Act. At any rate, current pharmacy systems would be subject to the 2014 start date.
   iii. The provider may not charge for the first accounting provided to the patient within any 12-month period; a reasonable cost-based fee may be charged for additional requests within 12 months.
   iv. Some disclosures made to law enforcement agencies or as a result of a court order may not be subject to the accounting. The pharmacist should consult legal counsel in these cases, since the rules are complex and involve both state and federal restrictions.

k. **The patient may request that communication of PHI to the patient be restricted** to confidential channels, such as:
   i. A particular address
   ii. A particular telephone number
   iii. A particular electronic address
If they choose one of these options, they must acknowledge that this may restrict communications with family members or caregivers.

**l. The patient may request that a PHI disclosure NOT be reported to his or her health plan if:**

i. The purpose of the disclosure is for payment or operations, and not for treatment; and

ii. The disclosure pertains solely to a healthcare item that the provider has been paid for in full out of pocket.

**m. Washington's rules are more stringent than HIPAA in the following ways**, and must be followed

i. **Time limits to respond to requests** to see or amend records

ii. **Consent by certain minors** (see below)

iii. **Consent by patients with STDs or HIV for certain otherwise permitted disclosures** (eg, oral communications with family member)

iv. **HIPAA allows reports to the military concerning military personnel; Washington law does not**

v. **Abuse of a vulnerable adult or child MUST be reported**

**n. Washington law – in ways that are consistent with HIPAA – allows disclosure without the patient's consent under the following circumstances** (RCW 70.02.050):

i. To a person who is reasonably believed to be providing health care to the patient

ii. To a provider who has previously treated the patient, if necessary for the patient's care, UNLESS the patient has previously instructed the pharmacist not to disclose to that provider

iii. To any person if it is reasonably believed to be needed to avoid or minimize imminent danger to the health or safety of the patient or another individual (this is allowed but not required)

iv. Oral disclosures, if made to immediate family members or other person with whom the patient is known to have a close relationship, in accordance with good medical or professional practice, UNLESS the patient has instructed the provider in writing not to make the disclosure

v. To a provider who is successor in interest to the provider maintaining the information (eg, on the sale of the pharmacy).

vi. Additional conditions are listed in RCW 70.02.050

**o. Board of Pharmacy rule is obsolete.** WAC 246-875-070(2) specifies that information in the patient medication record is confidential, and restricts its disclosure more stringently than the HCIA. This rule was promulgated in 1992, prior to the adoption of
RCW 70.02.050; to the extent that it conflicts with the RCW, it is probably not enforceable.

p. **State-registered domestic partners have same rights as family members or spouses.** Legislation in 2007 (RCW 26.60) and extensive additional legislation in 2008 amended a wide range of other statutes to create substantive rights for domestic partnerships equivalent to those for married couples. (2008 c 6). For example, in multiple statutes the phrase “husband or wife” was amended to read “spouse or either domestic partner.” The statute was amended again in 2009 to give domestic partners the same rights in every case as attach to married couples. (2009 c 21) Opponents obtained sufficient signatures to place a referendum on the November 2009 ballot (Referendum 71), and voters upheld the statute. Changes took effect on December 3, 2009.

i. **Purpose.** “It is the intent of the legislature that for all purposes under state law, state registered domestic partners shall be treated the same as married spouses.”

ii. Domestic partnerships may be entered into by two individuals who

1. are 18 years or older;
2. share a common residence;
3. not be married or in a domestic partnership with a third person;
4. be capable of consenting;
5. not be nearer in kinship than second cousins, nor be a sibling, child, grandchild, aunt, uncle, niece, or nephew to the other person;
6. be members of the same sex, unless one of the members is at least 62 years of age.

iii. Among the powers and rights granted to domestic partners are the following:

1. Health care facility visitation rights
2. Ability to grant informed consent for health care for a patient who is not competent
3. Authority of health care providers to disclose information to the domestic partner under the same conditions that such disclosure to a spouse would be allowed
4. Domestic partners who are residents of long-term-care facilities may share the same room.
5. Insurance policies that cover spouses must also cover domestic partners, including rights under group policies, policy rights after death of partner, continuing coverage rights
6. Right to use sick leave to care for a domestic partner
7. The right to disability insurance benefits
8. Workers’ compensation coverage

iv. Other non-healthcare-related rights extended by the statute include:
   1. Spousal testimony privilege
   2. Ability to share a bank account
   3. Community property rights
   4. Divorce rights
   5. Child-custody provisions
   6. Domestic partners of public officials must submit financial disclosure forms
   7. The right to wages and benefits when a partner is injured, and to unpaid wages upon death of a partner.

v. Providers may confirm the existence of a specific state-registered domestic partnership via a website for the Office of the Secretary of State[^237]. As of 1/11/10, there were 6,848 state-registered domestic partnerships listed on the site.

q. Age of consent. As with most other legal issues, persons who are 18 years of age or older are considered adults and must consent to medical treatment for themselves; they control the disclosure of PHI as it pertains to them, and have a right to see their medical records.

i. A key issue deals with whether parents or minors have control of PHI for the minor. HIPAA defers to state rules on this issue. Generally, parents or legal guardians have control over health care decisions for minors. Important exceptions include:[^238]
   1. **Emancipated minors.** Minors over age 16 may petition the court to become emancipated, and if successful may consent to health care services. (RCW 13.64.060)
   2. **Minors married to a person who is not a minor.** (RCW 26.28.020)
   3. **Minors who may have come in contact with an STD and are 14 years of age or older** may consent to treatment. (RCW 70.24.110)
   4. **Minors seeking contraceptive or pregnancy termination services at any age** may consent to treatment. (State v. Koome, 84 Wn.2d 901; 530 P.2d 260, 1975)
   5. **Minors 13 years of age or older may consent to inpatient** (RCW 71.34.500) or **outpatient** (RCW 71.34.530) **mental health treatment.**


6. **Minors 13 years of age or older may consent to outpatient treatment for chemical dependency.** (RCW 70.96A.095)

7. **Minors capable of understanding or appreciating the consequences of the medical procedure under the Mature Minor Doctrine** may consent to non-emergency medical procedures based on the health care provider’s evaluation of the child’s:
   a. age
   b. intelligence
   c. maturity
   d. training
   e. experience
   f. economic independence
   g. general conduct as an adult
   h. freedom from the control of parents

The mature minor doctrine was noted by the Washington Supreme Court in 1967, holding that an 18-year old (a legal minor at the time) could consent to a vasectomy.\(^{239}\) The Court cited this decision in 1975 when it concluded that a 16 year old female had a constitutionally-protected interest in consenting to an abortion without parental consent. As noted above, the legislature has also specifically extended to minors the right to consent to mental health therapy and treatment for sexually transmitted diseases. In many other settings, where the benefits to the minor are obvious, and the risks remote, such as in immunizations, providers should not hesitate to undertake the analysis required under the mature minor doctrine.

ii. **Power to consent to disclosure of PHI is vested in the minor for any information relating to treatment for which the minor was allowed to consent.** (RCW 70.02.130)

Thus, the pharmacist should presume that the minor can control disclosure of treatment with contraceptives, psychotropics, or drugs used for STDs or pregnancy. Treatment for other conditions could be disclosed with permission of the parent or guardian, but the safest approach is to consult the minor prior to disclosure if any part of the PHI is related to matters over which the minor has control. Minors who are clearly “on their own” should be

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\(^{239}\) Smith v. Seibly, 72 Wn.2d 16 (1967), cited in State v. Koome, 84 Wn.2d 901,911-912 (1975): “The common law requires that a physician subjectively evaluate the capacity of a minor to give informed and meaningful consent to any type of medical care.”
given the opportunity to determine to whom their PHI should be disclosed.

iii. **Washington law specifically protects health care providers from liability when they disclose PHI for a minor (other than when the minor has control of the record) based on permission of either parent or any legal guardian**, as long as the parent or guardian represents to the health care provider that they are authorized to give consent. (RCW 70.02.130) This protects the health care provider from disputes when parents are divorced or separated.

iv. **Relatives of minors may consent for minors under certain circumstances.** So-called “kinship caregivers” may consent to health care for a child even if they do not have a court order and if the parents are not available. The individuals include any adult with signed authorization, and adult relatives. The law does not define “relatives” but general usage would suggest that grandparents, aunts/uncles, sisters/brothers would be among adult relatives covered by the law.

1. An individual who has a signed authorization from the child’s parent to make health care decisions for the child;
2. An adult representing himself or herself to be a relative responsible for the health care of the child; or
3. A relative caregiver who has signed and dated a declaration that says the caregiver is an adult relative responsible for the health care of the minor child.240

r. **Preventing incidental release of PHI.** Under federal regulations implementing HIPAA, each pharmacy is responsible to assure that it provides administrative, technical, and physical safeguards to prevent the intentional or unintentional disclosure of its patients’ PHI. An important element is proper training of staff, monitoring of staff to assure that they comply, and discipline of staff who do not. Many state laws also protect the privacy of patients, and either the federal government or state governments may be able to prosecute pharmacies for failure to prevent release of PHI. In January 2009, CVS entered into a settlement with the Office of Civil Rights, DHHS, for $2.5 million over charges that CVS employees were dumping pharmacy records, labels, and other PHI into unsecured dumpsters. In July, 2008, Seattle’s Providence Health & Services agreed to a fine of $100,000 arising from thefts of employees’ laptops and other media containing unencrypted PHI. Enhanced provisions of the HITECH Act require covered entities to notify customers and patients of any security breaches that have caused

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240 RCW 7.70.065
the release of their PHI, and empowers State Attorneys General to bring cases under HIPAA.

s. **Enforcement.** Civil penalties for willful neglect of the privacy rule are mandatory under the law, and can be as much as $250,000 per violation, with repeated/uncorrected violations extending up to $1.5 million. Civil and criminal penalties may extend to Business Associates of covered entities. Individual patients may not bring an action to enforce HIPAA or HITECH, but either the federal government or state attorneys general may bring actions. To discover violations, the Department of Health and Human Services is required to undertake periodic audits of covered entities and business associates beginning in 2010.

7. **Quality Assurance Activities**
   a. **IOM Report.** The 1999 publication of *To Err is Human* by the Institute of Medicine generated significant national attention concerning medical errors, of which medication errors constitute a significant segment.
   b. **Required CQI Programs.** In general, hospitals are now required by state law and/or JCAHO accreditation requirements to have a continuous quality improvement process in place by which quality-related events (QREs) are reported, investigated, tracked, and efforts made to improve the system of care so as to reduce the incidence and impact of these events. Washington’s law requiring all hospitals to maintain a Coordinated Quality Improvement Program (CQIP) is [RCW 70.41.200 et seq.](http://www.qualityforum.org/projects/completed/sre/)
   c. **Required Reporting of Adverse Events.** The Washington Medical Malpractice Act of 2006 (2006 c 8 § 106) requires medical facilities to notify the Department of Health of adverse events using an online reporting system.
      i. **Adverse events** are those events found on the list of serious reportable events adopted by the National Quality Forum in 2002.²⁴¹
      ii. **The report shall identify the facility**, but not any health care professionals, employees, or patients involved.
      iii. **A root cause analysis** shall be conducted and included as part of the report.
   d. **Hospital Notification of Unintended Outcomes.** Effective January 1, 2006, Washington hospitals shall have in place policies to assure that, when appropriate, information about unanticipated outcomes is provided to patients or their families or any surrogate decision makers. (RCW 70.41.380)
   e. **Community pharmacies are not generally required to implement quality improvement activities at present,** but a clear national trend is emerging. As of 2005, four states, California,
Florida, Massachusetts, and Texas, have implemented requirements for pharmacies in all settings to have in place a quality assurance or quality improvement program.

f. **Most states have now enacted legislation to encourage continuous quality improvement programs**, including Washington. Under Washington law, entities other than hospitals (for whom CQIPs are required) wishing voluntarily to develop CQIPs may apply to the Department of Health to be recognized, in accordance with RCW 40.73.510. The DOH CQIP website provides information needed to develop CQIPs (http://www.doh.wa.gov/CQIP/default.htm). Regulations governing CQIPs are contained in RCW 246-50. Eligible entities may be developed by
   i. Professional societies or organizations
   ii. Health care service contractors
   iii. Health maintenance organizations
   iv. Health carriers
   v. Health care institutions and medical facilities, other than hospitals
   vi. Provider groups of ten or more. This may take many forms, as long as its members are practitioners regulated under the state’s laws for health professionals (Title 18)
      1. A group might consist of providers sharing treatment modalities and perspectives.
      2. A community of providers which cross-disciplinary lines.
      3. Solo practitioners may form a group to create a Coordinated Quality Improvement Program.

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290
j. To assure the same protection to quality improvement programs that transcend state lines, Congress enacted the Patient Safety and Quality Improvement Act of 2005. The information used in these programs is defined in the Act as “Patient Safety Work Product” (PSWP), and as with most of the state laws, is protected from being discovered or used in civil lawsuits, administrative hearings, and most criminal proceedings.
   i. These protections are found in Washington law in RCW 4.24.250. In addition to protecting quality review or provider review information from discovery, it immunizes providers who in good faith file charges or provide evidence to review bodies concerning incompetence or gross negligence of other members of their profession.

k. To qualify as PSWP, the protected information must be gathered for patient safety purposes, kept separate from other health care information collected by the provider, and communicated to a Patient Safety Organization (PSO) that is registered with the Department of Health and Human Services (through the Agency for Healthcare Research and Quality – AHRQ).

l. In general, state and federal laws prohibit unauthorized disclosure of PSWP that contains the identity of any provider (including individual practitioners as well as provider entities). This identifiable PSWP may only be used for patient safety activities. In a way, these laws protect the identity of practitioners in the same way as HIPAA protects the privacy of patients.

m. The federal law specifically protects employees of a provider from retaliation for reporting errors, either to the provider or to a PSO.

n. Increasingly, pharmacists will need to understand the operation of patient safety programs, including patient safety tools such as Root Cause Analysis (RCA) and Failure Mode Effects Analysis (FMEA). Excellent resources on FMEA available from the Institute for Healthcare Improvement.

Rev. 1/10/10

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243 http://www.ihi.org/ihi
1. **Discipline.** Licensees of the Board of Pharmacy are subject to the provisions of *Washington’s Uniform Disciplinary Act* (RCW 18.130). The conduct of disciplinary actions by the Department of Health and its Boards is governed by a set of Model Procedural Rules for Boards contained in WAC 246-11. The UDA establishes the bases for discipline and the Model Rules describe how the various stages of the disciplinary process are carried out. The conduct of hearings and discipline by state agencies is governed by the Administrative Procedures Act (RCW 34.05). The major features of the UDA of interest to pharmacists are:
   a. **Establishment of the Board of Pharmacy as the disciplinary authority** for pharmacists (RCW 18.130.040(viii))
   b. Granting the following powers to the disciplinary authority:
      i. Discipline licensees
      ii. Grant or deny licenses based on the provisions of the Act
      iii. Adopt, amend, or rescind rules needed to carry out the Act
      iv. Investigate all complaints or reports of unprofessional conduct and to hold hearings
      v. Issue subpoenas or administer oaths in conjunction with hearings or proceedings authorized by the Act
      vi. Take or cause depositions to be taken
      vii. Compel the attendance of witnesses at hearings
      viii. To conduct practice reviews in the course of investigating complaints
      ix. To take emergency action ordering summary suspension of a license pending further proceedings
      x. Board members may be used to direct investigations; however, such members may not participate in the hearing
      xi. Adopt standards of professional conduct or practice
      xii. Establish panels of three or more members to carry out any functions allowed in the Act
   c. **All licensees required to report knowledge of discipline or unfitness to practice of colleagues.** The legislature in 2006 (2006 c 99 § 1(6) and § 2 (1)(a)) amended RCW 18.130.070 to require the Secretary of the Department of Health to “adopt rules requiring every license holder to report to the appropriate disciplining authority any conviction, determination, or finding that another license holder has committed an act which constitutes...
unprofessional conduct, or to report information to the disciplining authority, an impaired practitioner program, or voluntary substance abuse monitoring program approved by the disciplining authority, which indicates that the other license holder may not be able to practice his or her profession with reasonable skill and safety to consumers as a result of a mental or physical condition.” Previously, these rules did not extend to individual practitioners, but only to organizations and employers. There are exceptions to these requirements related to peer review and quality assurance activities, and to recovery programs. Additional legislation in 2008 further modified these reporting requirements. (See also the discussion in Chapter 2)

i. Reporting of unprofessional conduct by another licensee. Every licensee (this includes pharmacists, interns, and technicians) must report to the DOH when they have knowledge that another licensee has been convicted of any gross misdemeanor or felony. Licensees must also report when they become aware that another licensee has been determined by an employer or institution to have committed unprofessional conduct. These reports are made to the DOH in accordance with WAC 246-16-220.

ii. Reporting of impairment of another licensee. Licensees are required to report impairment of another licensee. If the impairment has not resulted in harm to a patient, the report may be made to WRAPP or to the DOH. If a patient has been harmed, the report must be made to the DOH.

d. Self-reporting Required. Pharmacy licensees are also required to report to the Board of Pharmacy any

i. Conviction, determination, or finding that he or she has committed an act which constitutes unprofessional conduct; or

ii. Disqualification from participation in federal Medicaid or Medicare programs. Among the reasons a pharmacist might be disqualified are:
   1. Conviction (or plea of guilty or nolo contendere) of misdemeanor fraud;
   2. License suspension or revocation in any jurisdiction;
   3. Default on federal student loans; or
   4. Felony conviction relating to the Controlled Substances Act

Comment: Because these requirements may implicate licensees’ Fifth Amendment or state constitutional rights against self-incrimination, licensees should seek advice from an attorney before making a self-report.

e. Unprofessional conduct is defined in RCW 18.130.180 to include the following – these are the bases by which pharmacists may be disciplined. The criteria set forth in BOLD print are probably the most common reasons for pharmacist discipline:
i. Commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person’s profession, whether or not the act constitutes a crime.
   1. Conviction of a relevant crime may be used in a disciplinary hearing as conclusive evidence that the crime was committed; please of nolo contendere or deferred sentencing are considered as convictions for this purpose.

ii. Misrepresentation or concealment of a material fact in obtaining a license or in reinstatement of a license

iii. All advertising which is false, fraudulent, or misleading

iv. Incompetence, negligence, or malpractice which
   1. Results in injury to a patient, or
   2. Which creates an unreasonable risk that a patient may be harmed

v. Suspension, revocation, or restriction of the person’s license to practice any health care profession in any state, federal, or foreign jurisdiction
   1. Note: legislation in 2006 now requires the Department to immediately suspend a license – pending resolution of departmental investigation and proceedings – when the holder of that license has had his or her license suspended or revoked in another jurisdiction. (RCW 18.130.370, 2006 c 99 §§ 3-4)

vi. Possession, use, prescription for use, or distribution of controlled substances in any way other than for legitimate or therapeutic purposes, diversion of controlled substances or legend drugs, the violation of any drug law, or prescribing controlled substances for oneself.

vii. Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice (Note – see discussion in Chapter 6 regarding how HIPAA sets objective standards of the structure, process, and content of patient counseling.)

viii. Failure to cooperate with the disciplinary authority
   1. not furnishing any papers or documents;
   2. not furnishing in writing a full and complete explanation covering the matter contained in the complaint filed with the disciplining authority
   3. Not responding to subpoenas issued by the disciplining authority
   4. Not providing reasonable and timely access for the disciplinary authority to perform practice reviews
ix. Failure to comply with an order of the Board
x. Aiding or abetting an unlicensed person to practice when a license is required
xi. Violations of rules established by any health agency
xii. Practice beyond the scope of practice defined by law or regulation
xiii. Misrepresentation or fraud in the conduct of the business or profession
xiv. Failure to adequately supervise auxiliary staff to the extent that the consumer’s health or safety is at risk
xv. Engaging in a profession involving contact with the public while suffering from a contagious or infectious disease involving serious risk to public health
xvi. Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure or service
xvii. Conviction of any gross misdemeanor or felony relating to the practice of the person’s profession.
xviii. Procuring, or aiding and abetting in procuring, a criminal abortion
xix. The offering, undertaking, or agreeing to cure or treat disease by a secret method, procedure, treatment, or medicine
xx. Willful betrayal of a practitioner-patient privilege as recognized by law
xxi. Violation of Chapter 19.68 RCW – The Anti-Kickback Statute
   1. It shall be unlawful for any person, firm, corporation or association, whether organized as a cooperative, or for profit or nonprofit, to pay, or offer to pay or allow, directly or indirectly, to any person licensed by the state of Washington to engage in the practice of medicine and surgery, drugless treatment in any form, dentistry, or pharmacy and it shall be unlawful for such person to request, receive or allow, directly or indirectly, a rebate, refund, commission, unearned discount or profit by means of a credit or other valuable consideration in connection with the referral of patients to any person, firm, corporation or association, or in connection with the furnishing of medical, surgical or dental care, diagnosis, treatment or service, on the sale, rental, furnishing or supplying of clinical laboratory supplies or services of any kind, drugs, medication, or medical supplies, or any other goods, services or supplies prescribed for medical diagnosis, care or treatment.
   2. In a recent Supreme Court Decision, it was held that charging patients for medications dispensed or administered directly to them by an authorized prescriber was not a violation of RCW 19.68.244
xxii. Willful interference with a Board investigation
xxiii. Current misuse of alcohol, controlled substances, or legend drugs

244 Wright v. Jeckle, 158 Wn.2d 375; 144 P.3d 301 (Wn. Supr. Ct., 2006).
xxiv. Abuse of a client or patient, or sexual contact with a client or patient
xxv. Acceptance of more than a nominal gratuity from a representative of a manufacturer or vendor of medical or health-related products or services intended for patients, where a recognized conflict of interest is presented

f. Sexual misconduct. The Department has worked with each disciplinary board to develop additional regulations regarding sexual misconduct by licensees. The Board of Pharmacy rules were adopted as WAC 246-860.

i. Among other requirements, the rules prohibit
   1. Romantic or sexual relationships with a patient, client, or key party (a key decision maker related to the patient or client);
   2. A variety of acts that are sexual or seductive in nature;
   3. Unpermitted touching of a sexual nature not required by legitimate health care purposes;
   4. Soliciting a date with a patient, client or key party.

ii. The rules permit
   1. Provision of health care services to a person with whom the provider is in a romantic relationship in case of emergency where the services cannot or will not be provided by another health care provider;
   2. Contact that is necessary for a legitimate health care purpose and that meets the standard of care appropriate to the profession; and
   3. Providing health care services for a legitimate health care purpose to a person who is in a preexisting, established personal relationship with the health care provider where there is no evidence of, or potential for, exploiting the patient or client.

g. Pharmacist’s professional responsibilities. The Board has defined by rule in WAC 246-853-095 those responsibilities which a pharmacist may not delegate to a technician or pharmacy assistant. To do so is considered unprofessional conduct. The Board amended this rule in response to issues related to pharmacist conscientious objection to dispensing certain drugs. The rule operates in conjunction with WAC 246-869-010 (Pharmacies’ Responsibilities – see Chapter 3). The portions below that are underlined represent changes to the former rule.

i. A pharmacist’s primary responsibility is to ensure patients receive safe and appropriate medication therapy.

ii. A pharmacist shall not delegate the following professional responsibilities:
1. Receipt of a verbal prescription other than refill authorization from a prescriber.

2. Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system; provided that this shall not prohibit pharmacy ancillary personnel from providing to the patient or the patient’s health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.

3. Consultation with the prescriber regarding the patient and the patient’s prescription.

4. Extemporaneous compounding of the prescription, however, bulk compounding from a formula and IV admixture products prepared in accordance with chapter 246-871 WAC may be performed by a pharmacy technician when supervised by a pharmacist.

5. Interpretation of data in a patient medication record system.

6. Ultimate responsibility for all aspects of the completed prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.

7. Dispense prescription to patient with proper patient information as required by WAC 246-869-220.

8. Signing of the poison register and the Schedule V controlled substance registry book at the time of sale … and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.

9. Professional communications with physicians, dentists, nurses and other health care practitioners.

10. Decision not to dispense lawfully prescribed drugs or devices or to not distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies.

iii. Utilizing personnel to assist the pharmacist.

1. The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel. The responsible pharmacist manager shall determine the extent to which personnel may be utilized to assist the pharmacist, and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities.
2. This does not preclude delegation to an intern or extern.

iv. It is considered unprofessional conduct for any person authorized to practice or assist in the practice of pharmacy to engage in any of the following:
   1. Destroy unfilled lawful prescription;
   2. Refuse to return unfilled lawful prescriptions;
   3. Violate a patient’s privacy;
   4. Discriminate against patients or their agent in a manner prohibited by state or federal law; and
   5. Intimidate or harass a patient.

As noted in Chapter 3, a federal district court has enjoined enforcement of this rule against any pharmacist who refuses to fill prescriptions for Plan B® but immediately refers the patient to a nearby source of PlanB®. This injunction is only related to dispensing of PlanB® and does not cover refusal to dispense other lawful prescriptions.

h. Discipline Process. The general order in which discipline is carried out can be outlined as follows

i. Receipt of a written complaint charging unprofessional conduct or unfitness to practice by a licensee, or, without a formal complaint, the Board has reason to believe that the licensee may be unfit to practice or have engaged in unprofessional conduct (for example, during the course of investigating an unrelated complaint at the same pharmacy) (RCW 18.130.080)

1. Complaints may come from individuals, other agencies, other licensees, corporations or treatment programs

2. In communicating with the complainant in writing, the Board may not include the address or telephone number of the licensee (RCW 18.130.085)

ii. Investigation by the Board

1. Initial Board Review. The Washington Appeals Court ruled in that the Uniform Disciplinary Act requires that “an investigation should not be conducted, and records should not be obtained, until the [relevant] Board determines that the complaint merits investigation.”

   a. Delegation of this review to a Department of Health Case Management Team was approved as a proposed rule (WAC 246-856-030) at the December 2007 Board of Pharmacy meeting. This will allow staff of the

department to initiate investigations in certain classes of cases without prior formal Board action.

2. A Board investigator then follows up on the complaint, which may include meeting with the licensee and asking the licensee to provide a written explanation of the circumstances related to the complaint.

3. The investigator will provide a memorandum to the Board, which may recommend closure or further investigation.

4. A Reviewing Board Member will examine the case; he or she may recommend:
   a. Closure
   b. A Notice of Correction – which is not considered discipline
   c. A Statement of Charges and Proposed Settlement

5. The RBM works with the assistant attorney general assigned to the Board to develop any charges and proposed settlement.

6. If a statement of charges is prepared, the Attorney General’s office notifies the licensee and provides them with a proposed agreement that:
   a. Stipulates to the matters of fact and law involved
   b. Sets forth a settlement of the matter which may involve various forms of discipline

7. The licensee may agree to the settlement, in which case the settlement is taken to the Board for approval and issue of a Board Order approving the settlement. In some cases, the Board does not accept the proposed settlement.

8. The licensee may, instead of agreeing to the settlement, demand a hearing before the Board, at which he or she may call witnesses and present a case to the Board.

iii. Hearings by the Board

1. Hearings are quasi-judicial proceedings that are somewhat less formal than court proceedings, but adhere to the rules of evidence inherent in a court proceeding. Witnesses are sworn, as in a court hearing, and both the State and the licensee may present witnesses and cross-examine them.

2. The hearings of the Board of Pharmacy generally consist of a panel of five Board members (excluding
the Reviewing Board Member), and are presided over by an Administrative Law Judge from the Office of Administrative Hearings.

3. Pharmacists and other licensees are entitled to be represented by an attorney in all matters before the Board. Because of the complexity of legal issues, procedures, and the implications for the future practice of the licensee, I believe it is generally a good idea to consult with an attorney when a pharmacist first learns of a complaint. A licensee should choose an attorney with specific knowledge and experience in dealing with administrative law.

   a. Some professional liability insurance policies will reimburse pharmacists for some of their costs in retaining an attorney to deal with complaints filed by the Board. This protects the interests of the licensee, as well as the insurance company, since discipline of a pharmacist may affect the likelihood and outcome of civil suits filed as a result of the incident that prompted the complaint.

   b. The standard of evidence needed to discipline a pharmacist in Washington is a clear and convincing evidence standard – this standard requires the hearing panel to find with a high degree of probability that the licensee committed the charged conduct, as a result of the Supreme Court ruling in Nguyen v. State, Dep’t of Health, 144 Wn.2d 516, 29 P.3d 689 (2001). The Court held that the Department of Health had failed to use a clear and convincing standard of evidence in the suspension of a physician’s license. The factors requiring a heightened standard when disciplining physicians have been applied to lawyers, to professional engineers, and in an unpublished opinion in a disciplinary case involving a pharmacist.

   c. The recent Supreme Court decision in the Ongom (see Chapter 1) case has extended the clear and convincing standard to licensed nursing assistants, a class of licensees similar to pharmacy technicians or assistants. This should set a precedent by which the Board must use a clear and convincing evidence
The hearing panel will reach a decision, which the Board will ultimately apply as a final order. Discipline may take one or more of several forms:

- Fines
- Suspension of a license
- Revocation of a license for a specific period (usually 10 years), after which time the person may seek to be licensed
- Permanent revocation, if the board finds that the licensee can never be rehabilitated or regain the ability to practice with reasonable skill or safety.
- Probation
- Limitations on practice; such as requiring work under supervision, or prohibition against being an RPM or preceptor
- A requirement for additional continuing education, internship, or retaking of the law exam, or participation in a recovery or treatment program
- Staying of the imposition of the discipline during a probationary period, with abeyance of the discipline at the end of the probationary period

Licensees may petition for a reconsideration of the final order, and/or may appeal the decision to the Superior Court. A decision of the Superior Court may be appealed to the Appellate Court, and, subject to Supreme Court rules, to that body.

Disciplinary status indicated on license copy. The Department indicates on the printed license certificate whether the holder is on probation or has restrictions on his or her practice. The notice will read “Active on Probation,” or “Active with Restrictions.” The “Provider Credential Search” link on the Board of Pharmacy website allows a person to determine if a given licensee or firm has had disciplinary action taken against its license.

Sanctioning Guidelines. In 2006 and 2007 the DOH developed its first attempt at standardizing the imposition of sanctions against licensees who are disciplined by one of the boards or commissions within the department. The goal was to treat similar cases similarly, assure protection of the public, and the approach is similar to that

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used to discipline lawyers. Certain of the independent boards or commissions were reluctant to abandon their own sanctioning rules and resisted implementing the DOH guidelines. The 2008 Legislature required joint review by the health boards and commissions of the 2007 guidelines, and establishment of a uniform sanctioning schedule by emergency regulation by January 1, 2009. (RCW 18.130.390). The resulting regulation is found at WAC 246-16-800.

i. The sanctioning rules apply to active or expired credentials, not to applicants.

ii. Selection of sanctions by disciplinary authorities must adhere to the following:

1. Sanctions selected must protect the public, and, if possible, rehabilitate the license holder.

2. Suspension or revocation will be imposed when the license holder cannot practice with reasonable skill or safety.

3. Permanent revocation may be imposed when the disciplining authority finds the license holder can never be rehabilitated or can never regain ability to practice safely.

4. Surrender of credential may be imposed when the license holder is at the end of his/her effective practice and surrender alone is enough to protect the public. The license holder must agree to retire and not resume practice.

5. Indefinite suspension may be imposed in default orders.

iii. Deviation from these rules is allowed when the disciplining authority determines that the schedule does not adequately address the facts in a case.

iv. Disciplining authorities will use their judgment to determine appropriate sanctions if the sanction schedules do not address the misconduct.

j. Sanctioning process. When the disciplining authority has determined that a violation of the uniform disciplinary act has occurred. It shall follow a four-step process in determining the sanction to be applied.

i. Step 1. The nature of the misconduct is described in the findings of fact in an order or in the allegations in an informal disposition. The disciplining authority uses the misconduct described as select the appropriate sanction schedule.

248 2008 c 134 § 12.
1. If the act of misconduct falls in more than one sanction schedule, the greater sanction imposed.
2. If different acts of misconduct fall in the same sanction schedule, the highest sanction is imposed and the other acts of misconduct are considered aggravating factors.

ii. **Step 2.** The disciplining authority identifies the severity of the misconduct and identifies a tier using the sanction schedule tier descriptions.

iii. **Step 3.** The disciplining authority identifies aggravating or mitigating factors using the list in WAC 246-16-890. The disciplining authority describes the factors in the order or stipulation.

iv. **Step 4.** The disciplining authority selects sanctions within the identified tier.
   1. Aggravating factors move the appropriate sanctions towards the maximum end of the tier.
   2. Mitigating factors move the appropriate sanctions towards the minimum end of the tier.
   3. Mitigating or aggravating factors may result in the termination of the sanction outside the range of the tier.

k. **Sanction Schedules.** Six separate sanctioning schedules were created by DOH.

   i. **Practice below standard of care (WAC 246-16-810)**

<table>
<thead>
<tr>
<th>Severity</th>
<th>Tier / Conduct</th>
<th>Sanction Range</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>In consideration of Aggravating &amp; Mitigating Circumstances</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum</td>
<td>Maximum</td>
</tr>
<tr>
<td>least</td>
<td>A – Caused no or minimal patient harm or a low risk of minimal patient harm</td>
<td>Conditions that may include reprimand, training, monitoring, supervision, probation, evaluation, etc.</td>
<td>Oversight for 3 years which may include reprimand, training, monitoring, supervision, evaluation, probation, suspension, etc.</td>
</tr>
<tr>
<td></td>
<td>B – Caused patient harm or risk of severe patient harm</td>
<td>Oversight for 2 years which may include suspension, probation, practice restriction, training, monitoring, supervision, probation, evaluation, etc.</td>
<td>Oversight for 5 years which may include suspension, probation, practice restriction, training, monitoring, supervision, evaluation, probation, suspension, etc. OR revocation.</td>
</tr>
<tr>
<td>greatest</td>
<td>C – Caused severe harm or death to a human patient</td>
<td>Oversight for 3 years which may include suspension, probation, practice restriction, training, monitoring, supervision, probation, evaluation, etc. In addition - demonstration of knowledge or competency</td>
<td>Permanent conditions, restrictions or revocation.</td>
</tr>
</tbody>
</table>
### ii. Sexual misconduct or contact (WAC 246-16-820)

<table>
<thead>
<tr>
<th>Severity</th>
<th>Tier / Conduct</th>
<th>Sanction Range in consideration of Aggravating &amp; Mitigating Circumstances</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>least</td>
<td>A – Inappropriate conduct, contact, or statements of a sexual or romantic nature</td>
<td>Conditions that may include reprimand, training, monitoring, probation, supervision, evaluation, etc.</td>
<td>Oversight for 3 years which may include reprimand, training, monitoring, supervision, evaluation, probation, suspension, etc.</td>
</tr>
<tr>
<td></td>
<td>B – Sexual contact, romantic relationship, or sexual statements that risk or result in patient harm</td>
<td>Oversight for 2 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc.</td>
<td>Oversight for 5 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. OR revocation</td>
</tr>
<tr>
<td>greatest</td>
<td>C – Sexual contact, including but not limited to contact involving force and/or intimidation</td>
<td>1 year suspension AND oversight for 5 additional years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. AND demonstration of successful completion of evaluation and treatment</td>
<td>Permanent conditions, restrictions, or revocation</td>
</tr>
</tbody>
</table>

### iii. Abuse – Physical and emotional (WAC 246-16-830)

<table>
<thead>
<tr>
<th>Severity</th>
<th>Tier / Conduct</th>
<th>Sanction Range in consideration of Aggravating &amp; Mitigating Circumstances</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>least</td>
<td>A – Verbal or nonverbal intimidating, forceful contact, or disruptive or demeaning behavior, including general behavior not necessarily directed to a specific patient or patients</td>
<td>Conditions that may include reprimand, training, monitoring, probation, supervision, evaluation, etc.</td>
<td>Oversight for 3 years which may include reprimand, training, monitoring, supervision, evaluation, probation, suspension, etc.</td>
</tr>
<tr>
<td></td>
<td>B – Moderately abusive unnecessary or forceful contact or disruptive or demeaning behavior, including general behavior not directed at a specific patient or patients causing mental or physical injury</td>
<td>Oversight for 2 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc.</td>
<td>Oversight for 5 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. OR revocation</td>
</tr>
<tr>
<td>greatest</td>
<td>C – Severe physical, verbal, or forceful contact; or emotional disruptive behavior that results in significant harm or death</td>
<td>1 year suspension AND oversight for 5 additional years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. AND demonstration of successful completion of evaluation and treatment</td>
<td>Permanent conditions, restrictions, or revocation</td>
</tr>
</tbody>
</table>
iv. **Diversion of controlled substances or legend drugs**  
(WAC 246-16-840)

<table>
<thead>
<tr>
<th>Severity</th>
<th>Conduct</th>
<th>Sanction Range</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least</td>
<td>A</td>
<td>Conditions that may include reprimand, training, monitoring, probation, supervision, evaluation, etc.</td>
<td>Oversight for 5 years which may include reprimand, training, monitoring, supervision, evaluation, probation, suspension, etc.</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>Oversight for 2 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc.</td>
<td>Oversight for 7 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. OR revocation.</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>1 year suspension AND oversight for 5 additional years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. AND demonstration of successful completion of evaluation and treatment.</td>
<td>Permanent conditions, restrictions OR revocation.</td>
</tr>
</tbody>
</table>

**DIVERSION OF CONTROLLED SUBSTANCES OR LEGEND DRUGS**
v. **Substance abuse (WAC 246-16-850)**

<table>
<thead>
<tr>
<th>Severity</th>
<th>Tier / Conduct</th>
<th>Sanction Range in consideration of Aggravating &amp; Mitigating Circumstances</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>least</td>
<td>A – Misuse of drugs or alcohol with no to minimal patient harm or risk of harm</td>
<td>Conditions that may include reprimand, training, monitoring, probation, supervision, evaluation, etc.</td>
<td>Oversight for 5 years which may include reprimand, training, monitoring, supervision, evaluation, etc.</td>
</tr>
<tr>
<td></td>
<td>B – Misuse of drugs or alcohol with moderate patient harm or risk of harm</td>
<td>Oversight for 2 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc.</td>
<td>Oversight for 7 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. OR revocation.</td>
</tr>
<tr>
<td></td>
<td>C – Misuse of drugs or alcohol with severe physical injury or death of a patient or a risk of significant physical injury or death</td>
<td>1 year suspension AND oversight for 5 additional years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. AND demonstration of successful completion of evaluation and treatment.</td>
<td>Permanent conditions, restrictions OR revocation.</td>
</tr>
</tbody>
</table>

vi. **Criminal convictions (WAC 246-16-860)**

<table>
<thead>
<tr>
<th>Severity</th>
<th>Tier / Conviction</th>
<th>Sanction Range in consideration of Aggravating &amp; Mitigating Circumstances</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>least</td>
<td>A – Conviction of a Gross Misdemeanor except sexual offenses in RCW 9.94A.030</td>
<td>Conditions that may include reprimand, training, monitoring, probation, supervision, evaluation, etc.</td>
<td>Oversight for 5 years which may include reprimand, training, monitoring, supervision, evaluation, etc.</td>
</tr>
<tr>
<td></td>
<td>B – Conviction of a Class B, C, OR Unclassified Felony, except sexual offenses in RCW 9.94A.030</td>
<td>Oversight for 2 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc.</td>
<td>Oversight for 5 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. OR revocation.</td>
</tr>
<tr>
<td></td>
<td>C – Conviction of a Class A Felony, except sexual offenses in RCW 9.94A.030</td>
<td>5 years suspension</td>
<td>Permanent revocation</td>
</tr>
</tbody>
</table>
I. Aggravating and mitigating factors listed in WAC 246-16-890:

i. Factors related to the misconduct
   1. Gravity of the misconduct;
   2. Age, capacity and/or vulnerability of the patient, client, or victim;
   3. Number and frequency of the acts of misconduct;
   4. Injury caused by the misconduct;
   5. Potential for injury to be caused by the misconduct;
   6. Degree of responsibility for the outcome;
   7. Abuse of trust;
   8. Intentional or inadvertent act(s);
   9. Motivation is criminal, immoral, dishonest or for personal gain;
   10. Length of time since misconduct occurred.

ii. Factors related to the license holder
   1. Experience in practice;
   2. Past disciplinary record
   3. Previous character;
   4. Mental and/or physical health;
   5. Personal circumstances;
   6. Personal problems having a nexus with the misconduct.

iii. Factors related to the disciplinary process
   1. Admission of key facts;
   2. Full and free disclosure to the disciplining authority;
   3. Voluntary restitution or other remedial action;
   4. Bad faith obstruction of the investigation or discipline process or proceedings;
   5. False evidence, statements or deceptive practices during the investigation or discipline process or proceedings;
   6. Remorse or awareness that the conduct was wrong;
   7. Impact on the patient, client, or victim.

iv. General factors
   1. License holder's knowledge, intent, and degree of responsibility;
   2. Presence or pattern of other violations;
   3. Present moral fitness of the license holder;
   4. Potential for successful rehabilitation;
   5. Present competence to practice;
   6. Dishonest or selfish motives;
   7. Illegal conduct;
   8. Heinousness of the misconduct;
   9. Ill repute upon the profession;
   10. Isolated incident unlikely to reoccur.
m. As indicated above, most discipline of pharmacists arises from a limited number of possible charges. A review of Board reports over the last several years indicates that two major areas account for most discipline:
   i. Substance or alcohol abuse, and charges of diversion arising from that abuse. See Chapter 5 for a discussion of impaired pharmacist recovery programs.
   ii. Dispensing errors, particularly where
      1. The pharmacist failed to counsel the patient and counseling would likely have revealed the error;
      2. The pharmacist mislead the patient or otherwise dealt improperly with a patient's report of an error; or
      3. A repeated pattern of errors over time.

Comment: The increased specificity and complexity of the sanctioning process seems to me to increase the importance of obtaining competent advice from an attorney experienced in administrative law and applications of sanctions whenever a pharmacist, intern, or technician is faced with potential discipline.

2. Civil Lawsuits based on Contracts or Warranties. A person may file a civil lawsuit against a pharmacist when the pharmacist has a contractual or professional obligation to that person, and by some failure on the pharmacist's part, has cause the person to suffer an injury or loss. Two broad categories of civil lawsuits are those based on contracts, and those based on intentional wrongdoings, also known as torts.
   a. Contracts are voluntary agreements between two or more parties that are enforceable under the law.
      i. To be a valid contract, it must meet certain tests:
         1. It must be voluntary (a contract obtained by force or threats is not enforceable)
         2. It must be for a legal purpose
         3. It must be the result of an offer and an acceptance
         4. It must have resulted in exchange of mutual consideration, that is, each party must have given up something and gained something in return
      ii. Contracts can be established either verbally or in writing.
         1. Certain contracts, such as real estate, must be in writing.
      iii. The parties must be competent to enter into the contract
         1. Legally competent generally means adult status (18 or over)
         2. Mentally competent means that the person is mentally capable of understanding the nature of the contract
3. **Minors can enter into certain contracts**, such as a promise to pay for medical care, when it is in the interest of the minor to have done so. As noted in Chapter 6, minors can consent to care in certain circumstances, which may create a contract that can be enforced against either the minor or the responsible parent or guardian.

**iv. Contracts can be express, or implied**

1. **Express** contracts specifically set forth what the terms are of the contract. This can be done in verbal as well as written contracts.
2. **Implied** contracts are established by the actions of the parties.

b. If one party **breaches**, or fails to fulfill the contract, the other can sue for damages.

i. **Breaches of contract** usually involve one of two acts
   1. Failure to perform or fulfill the contract
   2. Negligent performance of the contract causing damages

ii. **Legal remedies** for breaches of contracts may include

   1. **Compelled performance**
      a. The party in breach may be forced to complete the service or deliver the goods as promised. For example, a person who has promised to buy a car, and then changes his mind, might be compelled to actually purchase the vehicle.

   2. **Monetary damages**
      a. Alternatively, the person in breach may be forced to pay the other party the losses incurred as a result of the breach
         i. These can include actual losses, such as decline in value of a piece of property as a result of the contract breach, or
         ii. Incidental losses, such as the cost of opportunities foregone

c. **“Promissory Estoppel.”** Sometimes an actual contract doesn’t exist, but the courts will treat a situation as if there were a contract

   i. **One party must have made representations** to the other
   ii. **The second party must have acted in reasonable reliance on those representations**
   iii. **The second party suffered a loss as a result of that reliance**
   iv. The **court will act as if an actual contract existed**
   v. This is called “promissory estoppel;” estoppel is Latin for an action to stop; the courts will “estop” the first party from claiming that a contract did not exist.
An example: A pharmacy chain manager contacts you in Spokane and asks you to come to Wenatchee to work in a new store. In reliance on the manager’s representations, you incur the cost of moving to Wenatchee, and also turn down a similar offer of employment in Spokane. However, the store does not open as planned, and you are now stuck in Wenatchee without a job. As seen below from employment law, most employment of pharmacists is “at will” and no employment contract actually exists. But because you reasonably relied on the manager’s representations that a job was waiting for you, and because you suffered direct costs of moving and also opportunity losses from turning down the Spokane job, you may have a valid claim for damages against the chain, based on the promissory estoppel doctrine.

d. **Warranties are “contracts”** that are attached to the sale of products.
   i. Like contracts, **warranties may be express or implied**.
      1. Some products, such as power tools, come with written warranties that are usually specifically limited in nature, and seek to establish exactly what the manufacturer is promising the product will do, and what will the manufacturer do if the product fails to perform. This limits the remedies available to the purchaser if the product is defective.
      2. Under common law, every sale of goods carries with it two **implied warranties**
         a. **Merchantability** or a warranty that the product meets the normal standards of goods of its type. For example, a pharmacy selling aspirin tablets should only sell tablets that are not decomposed into acetic acid.
         b. **Fitness for a particular purpose.** This warranty comes into play if the purchaser makes it clear to the seller that he or she intends to use the product for a particular purpose and the seller completes the sale. A pharmacist was approached by a group of high school students who had formed a “rocket club,” and were seeking potassium chlorate, sulfur, and charcoal to make the fuel. The pharmacist sold these ingredients to the boys. After one of the boys was injured in the resulting explosion, the pharmacist was sued, successfully. Although this particular case was decided on a negligence basis, it illustrates a
situation where a lawsuit might also be grounded in warranty law, since the pharmacist knew the purpose of the supplies was to make an explosive mixture. (*Krueger v Knutson*, 111 N.W.2d 526 (Minn. 1961))

c. Usually, manufacturers that provide written limited warranties specifically disclaim both of these common law implied warranties.

3. **Sales of commercial products in their own packaging.** Normally, when a pharmacist sells a commercial product (such as Tylenol PM) in its original package, the only warranties implied are those of the manufacturer, not the seller. However, if the pharmacist makes a claim for the product, he or she may create a warranty of fitness for a particular purpose, and become liable from any damages arising from the product’s use. Generally, this isn’t a problem for pharmacists, since they are knowledgeable about the products they sell and generally correct in the claims they make. However, the pharmacy can be bound by the representations of any of its employees, and a sales clerk or pharmacy assistant can create a warranty by the statements they make to purchasers of OTC drug products. To avoid this, pharmacies should have strong policies about who can make recommendations to patients.

e. **Layaways.** Many retailers, including pharmacies, sell non-pharmacy merchandise to customers on “lay-away plans.” These plans have been less used in recent years owing to the use by customers of credit cards. With the recent credit crunch and decreased availability of consumer credit, lay-away plans are becoming an import option to help convince customers to buy in a store rather than on-line. The Federal Trade Commission has published a guide to retailers to help them avoid misunderstandings and legal actions relating to lay-away programs. There are no specific federal laws (a few states have them) regarding lay-away programs, but the FTC Act prohibits deceptive trade practices, and the Truth-in-Lending Act may affect retailers who require customers to make all payments until the lay-away item is paid in full. Full and fair disclosure of your policies is the best approach to dealing with customers regarding lay-aways.249

f. **Products liability.**

   i. Generally, manufacturers may be held liable if they are negligent in the design or manufacture of a product, and under some circumstances may be held “strictly” liable, even

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312
if they can’t be shown to be negligent, as long as the product was defective and injured a party.

ii. **Usually, pharmacists are insulated from liability for dispensing a manufactured product** when the injury was caused by a defect that the pharmacist could not foresee or be aware of at the time of sale or dispensing, rather, the liability will be on the manufacturer.

iii. **Pharmacists who are the manufacturer of a product**, such as when they have promoted and compounded the product, may bear any liability that would normally attach to the manufacturer.

iv. **Pharmacists may also be held liable when they alter the manufacturer’s product in such a way as to make it defective.** For example, a pharmacist in Oregon was held liable for damage from the use of Lindane lotion when he dispensed the product without including the instructions and warnings provided by the manufacturer of the product.

   1. **Washington law (RCW 18.64.275) limits exposure of pharmacists for lawsuits based on**
      a. Strict liability
      b. Implied warranties under the Uniform Commercial Code

   2. **If they dispense a manufacturer’s product pursuant to a prescription without altering the product.**

   3. **Claims against pharmacists under these circumstances are limited to**
      a. Negligence
      b. Breach of an express warranty issued by the pharmacist
      c. Or intentional misrepresentation about the product or intentional concealment of information about the product

3. **Civil Lawsuits based on Torts.** Torts include a wide range of civil wrongs committed by one person against another.

   a. Some of the major torts are
      i. Libel, slander, and defamation of character.
      ii. Assault or battery
      iii. False imprisonment or false arrest
      iv. Intentional infliction of emotional distress or outrage
      v. Invasion of privacy
      vi. Negligence

   b. **Libel, slander and defamation**
      i. **Defamation** – written or spoken words that falsely and negatively reflect on a living person’s character. In
Washington law, there are not separate offenses of libel or slander – both are treated as defamation.

ii. **Libel** – written or broadcast defamation

iii. **Slander** – spoken defamation

iv. **Defenses:**

1. Truth of the statements
2. Statements were not made to other persons
3. Statements were made in circumstances which afford a conditional privilege
   a. Made in the public interest;
   b. Made without malicious intent; and
   c. Made without actual knowledge of their falsity or in reasonable reliance on the source of the information

c. **Assault or battery**

i. **Assault** –

1. An intentional, unlawful threat or "offer" to cause bodily injury to another by force;
2. Under circumstances which create in the other person a well-founded fear of imminent peril;
3. Where there exists the apparent present ability to carry out the act if not prevented.

ii. **Battery** –

1. A battery is the willful or intentional touching of a person against that person’s will by another person, or by an object or substance put in motion by that other person. Any offensive touching can constitute a battery even if it does not cause injury, and could not reasonably be expected to cause injury. A defendant who emphatically pokes the plaintiff in the chest with his index finger to emphasize a point may be culpable for battery (although the damages award that results may well be nominal). A defendant, who spits on a plaintiff, even though there is little chance that the spitting will cause any injury other than to the plaintiff's dignity, has committed a battery.

iii. **Privilege** – to be assault or battery, the defendant must have lacked “privilege” to commit the act. Some bases for privilege are:

1. **Consent** -- if the person consents to the assault, as in football, or the touching, as in authorized medical procedures or physical exams, there is no offense. However, lack of informed consent to a medical procedure creates a battery.
2. **Police conduct** – police are authorized to use reasonable force in the performance of their duties
3. **Self defense or defense of others** – a pharmacist who physically restrained a customer who was about to attack another customer could be found to have privilege on the grounds of defense of others.

4. **Merchant’s Privilege** -- Most jurisdictions grant merchants the right to apply reasonable force to detain shoplifters, or other persons who the merchant reasonably believes are attempting to steal the merchant's property. This privilege might justify a pharmacist detaining a person who is caught trying to walk off with controlled substances from the pharmacy.

   iv. **Absent privilege**, pharmacists and pharmacy employees need to avoid physical touching of customers or patients without their permission, or threatening force. If needed, it is best to call police and allow them to exercise their authority.

   d. **False imprisonment or false arrest.** These torts involve physically or by threat of force detaining a person without a legal reason. Pharmacies are often involved in claims of false arrest when dealing with shoplifters, or when the pharmacist delays delivering a prescription to a patient while waiting for the police to arrive to investigate a suspicious prescription. Unless the pharmacist has personally used force or intimidation, these claims rarely prevail, but they do require defending. To avoid liability, the pharmacist should not imply to the person that they aren’t free to leave the pharmacy. If the police cannot arrive in a reasonable time, it is better to let the patient leave with the medication or their prescription and the police have the option of following up later.

   i. The “merchant’s privilege” may be a bar to false arrest claims in some jurisdictions

   e. **Intentional infliction of emotional distress**

      i. The tort of intentional infliction of emotional distress has four elements:

         1. the defendant must act intentionally or recklessly;
         2. the defendant's conduct must be extreme and outrageous; and
         3. the conduct must be the cause
         4. of severe emotional distress.

      ii. Examples of claims that have been filed against pharmacists include

         1. charges of sexual harassment in the work place (the pharmacist supervisor being sued by an employee)
         2. that a pharmacist revealed a patient’s HIV status to his family.
         3. These claims are often alleged following a dispensing error, for example, by the parents of a child who died
while they were administering the drug that was dispensed wrongly.

4. These claims are often a means to seek damages for a family member who was not the one directly injured by a pharmacist’s negligence.

f. **Invasion of privacy** may be alleged when the pharmacist reveals confidential information to others.
   i. Many cases arise from release of medical records to a spouse, particularly in relationship to divorce proceedings and child custody cases. Even when the pharmacy has received a subpoena from a party in a civil lawsuit, the records should not be released until the patient has been informed of the subpoena and given an opportunity to have it “quashed,” or invalidated by a court. A 1977 Rhode Island case illustrates this issue. In response to a subpoena by the patient’s estranged husband, the pharmacy mailed the records without first informing the patient or obtaining her consent. The Rhode Island Supreme Court found that there was a legal basis for the patient to sue the pharmacy for violation of the state’s confidentiality act as well as for violating her rights of privacy.
   ii. In a Washington case, a county sheriff was obtaining controlled substances from multiple physicians and multiple pharmacies. A pharmacist in the community notified the Board, who then examined the records of the other pharmacies and ultimately filed a report with the County Prosecutor that led to charges filed against the sheriff. He ultimately sued the Board for invasion of privacy. In this case, the courts ultimately held that the Board had the right to inspect pharmacy records and the sheriff had no expectation that his records could not be so examined.
   iii. Some bizarre behavior has been reported in which pharmacists have been sued for invasion of privacy, for example an independent pharmacy owner who installed cameras in the restrooms of the pharmacy – ostensibly to protect against shoplifting.

g. **Negligence.** The most common tort cases against pharmacies involve allegations of malpractice, or professional negligence.
   i. To establish a case of negligence, the plaintiff must prove **four elements:**
      1. That the pharmacist owed a **duty** to the plaintiff.
      2. That the pharmacist **breached** the duty.
      3. That the plaintiff was **injured**.

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250 Washburn v Rite Aid Corp, 695 A.2d 495 (Supr. Ct. R.I., 1997)
4. That the **proximate cause** of the injury was the pharmacist’s breach of his or her duty.

**ii. Duty of care**

1. Pharmacist must use the degree of care of a reasonable and prudent person under similar circumstances.
2. The “person” is a well-educated pharmacist considered competent to practice
3. Duty arises from relationship to patient
4. Existence of duty arises from foreseeability of harm

**iii. Breach of duty**

1. Pharmacist’s conduct fell below the standard of practice
2. National or statewide standard, not local
3. Courts may impose a higher standard than current practice
4. Standard is usually established by expert witness
5. Standard may be set by a law or regulation
6. Traditional duties
   a. Accurate dispensing
      i. Interpretation of Rx
      ii. Skilled compounding
      iii. Correct product
      iv. Correct label
   b. Detect obvious errors, particularly lethal overdoses
   c. Give package to the correct patient
   d. Don’t fill/refill beyond instructions
   e. Recognize false/fraudulent prescriptions
7. Negligence per se
   a. Pharmacist clearly violates a statute or regulation, and
   b. Plaintiff is member of class of persons the statute or regulation was intended to protect, and
   c. Harm that resulted was the type of harm the statute or regulation was intended to prevent; then
   d. Court may adopt the statute or regulation as standard of care, and
   e. Plaintiff need only prove causation and damages

**iv. Causation**

1. The plaintiff must prove that the pharmacist’s breach was the proximate cause of the injury. This involves proving that unless the pharmacist had breached the
duty the injury would not have occurred, and also that no subsequent act or omission of another – unforeseeable by the pharmacist – was more a more direct cause of the injury.

v. **Damages**

1. **Goal:** return plaintiff to the position in which the plaintiff would have been were it not for the pharmacist’s negligence
2. **Actual damages**
   a. Dollar losses (care, lost wages, etc.)
   b. Pain and suffering
   c. Emotional and relational
3. **Punitive (exemplary) damages**
   a. Wanton and reckless disregard of patient’s rights, or morally culpable behavior
   b. Designed to punish defendant or set an example to discourage similar conduct
   c. Often treble; not taxable to plaintiff
   d. One of the goals of “tort reform” at the state and federal level is to either eliminate punitive damages or place a “cap” on how much can be awarded.

vi. **Informed consent.** One of the duties a prescriber owes to a patient is the duty to obtain the informed consent of the patient to the treatment. Providing treatment without consent is an assault under common law. This obligation grew in importance during the latter half of the 20th century, with the recognition of the legal and ethical obligation to allow patients to participate in decisions concerning their care.

1. **Underlying Basis of the Doctrine.** The great American jurist, Benjamin Cardozo, when he was a Justice of the New York Court of Appeals, characterized the underlying basis of informed consent in a famous opinion: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages."^[252]

2. **Patients May Refuse Treatment.** It is generally recognized that if competent patients must give consent to care, they can also refuse it; this applies to even life-saving therapy or life-sustaining treatments, including food and hydration.^[253] One of the exceptions

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^[252] Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914)

to this rule is that mentally ill prison inmates may be forced to take psychotropic medications if necessary to reduce their danger to others as long as it is medically in their interest as well.\textsuperscript{254}

3. Sometimes the duty to obtain informed consent is characterized as a “\textit{duty to warn}” of the hazards of treatment. In general, courts have found this duty to fall on the prescriber, not the dispenser, of prescription drugs. The Washington Supreme Court has held that a pharmacist, who is dispensing medications pursuant to a lawful prescription, has no duty to warn patients of all dangers of prescription drugs: “Nothing in RCW Ch. 18.64 nor in WAC 360-16 [now WAC 246-869] requires pharmacists to disclose all contraindications or warnings.”\textsuperscript{255} This opinion in the landmark McKee case, was written before the passage of OBRA-90, but it was reasserted in an appellate decision in 1999.\textsuperscript{256}

\begin{itemize}
\item[a.] However, this was based on the Court’s holding that the \textit{duty to warn} rested with the \textit{prescriber of the drug}. It is clear to all, though there has yet to be a case to test the assumption, that if the pharmacist is the \textit{prescriber of a drug}, he or she has the same obligation to obtain informed consent from the patient that any other prescriber obtains.
\end{itemize}

4. In general, the \textbf{following elements must be included} in the information provided to patients when obtaining their consent to therapy.

\begin{itemize}
\item[a.] The nature and purpose of the therapy.
\item[b.] The likely benefits.
\item[c.] The material risks of therapy.
\item[d.] The alternatives which are available, including the alternative of doing nothing. (See the section below discussing Washington’s codification of these requirements in RCW 7.70.050.)
\end{itemize}

5. \textbf{Consent may be obtained orally or in writing.} The use of a consent form, signed by the patient or other person competent to give consent for the patient, is evidence that consent was obtained.

\textsuperscript{255} McKee v American Home Products, 782 P.2d 1045, 1054 (1989)
\textsuperscript{256} Silves v. King, 93 Wn. App. 873 (1999)
6. **Minors may consent to care in Washington State.** Both statute and court decisions in Washington have made it legally viable for minors to consent to necessary medical care (see Chapter 6). The same consent procedures are necessary for a qualified minor as for adults.

vii. **Defenses to negligence claims**

1. **Contributory or comparative negligence** – the plaintiff contributed to the harm by his or her own actions
   a. In most states, the jury can assign some percentage of the damages to the plaintiff, thus reducing the damage award imposed on the defendant, however, the defendant will still be liable.

2. **Statute of limitations**
   a. A time in which the injured party must file or the case cannot be brought.
   b. Dates from time of injury
      i. If the patient could not reasonably have discovered the injury, then the time can begin when the injury was actually discovered
      ii. May be extended if the defendant undertook to prevent discovery or hide the fact of injury from the patient
      iii. May be extended in the case of injury to minors (not in WA)

viii. **Washington rules governing negligence lawsuits against pharmacists.**

1. **90-day notice and mandatory mediation.** In Washington, no lawsuit may be filed against a health care provider for negligence unless the plaintiff provides a notice to the defendant at least 90 days prior to filing the lawsuit. During the 90-day period, the suit is subject to mandatory mediation.
   a. **Certificate of Merit not required in Washington.** About 25 states have passed statutes to require the plaintiff to submit, at the time the lawsuit is filed, a certificate of merit (sometimes known as affidavits of reasonable cause) in which a licensed health professional in the same profession as the defendant must attest there is a reasonable probability that the

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257 RCW 7.70.100
defendant fell below the standards of care.\textsuperscript{258} Washington law required a certificate of merit starting in 2006.\textsuperscript{259} The Washington Supreme Court in 2009 determined that this statute violated the constitutional separation of powers between the Legislature and the Courts and declared the statute invalid.\textsuperscript{260}

2. **Statute of Limitations for Health Care Negligence Lawsuits.** The state of Washington has enacted statutory rules for limiting the time to file claims of negligence against health professionals, in RCW 4.16.350.

   a. **Who’s covered?** The chapter applies to lawsuits alleging professional negligence against “A person licensed by this state to provide health care or related services, including, but not limited to, a physician, osteopathic physician, dentist, nurse, optometrist, podiatric physician and surgeon, chiropractor, physical therapist, psychologist, pharmacist, optician, physician’s assistant, osteopathic physician’s assistant, nurse practitioner, or physician’s trained mobile intensive care paramedic.” Also covered are suits against employees of the foregoing or employers of the foregoing.

   b. **Time limit for filing.**
      
      i. 3 years from date of the act or omission alleged to have caused the injury; or
      
      ii. 1 year from the time at which the patient discovered or should have discovered that the act caused the injury, whichever is later; but
      
      iii. No more than 8 years in any case
         
         1. Exception: proof of fraud, concealment, or presence of a foreign body not intended to have a therapeutic effect, in which case the time limit is 1 year from the plaintiff’s actual knowledge
         
         2. This 8-year “statute of repose” was challenged in a 1998

\textsuperscript{258} Fassett WE. Do affidavits of reasonable cause and certificates of merit impair access to courts or violate the separation of powers? Rx Ipsa Loquitur 2009 Sep/Oct; 36(5): 2,5.

\textsuperscript{259} RCW 7.70.150

\textsuperscript{260} Putman v. Wenatchee Valley Medical Ctr.,166 Wn.2d 974, 216 P.3d 374 (2009)
Supreme Court case\textsuperscript{261} on the basis that the legislature had failed to articulate a rationale for the limit. The 2006 Legislature re-enacted this 8-year limit, with a statement of its rationale, which will apply to actions commenced on or after June 7, 2006.\textsuperscript{262}

iv. Washington law relating to health care malpractice suits imputes knowledge of the custodial parent or guardian of a minor to the minor, so there is no extension of these limits for minors; they are treated as if adults were injured.

3. The elements necessary to establish a negligence claim against a pharmacist are specified in RCW 7.70.

\ \textit{a.} No award shall be made in any action or arbitration for damages for injury occurring as the result of health care which is provided after June 25, 1976, unless the plaintiff establishes one or more of the following propositions:

\begin{enumerate}
\item That injury resulted from the failure of a health care provider to follow the accepted standard of care;
\item That a health care provider promised the patient or his representative that the injury suffered would not occur;
\item That injury resulted from health care to which the patient or his representative did not consent.
\end{enumerate}

Unless otherwise provided in this chapter, the plaintiff shall have the burden of proving each fact essential to an award by a preponderance of the evidence. (RCW 7.70.030)

\textit{b.} The following shall be necessary elements of proof that injury resulted from the failure of the health care provider to follow the accepted standard of care:

\begin{enumerate}
\item The health care provider failed to exercise that degree of care, skill, and learning expected of a reasonably prudent health care

\textsuperscript{261} DeYoung v. Providence Medical Ctr., 136 Wn.2d 136 (1998)
\textsuperscript{262} 2006 c 8 §§ 301-302.
provider at that time in the profession or class to which he belongs, in the state of Washington, acting in the same or similar circumstances;

(2) Such failure was a proximate cause of the injury complained of. (RCW 7.70.040)

C. Claims for failure to obtain informed consent.

(1) The following shall be necessary elements of proof that injury resulted from health care in a civil negligence case or arbitration involving the issue of the alleged breach of the duty to secure an informed consent by a patient or his representatives against a health care provider:

(a) That the health care provider failed to inform the patient of a material fact or facts relating to the treatment;

(b) That the patient consented to the treatment without being aware of or fully informed of such material fact or facts;

(c) That a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of such material fact or facts;

(d) That the treatment in question proximately caused injury to the patient.

(2) Under the provisions of this section a fact is defined as or considered to be a material fact, if a reasonably prudent person in the position of the patient or his representative would attach significance to it deciding whether or not to submit to the proposed treatment.

(3) Material facts under the provisions of this section which must be established by expert testimony shall be either:

(a) The nature and character of the treatment proposed and administered;

(b) The anticipated results of the treatment proposed and administered;

(c) The recognized possible alternative forms of treatment; or

(d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment administered and in the recognized possible alternative forms of treatment, including nontreatment.
(4) If a recognized health care emergency exists and the patient is not legally competent to give an informed consent and/or a person legally authorized to consent on behalf of the patient is not readily available, his consent to required treatment will be implied. (RCW 7.70.050)

d. **Use of Consent Forms.** Washington specifies that the use of a consent form with certain required elements is sufficient to prove that the patient consented. If a patient while legally competent, or his representative if he is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:

- (1) A description, in language the patient could reasonably be expected to understand, of:
  - (a) The nature and character of the proposed treatment;
  - (b) The anticipated results of the proposed treatment;
  - (c) The recognized possible alternative forms of treatment; and
  - (d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;

- (2) Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in subsection (1) of this section.

Failure to use a form shall not be admissible as evidence of failure to obtain informed consent. (RCW 7.70.060)

As noted above, minors may also consent to several types of medical care as a result of statute or court decision. It is likely that a minor's signature on a consent form for a procedure that he or she has a legal right to consent to will be treated under this statute as
if an adult had consented. Where the minor is consenting based on a provider’s determination that they meet the requirements of the Mature Minor Doctrine, it is probably advisable that the consent form or related record document the provider’s evaluation and determine of the minor’s status under the doctrine. (See Chapter 6)

e. **The Washington Supreme Court has held** that **expert testimony concerning the standard of practice of a given health profession must be provided by a member of that profession**, and, more particularly, that a “licensed pharmacist is not competent to testify as an expert regarding the standard of care that a physician must meet when prescribing medication.”\(^\text{263}\) This holding has led the courts in Washington to be highly restrictive in allowing non-physician testimony in negligence cases. For example, the Washington Appeals court decided that nurses could never testify to causation in a medical malpractice action.\(^\text{264}\) This same court, however, had decided a year previously that a physician with extensive experience supervising nurses could testify to the standard of care of a nurse.\(^\text{265}\) More recently, though, the same appellate division concluded that “we now question that decision,” and opined that “the scope of the expert’s knowledge, not his or her professional title, should govern the threshold question of admissibility of expert medical testimony in a malpractice case.”\(^\text{266}\) The same Court held in the same year that under the specific facts of a case, the physician expert (a radiologist) did not demonstrate actual expertise sufficient to testify to the standard of care owed by nurses or other hospital employees.\(^\text{267}\) Nevertheless, unless the specific facts of the case demand, most of the time when a pharmacist is sued for

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malpractice, the expert who is providing a conclusion about the quality of the defendant’s practice will be a pharmacist.

ix. Malpractice insurance
1. Pays damages awarded against insured, up to policy limits
2. In addition, pays costs of defending insured and providing services of an attorney
3. Does not pay for defending against damages due to illegal acts
4. Employees should have own insurance
   a. Provides insured with his or her own attorney
   b. Interests of employer and employee may differ
      i. Settlement may be desired by employer, but not employee
      ii. Settlement may be used as evidence by board of pharmacy in a hearing
      iii. Employers may sue employee to recover their insurance losses

4. Employer-employee issues. In the US and Washington, employer-employee relationships are governed by a variety of statutes and common law principles. Among the issues are
   a. The nature of the employment contract
      i. At Will. Most employees are “at will,” meaning that they may be terminated without notice, and they may quit without notice. If a pharmacist does not have a written contract, or a company employee’s manual that specifies otherwise, he or she should presume that he or she is an at-will employee
         1. Company manuals may constitute a contract. For example, if they specify certain procedures to be followed before an employee can be terminated for cause, the company must follow those procedures. In general, employers must follow their own policies.
         2. Termination. At will employees can be terminated “for cause”, or can be terminated with no reason given
            a. If a reason is given, the employee may be able to challenge the underlying facts
         3. Members of a union are governed by the terms of the union contract, and the union has a right to represent their members’ interests.
            a. Private-sector collective bargaining is federally regulated by the National Labor Relations Act of 1935 (the Wegner Act), as amended by the Labor-Management Relations Act of 1947 (the
Taft-Hartley Act; 29 USC 141). The National Labor Relations Board enforces the law.

b. Once a union has been recognized, it is mandatory that employer and union negotiate on “wages, hours, and other terms and conditions of employment.” Refusal to bargain is an “unfair labor practice.”

4. Employees of governments obtain property and liberty interests in continued employment, and have constitutional due process rights that can be asserted, in addition to provisions of state civil service laws, agency policies, and written contracts of employment. States may by statute specify the rules for collective bargaining by state employees. Washington has done so.

ii. Term Contracts. Employees with contracts are said to be “term” employees, and have rights to continued employment during the term of the contract:

1. They may be terminated, furloughed, layed off, or reduced in hours under the terms of the contract, including a certain notice period;
2. They may be restricted from quitting without a minimum notice, or lose certain benefits or be forced to pay damages;
3. They may be terminated “for cause,” such as
   a. Non-performance
   b. Inadequate performance
   c. Violations of law or company policy
   d. Actions against the interest of the company
   e. Insubordination (failing to follow orders of superiors)

iii. Covenants not to compete. Some employers may seek to have certain professional employers sign “non-competition” clauses, preventing them for working for a competitor or setting up a competing business in the same locale. This is unusual for pharmacists working in retail pharmacies or chains, but is often done for consultant pharmacists, who might take substantial business away from the employer upon their leaving. Courts will look to the reasonableness of such clauses:

1. They must be for a reasonable time limit
2. They must be reasonable in scope (eg, cannot prohibit all employment, only that which is truly competitive with the employer)
3. They must be reasonable in geographic area
4. There should be **specific consideration** related to the non-competition portion of the employment contract, such as a specific payment to the employee if the employer exercises the options under the non-competition agreement. In Washington, specific consideration is considered to exist if the non-competition agreement is entered into at the time of employment. However, specific independent consideration must be proven if the non-competition agreement is developed after the start of employment.\(^\text{268}\)

iv. **Personnel files.** Every employer in Washington is required to maintain a record of every employee, and to permit the Department of Labor and Industries to inspect the record.

1. **Employees may inspect their own personnel files at least annually.** (RCW 49.12.240)

2. **Employees may petition employer to review** their personnel files and correct or remove irrelevant or erroneous information. If the employee disagrees with the employer’s determination, the employee may have his or her rebuttal or correction statement placed in the file. The right to rebut or correct the file shall continue for 2 years following termination of employment. (RCW 49.12.250)

3. Inspection rights do not apply to the records of an employee related to investigation of a possible criminal offense, or to records compiled in preparation for an impending lawsuit which would not otherwise be discoverable. (RCW 49.12.260)

v. **Providing references.** Employers are often asked to provide references concerning, or information about the performance of former employees. Employers often limit themselves to reporting the bare facts of employment, such as dates of employment. They fear being sued for defamation if they make negative comments concerning an employee’s performance. As a result, “problem employees” are often passed on from one firm to another. In the case of health care practitioners, this perpetuates danger to patients.

1. The 2005 Washington Legislature established **immunity for disclosure of employee information to a prospective employer** in RCW 4.24.730. If an employer provides information to another prospective employer, or employment agency, at the specific request of that employer or agency, he or she is “presumed to be acting in good faith and is immune

from civil and criminal liability for such disclosure or its consequences,” provided that the disclosed information relates to:

a. The employee’s ability to perform his or her job
b. The diligence, skill, or reliability with which the employee carried out the duties of his or her job; or
c. Any illegal or wrongful act committed by the employee when related to the duties of his or her job.

2. The Act states that the employer making the report should keep a record of the identity of the person or agency to whom the disclosure was made for a minimum of 2 years.

a. The former employee has a right to inspect such a written record upon request;
b. Such a written record becomes part of the employee’s personnel file.

3. The presumption of good faith may be rebutted by the former employee by showing clear and convincing evidence that the information was

a. Knowingly false;
b. Deliberately misleading; or
c. Made with reckless disregard for the truth.

b. Is the employer liable for the acts or omissions of his or her employees?

i. Vicarious Liability: Common law makes employers “vicariously liable for the acts of their employees.” This is sometimes called the doctrine of “respondeat superior” (“let the Master answer”). Any act or omission of an employee, which is committed within the scope of his or her employment, can make the employer liable for damages to a third party.

ii. Employer negligence. Employers can also be sued for damages arising from their negligence in selecting, training, or supervising their employees. For example, a pharmacy that hires a pharmacist without demanding to see a current license, and without checking to see if the pharmacist is currently disciplined or suspended, may be found negligent in selecting that employee if the employee injures a patient through his or her actions.

1. Note that WAC 246-869-060 requires pharmacy employers to obtain suitable evidence of the pharmacist’s licensure and qualifications before allowing the pharmacist to practice in the pharmacy.
Washington’s employer liability law is fairly stringent, and regards an employee’s acts as being imputed to the employer as long as any portion of the act is done for the employer’s benefit. For example, a technician agrees to deliver several prescriptions to a nursing home on his way home after his shift has ended. Believing that there is “no rush,” the technician stops off at a tavern and becomes intoxicated. On the way to the nursing home, the technician’s car collides with a pedestrian, severely injuring him. Under Washington law, the pharmacy may be held liable for the injuries. This hypothetical example relating to pharmacy is loosely based on actual cases involving other businesses, including Smith v. Leber, 34 Wn.2d 612 (1949).

c. Laws providing for non-discrimination in employment. A very significant percentage of lawsuits against pharmacies are based on employment discrimination. The consequences for the employer can be substantial. In a recent case, a verdict of $2 million, which included $1 million in punitive damages, was upheld by the Massachusetts Supreme Court against a pharmacy chain for failing to pay a woman pharmacist a salary equivalent to her male counterparts, and for retaliating against her when she complained. The federal laws listed below typically have state counterparts.

i. Title VII of the Civil Rights Act of 1964 (42 USC 2000) is the principal federal anti-discrimination law, and it applies to all firms who employ 15 or more employees. It makes it an unlawful employment practice for an employer

1. To fail or refuse to hire or to discharge any individual, or otherwise discriminate against any individual with respect to his
   a. Compensation
   b. Terms
   c. Conditions, or
   d. Privileges of employment

2. Because of such individual’s
   a. Race
   b. Color
   c. Religion
   d. Sex, or
   e. National origin.

ii. Other federal laws prohibit discrimination based on
   1. Age (greater than 40) – the Age Discrimination in Employment Act (ADEA) of 1967
      a. Applies to employers of 20 or more people

b. Prohibits mandatory retirement for most employees
c. Prohibits Title VII-type discrimination based on age greater than 40

a. Prohibits discrimination in hiring or employing individuals on the basis of their pregnancy
b. Requires pregnant employees to be treated the same as other individuals with medical disabilities
c. Prohibits “fetal protection policies” restricting pregnant women from “dangerous” jobs as long as the woman can perform the essential functions of the job (eg, prohibiting a pregnant pharmacist from working with chemotherapy agents)
d. Requires that employers who provide parental leave for new mothers must provide same leave for new fathers

3. Gender – Equal Pay Act of 1963
a. Applies to employers of 2 or more employees engaged in interstate commerce or in the production or handling of goods in interstate commerce (eg, prescription drugs)
b. Requires “equal pay for equal work” – may not pay men more for the same work, or work requiring
   i. The same skill,
   ii. The same effort,
   iii. The same responsibility, and which is
   iv. Performed under similar conditions

4. Disability – the Americans with Disabilities Act of 1990
a. Applies to employers with 15 or more employees
b. Prohibits discrimination against individuals with disabilities in
   i. Employment
   ii. Public services
   iii. Public accommodations (a pharmacy open to the public generally is considered a public accommodation)
c. In employment, cannot discriminate against “qualified” individuals based on their disability
   i. A qualified individual is one who
1. can perform the “essential functions” of the job
2. with or without accommodation
   ii. Must make “reasonable accommodations” for employees with disabilities to help them perform a job function
   1. Not required to make an accommodation that would be an “undue financial hardship”
      1. Financial hardship is measured against the size and resources of the employer
      2. For employers with multiple divisions or units, the resources are measured at the corporate level
   2. Not required to make an accommodation that would pose a danger to the employee, the public, or co-workers

d. The Rehabilitation Act of 1973 applies to employers with $2,500 or more worth of federal government contracts (including pharmacies accepting Medicaid or Medicare payments); also to states receiving federal assistants
   i. May not discriminate on the basis of mental illness or physical handicap
   ii. Must make accommodations similar to those required under the ADA
   iii. Qualified individuals determined as under the ADA

iii. General procedure for proving a case of discrimination
   1. Discrimination can take one of two forms
      a. Disparate treatment – an individual protected by the law is actually treated differently than similarly situated persons because of his membership in a protected class
         i. Example: a woman staff pharmacist in a hospital is paid less than the three male staff pharmacists
      b. Disparate impact or adverse impact – members of a protected class are treated
differently as a result of an ostensibly neutral company policy
  i. Example: job sharing is allowed (a policy whereby two employees can share the same position, with each working less than full time – desirable to many working mothers), but no one in a job sharing situation can be the Head Pharmacist.

2. The following **process** must be followed
   a. The employee files a complaint with the federal Equal Employment Opportunity Commission (or a state equal opportunity commission which has been delegated authority to investigate these claims – in Washington, employees contact the EEOC)
      i. The employee must establish a “prima facie” case of discrimination
      ii. Must show that the employee is in a protected class
      iii. Must show that the employee was treated differently than other members who are not in the class, either because of disparate impact or disparate treatment
      iv. The evidence must create an “inference of discrimination”
   b. If this burden is met, then the EEOC certifies the action, and the employer now bears the burden of rebutting the inference of discrimination, by demonstrating a “legitimate nondiscriminatory reason for the action or policy that the employee alleges is discriminatory.”
      i. Example: We paid the woman pharmacist less, but she has a BS degree with no advanced training, whereas all three male employees have PharmD degrees and have completed residencies or MS degrees.
   c. The burden then shifts to the employee to demonstrate that the “legitimate nondiscriminatory reason” is a pretext, that it is unworthy of belief
      i. Example: I only have a BS degree, but I have 20 years of experience, and all of
us do exactly the same thing – compound IV admixtures, so their extra credentials aren’t a bona fide qualification for the position.

iv. **Managerial Responsibility.** Managers or supervisors can make the firm liable for discrimination even if they are not the person doing the discriminating, as long as they have notice and have not taken immediate and appropriate corrective action.

1. This is especially an issue when sexual harassment is being alleged.
   a. Harassment can be “quid pro quo,” where employment or benefits of employment are conditioned upon exchange of sexual favors, or are threatened if sexual favors are not granted.
   b. Harassment can also arise from a hostile or offensive environment, where the employer and managers tolerate unwelcome sexual advances, jokes, or ridicule, or other behaviors that are based on sex and interfere with the employee’s work performance or create an intimidating, hostile or offensive working environment.

2. A pharmacist may be a manager or supervisor to whom a report of harassment creates a need for the company to take action. In a recent Washington case, an employee of a large retailer alleged harassment by a manager of a non-pharmacy department. The employee worked at part time in the pharmacy, and part-time in another department, but not the one managed by the harassing manager. At one point, the employee mentioned to the head pharmacist that she was being harassed by the other employee. She alleged that the head pharmacist did not notify anyone above him in the organization, and that the company failed to take action until after she reported additional incidents to another assistant manager some months later. The court held that the communication to the pharmacist created knowledge on the part of the firm of the harassment, thus making them liable for not taking immediate corrective action.⁷⁷⁰

**d. Salaries and payment of overtime.** The federal **Fair Labor Standards Act** (FLSA) affects salaries for employees engaged in

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interstate commerce or in the production of goods for interstate commerce.

i. It sets a federal minimum wage -- $7.25 per hour effective July 24, 2009.
   1. Many states have minimum wage laws – Washington’s minimum wage is $8.55 per hour in 2009, with a mandatory time-and-a-half for work beyond 40 hours in a week (14- and 15-year olds may be paid 85% of the minimum wage, or $7.27 per hour). In 2009, Washington has the highest minimum wage in the U.S.

ii. It requires premium pay for more than 40 hours work in a given week

iii. Salaried managers and professionals are exempted from the overtime and minimum hourly wage requirements of the FLSA.

e. Employment of minors. State laws govern employment of minors; for Washington, the minimum age for most jobs is 14, and minors under age 18 must have a work certificate issued by the Department of Labor and Industry. There are limits on how many hours can be worked by minors during a school week. Prohibited work activities for minors include:
   i. Regular driving of motor vehicles to make deliveries. 17 year olds may drive only during daylight hours, if properly licensed for the type of driving involved, subject to other restrictions.271 (RCW 49.12, WAC 296-125-030)
   ii. Working at heights greater than 10 feet off the ground or floor level.
   iii. Working past 8 p.m. without supervision by someone 18 years or older who is on the premises at all times.
   iv. Working in jobs with possible exposure to bodily fluids, or radioactive and hazardous substances.

f. Unemployment compensation. The Washington Employment Security Department provides unemployment compensation that is funded through mandatory employer contributions. It also provided job training and retraining programs, and employment assistance resources statewide. Its website is http://www.esd.wa.gov/

g. Laws governing employer-provided health care plans or other benefits. (See also Chapters 6 and 8)
   i. ERISA. Retirement and benefit plans are established under the federal Employee Retirement Income Security Act (ERISA) which preempts state laws to the contrary for qualifying plans. Companies’ prerogatives to use Pharmaceutical Benefits Managers or limit employees to

certain providers have generally not been assailable by state insurance laws because of ERISA protection.

ii. **COBRA and HIPAA.** The right to maintain insurance protection upon termination of employment is covered by certain provisions of COBRA-86 and HIPAA, which are discussed in Chapter 6.

h. **Occupational Safety**

i. **OSHA.** Federal law governs provision of safety in the workplace under the Occupational Safety and Health Act, which is administered by the Occupational Safety and Health Administration (OSHA). Similar state requirements for on-the-job safety are established by the Washington Industrial Safety and Health Act (WISHA), administered by the Department of Labor and Industries. See [http://www.lni.wa.gov/safety/rules/](http://www.lni.wa.gov/safety/rules/)

ii. **Washington Department of Labor and Industries.** Most employers in Washington are required to participate in a state-sponsored insurance program that compensates individuals who are injured on the job, a program administered by the Department of Labor and Industries. Prescriptions issued to beneficiaries are filled in Washington pharmacies who submit claims to the Department. (See also Chapter 8)

1. Employers may set up a self-insurance program to provide equivalent coverage
2. Sole proprietors may elect to participate in order to provide protection for themselves

i. **Family Medical Leave.** The federal Family Medical Leave Act and the **Washington State Family Leave Act** require employers to allow employees leave from work for certain medical reasons, for birth or adoption of a child, and for care of certain family members with a serious health condition. The Washington law extends additional benefits to women who are pregnant. Covered employers are those who employ 50 or more persons and are engaged in interstate commerce. Pharmacies, hospitals and other healthcare facilities are covered employers if they employ the requisite number of people.

1. **Up to 12 weeks per year of unpaid leave are provided.**
2. **Other statutes or regulations provide additional protected family leave.** A comparison of applicable state and federal laws is available at [http://www.lni.wa.gov/WorkplaceRights/files/FamilyLeaveLawsTable.pdf](http://www.lni.wa.gov/WorkplaceRights/files/FamilyLeaveLawsTable.pdf)
j. **Military Service Leave and Reinstatement.** The Uniformed Services Employment and Reemployment Act of 1994 (USERRA) provides certain rights to employees who are called to serve in the uniformed services. Reemployment rights end after five years cumulative total of military service.

   i. **Employers must provide leave** to an employee who is
      1. Drafted or
      2. Enlists in a uniformed service; and is
      3. Called to active duty for combat, training, or inactive duty.

   ii. **Employee must give advanced notice of military duty, and notice of intent to return to work; notice should be in writing**

   iii. **Employer must**
      1. Place employee in same position if leave < 91 days; or
      2. Place employee in position of like status, pay and opportunity if leave >90 days; and
      3. Reasonably accommodate any disability due to injury while on military duty

   iv. **Reinstatement not required** if employee would have been involved in a layoff during the leave

   v. **Leave for Reserve or National Guard training duty** or response to local disasters is up to state law
      1. **Washington** mandates a military leave of absence for a period not to exceed 21 days during each year beginning October 1. (RCW 38.40.060)

      2. **Employees with a military spouse** are entitled under WA law to up to 15 days of unpaid leave while their military spouse is on leave from a deployment or before and up to deployment once the spouse receives official notification of an impending call to active duty.

   vi. **Employees caring for a family member injured in military action** are entitled to up to 26 weeks of leave under the Family Medical Leave Act. (National Defense Authorization Act of 2008)

k. **Employers in Washington must treat registered domestic partners of employees the same way they treat spouses of employees.** All insurance, retirement, and other employee benefits that are extended to spouses of heterosexual employees must, after December 2009, be extended equally to registered domestic partners of employees. Any notices, e.g. regarding garnishments,

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272 38 U.S.C. § 4303 et seq.
273 2008 c 71.
change of benefits, etc., that would be sent to an employee’s wife or husband, must be sent to an employee’s registered domestic partner.\textsuperscript{275}

I. \textbf{Laws governing whistle blowers} who report employer violations of the law

   i. Employees who report employer violations of laws or rules to an appropriate agency are protected in their jobs from discharge, demotion, or other retaliation because of their “whistle blowing” activity.

      1. Washington recognizes a “public policy exception” to the at-will employment doctrine that protects employees in four situations:\textsuperscript{276}

         a. Employees who are fired for refusing to perform an illegal act
         b. Employees are fired for performing a public obligation, such as jury duty
         c. Employees are fired for exercising a legal right or privilege, such as filing workers’ compensation claims
         d. Employees are fired in retaliation for reporting employer misconduct

      2. Establishing a claim for wrongful discharge in violation of public policy is done in the same manner as for discrimination claims, generally.\textsuperscript{277}

   ii. Employees of the State of Washington are protected by the State Employee Whistleblower Act of 1982 (RCW 42.40).

   iii. Healthcare workers, as well as consumers and other citizens in WA are specifically protected against retaliation or other adverse employment actions, and immune from civil liability, for complaining in good faith to the DOH about improper quality of care. (RCW 43.70.075, WAC 246-15)

Rev. 1/11/10

\textsuperscript{275} 2009 c 21
\textsuperscript{276} Dicomes v State, 113 Wn2d 612, 1989;
\textsuperscript{277} Gardner v Loomis Armored, Inc., 128 Wn2d 931, 1996.
Chapter 8. Legal Issues involving Payment for Pharmaceutical Services and Third Party Payers

Note: this Chapter was revised in early January, 2010, while Congress was awaiting the reconciliation of the Senate and House versions of health care/health insurance reform bills. It is likely that many changes will be made in federal health care programs as well as the provision of private health insurance.

1. Overview of Prescription Drug Benefits. Primarily since the end of World War II, it has been a growing assumption that health care is a necessity of modern life, and that it is inappropriate in a society and economy such as that in the United States for individuals to suffer from lack of health care simply because they do not have the funds. Since the 1960s, the role of drug therapy has grown to occupy such an important place in health care that affordable drug therapy is considered a necessity as well. Currently, the many ways in which health care is paid for in the US include:
   a. Private health care – generally individually purchased or employer-provided
      i. Cash, out of pocket.
      ii. Private health insurance
         1. Individually-purchased
         2. Employer-provided
      iii. Prepaid health care coverage (individually purchased or employer provided)
         1. Health care cooperatives
         2. Health Maintenance Organizations
      iv. Employer-provided direct care
         1. Industrial health programs
         2. Vaccinations and/or travel medicine
         3. Company owned clinics
   b. Government programs
      i. Federal
         1. Public Health Service
            a. Merchant Marine, etc.
            b. Indian Health Service
            c. Federal prisons
         2. Military health care
            a. Military Hospitals and Clinics
            b. TRICARE program
         3. Veterans Affairs
         4. Public employees
         5. Medicare
         6. 340B drug program eligible clinics
ii. **State and Municipal**
   1. Public employees
      a. Special programs for firefighters and police
   2. Public health (vaccinations, etc.)
   3. Basic health plans
   4. Mental health hospitals and programs
   5. TB sanitariums
   6. Jails
   7. State soldier’s homes (prior to VA)
   8. Workman’s compensation programs and care for on-the-job injuries

iii. **Federal/State Shared Funding**
   1. Medicaid
   2. SCHPs

iv. **Other**
   1. Flexible spending health care accounts
   2. Health care savings accounts

Each of these approaches or programs is associated with specific legal issues for pharmacists relating to receipt of payment for services rendered.

2. **Importance of Federal Programs to Pharmacists.** Currently, 40% of all retail prescriptions are paid for by federal government through programs providing care for patients enrolled in Medicare Part D, Medicaid, and SCHIPS. It is estimated that within 10 years, this total will increase to 50% of all prescriptions.\(^{278}\) Add the involvement of Medicare and Medicaid with care of patients in hospitals, hospices, and long-term care settings,\(^ {279}\) and it is clear that almost every patient care pharmacist’s career will be affected by policies and legal issues associated with the administration of these programs.

3. **“Cash” Payment Mechanisms**
   a. **Fee for Service.** The pharmacist determines a fee for the service he or she provides, which may include a portion covering professional services, and another portion covering the cost of drugs, packaging, etc., plus a margin for profit. This calculation results in a **Usual and Customary Fee (UCF)**. In general, pharmacies are expected to charge the same UCF to all patients who belong to the same class of trade, or in other words, not to discriminate unlawfully.
      i. **Unfair or deceptive practices** are prohibited by Washington’s Consumer Protection Act (RCW 19.86). The CPA parallels federal antitrust and price fixing law as well as


protection of consumers. As related to pharmacy, these may include:

1. Any unfair or deceptive practice, such as charging for a brand name drug but substituting a generic, charging for services never delivered, knowingly dispensing fewer doses than charged for, or acting in a way so as to economically injure a patient or customer. Failure to pass on to the consumer 60% of the savings from generic substitution could be a basis for a CPA claim in WA.

2. Price fixing agreements. Pharmacies not under the same ownership may not agree, directly or indirectly, to charge a set price for any service or product. Local or state associations must be careful not to allow their organizations to act in any way that would be considered price fixing. It was common in the 1950s for local associations to publish pricing guides or tables from which pharmacies would calculate prescription fees. In the early 1960s, the Justice Department took action against a variety of trade associations including associations of physicians, dentists, attorneys, realtors, and pharmacists. Two key lawsuits were won by the government against pharmacy associations in California\(^{280}\) and Utah.\(^{281}\)

3. Agreements to restrain trade. Pharmacies may not agree or conspire to restrain trade. The WSPA ended up in the early 1980s settling a lawsuit because of discussions among members of ways to vitiate a certain contract for nursing home services.

4. Any consumer who is “injured in his or her business or property” by a violation of the CPA can bring a civil lawsuit and recover damages, costs, attorneys fees, and up to 3 times the damages as a punitive award. In a recent Washington Appeals Court case, a patient sued her surgeon for negligently performing surgery, and also filed a CPA lawsuit alleging that the surgery as recommended was unnecessary, and therefore its recommendation was a deceptive practice. The court held that even though she lost on her negligence claim, the plaintiff could proceed with a CPA claim against the surgeon as it related to the business aspects of his profession.\(^{282}\)

\(^{280}\) Northern California Pharmaceutical Association v. United States, 306 F.2d 379 (9th Cir. 1962)
\(^{281}\) United States v Utah Pharmaceutical Association, 201 F.Supp. 29 (D. Utah 1962)
ii. **Accepted business practices.** It is generally accepted to allow discounts or other enticements as long as they are not deceptive, unfair, or based on unlawful discrimination. Some examples include:

1. Senior Citizen Discounts
2. Quantity Discounts
3. Promotional Discounts, such as when a new pharmacy opens, or on certain days.
   - a. Promotions may include points, stamps, coupons, etc.
   - b. Note: some Boards of Pharmacy may restrict promotional discounts, including promotions such as “double savings stamps,” if they believe the promotion encourages overuse of drugs or creates situations (such as overly busy pharmacy) that are not conducive to patient safety.
4. Lower fee for delayed service (e.g., calling in for refills in advance, or picking up prescriptions on “slow days”)
5. Free shipping or delivery
6. Reduction in fee to meet specific competition

iii. **Price Posting or Disclosure.** Many states have at times required posting of drug prices to the public. Washington did this formerly, but now merely requires that pharmacies provide their price to any consumer on request. (WAC 246-881-040)

iv. **Advertising of Drug Prices.** At one time, pharmacies were prohibited from advertising prescription drug prices, but rising consumerism led to a change in public policy. Pharmacies may, but are not required, to advertise prescription prices, subject to the following (WAC 246-881-020):

1. Advertising must comply with federal laws and the Washington Consumer Protection Act
2. The advertising is not intended to promote the use of prescription drugs, but is solely to advice the public of prices
3. The following information must be provided concerning the drug product advertised:
   - a. The proprietary name, if any
   - b. The generic name,
   - c. The strength,
   - d. The dosage form, and
   - e. The price for a specified quantity.
4. If the price advertised compares a generic to a brand name, the advertising may not imply in any way that the brand name is the product advertised.

v. Disclosure of Patient Costs to Prescribers (RCW 18.64.430). A Washington statute enacted in 2000 requires that “The registered or licensed pharmacist under this chapter shall establish and maintain a procedure for disclosing to physicians and other health care providers with prescriptive authority information detailed by prescriber, of the cost and dispensation of all prescriptive medications prescribed by him or her for his or her patients on request.”

b. Out of pocket expense reimbursement to patient. In this situation, the patient pays the usual and customary fee, and receives an appropriate receipt from the pharmacy, which the patient submits to a third party for reimbursement. In many cases, the third party deducts a co-pay amount from the reimbursement. Insurance that reimburses an insured after the fact for actual costs is termed “indemnity” insurance. The cost-sharing involved with a co-payment is intended to encourage the insured to attempt to purchase at a reasonable cost.

i. The pharmacist’s receipt must be true and accurate. The pharmacist will be complicit in fraud if he or she knowingly provides the patient with a deceptive receipt. The receipt should accurately reflect the actual amount charged for the transaction.

1. It is appropriate to provide a receipt for charges when the patient has a credit account with the pharmacy, and the amount on the receipt is debited to the patient’s account with good faith expectation of ultimate payment.

2. It may not be appropriate to issue an inflated receipt to “cover” the patient’s co-pay, and later waive the co-pay as a credit to the patient’s account. In some cases, the third party payer has policies that are communicated to the pharmacy to allow the pharmacy to waive the co-pay, but this is unusual in the case of indemnity insurance.

ii. TrOOP is the acronym used in the Medicare Part D program to stand for true out-of-pocket expense. The government considers it fraud when the pharmacy manipulates TrOOP to either push a beneficiary through the coverage gap so that the beneficiary may gain catastrophic coverage, or manipulates TrOOP to keep a beneficiary in the coverage gap.
4. **Contracted or Voluntarily Accepted Payment Mechanisms.** These mechanisms require that the participating pharmacy voluntarily accept them by contract or other means. Acceptance of them indicates acceptance of the terms offered by the third party.

   a. **Reimbursement to the patient based on a fee schedule.** This approach is used by indemnity insurers as well as other third party payers. The pharmacy must submit the claim electronically to the insurer, which informs the pharmacy of the allowable charge, which is then charged to the patient, who is later reimbursed for their out of pocket expense, with or without a co-pay. It may be possible for the pharmacy to “accept assignment” of the amount due to the patient, and the payment is made directly to the pharmacy. If a co-pay is involved, the pharmacy must collect it from the patient.

   b. **Fee set by a third party, with no reimbursement to patient or pharmacy by the third party.** This approach is taken by the various “discount cards” available to consumers. The patient pays cash for the prescription, but the price is determined by the issuer of the discount card.

      i. The 2009 Legislature passed the Health Care Discount Plan Organization Act, establishing standards for discount plan organizations, protecting consumers from unfair or deceptive marketing, sales, or enrollment practices, and to facilitate consumer understanding. It requires licensing of discount plans by the Insurance Commissioner, and plans must have written provider agreements that include the services and products that are discounted and the amount of the discounts. Plans may not restrict access to providers, must refund plan charges to a member who cancels within 30 days of enrolling, charge no more than a one-time $30 processing fee, and must provide written materials to the customer on request.

   c. **Reimbursement to the pharmacy based upon a contracted fee system, with or without a patient co-pay.** The pharmacy electronically exchanges information with the third party, and is reimbursed based on a calculation by the third party payer, typically within 15 to 45 days following the transaction. This is now the predominant form of reimbursement to pharmacies for dispensing of prescription drugs.

5. **Private Contracts vs. Government Contracts**

   a. **Private contracts are enforceable by civil lawsuit, or by arbitration as specified in the contract.** In general, a pharmacist who disputes a payment with a private third party must file a civil lawsuit to gain redress. If the contract specifies, the pharmacist may need to submit to binding arbitration. Only if the contract

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283 2009 c 175; WAC 284-38-005
allows it can the pharmacist recover legal fees if he or she is successful. Likewise, the recourse that a private third party has is to sue the pharmacy. Either or both parties may terminate a contract in accordance with its provisions.

b. **Government contracts are enforceable by civil suit, but also by administrative action, and are subject federal or state fraud statutes.** Unlike private contracts, the terms of government contracts are set by law or regulation, and are typically not negotiable. However, government programs usually have other mechanisms for resolving problems, including appeals to the relevant agency, prior to filing a lawsuit. These mechanisms (“administrative remedies”) must be fully utilized or “exhausted” before a suit can be filed. Violation of a government contract can expose the pharmacy to civil or criminal fraud charges and severe consequences and penalties. Finally, patients have legislatively been given certain rights under federal contracts that may not exist under private insurance contracts.

c. **Risk is Associated with 3rd Party Contracts, and Vigilance is the Key to Risk Reduction.** As will be seen from the discussion below, pharmacies are at risk for numerous problems with 3rd party payments, and are not always in a good position to deal with inequities in the plans or their contracts. A pharmacist should not assume that 3rd party payers are guaranteed to deal fairly or even honestly with the pharmacy, and since they are debtors to the pharmacy, they should be taken on with care and vigilance. Once entering into a contract, it is critical to know the terms and requirements, for failure to abide by all of the terms can be very costly. Many of the audit problems discussed below arise from careless day-to-day claims and prescription processing on the part of the pharmacists and technicians in the pharmacy. Management of the pharmacy must develop a compliance monitoring plan to assure its staff are properly trained, that they follow proper procedures, and that records are kept and secure.

6. **Employee Retirement Income Security Act (ERISA) Preemption of State Law**
   a. **ERISA is the major federal statute dealing with employee benefit plans.** Its primary impact on legal issues related to 3rd party payments for pharmacy benefits is that its provisions preempt state law. In general, state law affecting the design of benefits, denial of benefits, or enforcement of beneficiaries’ rights under the plan is preempted by ERISA. A variety of state lawsuits by individual patients against plans, related to denial of benefits (such as denying “experimental” cancer treatment) have been deemed preempted by ERISA.
7. **Pharmacists’ Attempts to be Included in Health Plans**

   a. **Any willing provider laws.** Pharmacies have worked for many years to achieve a goal of not being “locked out” of 3rd party contracts, whereby a 3rd party contracts with some, but not all willing pharmacies. For many years, the federal courts held that such state laws did not apply to ERISA plans. However, Kentucky passed a law that stated that a “health insurer shall not discriminate against any provider who is located within the geographic coverage area of the health benefit plan and who is willing to meet the terms and conditions for participation established by the health insurer, including the Kentucky state Medicaid program and Medicaid partnerships.”\(^{284}\) In 2003 the US Supreme Court reversed its previous decisions and held that ERISA did not preempt the Kentucky statute because of the provision in ERISA that “nothing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking or securities.” In its opinion the Court indicated that “Today we make a clean break from the McCarran-Ferguson factors and hold that for a state law to be deemed a 'law … which regulates insurance' under § 1144(b)(2)(A), it must satisfy two requirements. First, the state law must be specifically directed toward entities engaged in insurance. Second … the state law must substantially affect the risk-pooling arrangement between the insurer and the insured.”\(^{285}\) The Washington State Pharmacy Association has attempted for several years since the Kentucky decision to persuade the Legislature to adopt a similar statute in Washington, but the attempts have so far been unsuccessful. This remains a legislative goal for the WSPA.

   b. **Any category of provider laws.** Another agenda for pharmacies has been to become eligible for payment for services, such as immunizations or medication therapy management, for which plans pay physicians but won’t pay legally authorized pharmacists. Washington law (RCW 48.43.045) requires that

   Every health plan delivered, issued for delivery, or renewed by a health carrier on and after January 1, 1996, shall:

   (1) Permit every category of health care provider to provide health services or care for conditions included in the basic health plan services to the extent that:

   (a) The provision of such health services or care is within the health care providers’ permitted scope of practice; and

   (b) The providers agree to abide by standards related to:

   (i) Provision, utilization review, and cost containment of health services;

   (ii) Management and administrative procedures; and

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\(^{284}\) KRSA § 304.17A-270

\(^{285}\) Kentucky Association of Health Plans v Miller, 123 S Ct 1471, 155 L Ed 2d 468 (2003)
(iii) Provision of cost-effective and clinically efficacious health services.

These requirements apply to private insurers who offer individual health plans in Washington; it does not require them to contract with any specific provider, but if they do, they must pay contracted providers for any covered services that are within the provider’s scope of practice. These rules do not apply to other state programs, such as Medicaid. Pharmacies who have been denied participation in violation of this rule must file claims with the Insurance Commissioner.

8. Basic Elements Needed to Participate in 3rd Party Plans. Although in recent years a growing number of independent pharmacies have stopped accepting third-party plans,286,287 it remains the reality that most pharmacies do accept at least Medicaid and Medicare, as well as local private plans. Key elements needed to accept 3rd party reimbursement include the following:

a. Application to the plan and agreement to the plan’s contract.
b. Ability to transmit and receive electronic claims data. This involves
   i. Claims processing software integrated with the pharmacy’s patient medication record and billing systems.
      1. For most prescription claims, this software must adhere to the current protocols adopted by the National Council on Prescription Drug Programs (NCPDP)
      ii. Dial-up or internet access to a “switch” which routes claims to the 3rd party’s claims server
   c. Administrative systems in place to monitor and reconcile claims, and retain the records and documentation required to withstand subsequent audits
d. Staff who are trained in the software, plan rules, and resolving issues with claims.

9. Claims for Payment
   a. Determination of the value of the claim. Under almost all 3rd party plans, the value of the claim is composed of the following:
      i. A dispensing fee
         1. The fee is determined by the contract. In most cases the pharmacy cannot negotiate the fee as an individual participant, but may be able to do so as part of a provider group.
         2. For government programs, it is possible to lobby the legislature or agency for changes in the rules by

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286 http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=110964
287 http://www.umich.edu/~pharmacy/morenews/college/preceptor_03.html
which the fee is determined; this is not always a successful effort, but it is an important advocacy agenda for state associations.

3. Fees for Medicaid programs may vary for different pharmacies depending on location (e.g., rural) and volume.

ii. An estimation of the cost of the drug. Depending upon the plan and contract, this may be defined as

1. The Average Wholesale Price (AWP), which does not ever reflect what a pharmacy actually pays for the drug, but which is set forth in commercially-developed databases, primarily by First DataBank and Medispan. It is rare for plans to pay based on AWP without some form of discount. Currently, there are federal and state lawsuits against manufacturers, wholesalers and the database providers alleging fraud in the setting of AWPs. Some generic manufacturers have been charged with setting artificially high AWPs, then covertly dropping their actual prices to pharmacies to gain sales, a strategy called “marketing the spread.” Cases against wholesalers and the database vendors include a specific claim that in the period after 2000, the spread between what wholesalers actually charged pharmacies and the AWP price was arbitrarily increased by wholesaler and database provider conspiracy. A proposed settlement in one such lawsuit resulted in across-the-board reductions in AWPs published by First DataBank to by 4%. The settlement was approved by the court, and changes took place on September 26, 2009. Within 2 years following approval of the settlement, FirstDatabank will independently discontinue publication of AWPs.

2. AWP minus a specified percentage. This is the most common approach, with AWP – 15% to AWP – 18% being fairly typical pricing factors. (A recent Congressional committee report indicated that in 2006, the average Medicare Part D insurer paid

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pharmacies a total fee comprised of AWP-15% plus a dispensing fee of $2.10.\textsuperscript{291}

3. **Maximum Allowable Cost (MAC).** Because of the wide range of prices available for generic drugs, and a desire to encourage pharmacies to use generics, many programs set a MAC for covered generics. The pharmacy may use that price basis for generic drugs. If they can buy a generic below the MAC, they make a larger profit.

4. **Medicaid** is operated by states, but the federal government reimburses the states for a large percentage of their costs. Federal rules require the states to set the following bases for reimbursing drug costs to pharmacies:
   a. **MACs for generic drugs**
      i. Washington determines two types of MACs: the State Maximum Allowable Cost (S-MAC), and an Automated Maximum Allowable Cost (A-MAC) (see below).
   b. **Estimated Acquisition Costs (EACs)** for single source drugs, for which the states often use an “AWP minus” or “WAC plus” approach.
   c. No cost basis can exceed the **Federal Upper Limit (FUL)**, which the federal government calculates when there are 3 or more versions of a generic available in a given geographical area.

5. **Other pricing bases** that may be used by certain plans include:
   a. **Wholesale Acquisition Price (WAC),** which is the “catalog price” a wholesaler pays to the manufacturer. It does not include rebates or promotional discounts. For many wholesalers, their net profit consists of rebates, promotional fees, and a discount for early payment. Many wholesalers depend on the fact that manufacturers frequently increase prices, and make a profit by buying in quantity and selling at the increased WAC. Some wholesalers set their prices to pharmacies as WAC plus a %,

typically 5% for smaller accounts, and WAC minus some % for large volume purchasers.

b. **Federal Supply Schedule price (FSS)** is the price that federal agencies purchase drugs from the manufacturer. It cannot be greater than the lowest price the manufacturer charges any non-federal purchaser. Clinics that are eligible for 340B pricing (see below) are able to purchase at approximately the FSS price.

c. **Average Sales Price (ASP).** The Office of the Inspector General entered into a Corporate Integrity Agreement with Tap Pharmaceuticals. As part of that agreement, the ASP was defined as the average of all final sales prices charged for a prescription drug in the United States to all purchasers (including mail order pharmacies) excluding those sales that are exempt from inclusion in the “best price” for Medicaid drug rebate purposes.

d. **Base Line Price (BLP).** This measure was formerly used by Washington’s Department of Labor & Industries for generic drugs. It is calculated by taking the mean AWP of all generics in a particular group, determining the standard deviation, then calculating the mean of those products within one standard deviation of the grand mean. The BLP is calculated and listed in the pricing database from First DataBank.

6. **Average Manufacturer’s Price (AMP).** One particular pricing basis is currently of importance for pharmacists providing services to federal programs. As a condition of OBRA 90 (see Chapter 6), manufacturers were required to provide rebates to Medicaid programs, which are set as a percentage of the cost of drugs paid for in a particular state. The AMP was established as the measure of the costs of these drugs, and is defined as the average price paid to manufacturers by wholesalers (less discounts) for a particular dosage form and strength of a prescription drug distributed solely to the retail pharmacy class of trade. Until recently, the AMP has not been published, nor has it been used for any purpose other than calculating rebates.
a. The Deficit Reduction Act of 2005\textsuperscript{292} required that the AMP now be used as the basis for limiting the amount paid to retail pharmacies in Medicaid programs for multi-source (generic) drugs, but not single-source drugs. It did this by setting the FUL at 250\% of the AMP. Use of the AMP for this purpose created significant political tension: manufacturers want the AMP to be as low as possible, because that will reduce the amount of rebates paid to the states. Pharmacists (and perhaps state governments) want the AMP to be as high as possible, because it will increase their reimbursement, and will increase rebate amounts to the states. The Act also requires CMS to publish the AMP data on a website, and it is anticipated that this data would be used by other 3\textsuperscript{rd} party payers in setting reimbursement rates for retail pharmacies.

b. CMS Final Rule. CMS published a final rule in July, 2007,\textsuperscript{293} and the revised AMP formula was to be put into place at the end of November 2007. Among the controversial issues in the AMP rule were the following:

i. Classification of sales to mail order pharmacies as sales through wholesalers to retail pharmacies. Chain and independent pharmacies opposed this, and argued that this was contrary to Congress’ intent, because these pharmacies buy directly and are not wholesalers. PhRMA favored this, arguing that retail means selling direct to patients.

ii. Rebates, discounts, and other price concessions paid to pharmaceutical benefits managers (PBMs) will not be included in calculating AMP. PhRMA wanted this to be included, but these are for drug purchases that are never physically handled by the PBM, but rather flow through network pharmacies, and are counted in the AMP from those sales.

\textsuperscript{292} Pub L 109-171.
\textsuperscript{293} 72 Fed Reg 39142, July 17, 2007.
iii. Price concessions to PBM-operated mail order pharmacies, such as Medco, ExpressScripts, and Caremark, were to be counted in establishing the AMP. This would significantly lower the AMP from its current level.

iv. Sales to purchasers other than retail pharmacies through wholesalers are included in the AMP calculation, and include sales directly to patients, to physicians, surgical centers, dialysis centers, mental health centers, home health providers, home infusion providers, clinics, to PBMs for their mail order pharmacies, and mail order pharmacies.294

c. NACDS and NCPA lawsuit. The National Association of Chain Drug Stores and the National Community Pharmacy Association had been lobbying for Congressional action to forestall implementation of the AMP pricing in November 2007, arguing that community-based pharmacies could not actually purchase a wide variety of generics in their regions at or below the revised FUL if the AMP rule was allowed. They also argued that the AMP rule was contrary to the plain language of the statute, and that implementation would cause irreparable harm to many pharmacies.

d. Federal Judge Issues Injunction. US District Court Judge Royce Lamberth issued a preliminary injunction on December 12, 2007,295 prohibiting CMS from implementing the AMP rule as it relates to use of AMP to establish FULs for pharmacy reimbursement under Medicaid. The judge held that

i. Plaintiffs are likely to succeed on the merits of their claim because the AMP rule does not comply with either the statutory definition of “average manufacturer price,” or the statutory definition of “multisource drug.”

294 NACDS v Leavitt, US Dist Ct (Dist DC), Case No. 1:07-cv-02017, Complaint for Injunctive and Declaratory Relief, p. 28, 11/7/07.

ii. Unless enjoined, plaintiffs are likely to suffer irreparable harm for which no adequate remedy at law exists.

iii. CMS can continue to require manufacturers to submit data under the rule for the purpose of calculating Medicaid rebates to states; but CMS is enjoined from publishing the resulting AMP or data or disclosing it to states.

e. Congress passes Medicare Improvements for Patients and Providers Act

i. In July 2008, Congress passed Pub. L. 110-245, overriding a veto by President Bush. The statute postponed for 18 months scheduled reductions in payments to physicians, and included several items of importance to pharmacies.

ii. Prompt payment of Medicare Part D claims – “clean” electronic claims must be paid within 14 days

iii. Updating of prescription drug prices every 7 days by Medicare Part D plans

iv. Coverage of benzodiazepines and barbiturates under Medicare Part D

v. Delay in implementing and revisions to a proposed competitive bidding process for durable medical equipment

vi. Delay until October 2009 of implementing the new AMP rule and of publishing of AMP data

f. In October 2008, CMS revised its definition of “multisource drug,” but the revision is being challenged by NACDS and NCPA in the ongoing AMP litigation.

iii. Professional service fees may be billed for non-dispensing activities, usually in accordance with either a

   1. Set fee schedule established by the plan; or
   2. A resource-based relative value scale (RBRVS) which applies a particular fee range to the complexity of the service and the time involved.

iv. Price to government may not be greater than the pharmacy’s UAC. Usually, and especially for government programs, the resulting claim value cannot exceed the pharmacy’s UAC for the same quantity of drug. In government programs, the contract may also specify that the
claim value cannot exceed that which would be charged to any other 3rd party.

b. **Determination of the drug or service provided**
   
   i. **Drugs** are almost universally identified in claims by the National Drug Code (NDC), an 11-digit code that indicates the manufacturer, the drug product, and the package quantity.

   1. **Fraudulent to record incorrect NDC.** It is considered fraudulent to misrepresent the product actually used by entering a different NDC than the one actually on the package from which the drug was dispensed.

   a. For example, 65427-158-73 is the NDC for Lipitor 20 mg tablets purchased from Pfizer in bottles of 500, and 65427-158-30 is the NDC for bottles of 30. A pharmacy could conceivably buy Lipitor at a significantly lower cost per tablet by buying in 500s than in 30s. If the computer is set, to record “65427-158-30” whenever Lipitor is dispensed, then the cost basis for a Lipitor claim will be greater than if “65427-158-73” is recorded. Certainly under Medicaid, and most private plans, this would be considered fraudulent, and if discovered on a subsequent audit, could result in denied claims, fines, and other penalties.

   b. Similarly, “13411-524-60” and “58016-529-60” are NDCs for two different bottlers’ propranolol 20 mg tablets, in bottles of 60. Dispensing one product but entering the NDC for the other is not only potentially fraudulent, but it also violates the state rule which requires recording the manufacturer of the drug actually dispensed in the patient medical record. It is very common to use a different product on refills of a generic drug, and if the technician or pharmacist does not be sure to change the NDC when the refill is dispensed, the pharmacy may be unwittingly committing a fraud. At least one national pharmacy chain is now under the terms of a Corporate Integrity Agreement (see below), in part because of lack of care of its personnel to properly record NDCs on generic drug prescriptions.

2. **Devices** in federal programs are identified by a "Healthcare Common Procedure Coding System
(HCPCS – pronounced “Hick-Picks”) code, which indicates the type of device used. HCPCS codes and associated reimbursement levels are established by Centers for Medicare and Medicaid Services (CMS). The codes for most devices distributed by pharmacies are alpha-numeric codes called HCPCS Level II codes. The pharmacy will be reimbursed the set amount for that device, regardless of their cost, and is not required to identify the particular manufacturer or source. Here are two examples for a similar device (in this case, a wheelchair):

KO836 -- POWER WHEELCHAIR, GROUP 2 STANDARD, SINGLE POWER OPTION, CAPTAINS CHAIR, PATIENT WEIGHT CAPACITY UP TO AND INCLUDING 300 POUNDS
KO838 -- POWER WHEELCHAIR, GROUP 2 STANDARD, SINGLE POWER OPTION, CAPTAINS CHAIR, PATIENT WEIGHT CAPACITY 301 TO 450 POUNDS

The reimbursement level in 2006 was $412.40 per month for the KO836 chair, and $429.46 per month for the larger chair. Entering the incorrect code could cost the pharmacy revenue, or result in increased revenue, which would be considered fraudulent.

Effective January 1, 2008, HCPCS Level II codes will be used for most devices.

3. Services. Professional services billed by physicians and other providers are encoded by the Current Procedural Terminology codes maintained by the American Medical Association. CMS uses these codes for payment in federal programs, where they are called HCPCS Level I codes. After many years of effort, pharmacists have persuaded AMA to adopt a set of CPTs for use by pharmacists in face-to-face medication therapy management sessions. These codes allow for complexity and time involved, so they constitute a type of RBRVS codes. Pharmacist providers using these codes will be subject to audits and their records must justify the complexity and nature of service provided.

4. Identify of the Pharmacist Provider. HIPAA established a National Provider Identifier which is to be used on all electronic interchange of patient data. The NPI is available to pharmacists to be used to identify individuals as providers of care. (See Chapter 7)
   a. **Order or Prescription or Claim as Entered.** Claims are frequently denied because the order or prescription is considered invalid for authorizing the drug, device, or service provided.
      i. Prescription must meet all the legal requirements. Some possible examples:
         1. Prescription not written, when program required written prescription.
         2. Prescription incomplete or not dated.
         3. Prescription not valid because it was “illegible” under Washington law (i.e., written in cursive)
         4. Prescription for Medicaid not valid because it is not written on tamper-resistant pad
         5. Patient’s full name not specified on prescription.
         6. Prescription is a transfer and all required information is not present
         7. Prescription not valid on date of service
         8. Identity of person who called in prescription not recorded
         9. Drug is for an unapproved use, as indicated by directions
         10. Prescription exceeds guidelines (e.g., methadone once daily for pain)
         11. Faxed prescriptions fail to meet state requirements
         12. Directions for use incomplete (Washington doesn’t allow “ud”)
      ii. Drug, device, or service ordered and provided must match the claim.
         1. Wrong NDC entered.
         2. NDC entered for a non-covered drug.
         3. NDC is not for package size used (discovered by comparing claims to invoices from wholesalers)
      iii. Prescriber identity and authority
         1. Invalid prescriber identifier (e.g., DEA number or NPI)
            a. The point-of-sale payment system for Washington Medicaid will require the NPI after 4/1/09.
         2. Beyond scope of practice of prescriber
         3. Wrong prescriber identified on claim
   b. **Patient Eligibility Issues**
      i. Patient was eligible under more than one program, and pharmacy did not properly bill all payers
      ii. Patient was not eligible at the time of the claim.
      iii. Patient hadn’t properly met spend down requirements and this was known to pharmacy
iv. Patient was deceased at time of service. This happens when the date of service was entered incorrectly or sometimes because a relative or other person was using a medical card of a deceased patient.

c. **Documentation, Justification, or Prior Authorization**
   i. DAW documentation not available
   ii. Documentation of step therapy not in place.
   iii. Documentation of need for MTM service not in records.
   v. Inadequate record that refill was authorized by prescriber
   vi. Original record of claim not available at audit time
   vii. Prior authorization not documented when needed
   viii. Failure to have a record that the patient actually received the drug, device, or service.

d. **Improper or invalid claims**
   i. Failure to correct claim or reverse claim for partial fills that aren’t picked up or prescriptions never picked up.
   ii. Evidence of waiving required co-pays (note; it is possible under certain circumstances to waive co-pays for Medicare Part D patients – see below).
   iii. Early refills
   iv. Unauthorized refills
   v. Using a dosage form not covered by FUL pricing instead of a covered form (e.g., ranitidine capsules dispensed instead of tablets)

e. **Point-of-Sale (POS) System Failures.** Most claims are adjudicated in real time using a POS system. Theoretically, this should avoid many of the eligibility, identification, excess quantity, early refill, and similar problems. Government rules are usually written in such a way as to put the burden on the vendor, not the government, even though the government has failed to implement its POS system properly. At best, the vendor should be able to avoid penalties, but may still have to repay the claim, even though the drug was dispensed in good faith. Private 3rd party payers are more likely to have to accept responsibility for failures of their adjudication system, but they may have contract language that insulates them in some way. Medicare Part D plans are likely to be backed by federal rules that place more of the burden on the pharmacy.
   i. The ability of the government to place the burden on pharmacies even when the failure is the government’s arises from the State’s (or federal government’s) **sovereign immunity** (see Chapter 1).
11. Typical Conduct of Audits. The following discussion is derived primarily from Medicaid audits, but private 3rd party payers use similar audit procedures and, in some cases, the same auditing firms. Medicare Part D plan providers (see below) are required to implement similar audits, following federal guidelines.

a. **Record Audit at 3rd Party Office.** Sample of claims and providers selected from claims records.
   i. Providers may be selected at random, based on a randomized schedule to audit all providers over a certain time frame, and/or “outlier” providers are selected based on total volume or unusual volume of claims per enrollee, etc. Some states will do an audit that looks at all providers.
   ii. Claims are usually sampled for audit. A set of claims, typically less than 1%, are selected at random. Some programs always review the most expensive group of claims, such as those comprising some set percentage of total payments to the vendors.

b. **Off-site Audits.** In many cases, an on-site audit is not performed unless the initial sample reveals a certain level of non-compliance. In such a case, a request may be made for documentation of selected claims by the auditor, and the vendor must supply copies of relevant documents. Discrepancies detected during this phase may be reported to the vendor with a proposed level of settlement for presumed invalid claims. In some cases, agreement to the proposed settlement will forestall an onsite audit.

c. **On-site Audits.** An onsite audit will examine a variety of elements of the vendor’s operation, including a claim-by-claim review for all of the claims selected in the sampling process.
   i. **Elements of Inspection.** According to Prudent Rx, one of the nation’s major Medicaid contract auditors, the following are elements of the on-site review in one state:
      1. Physical prescription
      2. Signature log/Delivery Receipt
      3. Inventory review (physical or purchasing records)
      4. Documentation of DAW requirements
      5. Tamper-proof prescription requirements (will be a feature of Washington Medicaid audits for claims made after April 2008)
      6. Usual and Customary pricing
   ii. **Recovery Calculation**
      1. Extrapolation from sample. Some states require extrapolation based on the random sample. In this process, the recovery value of each sample prescription is determined, and the total for all the sample prescriptions is then extrapolated to the total claims during the sampling period. If 1% of claims
were sampled for a pharmacy, and the total recovery value of those claims were set at $800, then the amount of recovery sought from the pharmacy would be $800 / $0.01 = $80,000. Washington Medicaid audits use extrapolation techniques.

2. Full recovery from high-cost claims. The high-cost claims that were specifically examined were excluded from the calculations involving sample claims, so the recovery value of those claims is added to the extrapolated amount.

iii. Audit Findings are provided to the vendor.

1. Proposed recovery amounts well exceeding $100,000 are not uncommon in Washington, and in at least one case an independent pharmacy in western Washington was issued an initial recovery claim of over $550,000, an amount that would have bankrupted the pharmacy.

2. During 2007, WSPA was successful in prompting legislative hearings on Washington Medicaid audit procedures, but not successful in getting legislative action to reform the audit process in 2007 through 2009. WSPA hopes to have better success in 2010.

iv. Appeal. The vendor has a set time limit to appeal the audit findings. If the appeal date is missed, the findings are final. Particularly where extrapolation is used, a detail appeal of each claim is usually necessary, which is very costly in staff time. Often, at the point of appeal, the vendor will find it necessary to hire an attorney and/or an audit consultant.

12. Anti-Kickback Laws. Most states and the federal government prohibit provision of kickbacks, which are considered a form of bribery, to persons in a position to refer government-paid for services, and these extend to payments for prescription drugs. In addition, most states have specific laws making it illegal for providers of health care to offer or receive kickbacks as they relate to referral of patients for healthcare services.

a. Why have anti-kickback laws? Two major concerns have led to this kind of legislation: (1) the concern that kickbacks to referral sources, particularly physicians, will diminish the referral source as an independent decision maker, and will likely lead to unnecessary utilization of services or use of more expensive services than appropriate; (2) physician self-interest will lead to unethical choices regarding patient care.

b. What are kickbacks? Kickbacks are payments or benefits given to a referral sources in return for directing business to the payer. They may be actual monetary payments, made either directly or indirectly, or they may be other items of value, such as free space
or equipment. As they pertain to pharmacy practice, here are some examples:

i. **Fee-splitting in any form.** Any arrangement whereby the prescriber obtains a percentage or set amount for each prescription written, or each patient referred for services (e.g., MTM), is an obvious kickback, and is the source of the term "kickback:" the pharmacy "kicks back" a portion of its fee to the prescriber. The following indirect returns of items of value to a referring physician are also considered kickbacks.

ii. **Allowing physicians to bill patients for pharmacy services, and then giving the physician a “collection discount.”** This has sometimes been done with injectable drugs, whereby the pharmacy sends a "prescription" for an individual patient to the physician for administration, and the physician collects the prescription price from the patient, but pays the pharmacy some amount, e.g., 80% of the price. The discount amount is almost always greater than the physician’s actual billing and collection costs, so it is truly a kickback.

iii. **Percentage rents based on prescription volume.** Pharmacies may be located in physician-owned clinics, and it is not unreasonable to pay rent for the space. However, if the rent is related to the volume of prescriptions generated by the clinic and referred to the pharmacy, such an arrangement amounts to paying the physician a percentage of the amount collected for each referred prescription, and is a kickback.

iv. **More than nominal entertainment costs.** Pharmaceutical sales representatives now are explicitly restricted in the amount they can spend on taking physicians to lunch or other expenditures related to continuing education programs, etc. (see below). Pharmacy owners who would fly local physicians to their condos in Hawaii or Cabo San Lucas, or who take physicians golfing at exclusive clubs and pick up the tab would be probably providing kickbacks under current rules. It’s fun to assume that pharmacy owners have these kinds of resources, but even less extravagant expenses – dinners and lunches, may be out of bounds.

v. **Sales of goods at a reduced price.** Pharmacies may sell supplies to physician’s offices at less than retail prices, providing the prices are consistent with competition and fair business practices. (Remember that if these sales are > 5% of total business, the pharmacy must register as a wholesaler – see Chapter 1). However, providing physicians or their families who refer patients to the pharmacy with
personal discounts below what would be charged to the general public may constitute a form of kickback.

vi. Providing free services for nursing homes. A pharmacy may seek a consulting contract with a nursing home based on implementation of a particular, e.g., unit dose, system, which includes pharmacy-maintained patient medical records or other services. These may legitimately reduce nursing costs and be of benefit to the home when compared to other ways of delivering drug therapy. However, pharmacies have sometimes offered additional services, such as bookkeeping services, provision of free dispensing carts, etc. To the extent that these confer a benefit to the home beyond the services contracted for, they represent a kickback.

vii. Receiving a fee from a manufacturer to contact patients to urge them to obtain their refills of the manufacturer’s product.

viii. Providing coupons to patients to encourage them to transfer prescriptions to the pharmacy. Under federal rules, nominal gifts of $10 or less per gift and $50 or less per person per year are excluded from enforcement.

c. Medicare Anti-Kickback Statute. This principal federal anti-kickback legislation has been described as “the mother of all anti-kickback/anti-rebate statutes.” Kickbacks are a form of bribery, and to be involved in a kickback is defined in the federal Medicare Anti-kickback statute as to “knowingly and willfully” solicit, receive, offer or pay any remuneration in return for (1) referring or arranging for services payable by any federal or state health care program, or (2) purchasing, leasing ordering or arranging for any goods, facilities or services which may be paid for in whole or in part by any federal or state health care program. Under the federal law, participating in a kickback scheme is a felony, punishable by up to 5 years in prison and a $25,000 fine (42 U.S.C. §§1320a-7b). Although this is labeled the “Medicare Anti-kickback Statute,” it applies to any federal program.

i. Additional sanctions include exclusion from participation in Medicare and Medicaid, and additional civil monetary penalties of up to $50,000 per violation, and assessments of up to 3 times the amount of remuneration paid under the agreement.

ii. Violations of the statute can also be considered violations of the Federal False Claims Act, bringing its civil penalties to bear.

iii. Generally, violations of the Medicare Anti-Kickback Statute must be “knowing and willful,” so the government must prove that the violator knew the action was a violation and committed it intentionally.

iv. The Act is enforced by the Office of the Inspector General (OIG) of the Department of Health and Human Services. The OIG also establishes “safe harbors,” which are guidelines for certain situations, which, if followed carefully, protect individuals from being charged with violations of the Act.

v. The statute does not apply to any payments “by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” While this is important particularly for hospitals, it also suggests that a pharmacy could employ a physician or nurse practitioner – on a non-volume-related basis (such as hourly) – to see patients in the pharmacy and write prescriptions to be filled in the pharmacy, without violating the Act (other state provisions might apply, however.)

d. Stark Act (the “Ethics in Patient Referrals Act”).

One commentator has suggested that “If the Anti-kickback statute is the mother of all anti-rebate statutes, then the Stark Law is the Gordian Knot of such laws.” This law, passed in 1989 and expanded in 1993, is designed to prevent physicians from referring Medicare or Medicaid patients to entities in which they or family members have an economic interest. Originally, it applied to referrals of Medicare patients to clinical laboratories in which the physician had a financial interest, but was extended later to referrals of Medicare and ten additional “designated health services” (DHS): physical therapy; occupational therapy; radiology; radiation therapy; DME equipment or supplies; parenteral and enteral nutrition services; prosthetics and orthotics; home health services, outpatient prescription drugs; and inpatient and outpatient hospital services.

i. Enforcement of and regulations under the Stark Act are the province of the Centers for Medicare and Medicaid Services (CMS). The most recent regulations were promulgated in 2008.

ii. The statute imposes strict liability for violations of its requirements: no intent is necessary, unlike the Medicare Anti-kickback statute. The Act’s civil penalties are quite severe, and can trigger charges of violation of the Federal False Claims Act. Both the physician and the participating entity (e.g., pharmacy) can be penalized and/or excluded from participation in Medicare or Medicaid.

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298 Black DW, op. cit., p. 10.
iii. In November 2009, Omnicare, the nation’s largest nursing home pharmacy, and IVAX paid $14 million to settle claims that Omnicare solicited, and IVAX paid Omnivstr $8 million in return for Omnicare’s purchase of $50 million worth of drugs from IVAX.  

iv. The many implications and exclusions under the Stark regulations are beyond the scope of this text; pharmacies must consistently seek legal counsel when entering into relationships with physicians that might bring them under the ambit of the Stark Act.

13. Washington Anti-kickback Laws

a. **Stark Act and Medicare Anti-kickback Act adopted in Washington.** Washington has incorporated the Stark Act and Medicare Anti-kickback statutes into state law as they apply to the Medicaid program (RCW 74.09.240). Equivalent provisions also apply to the health care programs funded by the Department of Labor and Industries industrial insurance pool (RCW 51.48.280). Certain differences exist between the state and federal acts, including that the state adoption of the Anti-kickback Act did not specify that intent was necessary to violate the statute, so it may be easier to convict under the state law than the federal law.

b. **Washington Anti-Rebate Law (RCW 19.68).** First enacted in 1949, the Washington anti-rebate law was one of the earliest attempts to deal with physicians’ business practices that were seen as disreputable. Its construction is quite awkward; Black notes that this statute “consists of one of the longest and most poorly worded sentences in the entire Revised Code of Washington.” A footnote to the most recent Supreme Court opinion interpreting the law noted dryly that “More precisely, we are as asked to interpret a 156-word sentence. We are up to the task.” Here is the sentence in question (RCW 19.68.010(1)):

> (1) It shall be unlawful for any person, firm, corporation or association, whether organized as a cooperative, or for profit or nonprofit, to pay, or offer to pay or allow, directly or indirectly, to any person licensed by the state of Washington to engage in the practice of medicine and surgery, drugless treatment in any form, dentistry, or pharmacy and it shall be unlawful for such person to request, receive or allow, directly or indirectly, a rebate, refund, commission, unearned discount or profit by

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301 For example, in the American Optical case (US v American Optical Co., 97 F.Supp. 66, (4th Cir. 1951)), the Justice Department sued over 2000 physicians for allegedly referring patients to American Optical to have their eyeglass prescriptions filled, at inflated prices, for which the physicians received a kickback.


303 Opinion of the Court, Wright v Jeckle, 158 Wn.2d 375, 375 (Fn. 1), 2006.
means of a credit or other valuable consideration in connection with the
referral of patients to any person, firm, corporation or association, or in
connection with the furnishings of medical, surgical or dental care,
diagnosis, treatment or service, on the sale, rental, furnishing or
supplying of clinical laboratory supplies or services of any kind, drugs,
medication, or medical supplies, or any other goods, services or supplies
prescribed for medical diagnosis, care or treatment.

In essence, the statute makes it unlawful to pay a physician,
drugless healer (e.g., naturopath), dentist, or pharmacist a rebate
for referral of patients for care or provision of health care supplies
or services. A violation of the statute is a misdemeanor, and can
lead to charges of unprofessional conduct. It is rarely enforced by
state agencies, but, as in the case discussed below, can be the
basis for a law suit under other laws, such as the Consumer
Protection Act.

i. It is not a violation of RCW 19.68 to make a profit on sales of
prescription drugs to one’s own patients. A recent case
(Wright v. Jeckle, 158 Wn.2d 375; 144 P.3d 301, 2006)
regarding the statute was of particular interest to
pharmacists, and the WSPA joined 26 other state or local
health care associations as amici curiae (friends of the
courts). The trial court had held that Dr. Milam Jeckle of
Spokane Valley had violated the Anti-Rebate Statute when
he sold his patients fen-phen tablets at a profit. It was
permissible, the court held, to sell drugs to patients, but not
at a profit. As a result, he could be found to have engaged in
a deceptive practice under the Consumer Protection Act.
(Such a finding would obviously have implications for
pharmacists with prescriptive authority.) On appeal to the
Supreme Court, Justice Chambers wrote in the opinion that
“We are asked today to determine whether RCW 19.68.010
is an ‘antikickback’ statute or an antiprofit statute. We
conclude the legislature intended to prohibit kickbacks, not
profits. Accordingly, we reverse the trial court.”

14. Health Care Fraud
a. Health Care Fraud is a Significant Problem. According to legend,
when asked by a reporter, “Why do you rob banks?” Willie Sutton
replied, “Because that’s where the money is.” In 2005, total
public spending on health care was $847 billion, with $653 billion of
that total due to Medicare and Medicaid. Not surprisingly, a
government enterprise with that much money involved will be of
real interest to persons who wish to commit fraud. Federal

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305 Ibid., at 375.
government recoveries from false claims pursued in 2006 exceeded $3.1 billion, with $2.2 billion coming from healthcare. One national organization of *qui tam* plaintiffs’ attorneys, Taxpayers Against Fraud, maintains a website that chronicles a variety of judgments and settlements in the courts for fraud against the government (http://www.taf.org/).

b. **Federal False Claims Act.** Originally enacted following the Civil War, to deal with fraud by federal defense contractors, the Federal False Claims Act (31 U.S.C. §§3729-3733), is the principal federal statute that provides a mechanism for recovering from federal contractors for claims that are made fraudulently. It applies to all claims against the government, except it does not apply to tax collections under the Internal Revenue Act. Congress amended the FCA in 2009 by enacting the Fraud Enforcement and Recovery Act (FERA).

   i. **Actions creating liability under the Act** include the following:

   1. Knowingly presenting a false or fraudulent claim for approval, or causing one to be presented, to an officer or employee of the US government or to an employee of the Armed Forces.
   2. Knowingly making or using a false statement or record, or causing a false statement or record to be made or used, to get a false or fraudulent claim approved by the Government.
   3. Conspiring to defraud the Government by getting a false or fraudulent claim approved.
   4. Intending to commit fraud by shorting the Government in money or goods in any transaction.
   5. Acting as an individual authorized to deliver a receipt to the Government, intentionally commits fraud by delivering the receipt without knowing that the information on the receipt is true.
   6. Knowingly buying government property from a government officer or employee, or member of the Armed Forces, who may not lawfully sell the property.
   7. Knowingly making or using a false statement or record, or causing a false statement or record to be made or used, to conceal, avoid, or decrease an obligation to pay or transmit money to the Government.
   8. Knowingly and improperly avoid[ing] or decreas[ing] and obligation to pay or transmit money or property to the government. Under FERA, it is not a requirement.

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308 Pub. L. 111-21
that the defendant submitted a claim directly to the
government, so pharmacies may now be in violation
of the FCA by knowing retention of government
overpayments, even if the provider made no false or
improper claim for the payments.

a. Another federal statute, the Medicare
Secondary Payer Act, requires that parties to
personal injury claims (including defendants),
protect Medicare’s interests when settling
cases. If a pharmacy is sued by Medicare
beneficiary, and the pharmacy or its insurer
agrees to a settlement, Medicare must be
notified of the settlement and any funds that
would have been paid to the plaintiff for
treatment costs must be paid to Medicare to
reimburse it for its share of those costs. Failure
to do so is now considered, under FERA, to be
avoiding or decreasing an obligation, and
subjects the pharmacy to FCA litigation. It is
important for pharmacies (and pharmacists)
involved in settlements with Medicare
beneficiaries to assure through their attorney
that the MSPA is complied with.

ii. Penalties under the Act include:
1. Civil penalties of not less than $5,500 nor more than
$11,000 per false or fraudulent claim or action, plus 3
times the amount of damages sustained by the
Government.
   a. Under certain circumstances, the person
committing the violation may notify the
Government within 30 days of the violation
and, if they cooperate fully with the
Government will be subject to no more than 2
times the damages sustained.
   b. All individuals violating the Act may be
assessed the costs to the Government of
bringing the action.

iii. Claims include those made to any government contractors if
any federal dollars are involved in paying for the goods or
services involved. Therefore, for example, pharmacy claims
to Medicaid, even though submitted to the State of
Washington, are subject to the Act.

iv. “Knowing” and “knowingly” mean that a person, with respect
to information:
1. Has actual knowledge of the information;
2. Acts in deliberate ignorance to the truth or falsity of the information; or
3. Acts in reckless disregard of the truth or falsity of the information. In this last case, the Government will not need to prove intent to defraud.

v. Private citizens may bring *qui tam* lawsuits on behalf of the Government for violations of the Act.

1. If an individual has knowledge of a false claim or other practice that violates the Act, that person may file a lawsuit for the person and for Government in the name of the Government. The person bringing the lawsuit is called a “*qui tam* relator.” The term *qui tam* is an abbreviation of the Latin phrase “*qui tam pro domino rege quam pro se ipso in hoc parte sequitur*”, meaning “he who sues for the king as well as for himself.” The complaint must be filed with the US Attorney General as well, and depending on the decision by the US Attorney, the government may take over the case and its prosecution, or the relator may pursue the case with his or her own attorney. If the case is won or settled, the relator may be awarded (with some exceptions):
   a. Not less than 15% nor more than 25% of the total recovery if the Government prosecuted the case; or
   b. Not less than 25% nor more than 30% of the total recovery if the relator pursued the case.
   c. Attorneys’ fees. In either case, the relator may also be awarded costs and attorneys’ fees needed to pursue the case, which shall be paid by the defendant. However, if the relator pursues the case after the government has declined to do so, and loses, the defendant may be awarded its costs and attorneys’ fees, to be paid by the relator.

2. Relators are protected by whistleblower provisions in the Act. A number of *qui tam* relators retain employment in the firms that they sued.

vi. Some examples of practices in pharmacy settings that have led to *qui tam* suits. Note that many of these would also be subject to rejection of claims in an audit (see above), but would only be sustained in a *qui tam* suit if intent or reckless disregard of the truth could be proven.

1. Billing for goods or services that were never delivered (e.g., failing to reverse a claim for prescriptions that

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were never picked up, or for unclaimed partial fills that were returned to stock)
2. Upcoding – billing for a higher class of service or goods than provided
3. Billing for brand name drugs when generics were dispensed.
4. Billing for a more expensive dosage form of the prescribed drug.
5. Being overpaid on a prescription claim and not reporting that overpayment.
6. Obtaining prescription business by kickbacks.
7. Billing for unapproved drugs, or for approved drugs for indications not recognized by USP-DI or AHFS.
8. Forging physician signatures when such signatures were needed to authorized billing to Medicare or Medicaid.

vii. Most qui tam suits are brought against major corporations. The principal reason is that the case must have sufficient value to be worth the cost of investigating and prosecuting it, and the defendants must have sufficient resources to pay the civil fines. Smaller firms typically declare bankruptcy when faced with treble damages in these suits.

b. State False Claims Acts. Washington has not adopted a state false claims act, but relies on criminal prosecution, or, for Medicaid, on the operation of the federal act. Jurisdictions with false claims acts that are equivalent to the federal act include: California, Delaware, the District of Columbia, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, and Virginia.310 The Deficit Reduction Act of 2005 enacted an incentive for states to adopt false claims acts that mirror the federal act: they obtain a 10% increase in their share of false claims recoveries.

c. Federal Criminal Statutes. The False Claims Act provides civil penalties for fraud against the government, but there are a large number of corresponding criminal statutes under which violators may be fined or imprisoned. These are not confined to one statute, but fraud against the Government may be criminally prosecuted under many laws. Without going into great detail, here’s a partial list:

i. Submitting False Claims (18 USC § 287). This is the criminal statute companion to the False Claims Act, and was also first passed in 1863. Penalties include fines and/or imprisonment up to 5 years.

ii. **Making False Statements** (18 USC § 1001). This was a companion to § 287, with similar penalties, adopted first in 1863.

iii. **Mail or Wire Fraud** (18 USC §§ 1341, 1343). The major statute used by the Department of Justice to prosecute fraud, including healthcare fraud, because almost every scheme to defraud at some point involves transmitting information, claims, contracts, etc., through the mails or by “wire.”

iv. **Medicare and Medicaid Fraud** (42 USC §§ 1320a-7b(a)(1)). This statute is found as part of the Medicare Anti-kickback statute (see above), with similar penalties, and it applies to all federal health programs, covering fraud other than kickbacks or self-referrals.

v. **HIPAA Fraud Statutes.** HIPAA included three major sections devoted to health care fraud, and unlike the Medicare and Medicaid fraud laws, the HIPAA statutes apply to fraud against “health care benefit programs,” which would include private insurers. The three sections are similar to equivalent sections of the Civil War statutes and the Medicare and Medicaid fraud and kickback statutes, with somewhat different sentencing rules.

1. **Health Care Fraud** (18 USC § 1637)
2. **Theft or Embezzlement in Connection with Health Care** (18 USC § 669)

vi. **Other Federal Statutes** that may be involved include the following (citations to the USC omitted):

1. **Money Laundering**
2. **RICO (Racketeer Influenced and Corrupt Organizations Act)**
3. **Conspiracy**
4. **Theft of Government Property**
5. **Obstruction of Justice**
6. **Disposing of Assets to Obtain Medicaid Coverage** (18 USC § 1320-7b(a)). This statute applies to prospective Medicaid recipients who “knowingly and willfully dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under title XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c).” One commentator has suggested that actually prosecuting a person under this section will be difficult, in part, because it is otherwise legal to do
exactly what the statute prohibits, and it results in a
delay of eligibility for Medicaid.\footnote{Bucy P. Health Care Fraud: Criminal, Civil and Administrative Law. New York: Law Journal
Seminars Press, 1997, p. 3-52.} Fraudulent
concealment of assets by a prospective Medicaid
recipient could be dealt with by any number of other
federal fraud statutes.

d. \textbf{Deficit Reduction Act of 2005 fraud reduction provisions.}
   
i. State Medicaid agencies must provide in the state plan that
   any entity that receives $5 million or more in Medicaid
   receipts must
   1. Establish written fraud control policies
   2. Include in those policies procedures for detecting
      fraud, waste, and abuse
   3. Include in the employee handbook a statement
      informing employees of their rights to be protected as
      whistleblowers.
   
   ii. The DRA expanded funding for federal anti-fraud resources:
   1. Increased CMS’ Program Integrity Team from 8
      individuals to 100 nationwide
   2. Increased CMS anti-fraud funding from $5 million/year
      in 2006 to $75 million per year in 2009 and thereafter.
   3. OIG receives an additional $25 million/year for FY
      2006 through FY 2010 for Medicaid integrity activities

15. \textbf{Corporate Integrity Agreements.} As a result of adverse audits, and/or
settlements in civil false claims or fraud lawsuits, the OIG may impose a
Corporate Integrity Agreement (CIA) as a condition of the settlement or
continuation of eligibility for participation in federal programs. The OIG
may also impose (or negotiate) Certification of Compliance Agreements
(CCA), or may supervise Settlements with Integrity Provisions.
Collectively, these are all considered Compliance Agreements. A related
alternative for criminal settlements is a Deferred Prosecution Agreement
(DPA), by which defendants charged with criminal offenses agree to
adhere to the DPA, and after a period of time of compliance, the charges
will be dismissed. The OIG website currently lists several hundred of these
agreements.\footnote{http://www.oig.hhs.gov/fraud/cia/cia_list.asp} Agreements are posted for at least: 12 pharmaceutical
manufacturers, 3 national pharmacy chains, 1 national long-term care
pharmacy chain, 6 independent pharmacies, 2 national PBMs, 4 medical
device manufacturers, and 14 major university medical centers. The CIAs
for the pharmaceutical manufacturers are all related to settlements which
total at least $4.35 billion.\footnote{http://www.taf.org/top100fca.htm, accessed 1/6/08.}

   a. \textbf{Typical elements} of a CIA include the following obligations:
i. Hire a compliance officer and appoint a compliance committee
ii. Develop written standards and policies
iii. Implement comprehensive employee training programs
iv. Review claims submitted to federal health care programs (may include submitting samples to CMS and/or use of an Independent Review Organization (IRO) to do the review and submit reports.
v. Establish a confidential disclosure program
vi. Restrict employment of ineligible persons
vii. Submit reports to OIG

b. **Typical Length of CIA.** CIAs typically operate for 5 years, but terms can vary and have included as little as 3 years and upwards of 9 years.

16. **Excluded Persons.** The OIG may exclude individuals or corporations from participation in federal programs. Excluded persons may not be hired by government contractors to do work related to any government program from which they are excluded. Entities may not bill federal programs for any claim that involves work or participation by an excluded individual. This applies whether or not the employer has a CIA. So, an excluded pharmacist cannot really work for any pharmacy that serves Medicare or Medicaid patients.

  a. **Reasons for exclusion include:**
     i. Misdemeanor conviction related to health care fraud
     ii. License revocation or suspension
     iii. Default on federal student loans
     iv. Felony conviction related to controlled substances.

  b. **Lists of excluded persons**
     iii. State Agencies may also exclude individuals, and may do so for different reasons than the federal government.

  c. **If excluded, must reapply; reinstatement is not automatic.** For example, a pharmacist’s license is suspended for 6 months, leading to exclusion. Upon reinstatement of the license, the pharmacist must apply for reinstatement of eligibility to participate in federal programs, and reinstatement is neither automatic nor immediate.

17. **Medicare – Overview.**

  a. Medicare is a federal system of health care for the elderly, and certain other permanently disabled persons. The Medicare legislation is part of the Social Security Act, and the program is administered by CMS. The SSA was first enacted in 1935, and did not cover medical care. Title XVIII of the SSA, “Health Insurance for the Aged and Disabled,” was enacted in 1965, to provide health
care coverage to complement existing Social Security provisions for
retirement, survivors, and disability insurance beneficiaries. Medicare is now a four-part program.  

i. **Part A – Hospitalization.** Pays for care provided to SSA beneficiaries in hospitals, skilled nursing facilities (SNFs), hospices, and home health care programs. Eligibility is automatic for citizens of the US if they or their spouse worked for 10 years in Medicare-covered employment and they are 65 years of age or older. In 2009, 45 million persons were enrolled in Part A (37.5 million aged and 7.4 million disabled).

1. No premium is charged for persons 65 or older if they are receiving or eligible to receive Old-Age, Survivors and Disability Insurance (OASDI) or Railroad Retirement (RR) benefits, or had Medicare-covered government employment.
2. A premium may be paid to purchase Part A coverage for persons 65 or older who do not meet these requirements (“uninsured aged”) which is reduced for individuals who have accrued 30 quarters of qualifying covered employment. For 2010, the monthly premium range is $461, or $254 if reduced.
3. Persons under age 65 who have received OASDI or RR benefits for 24 months are eligible for Part A without a premium; persons with amyotrophic lateral sclerosis (ALS) may waive the 24-month waiting period.
4. Persons with end-stage renal disease (ESRD) who require kidney dialysis or renal transplant may enroll in Part A without a premium.
5. Part A benefits are limited to a “benefit period,” which begins when the beneficiary first enters a hospital, and ends with a break of at least 60 consecutive days since inpatient hospital or SNF care was provided. There is no limit on the number of benefit periods that will be covered for a particular beneficiary during his or her life, but there is a limit on the number of days of care that are paid for during a single benefit period.
   a. Inpatient hospitalization – 90 days of care per benefit period, with an up-front deductible, and with co-pays required from days 61 through 90. A lifetime reserve of 60 days can be drawn.

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upon, again with co-pays. In 2010, the up-front deductible is $1,100, and co-pays are $275 per day or $550 per day if reserve days are used.

b. SNF care – 100 days of care per benefit period. Generally, care must start within 30 days of a hospitalization of 3 days or more. No deductible is charged, and 20 days of SNF care are fully covered per each benefit period, with co-pays for days 21-100 per benefit period. In 2010, the co-pay is $137.50 per day.

c. Home health care – there is no deductible or coinsurance payment for home health care services covered under Part A, which applies to the first 100 visits following a 3-day hospital stay or SNF stay.

ii. **Part B – Medical Insurance.** Pays for physicians’ services, outpatient hospital care, and other services not covered under Part A. It also covers home health care services not associated with a prior hospitalization or SNF care. Enrollment is voluntary, and requires a monthly premium. Persons eligible to purchase Part A may also purchase Part B, even if they do not participate in Part A. Almost all persons entitled to Part A choose Part B as well; in 2009, 42 million persons were enrolled in Part B (35 million aged and 7 million disabled).

1. Among its other coverages, Part B pays for approved DME for home use, such as respiratory care, oxygen, prostheses, mobility aids, surgical dressings, and braces. It also pays for injectable drugs that are not normally self-administered (e.g., vaccines, immunosuppressives) and certain self-administered oncology drugs. It pays for drugs that are administered by approved devices (e.g., bronchodilators administered by nebulizer, but not MDI). It also pays for certain services and supplies to patients with diabetes.

2. To be covered, services must be one of several enumerated preventive benefits, or must be medically necessary. Documentation of the medical need must be retained by the provider of the service.

3. Certain services are subject to special payment rules, including deductibles (for blood), maximum approved amounts (for non-hospital based PT, OT, or speech therapy), or higher cost-sharing levels (e.g., outpatient treatment of mental illness).

4. Cost-sharing under Part B includes:
a. One annual deductible ($155 in 2010)
b. 20% co-insurance for most services (based on remaining allowed charges)
c. A deductible for blood
d. Patient pays in full for non-covered services.
e. 50% co-pay for outpatient mental health services (in 2009 - will phase down to 20% over the years 2010 through 2014)

5. Premiums for 2010 are as follows:

<table>
<thead>
<tr>
<th>Annual Income*</th>
<th>Premium**</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; $85,000 per year</td>
<td>$110.50 per month</td>
</tr>
<tr>
<td>$85,001 - $107,000 per year</td>
<td>$154.70 per month</td>
</tr>
<tr>
<td>$107,001 - $160,000 per year</td>
<td>$221.00 per month</td>
</tr>
<tr>
<td>$160,001 - $213,000 per year</td>
<td>$287.30 per month</td>
</tr>
<tr>
<td>&gt; $213,000 per year</td>
<td>$353.60 per month</td>
</tr>
</tbody>
</table>

*Income levels double for joint tax return filers.

"Hold-harmless" provisions will keep the 2010 premium at $96.40 for about 73% of enrollees because of reduced cost-of-living-adjustments due to the recession. – As of November 2009, it was possible that Congress would modify the bottom rate.

iii. Part C – Medicare Advantage. The original approach to Medicare is called the “fee-for-service” (FFS) program, in which individual providers are paid a fee for allowable services provided to Medicare patients. Part C allows participants in both Part A and Part B to receive their care from organizations that will provide Part A and B services as a package of benefits. Three types of Part C providers currently are available:

1. Coordinated care plans (CCPS), such as health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs), and other plans (Special Needs Plans and Medical Savings Accounts) that fit the standard of Part C.

2. Private, unrestricted FFS (PFFS) plans, which allow beneficiaries to select certain participating private providers. These plans have an advantage for participating providers in that, as long as they accept the plan’s payment terms and conditions, they are not at risk, nor do their payment rates vary based on utilization.

3. Regional Medicare Advantage plans, which agree to provide services throughout one or more of 26
regions in the US. These plans began enrollment in 2005.

4. CCPs and PFFS plans must offer the basic Medicare benefit package, excluding hospice services, and must either offer additional covered services if plan costs are lower than the Medicare payments received by the plan, or return excess payments.

iv. **Medigap Insurance Policies.**315 The payment limits and service restrictions under Part A, and co-pays under Part B have led to the development of private insurance offerings (also called Medicare Supplement Insurance) that fill in “gaps” in Medicare Part A and B (but not Medicare Advantage) plans. In most states, insurance companies can only issue a “standardized” Medigap policy, with variable benefits according type of plan. The plan types are labeled A through L. Two plan types, F and J, have a “high-deductible” option. Therefore, within a type of plan, the only major variable across insurance providers is the plan premium. State and federal laws restrict Medigap policies, among other rules:

1. The policy must clearly identify it as “Medicare Supplement Insurance.”
2. It can only cover one person, so a husband and wife must each purchase their own policy.
3. All plans cover Part A coinsurance and other uncovered items related to hospitalization, and all plans cover preventive care coinsurance. All plans cover all or at least half of Part B coinsurance or copayments. Plan J covers virtually all coinsurance, deductibles, or co-pays, except hospice care.
4. Medigap insurance has guaranteed renewability, and patients have a guarantee of being able to purchase Medigap insurance if:
   a. It is during a Medigap open enrollment period (6 months from a person’s 65th birthday), or
   b. The patient has “guaranteed issue rights,” primarily because of the type of plan he or she is already enrolled in.
5. Typical premiums for Medigap J policies available for a 65-70 year old in good health in Spokane in 2010 were around $173 per month, depending on the sponsoring insurance company.

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v. **Part D – Prescription Drugs.** Starting in 2006, Medicare Part D provided subsidized access to voluntary prescription drug insurance for individuals entitled to Part A or enrolled in Part B. Two types of offerings are available: stand-alone prescription drug plan (PDP) or a Medicare Advantage Plan that offers prescription coverage (Advantage-D plan). Additional detail on Medicare Part D is found in the next section. Approximately 32 million people enrolled in Part D in 2009.

vi. **Services Not Covered by Medicare.** No part of Medicare provides coverage for certain services, including long-term nursing care, custodial care, dentures and dental care, eyeglasses, and hearing aids. Some of these services may be provided by a Medicare Advantage plan, but most, such as dental coverage, will require a separate monthly premium (the premium for one dental insurance plan available in Spokane for a person > 65, with coverage similar to the WSU dental coverage, ranges from $57 – $68 per month per person.)

b. **Payments to Providers.** In general, the original Medicare plan is a fee-for-service plan where individual providers submit claims to Medicare for services rendered. Some of the Medicare Advantage plans reimburse providers on a FFS basis as well.

i. **Part A.** Payments to hospitals are based on a prospective payment system (PPS). Acute inpatient admissions are categorized by diagnosis-related group (DRG), and each DRG has a predetermined payment amount, which is the basis for payment. Certain adjustments may be made to the DRG’s pre-determine rate, but in the long run, the hospital is expected to make a profit on some admissions for a given DRG and lose on others. If the hospital is able to reduce its costs per DRG, then it will theoretically profit in the long run. Separately developed PPSs are used for SNFs, home health care, inpatient rehabilitation care, long-term care hospitals, and hospice. The pharmacy department’s contribution to reducing length of stay and complications of care for a given DRG are essential to a hospital’s financial success under a PPS.

ii. **Part B.** Physicians and other primary care providers are reimbursed on the basis of allowable charges, which are the lesser of the submitted charges, or the amount determined by a fee schedule based on a relative value scale (RVS). Coverage for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) is in Part B. Payments for DME and laboratory services are based on a fee schedule. Hospital outpatient services are reimbursed on a
PPS, as is home health care. The HCPCS coding system described above is used to describe the services provided.

1. **Accepting Assignment.** If the provider agrees to accept the Medicare-approved rate as payment in full, this is called “taking assignment.” The provider may not take any additional payments (aside from annual deductible and coinsurance) from the beneficiary or insurer. If the provider does not take assignment, then the beneficiary (or the Medigap insurer) will be charged for the excess, up to limits imposed by law. Physicians are “participating physicians” if they agree at the beginning of the year to take assignment for all Medicare services they provide during the year.

2. **DME providers must be accredited.**
   iii. **Part C.** Medicaid Advantage plans are paid on a capitation basis (a certain amount per beneficiary per month), but may pay contracting providers according to a FFS basis using their own rates.
   iv. **Part D.** PDPs and the prescription drug portions of the Advantage-D plans are reimbursed on a per enrollee per month basis based on a complex set of rules and the plan’s “risk-adjusted” bid to CMS. Individual providers, such as pharmacies, who contract with a given PDP are reimbursed according to the contract rates agreed to between the pharmacy and the plan.

18. **Medicare Part D in greater detail.**
   a. **Choice of providers.** As noted above, Part D enrollees may purchase Part D coverage from PDPs or Medicare Advantage-D plans that are available in their area.
   b. **Premiums.** The Part D base beneficiary premium for 2010 will be $31.94. However, plan providers may deviate from this level. It is estimated that the average premium in 2010 will be $30 per month.
   c. **Basic Benefit Design.** The Medicare Part D legislation established basic benefits, but individual plans may offer an alternated benefit design that provides the same actuarial benefit as the standard design. The basic design covers most FDA-approved drugs and biological, except for drugs covered under Parts A or B. Note in particular that the drugs must be FDA-approved in order to be covered. The deductible, co-pay, and limits are recalculated by CMS annually. For 2010, the following benefits are available under the basic design (pending Health Care Reform Legislation may change these):
      i. $310 initial deductible
      ii. For each covered prescription, beneficiary pays 25% of the remaining cost, based on a price calculated by the plan. For
a given plan, the price will be the same at all participating pharmacies.

iii. There is an initial coverage limit of $2,830 in total costs. At the point in which this limit is met, the patient will have paid $940 out of pocket.

iv. The patient then pays 100% of costs until his or her total out-of-pocket expenses reach $4,550. At this point total covered drug costs will have been $6,440.00). This gap in coverage has been called the “donut hole.” Calculation of the patient’s actual out-of-pocket expenses is established by Medicare Part D rules, and the resulting measure is called the beneficiary’s True Out of Pocket Expenses, or TrOOP. The proposed PhRMA contribution of $80 billion to reduce the donut hole that is part of the health care reform legislation is intended to affect this greatly.

v. Once the TrOOP limit is reached, for the rest of the remaining year the catastrophic coverage provisions come into play, and the patient pays the greatest of 5% coinsurance or a defined copayment of $2.50 for generics or $6.30 for single source drugs.

d. **Drugs Not Covered in Standard Plan.** The following drugs or indications are *not* covered by standard plans, but may be covered by plans using alternate designs:

   i. Anorexia, weight loss, or weight gain
   ii. Fertility promotion
   iii. Hair growth
   iv. Symptomatic relief of cough and colds
   v. Prescription vitamins and minerals (except prenatal vitamins and fluoride)
   vi. Nonprescription drugs
   vii. Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale
   viii. Any drug covered by Part A or Part B
   ix. Drugs or indications not approved by the FDA, however, non-approved indications (other than those listed above) for approved drugs will be covered if the indication is supported by one or more citations in at least one of the following compendia:
      1. AHFS Drug Information
      2. USP-DI
      3. DRUGDEX Information System
      4. AMA Drug Evaluations

All plans, including those with alternate designs, must ensure that drugs are used for medically acceptable indications.
There are certain exceptions for combination products; for example, Fioricet with Codeine can be covered, even though it contains butalbital. A more complete list of excluded and allowed drugs is available on the CMS website (http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDDrugsPartDExcludedDrugs_04.19.06.pdf).

e. **Alternate designs.** The majority of patients have enrolled in Part D plans with low or no deductibles, flat payments for covered drugs, and/or partial coverage in the donut hole. Choosing among available plans is one of the challenges facing the elderly, and the opportunity to change plans occurs annually.

f. **Low Income Medicare Beneficiaries** are eligible for reduced cost-sharing, and if otherwise qualified for Medicaid, may have Medicaid coverage, but Medicaid will not pay for covered drugs; rather, individuals receive a low-income subsidy (LIS) for their Part D premium. (See dual-eligible patients, below.)

g. **Medication Therapy Management (MTM).** All Part D plans are required to provide for MTM services as an effort to reduce total Medicare costs for patients with multiple chronic diseases (MCDs), multiple Part D drugs (MPD), and the likelihood of incurring high annual costs. These services may be performed in a variety of ways, and plans may reimburse pharmacists for performing them.

h. **Pharmacist Reference Guides.** CMS provides a variety of Medicare resources specifically for pharmacists, in the CMS Pharmacy Center.  

i. **Assisting patients in selecting a plan.** The official CMS Medicare website for patients is www.medicare.gov. CMS provides a plan finder tool on their website. There are also commercial “Medicare Part D Plan Finders,” such as www.Q1Medicare-PartD.com, which is sponsored by a group of insurance brokers, and pharmacy-sponsored tools, such as the CVS/pharmacy Medicare Decision Tool. Pharmacists may assist patients in using any unbiased plan finder tool, but may not steer the patient toward a plan that may be economically preferable to the pharmacy.

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316 http://www.cms.hhs.gov/center/pharmacist.asp
317 http://www.medicare.gov/MPDPF/Public/Include/DataSection/Questions/MPDPFIntro.asp
319 http://www.pharmacist.com/AM/Template.cfm?Section=APhA_Resources_Medicare1&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=13204
j. Required notice to patients about their rights. Plans must distribute the following or equivalent notice to participating pharmacies, to make available to enrollees:

<table>
<thead>
<tr>
<th>MEDICARE PRESCRIPTION DRUG COVERAGE AND YOUR RIGHTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>You have the right to get a written explanation from your Medicare drug plan if:</td>
</tr>
<tr>
<td>• Your doctor or pharmacist tells you that your Medicare drug plan will not cover a prescription drug in the amount prescribed by your doctor.</td>
</tr>
<tr>
<td>• You are asked to pay a different cost-sharing amount than you think you are required to pay for a prescription drug.</td>
</tr>
<tr>
<td>The Medicare drug plan’s written explanation will give you the specific reasons why the prescription drug is not covered and will explain how to request an appeal if you disagree with the drug plan’s decision.</td>
</tr>
<tr>
<td>You also have the right to ask your Medicare drug plan for an exception if:</td>
</tr>
<tr>
<td>• You believe you need a drug that is not on your drug plan’s list of covered drugs. The list of covered drugs is called a “formulary;” or</td>
</tr>
<tr>
<td>• You believe you should get a drug you need at a lower cost-sharing amount.</td>
</tr>
<tr>
<td>What you need to do:</td>
</tr>
<tr>
<td>• Contact your Medicare drug plan to ask for a written explanation about why a prescription is not covered or to ask for an exception if you believe you need a drug that is not on your drug plan’s formulary or believe you should get a drug you need at a lower cost-sharing amount.</td>
</tr>
<tr>
<td>• Refer to the benefits booklet you received from your Medicare drug plan or call 1-800-MEDICARE to find out how to contact your drug plan.</td>
</tr>
<tr>
<td>• When you contact your Medicare drug plan, be ready to tell them:</td>
</tr>
<tr>
<td>1. The prescription drug(s) that you believe you need.</td>
</tr>
<tr>
<td>2. The name of the pharmacy or physician who told you that the prescription drug(s) is not covered.</td>
</tr>
<tr>
<td>3. The date you were told that the prescription drug(s) is not covered.</td>
</tr>
</tbody>
</table>

Specific instructions concerning posting of the notice are contained in the Medicare Part D Reference Guide for Pharmacists in its list of Model Documents (p. 6 in the December 2007 edition).

k. Pharmacies Must Inform Beneficiaries About Generics. Plans must ensure that pharmacy staff members inform beneficiaries of any price differential between a covered Part D drug and the lowest priced generic version of that drug that is available under the plan at the pharmacy. Pharmacy staff must provide this information at the time the beneficiary purchases the drug, or in the case of drugs purchased from mail service pharmacies, at the time of delivery.

l. Pharmacists may waive patient co-pays under certain circumstances. The Medicare Part D legislation modified the Anti-kickback statute to allow pharmacies to waive or reduce cost-sharing amounts provided they do so in an unadvertised, non-routine manner after determining that the beneficiary in question is financially needy or after failing to collect the cost-sharing amount.
despite reasonable efforts. Pharmacies may also waive or reduce a LIS beneficiary’s co-pay or cost sharing amount without determining the patient is financially needy or attempting to collect the cost-sharing amount. However, they cannot in any way advertise the provision of the waiver or cost-sharing reduction. As long as pharmacies follow these procedures, the waived amounts can still count toward the beneficiary’s TrOOP.

19. Medicaid -- Overview. The 1965 Social Security Amendments established a second federally-funded health care program in Title XIX, called “Grants to the States for Medical Assistance Programs.” It is more commonly known as Medicaid. Under the plan, states would continue to provide medical assistance for low income persons, but the federal government would share in the costs. One commentator has suggested that Medicaid may have been considered a “stopgap” piece of legislation, because it was widely expected that if Lyndon Johnson or Hubert Humphrey were elected to the Presidency in 1968, then a national health care system would shortly follow. In 2006, total state and federal expenditures on Medicaid approached $317 billion, with the federal government picking up approximately 57% of the total ($161 billion).

a. **States Administer Medicaid** programs under broad federal regulation. In Washington, Medicaid is administered by the Health and Recovery Services Administration (HRSA) in the Department of Social and Health Services. Every state must provide at least the following **Mandatory Benefits**:
   i. Inpatient and outpatient hospital services
   ii. Services by physicians and clinical laboratories
   iii. Nursing home care
   iv. Home health care

b. **Mandatory Eligible Groups (“Categorically Needy”)** include:
   i. Poor children and families who would have qualified under the former Aid to Families with Dependent Children (AFDC) program
   ii. Certain other poor and pregnant women
   iii. Elderly and disabled individuals who qualify for the Supplemental Security Income (SSI) program.
   iv. Enrollees must generally have both a low income and low level of assets, with upper limits varying according to the basis for eligibility.

c. **Optional Eligible Groups and Benefits.** States have fairly broad authority to administer the program and determine its scope. Some of the more common options adopted by states are:
   i. Prescription drugs – all states provide for categorically needy; more than half cover prescription drug for all

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recipients. If a state provides prescription drug coverage to any group of enrollees, it must cover:

1. All FDA-approved prescription drugs marketed by drug manufacturers who have entered into a rebate agreement with the Secretary of Health & Human Services;
2. All additional FDA-approved drugs that are on the state-developed Medicaid formulary;
3. Any non-formulary FDA-approved prescription drug that is specifically requested and approved through a prior authorization process.
4. Notwithstanding the above, states may exclude the 9 categories of drugs that are also excluded from the standard prescription drug plan under Medicare Part D (see above). Note, however, that Washington does cover several of the optional 9 categories (e.g., cough and cold, smoking cessation).

ii. Dental coverage

iii. Medically Needy. This group includes persons who would not normally qualify on the basis of income and assets, but have unusually high medical expenses. They are provided coverage after they have “spent down” their assets. The term “medically needy” may also apply to other optional groups who would not be eligible for welfare payments.

iv. States may seek federal waivers to allow them to provide benefits and cover groups that would otherwise be excluded under Medicaid.

v. In 2001, approximately 60% of Medicaid expenditures were for optional populations and benefits (net spending on prescription drugs after rebates accounted for 9.5% of Medicaid expenditures in 2002).321

d. Fee-for-service or Managed Care. Medicaid recipients may be covered under traditional FFS programs (and most are), or may participate in a managed care organization. In the latter case, the MCO is paid a fixed monthly payment; federal law allows deviations from the normal formulary requirements, but most states enforce the basic coverage requirements in their contracts with MCOs.

e. Medicaid Recipient Profile. In 2006, 61 million persons were receiving Medicaid benefits in the US. Approximately 30 million of these were poor children (about half), and another 25% were either the parents of these children or were poor pregnant women. The cost of benefits for these groups is fairly low. The remaining 25% of covered persons are elderly persons or persons with disabilities

requiring long-term care; however, these groups account for 2/3 of total Medicaid spending.\footnote{Meyerson N et al. The Long-Term Outlook for Health Care Spending, Congressional Budget Office, November 2007, Appendix A (http://www.cbo.gov/ftpdocs/87xx/doc8758/AppendexA.4.1.shtml, accessed 1/4/08).}

f. **Washington Provides Medical Assistance to Five Groups:**
   i. Medicaid – Categorically Needy (CN) Coverage
   ii. Medicaid – Medically Needy (MN) Coverage
   iii. Children’s Medical Program
   iv. Pregnant Women Program
   v. General Assistance
   vi. Alien Emergency Medical Program

g. **Provider Requirements for Participation**
   i. Properly licensed
   ii. Have a signed core provider agreement (CPA)
   iii. Follow guidelines in billing instructions and applicable WACs
   iv. Retain documentation that all other possible payers have been billed appropriately
   v. Participating pharmacies may be required to
      1. Obtain authorization on a drug or product
      2. Ascertain and document that certain diagnosis requirements are met
      3. Meet other requirements for client safety and program management.

20. **Medicaid Outpatient Prescription Drugs in WA – In Greater Detail**

   a. **Non-covered drugs in WA**
      i. Drugs used to treat sexual or erectile dysfunction, unless these are used for another indication approved by FDA.
      ii. Non-FDA approved drugs
      iii. Non-medically accepted indication or dosage level
      iv. Drugs from manufacturers without federal rebate agreements
      v. Drugs and indications excluded by rule, such as
         1. Weight loss or gain (does not exclude treatment for certain wasting disorders)
         2. Infertility, frigidity, or impotence
         3. Sexual or erectile dysfunction
         4. Cosmetic purposes or hair growth
      vi. More than a 34-day supply of any product except:
         1. When the smallest package size exceeds a 34-day supply;
         2. When special packaging instructions would require dispensing of a quantity that exceeds a 34-day supply
         3. Contraceptive patches, contraceptive rings, and oral contraceptives not used for emergency contraception.
These must be dispensed in a minimum three-month supply, unless otherwise directed by prescriber.

4. When the drug is specifically identified as exempt from the limit.

vii. Vitamins other than:
   1. Prenatal vitamins prescribed for pregnant women
   2. Vitamins prescribed for a diagnosed condition

viii. Fluoride preparations, except when prescribed for children under the EPSDT program

ix. Cough and cold products except for the following generic products:
   1. Guaifenesin 100 mg/5mL
   2. Dextromethorphan 15 mg/5mL
   3. Dextromethorphan 10-100 mg/5 mL
   4. Pseudoephedrine 30 mg and 60 mg tablet
   5. Saline nasal spray

x. Non-preferred drugs in classes on the Washington Preferred Drug List (PDL)

xi. Drugs prescribed for an indication that is not evidence-based as determined by:
   1. HRSA in consultation with federal guidelines;
   2. The Drug Use Review (DUR) Board; and
   3. HRSA medical consultants and pharmacist(s).

xii. Drugs prescribed on pre-signed prescription blanks completed by SNF operators or pharmacists. Pharmacies involved in this practice may have their CPA terminated.

xiii. HRSA will not reimburse the cost differential between the least costly dosage form of a drug and a more expensive dosage form with the same route of administration, unless the prescriber designated the costlier dosage form as medically necessary.

b. **Coverage of family OTC family planning products.** HRSA reimburses for the following OTC products, when dispensed, with or without a prescription, to any client with a current medical ID card:
   i. Condoms (including female condom)
   ii. Vaginal spermicidal foam with applicator and refills
   iii. Vaginal spermicidal jelly with applicator
   iv. Vaginal spermicidal creams and gels
   v. Vaginal spermicidal suppositories
   vi. Plan B® to clients age 18 or over (see ECP, below).

c. **Smoking Cessation**
   i. **OTC Nicotine Replacement Therapy** is reimbursed for specific products when distributed by a Department-approved smoking cessation program to clients 18 years or older.
ii. Covered products include
   1. Nicotine gum
   2. Nicotine transdermal patches
   3. Bupropion SR (Zyban®)
   4. Chantix® (varenicline tartrate)

iii. For pregnant women, only bupropion SR will be covered, for up to 11 months.

d. Prior Authorization is required by the point-of-sale (POS) billing system
   i. For certain drugs in the formulary;
   ii. For non-formulary drugs;
   iii. For certain drugs when limits are exceeded on dosage, quantity, utilization or duration of use;
   iv. For certain situations:
      1. Early refills
      2. Therapeutic duplication
      3. Clients whose utilization patterns are under review
      4. More than 4 prescriptions or refills per calendar month for the same product in any of the following categories:
         a. Antibiotics
         b. Antiasthmatics
         c. Schedule II and III drugs
         d. Anti-neoplastic agents
         e. Topical preparations; or
         f. Propoxyphene salts or combinations
      5. More than 2 prescriptions or prescription refills per calendar month for any other product
   v. Prior authorization is obtained by faxing a proper form to HRSA or by calling a prior authorization hotline for pharmacists.
      1. Expedited Authorization. A large number of drugs may be handled in the POS if the pharmacist indicates via a specific code a justification for the drug’s use. Documentation supporting the use of the code (including specific diagnosis and the full name of the person that supplied the diagnostic information) must be maintained and retained in the pharmacy.
   vi. Pharmacists may fill without prior authorization in emergency situations, provided that justification is supplied to HRSA within 72 hours after the fill date (excluding weekends and state holidays).

e. Compliance Packaging.
   i. HRSA will reimburse the cost of a compliance device (e.g. Medisets, bubble or blister packs) plus a fee for dispensing a
client’s drugs in compliance packaging (WAC 388-530-7400) based on the type of packaging:

1. Reusable compliance device or containers
   a. “Regular capacity” - $6.00 maximum per device, up to 4 per client per year
   b. “Extra large capacity” - $16.91 maximum per device, up to 4 per client per year
   c. Filling fee for reusable device - $2.50 per fill, up to 4 fills per client per month

2. Non-reusable device or container - $3.00 per fill, up to 4 fills per client per month (fee includes cost of container)

ii. Patient’s eligible for compliance packaging include those who
   1. do not reside in an SNF or other inpatient facility; AND
   2. have one or more of the following representative disease conditions:
      a. Alzheimer’s disease
      b. Blood clotting disorders
      c. Cardiac arrhythmia
      d. CHF
      e. Depression
      f. Diabetes
      g. Epilepsy
      h. HIV/AIDS
      i. Hypertension
      j. Schizophrenia or
      k. Tuberculosis, AND

3. Concurrently consume two or more prescribed medications for chronic medical conditions that are dosed at three or more intervals per day OR have demonstrated a pattern of noncompliance that is potentially harmful to the client’s health. The pattern of noncompliance must be fully documented in the pharmacy’s file.

f. **Compounded Drugs.** HRSA reimburses for covered compounded drugs, without prior authorization, except if any ingredients require prior authorization. However, the pharmacy must retain documentation that the client’s drug therapy needs cannot be met by commercially available dosage strengths and/or forms of the medically necessary drug. Detailed billing instructions must be followed. HRSA pays for the costs of each ingredient, plus the standard dispensing fee, but does NOT pay a separate compounding fee for the time involved.
g. **Emergency Contraception.** ECP is reimbursed for female clients aged 17 or under with a prescription, or female clients 18 and older without a prescription.\(^{323}\)
   i. HRSA notes that “it is common practice to dispense two packages at a time, especially for clients using barrier contraceptive methods. Pharmacies are instructed to dispense the quantity requested by the client (or prescribed).
   ii. When a pharmacist with an EC protocol approved by the Board of Pharmacy prescribes ECPs, the pharmacy may bill HRSA for the counseling portion. The maximum EC counseling fee is $13.50. It is critical that the approved protocol covering the date of service is on file at the pharmacy where the service was performed.
   iii. Pharmacists prescribing EC under protocol may also prescribe and bill for selected anti-emetics when dispensed in conjunction with the ECP.

h. **Clozapine Related Services.** Pharmacists with clinical experience in monitoring patient mental and health status may provide and bill for case coordination (medication management) for clients receiving clozapine.
   i. Up to 5 refills will be allowed/month for clozapine when closely monitored
   ii. Pharmacists may bill for
      1. Case coordination - $10/week per client
      2. Venipuncture – per RBRVS schedule
      3. CBC – per RBRVS schedule

i. **Vaccines.** Qualified pharmacists are reimbursed for cost of the vaccine plus a fee for administration of HRSA-covered vaccines for clients in eligible programs.
   i. Does not reimburse for the cost of any vaccine available free from DOH.
   ii. Administration of pneumococcal and flu vaccines provide a fee of $11.47. Payment is only made if pharmacist has a vaccination protocol on file with the Board of Pharmacy. Administration to ages 19 and older is through the POS system, pediatric vaccines and vaccines other than flu or pneumococcal are billed on a HCFA 1500 form.
   iii. Gardasil® is only covered for clients between the ages of 9 and 20.

j. **Prefilled syringes.** A fee is paid for dispensing pre-filled syringes for eligible patients. Each dispensing must be of sufficient syringes for a two-week supply, and the total fee is $10 per two week supply, and up to 3 supplies per month, with exceptions specified in the billing rules.

\(^{323}\) As of January 2010, this has not be revised to account for the ability to sell Plan B OTC to women 17 and under.
k. **Special Drug Use Projects and Initiatives.** HRSA has undertaken a variety of initiatives to improve safety and drug use. To the extent that some of these projects have resulted in dosage guidelines, they also now establish evidence that pharmacists can (and should) consider when reviewing drug therapy for non-Medicaid clients. Among the projects are:

i. **ADHD drug initiatives**
   1. Mandatory second opinion for children < 5
   2. Maximum doses for clients aged 5 or older
   3. Prior authorization for ADHD Drug Combinations

ii. **Anticonvulsants Off-label Use**

iii. **Antidepressants, Therapeutic Duplication**

iv. **Narcotic Use Review**

v. **Opiod Dosing Guidelines** (see [http://maa.dshs.wa.gov/pharmacy/toolkit.htm](http://maa.dshs.wa.gov/pharmacy/toolkit.htm))

vi. **Sedative/Hypnotic Restrictions in Children < 18** (one-time authorization of < 5 doses in a 30-day period)

l. **Patient Review and Coordination (PRC) Program.** This program may restrict a patient’s access to providers. An “X” is entered in the Restricted column of the ID card. Patients may be restricted to a particular primary care provider (PCP), narcotic prescriber, pharmacy, hospital, or another qualified provider type. The basis for placing a client in the PRR is the occurrence of

   i. Two or more of the following conditions in a 90-day period:
      1. Received services from four or more different physicians, ARNPs, or PAs
      2. Had prescriptions filled by 4 or more different pharmacies
      3. Received 10 or more prescriptions
      4. Had prescriptions written by 4 or more different prescribers
      5. Received similar services from 2 or more providers in the same day
      6. Had 10 or more office visits. —OR—

   ii. Any ONE of the following occurred within a 90 day period:
      1. Made 2 or more emergency department visits
      2. A medical history that indicates “at-risk” utilization patterns
      3. Made repeated and documented efforts to seek health services that are not medically necessary
      4. Been counseled at least once by a health care provider or an HRSA or MCO staff member, with clinical oversight, about the appropriate use of health care services. —OR—

   iii. The client or enrollee received prescriptions for scheduled drugs from two or more different prescribers in any month.
iv. TO AVOID ABUSE, HRSA encourages pharmacists not to accept cash from clients for prescriptions that would otherwise be covered.

m. Records Must Be Kept for 6 years. Among other specific items listed in the Billing Instructions, pharmacies must keep the following records

   i. Prescription Documentation. Copies of all prescriptions must be kept on file to document authorization for a Medicaid claim. Whereas Board of Pharmacy and DEA rules require that prescription records must be kept for 2 years (see Chapter 4 and 5), records needed to document Medicaid claims must be kept for 6 years (WAC 388-502-0020).

   ii. Proof of Delivery Records

   iii. Clinical Records for clinical services provided.

   iv. Specific additional records are specified for SNF pharmacies using unit-dose dispensing.

n. Tamper Resistant Prescription Pads. Written prescriptions that authorize Medicaid claims must be issued on tamper-resistant prescription pads.

   i. Phoned, faxed, or electronic prescriptions need not be recorded on tamper-resistant paper.

   ii. Pharmacists may fill prescriptions written on non-conforming pads if they obtain verification of the prescription from the prescriber by fax, phone, or e-mail prior to dispensing the prescription, and they retain documentation that the verification was received prior to release of the drug to the patient.

   iii. In documented emergencies, pharmacists may dispense pursuant to a non-conforming prescription provided they have received verification from the prescriber via fax, phone, or e-mail within 72 hours and retain documentation of that fact.

   iv. If the pharmacist receives a prescription transferred from another pharmacy, the pharmacist must obtain and record verification from the transferring pharmacist that the original prescription was, if in writing, written on a tamper-resistant prescription.

   v. If a patient is retroactively qualified for Medicaid, the pharmacist may submit a claim for the previously-dispensed prescription providing it was written on tamper-resistant paper, or was originally telephoned, faxed, or e-prescribed. Otherwise, the pharmacist must obtain verification of the original prescription from the prescriber.

   vi. Tamper-resistant pads are not required for the following enrollees:
1. Healthy Options managed care (HO)
2. Basic Health Plan (BHP+)
3. General Assistance Unemployable-Managed Care (GAU-MC)
4. Washington Medicaid Integration Partnership (WMIP)
5. Medicare/Medicaid Implementation Program (MMIP)

o. **Important Abuse Notifications in Billing Instructions.** The billing instructions particularly caution that the following practices constitute program abuse:
   i. Prescription splitting, or dispensing in ways intended to gain more than one dispensing fee:
      1. Supplying medication in amounts less than necessary to cover the days prescribed (unless limited by program rules in other ways); and/or
      2. Supplying medication in strengths less than those prescribed to gain more than one dispensing fee.
   ii. Excessive filling: Billing for an amount of a drug or supply greater than the prescribed quantity (except for specified mandatory minimums for covered OTC drugs)
   iii. Prescription shorting: billing for a drug or supply greater than the quantity actually dispensed
   iv. Substitution to achieve a higher price: billing for a higher priced drug than prescribed even though the prescribed lower priced drug was available (except when program rules identify a higher-priced drug as preferred).

p. **Client Eligibility ID:** Several forms of possible identification are used to indicate that a person is eligible for Medicaid coverage. Pharmacies should photocopy and retain a copy of proof of eligibility:
   i. DSHS Medical Identification card – white with green print.
   ii. Printout of a medical information screen from the local Community Services Office (CSO), Home and Community Services (HCS) office, or DSHS
   iii. An award letter from the CSO or HCS
   iv. Medical eligibility verification (MEV) receipt provided by an authorized MEV vendor with an "as of" date within the same month as date of service
   v. Printout of the client eligibility entry screen from the WAMedWeb.

q. **Program Identifiers:** The ID form includes an indication of the particular program in which the client is eligible. It is important for pharmacists to recognize these, for limited eligibility applies to several categories.
r. **CLIENTS WITH THE FOLLOWING IDENTIFIERS ARE ELIGIBLE FOR PHARMACY SERVICES:**

<table>
<thead>
<tr>
<th>Medical Program Identifier</th>
<th>Medical Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNP</td>
<td>Categorically needy AND childrens health program</td>
</tr>
<tr>
<td>CNP-CHIP</td>
<td>Categorically needy – children’s health insurance program</td>
</tr>
<tr>
<td>CNP-Emergency Medical Only</td>
<td>Categorically needy – emergency medical only</td>
</tr>
<tr>
<td>CNP-QMB</td>
<td>Categorically needy – Qualified Medicare Beneficiary (Dual-eligible with Medicare Part D)</td>
</tr>
<tr>
<td>Family Planning Only</td>
<td>Family Planning (limited coverage)</td>
</tr>
<tr>
<td>GA-U No Out-of-State Care</td>
<td>General Assistance – Unemployable; no out-of-state care</td>
</tr>
<tr>
<td>General Assistance</td>
<td>Alcohol and Drug Addiction Treatment and Support Act (ADATSA), ADATSA Medical Only</td>
</tr>
<tr>
<td>LCP-MNP</td>
<td>Limited Casualty Program – Medically Needy</td>
</tr>
<tr>
<td>LCP-MNP Emergency Medical Only</td>
<td>Alien Emergency Medical (AEM) Emergency Medical Only</td>
</tr>
<tr>
<td>TAKE CHARGE Family Planning</td>
<td>TAKE CHARGE (limited coverage)</td>
</tr>
</tbody>
</table>

**CLIENTS WITH THE FOLLOWING IDENTIFIERS ARE NOT ELIGIBLE FOR PHARMACY SERVICES:**

<table>
<thead>
<tr>
<th>Medical Program Identifier</th>
<th>Medical Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detox Only</td>
<td>Detox</td>
</tr>
<tr>
<td>MIP-Emergency Hospital Only; No Out-of-State Care</td>
<td>Psychiatric Indigent Inpatient (PII) program</td>
</tr>
<tr>
<td>QMB-Medicare Only</td>
<td>Qualified Medicare Beneficiary – Medicare Only</td>
</tr>
</tbody>
</table>

s. **Reimbursement of Pharmacies.** As discussed above, Medicaid payments to FFS pharmacies involve two components: the cost of the drug and a professional fee. The following are significant rules related to pharmacy reimbursement in Washington:
i. Medicaid is a payer of last resort; pharmacists must seek payment from all possible other providers before billing Medicaid.

ii. Pharmacies must bill their usual and customary charge using the specific 11-digit NDC of the drug product dispensed.

iii. Accurately report the quantity dispensed using metric quantities:
   1. Tablets, capsules, etc., in units dispensed.
   2. Liquids in milliliters

iv. The POS system calculates the allowable drug cost using the lesser of the applicable:
   1. EAC plus a dispensing fee*
      a. The EAC (primarily for single-source drugs) is currently calculated as AWP-16%.
      b. Multiple source drugs with five or more manufactures have an EAC calculated as AWP – 50%.
   2. S-MAC plus a dispensing fee*
      a. The S-MAC is established by HRSA based on an estimate of the lowest price of a multiple source drug that is generally available.
   3. FUL plus a dispensing fee*
   4. A-MAC plus a dispensing fee*
      a. The A-MAC is determined by picking either the 2nd lowest price among multiple source drugs for which an S-MAC has not been set; or the lowest price for a multisource drug manufactured by a company with a rebate agreement.
   5. The provider's UAC fee for the prescription charged to the non-Medicaid public; or
   6. The AAC plus a dispensing fee* for 340B drugs dispensed to Medicaid clients.

v. If the pharmacy provider offers a discount, rebate, promotion or other incentive that directly relates to the reduction of the price of a prescription to the individual non-Medicaid customer, the provider must similarly reduce its charge to HRSA for the prescription. (Example: A $5.00 off coupon for purchases elsewhere in the store.)

vi. The pharmacy must supply free to Medicaid recipients any drugs or products that it supplies free to the public.
vii. *The dispensing fee is determined by the pharmacy’s prescription volume for both Medicaid and non-Medicaid prescriptions:

<table>
<thead>
<tr>
<th>Pharmacy Volume</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-volume pharmacies (over 35,000 Rx/yr)</td>
<td>$4.24/Rx</td>
</tr>
<tr>
<td>Mid-volume pharmacies (15,001-35,000 Rx/yr)</td>
<td>$4.56/Rx</td>
</tr>
<tr>
<td>Low-volume pharmacies (15,000 Rx/yr and under)</td>
<td>$5.25/Rx</td>
</tr>
<tr>
<td>Unit dose systems</td>
<td>$5.25/Rx</td>
</tr>
</tbody>
</table>

viii. Pharmacies must file an annual Prescription Count Survey with HRSA.

t. **Time Limits on Billing.** All claims must be submitted within 365 days of service. Corrections to claims may be made for up to 15 months. Refunds owed to HRSA by a pharmacy may be made through the POS system for up to 15 months; refunds after 15 months are still payable, must be made by check or money order outside of the POS system.

u. **Spend-down requirements.** Certain medically needy clients may have a spend-down requirement before they become eligible for medical assistance. In general, at the beginning of the spend-down period, the client pays the UAC for the prescription, and receives a receipt which is used to document the expenditure. Receipts from other providers can help meet the spend down requirement. The client goes to his or her CSO and documents achievement of the spend down, and receives documentation of eligibility for the remainder of the spend down period.

   i. **Some clients try to game the system.** One approach is to pay for the prescription, obtain the receipt, but ask the pharmacy to hold the prescription in the pharmacy. The client may then go to the CSO and get his or her Medicaid ID, and then return to the pharmacy, ask the pharmacist to refund his or her money and process the prescription via POS to Medicaid. Some CSO staff members have actually encouraged clients to do this, and the current DSHS systems do not have a good way to identify this type of fraud. A pharmacy that knowingly cooperates in this strategy is at risk of later prosecution under one or more of the various anti-fraud statutes discussed above.

v. **Collections from the Client.** (WAC 388-502-0160) The general rule is: PHARMACIES MAY NOT BILL OR COLLECT FROM MEDICAID CLIENTS ANY AMOUNT FOR ANY COVERED SERVICE.

   i. Providers may not bill the client, or the client’s estate, for otherwise covered charges unpaid by HRSA because of any failure on the part of the provider to bill in accordance with the rules.
ii. Providers are responsible to verify whether the client has medical assistance coverage for the date of service, and to check the limitations of the client’s medical program.

iii. A POS message requiring authorization of a prescribed drug is not a denial, but requires the pharmacist to attempt to obtain authorization.

iv. FFS pharmacy providers may bill a Medicaid client for a prescription service when the client is not enrolled in medical assistance managed care, and the client and provider sign an agreement regarding payment for service.
   1. The agreement must be translated or interpreted into the client’s primary language and signed before the service is rendered. The provider must give the client a copy and maintain the original in the client’s file for department review upon request.
   2. The agreement must include each of the following elements to be valid:
      a. A statement listing the specific service to be provided;
      b. A statement that the service is not covered by HRSA;
      c. A statement that the client chooses to receive and pay for the specific service; and
      d. The client is not obligated to pay for the service if it is later found that the service was covered by HRSA at the time it was provided, even if HRSA did not pay the provider for the service because the provider did not satisfy HRSA’s billing requirements.

v. An actual Medicaid client who represents to the pharmacist that he or she is a private pay patient may be billed for a prescription if the pharmacy obtains documentation that the client made such a representation. This requires a written statement that the client is a private pay patient that is signed by the client or representative; a copy must be maintained on file and a copy given to the client.

vi. Pharmacies may collect from a Medicaid patient if the collection is part of a spend-down requirement or co-pay required by HRSA regulations.

vii. No charge may be made for copying or transferring records or information regarding a Medicaid client to another provider.

w. Long-term Care prescriptions covered by Medicaid are billed under a particular additional set of regulations covered in the Billing Instructions. Medicaid offers different fees and options for pharmacies that use unit-dose dispensing.
x. **Coordination of Benefits.** It is the provider’s responsibility to bill HRSA appropriately after pursuing any potentially liable third-party resource when:
   i. Health insurance is indicated on the Medical ID Card;
   ii. The Point-of-Sale (POS) system alerts the provider to a client’s insurance; or
   iii. The provider believes insurance is available.

21. **Labor and Industries.** The Department of Labor and Industries administers a program to compensate injured workers in covered industries, and will pay for medical care for job-related injuries. Because these are state funds, all of the normal state laws concerning accountability and fraud are in operation, as they are for Medicaid. Participating pharmacies may fill prescriptions written by physicians or other prescribers only if the prescriber is also a participating L&I provider.

   a. **Eligible patients are those who are covered by an approved and open Labor and Industries State Fund (SF) claim.** Upon initial injury, a worker completes a Report of Accident (ROA) and obtains an examination, diagnosis, and initial treatment from a participating physician. The ROA contains a Claim ID number and a Claim ID card. Upon review by L&I of the ROA and physician’s report, the claim is approved or denied.
      i. **L&I also administers a medical care program for Crime Victims.** Participating pharmacies may provide covered services to these patients as well, under the same rules.

   b. **Pharmacies may bill L&I according to its rules if they have a claim number, but if the claim is later denied, they must seek to recover from the patient.**
      i. First Fills. Effective January 1, 2008, L&I guarantees to pay for the first fill of prescriptions issued during the initial visit for any new claim.
         1. Pharmacists must verify the claim ID using the L&I POS system, or actually see a copy of the ROA or Claim ID card. (It’s advisable to make a copy for the pharmacy records.)
         2. L&I will not pay for any refills or additional prescriptions until claim is approved.
         3. L&I will not pay if it is a federal claim or a self-insured claim, but pharmacies can submit the bill to the proper insurer. Self-insured claim numbers begin with S, T, or W.

   c. **Drugs must be on the L&I Formulary, or approved by prior authorization.**
      i. The provisions of the Preferred Drug List apply to L&I prescriptions.
ii. Specific control policies exist for certain drugs that are frequently misused in the workman’s compensation arena. In particular, L&I will not pay for prescriptions for carisoprodol or oral fentanyl products. Other specific control policies are listed on the L&I website.

d. Billings may be made in three ways
   i. POS system
   ii. Paper form
   iii. Using 3rd party billers. A specific agreement with L&I is necessary.

e. Payments to pharmacies.

<table>
<thead>
<tr>
<th>Generics and single Brand</th>
<th>AWP – 10%, plus $4.50 fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand name drug instead of generic equivalent (substitution permitted)</td>
<td>AWP – 10%, plus $3.00 fee</td>
</tr>
<tr>
<td>Compounded drugs</td>
<td>AWP – 10%, plus $4.00/15 minutes compounding fee, plus $4.50 fee. Prior authorization required.</td>
</tr>
<tr>
<td>Covered OTC drugs written on Rx – these are not subject to sales tax.</td>
<td>40% margin (i.e., $AWP \div 0.6$)</td>
</tr>
<tr>
<td>Medical devices</td>
<td>UAC, bill with HCPCS code for covered items: Note some items may only be rented, not sold. Prior authorization required for many items.</td>
</tr>
</tbody>
</table>

The complete billing manual for all professional services is found on the L&I website.

22. Basic Health Plan. Washington’s Basic Health Plan is designed to provide affordable health care insurance to otherwise uninsured individuals; it is an insurance package that meets core requirements set in the statute. Insurers who offer the plan in a region provide the entire package of benefits described in the statute, and the state provides subsidies to low-income families to offset the premium. Depending on family size, age, and income, Spokane County 2008 premiums for each covered member range from $17 per month at age 19 to a little less than

324 http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/Presc/Policies/default.asp
326 http://www.basichealth.hca.wa.gov/
$226 at age 64; coverage for children can be fully subsidized. No coverage is provided for persons 65 or older.

a. Prescription drugs are covered in 30-day supplies with a $10 co-pay for tier 1 drugs and 50% co-pay for tier 2 drugs, as set by each plan’s formulary. They are not subject to any other deductible or out-of-pocket limit.

b. Pharmacies that are part of a Basic Health Plan insurer’s network will be reimbursed for BHP prescriptions under the terms of their contract with the network.

c. Governor Gregoire’s budget proposal for 2010-11 proposes eliminating the Basic Health program effective June 30, 2010.

23. 340B Pricing of Pharmaceuticals. The federal government purchases drugs for the military and the VA at significant discounts. Under 1992 amendments to the Public Health Service Act, which became Section 340B of that act, manufacturers who participate in Medicaid must also participate in a program that sells drugs to qualified entities at the federal price. Drugs purchased under this program are called “340B drugs.” The pricing schedule for these drugs may also be called “PHS pricing” or “602 pricing.” The program is administered by the Health Resources and Services Administration (HRSA). HRSA maintains a 340B website for pharmacists at http://pssc.aphanet.org/default.htm.

a. The 340B price is a ceiling price, or the highest price that may be charged to a qualified entity. CMS determines and updates the 340B pricing schedule quarterly, using a formula designed to set the price at least as low as what Medicaid would pay after manufacturer rebates. 340B prices are typically 25% to 50% lower than AWP.

b. A national Prime Vendor is the single “preferred” wholesaler that serves 340B covered entities, provides value added services, and attempts to negotiate sub-340B prices with manufacturers based on volume. The current prime vendor manager is Apexus, and three national wholesalers serve as distributors: AmerisourceBergen, Cardinal Health, and McKesson Pharmaceuticals.

c. Qualified entities include the following:

i. Federally-qualified health centers (FHQC), which may take the form of
   1. FHQC Look-alikes
   2. Consolidated Health Centers
   3. Migrant Health Centers
   4. Health Care for the Homeless
   5. Health Schools/Health Communities
   6. Health Centers for Residents of Public Housing
   7. Office of Tribal Programs or urban Indian organizations

ii. A family planning project receiving certain federal grants
iii. Entities receiving grants under the Ryan White Act for Early HIV Intervention Services
iv. A state-operated AIDS Drug Assistance Program
v. A black lung clinic receiving certain federal funds
vi. A comprehensive hemophilia diagnostic center receiving certain federal grants
vii. A Native Hawaiian Health Center
viii. An urban Indian organization
ix. Certain PHS-funded entities certified by the Secretary of HHS
x. Certain entities certified by the Secretary receiving funds for treatment of STDs or tuberculosis
xi. A “disproportionate share” hospital
d. Qualified patients are any patient of a 340B entity if the entity maintains control of the patient’s medical records and has primary responsibility for the patient’s care.
e. Pharmacy Services Contract. 340B entities may contract with a local pharmacy to provide services and dispense 340B drugs to their patients. This allows the entity to avoid the startup and ongoing costs associated with maintaining its own in-house pharmacy.
   i. The entity must have an agreement with the pharmacy that meets the elements outlined in the Contract Pharmacy Services Model Agreement. 327
      1. The covered entity will order the drugs from the distributor, arrange to be billed directly for the drugs, and arrange to have the drugs shipped to the pharmacy.
      2. The covered entity will use the pharmacy’s business records to verify that a tracking system exists to assure that 340B drugs are not diverted to individuals who are not patients of the covered entity.
      3. The entity will have opportunity to inspect the tracking system prior to start of services.
      4. The contract pharmacy will dispense covered drugs only upon presentation of a prescription from the entity indicating that the patient is eligible for 340B drugs
   ii. The covered entity must certify to the PHS Office of Pharmacy Affairs that they have signed an agreement with the pharmacy.

Rev. 1/12/10

327 61 FR 43549, August 23, 1996.
Index

340B Pricing of Pharmaceuticals, 397
503A
  Section of FDAMA, 196
Abbreviated ndas, 117
Abortion, 55
AB-rated drugs. See Generic Drugs, Equivalency Ratings
Abuse reporting
  Children, 60
  Vulnerable adults, 60
Access to Care
  WSPA Policy, 58
Access to pharmacies restricted, 51
Accommodation Sales, 209
Acupuncturists
  Use of certain legend drugs, 209
Address
  Of patient, defined, 151
Address changes
  Sending to Board of Pharmacy, 33
Address Confidentiality Program, 32
Administer, defined, 30
Administration of Drugs by non-practitioners. See Drugs, Administration of by ...
Administration of drugs, defined, 77
Administrative law, 6
Adult family homes, 84
Adult foster care, 85
Adult habitation centers, 85
Adult living facilities, 84
Adulterated
  Defined, 122
Adverse Events
  Reporting required, 289
Advertising of Drug Prices, 342
Age Discrimination in Employment Act, 330
Age of consent, 286
Agencies
  Legislative Oversight of, 14
Aggravating and mitigating factors, 308
AHRQ, 22
Aid-in-dying, 56
Americans with Disabilities Act, 331
AMP, 350
AMP Litigation, 352
Amphetamine
  Limits on use in WA, 235
Ancillary Personnel. See Pharmacy Assistants
Ancillary personnel, pharmacy
  Non-delegatable responsibilities, 35
Animal Drugs, 121
Anslinger, Harry, 214
Anti-kickback Laws
  Washington state laws, 363
Anti-Kickback Laws, 359
Antineoplastic medications
  Home IV Therapy, 97
Any category of provider laws, 346
Any willing provider laws, 346
Appeals Courts, 9
Approved Drug Products, 105
ARNP, 139
Assault, 314
Assault and battery, 6
Assisted living, 84
ATSDR, 22
Audits
  Conduct of, 358
Audits
  Pharmacy claims, 356
Authenticated or authentication, defined, 77
Automated drug dispensing devices
  Facility responsibilities, 94
  Security, 93
Automated Drug Distribution Devices, 82, 92
  Approval required, 92
  Definition, 92
  Pharmacist oversight required, 93
Stocking of drugs, limited to intern, pharmacist or technician, 93
Average Manufacturer's Price, 350
Average Wholesale Price, 348
AWP, 348
Bar coding
  Institutional use drugs, 130
Basal thermometers, 121
Basic Health Plan, 396
Battery, 314
Behind the Counter. See BTC
BHRT, 201
Bingo cards. See Med-pack
  containers
Bio-identical hormone replacement
  therapy, 201
Board and care facilities
  Senior, 84
BTC drugs, 112
Buprenorphine
  Use in addiction treatment, 252
Buprenorphine
  Use for treatment of pain, 253
Bureau of Narcotics and Dangerous
  Drugs (BNDD), 215
Bureau of Prohibition, 214
Business, forms of, 63
Cabinet, US Executive Branch, 21
California licensure, 52
California Pharmacy Jurisprudence
  Exam, 53
Capital crimes, 7
Care, Levels of, defined, 84
Carisoprodol
  Schedule IV in Washington, 238
Caustic Poison Act of 1929, 114
CDC, 22
Central Hudson Tests
  For regulating commercial speech, 198
Changes of name, address
  Report to Department, 32
Child-resistant containers. See crcs
Citation Format, published opinions, 20
Civil law, 6
Civil Rights Act of 1964, 274, 330
Claims for Payment, 347
Class A Pharmacy, 72
Class I Device, 119
Class I Recalls, 186
Class II Recalls, 187
Class III Device, 119
Class III Recalls, 187
Clean Water Act (US), 189
Closing of a Pharmacy, 99
CMS, 22
COBRA, 276
Codes, 17
Common Law, 17
Compliance Policy Guide
  On Compounding, 199
Compounding
  FDAMA requirements, 196
Compounding, 194
  Compliance Policy Guide, 199
  Products liability, 313
  Using controlled substances, 240
  Voluntary Accreditation by PCAB, 204
  WA regulation of, 205
Compounding Pharmacists,
  International Association of, 204
Compounding, defined, 30
Confidentiality of patient records.
  See HIPAA
Congregate care facilities, 84
Conscientious Objection, 55
Consolidated Omnibus Budget
  Reconciliation Act of 1986. See
  COBRA
Constitution, 10
Consultant pharmacist, 86
Consultant pharmacist
  Federal law requirement, 89
  Consultation, defined, 45
Consumer Protection Act, 340
Containers
  USP requirements, 179
Continuing Pharmacy Education, 33
  First year renewal for new
  graduates, 34
Contracts, 6, 309
Contracts or Warranties, 309
Contraindication, 134
Controlled substances
   Authorized prescribers of, 224
   Internet distribution, 221
   Loss or theft, 227
   Prescribing for self not allowed, 217
   Required records, 65, 228
   Carisoprodol, 238
   Compounded products, 240
   Determining legitimacy of prescription, 255
   Emergency supply of Schedule II, 231
   Hospitals, Schedule II perpetual inventory, 82
   Hospital-based prescribers, 226
   In hospitals, 240
   In Long-term care facilities, 242
   Multiple Schedule II prescriptions, 231
   Out-of-state prescriptions, 225
   Partial filling of Schedule II prescriptions, 232
   Partial filling of Schedule III and IV prescriptions, 238
   Periodic inventories, 228
   Pharmacist editing of Schedule II prescriptions, 233
   Sales to researchers, 210
   Sales to teaching institutions, 210
   Schedule II requirements, 229
   Schedule III and IV computer records, 238
   Schedule III requirements, 236
   Schedule IV requirements, 236
   Schedule V Legend Drugs, 236
   Schedule V OTC drugs, 239
   Transfer of refill information, 236
   Transfer Warning Label, 233
   Use for aid-in-dying, 217
   Controlled Substances Act, 215
   Coordinated Quality Improvement Program, 289
   Corporation, 63
   Correctional facilities, 89
   Washington laws, 90

Cosmetics, 118
   CRCs, 124
      Exempted prescription drugs, 180
      Liability for use of non-crcs, 182
      Required for prescription drugs, 180
      Use of non-crcs, 181
   Criminal background checks, 59
      For out-of-state applicants, 60
   Criminal law, 7
   CRNA, 139
   CSA
      Prescription requirements, 216
      Reporting of suspected violations, 255
   Customized patient medication packages. See Med-Packs
   DailyMed, 134
   DATA. See Drug Addiction Treatment Act
   DAW (Dispense As Written), 164
   DEA
      Online registration application, 64
      DEA number
         Validation of, 225
   Death with Dignity Act, 218
   Deceased prescriber, 144
   Defamation, 313
   Deficit Reduction Act of 2005, 351
      Fraud, Waste, and Abuse provisions, 370
   Deliver, defined, 30
   Department of Health & Human Services, 22
   Department of Justice – Drug Enforcement Administration., 23
   DESI, 105
   Devices, 118
      Mercury-containing, 121
   Dietary Supplement Health and Education Act of 1994. See DSHEA
   Dietary supplements, 128
   Differential hours, 51
   Directions for use, 152
   Discard After Dates, 137
<table>
<thead>
<tr>
<th>Discipline</th>
<th>Administration by Respiratory Care Practitioners, 184</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggravating and mitigating factors, 308</td>
<td>Administration by school personnel, 185</td>
</tr>
<tr>
<td>Of Pharmacies and Pharmacists, 293</td>
<td>Recalls, in hospitals, 83</td>
</tr>
<tr>
<td>Process of, 299</td>
<td>Return or exchange prohibited, 185</td>
</tr>
<tr>
<td>Sanctioning guidelines, 302</td>
<td>State Regulation of, 113</td>
</tr>
<tr>
<td>Sanctioning process, 303</td>
<td>Drugs, investigational</td>
</tr>
<tr>
<td>Sanctioning schedules, 304</td>
<td>In hospital pharmacies, 83</td>
</tr>
<tr>
<td>Disciplined prescriber</td>
<td>DSHEA, 128</td>
</tr>
<tr>
<td>Validity of prescriptions, 144</td>
<td>Due Course of Medical Practice, 145</td>
</tr>
<tr>
<td>Disclosure of Patient Costs, 343</td>
<td>EAC, 349</td>
</tr>
<tr>
<td>Dispense, defined, 30</td>
<td>Effectiveness Required, 105</td>
</tr>
<tr>
<td>Dispensing</td>
<td>Emergency supply</td>
</tr>
<tr>
<td>By prescribers, 137</td>
<td>Of legend drugs in WA, 171</td>
</tr>
<tr>
<td>Disposal of Drugs</td>
<td>Eminent Domain, 15</td>
</tr>
<tr>
<td>By Patients, 193</td>
<td>Employee Retirement Income Security Act, 345</td>
</tr>
<tr>
<td>Disposal of Outdated Drugs, 187</td>
<td>Employees with a military spouse, 337</td>
</tr>
<tr>
<td>Distribute, 30</td>
<td>Employer Liability for employees' acts, 329</td>
</tr>
<tr>
<td>Divisions of law, 8</td>
<td>Employment</td>
</tr>
<tr>
<td>Divisions of the Law, 5</td>
<td>At will, 326</td>
</tr>
<tr>
<td>Domestic partners</td>
<td>Employees with military spouse, 337</td>
</tr>
<tr>
<td>Rights of, 285</td>
<td>Employers provision of references, 328</td>
</tr>
<tr>
<td>Drug Abuse Control Amendments of 1965, 215</td>
<td>Family medical leave, 336</td>
</tr>
<tr>
<td>Drug Development, 116</td>
<td>Non-competition clauses, 327</td>
</tr>
<tr>
<td>Drug Efficacy Review, 105</td>
<td>Non-discrimination in, 330</td>
</tr>
<tr>
<td>Drug Enforcement Administration.</td>
<td>Occupational safety, 336</td>
</tr>
<tr>
<td>See DEA</td>
<td>Of minors, 49, 335</td>
</tr>
<tr>
<td>Drug Product Selection, 157</td>
<td>Public policy exception to at will, 338</td>
</tr>
<tr>
<td>Drug Topics Red Book, 129</td>
<td>Salaries and overtime, 334</td>
</tr>
<tr>
<td>Drugs</td>
<td>Term contracts, 327</td>
</tr>
<tr>
<td>Administration by Dental Hygienists, 185</td>
<td>Unemployment compensation, 335</td>
</tr>
<tr>
<td>Administration by emts, 185</td>
<td>Employment contract, 326</td>
</tr>
<tr>
<td>Administration by Health Care Assistants, 184</td>
<td>English Language Required</td>
</tr>
<tr>
<td>Administration by Licensed Midwives, 185</td>
<td>OTC labels, 124</td>
</tr>
<tr>
<td>Administration by Nursing Technicians, 184</td>
<td>Ephedra, 127</td>
</tr>
<tr>
<td>Administration by OT or PT, 185</td>
<td>Ephedrine, 113, 244</td>
</tr>
<tr>
<td>Administration by other health professionals, 184</td>
<td></td>
</tr>
</tbody>
</table>
E-prescribing. See Prescriptions, electronic
Equal Pay Act of 1963, 331
ERISA, 345
Estimated Acquisition Costs, 349
Estrogens
  PPI requirements, 134
Ethics in Patient Referrals Act, 362
Excluded Persons, 371
Executive Branch, 21
Executive Order 13166
  And LEP, 274
Expedited Partner Therapy, 146
Expiration Dates, 136
Extended-care facilities, 84, 85
  Consultant or staff pharmacist duties, 86
  Destruction of discontinued drugs, 87
Drug regimen review by pharmacist, 86, 89
Drug storage and security, 86
Emergency drug kits, 88
Medicaid and Medicare requirements, 88
Medication labels, 86
Medication labels, non-prescription drugs, 87
Medication labels, traditional system, 86
Medication labels, unit-dose system, 87
Pass meds, 88
Pharmaceutical Services Committee, 85
Pharmacy provisions, 85
Reference material required, 86
Supplemental dose kit, unit-dose system, 88
Facsimile. See FAX
False arrest, 315
False Claims Acts
  State laws, 368
Family Medical Leave, 336
FAX
  Transmission of prescriptions, 155

FDA, 22
  Inspection powers, pharmacies, 73
FDAAA, 109
FDAMA, 109
  Compounding section, 196
FDCA, 103
  Washington State equivalent, 113
Federal Anti-Tampering Act, 126
Federal Codes, 19
Federal False Claims Act, 365
Federal preemption of state laws, 10
Federal Supply Schedule price, 350
Federal Tort Claims Act, 16
Federal Upper Limit, 349
Fee for Service, 340
Fee-splitting, 360
Fellowships, 55
Felonies, 7
Florida licensure, 52
Food and Drug Administration, 103
Food and Drug Administration (US). See FDA
Food and Drug Administration Amendments Act of 2007. See FDAAA
Food and Drug Administration Modernization Act of 1997. See FDAMA
Food, Drug and Cosmetic Act. See FDCA
Foods, 118
Formularies, negative
  For generic substitution, 164
Formularies, positive
  For generic substitution, 163
Fraud
  Federal criminal statutes, 368
FUL, 349
Generic drugs
  Hatch-Waxman Act, 159
  Innovator product, 158
Generic Drugs, 158
  Equivalency Ratings, 162
Generic substitution, 158
  Savings must be passed on to consumer, 165
Generic substitution
Notice to Public, 166
Out-of-state prescriptions, 164
Gonzales v. Oregon, 218
Comment on, 234
GRAS, 103
Gross misdemeanors, 7
Hague Convention, 213
Harrison Narcotic Act, 213
HCPCS, 355
Health care facilities, defined, 75
Health Care Fraud, 364
Health Information Portability and Accountability Act of 1996. See HIPAA
Healthcare Common Procedure Coding System, 354
Hierarchy of Laws, 10
HIPAA, 276
Allowable disclosures of PHI, 284
Confidentiality rules, 278
Fee for searching or copying records, 282
Notice of Privacy Practices, 280
Standard identifiers, 277
Time limits to respond to record requests, 281
HITECH Act of 2009, 268
HIV/AIDS Training
Requirement for Technicians, 46
Requirements for Pharmacists, 37
Home IV Therapy, 95
Homeland Security
Restrictions on preventing transport of legend drugs, 211
Hospital, defined, 76
HRSA, 22
IACP, 204
Identical, Related, or Similar Drugs, 104
IHS, 23
Immediate supervision, defined, 46
Impaired Health Professionals, 253
Impaired professionals
Referral to WRAPP, 254
Importation of Drugs, 210
Informed consent
Pharmacist must obtain if prescribing, 140
Informed consent, 318
Initiative 1000. See Death With Dignity Act
Inpatient drugs. See Drugs, inpatient
Institutional use drugs
Bar coding required, 130
Intentional infliction of emotional distress, 315
Intern pharmacist
Absence of preceptor, 40
Activities allowed, 38
Application form, 39
Defined, 38
Direct supervision, defined, 41
Eligibility, 38
Notify BOP of change of address, 42
Preceptor-student ratio, 41
Registration fee, 42
Reporting hours to other states, 42
Required Hours, 42
Residency Programs, 54
Satisfactory progress, 39
Supervision by a Preceptor, 36, 40
International Treaties, 10
Internet, 145
Internet pharmacies, 221
Invasion of privacy, 316
Ipecac syrup, 71
Itinerant Vendors, 128
Job shadow by high school students, 51
Joint Commission, 75
Kelo v. City of New London, 16
Kickbacks, 359
LAAM. See Levomethadyl
Of prescriptions, 130
Labeling
Antidepressant drugs, 136
Ambulatory prescriptions, 131
Ambulatory prescriptions, special situations, 153
Defined, 30
Market withdrawal
   Class of recalls, 187
Master License Application, 64
Maximum Allowable Cost, 349
Mckee v American Home Products, 270
MedGuides, 110, 135
Medicaid
   Compliance Packaging, 385
   Overview, 381
   Washington Outpatient Drugs, 383
Medical Center Pharmacy v. Mukasey, 200
Medical Device Amendments, 119
Medical Devices. See Devices
Medical facilities, defined, 76
Medicare
   Overview, 371
Medicare Anti-Kickback Statute, 361
Medicare Improvements for Patients and Providers Act, 353
Medicare Part A, 372
Medicare Part B, 373
Medicare Part C, 374
Medicare Part D, 376, 377
   Non-covered drugs, 378
Medication Therapy Management, 379
Medicine Equity and Drug Safety (MEDS) Act, 211
Medigap Insurance, 375
Med-pack containers, 85
Mensing v. Wyeth, 14
Mercury-containing devices, 121
Methadone
   Use in narcotic treatment programs, 251
   Use in pain treatment, 251
Methadone maintenance programs. See Narcotic Treatment Programs
Methamphetamine precursors, 126, 244
Methamphetamine Production Improvement Act of 2008, 248
Methylphenidate
   Limits on use in WA, 235
Midlevel practitioners
   Authorized in WA, 139
   Controlled substance authority, 225
Midwives, 139
Military Service Leave and Reinstatement, 337
Minors
   Mature Minor Doctrine and right to consent to therapy, 287
   Rights to control disclosure of PHI, 286
Misbranded
   Defined, 123
Misdemeanors, 7
Monitoring of drug therapy, defined, 30
MPJE, 53
Multi-state Pharmacy Jurisprudence Exam. See MPJE
NAPLEX, 52
   Pre-NAPLEX exam, 52
NAPLEX and MPJE
   Disability accommodations, 53
Narcotic Addict Treatment Act of 1974, 251
Narcotic Treatment Programs, 251
National Drug Code, 354
   Required on filled prescription, 154
National Provider Identifier, 277, 355
Naturopaths, 139
NDA, 117
NDC, 354, See National Drug Code
Needle exchange programs, 119
Negligence, 7, 316
New Drug Application. See NDA
New drugs, 103
New products
   FDA Classification Scheme, 117
NIH, 23
Nitroglycerine, sublingual
   Containers, 183
Non-CRC Containers
   Requirements for using, 181
Nonprescription Drugs. See OTC
North American Pharmacy Licensure Examination. See NAPLEX
Notice to Public
  Generic substitution, 166
NPI, 355, See National Provider Identifier
Nuclear Pharmacies, 98
Nurse Anesthetists. See CRNA
Nurse Midwives. See ARNP
Nurse Practitioners. See ARNP
OBRA-87, 88
  Patient Record Requirements, 263
OBRA-90
  Patient Record Requirements, 263
OD (optometrist)
  Prescribing by, 139
Offer to counsel, 272
Office use
  Prescriptions for, not valid, 216
Office-based narcotic maintenance programs, 252
Official Name, 158
Off-label uses, 148
OIG, 23
Old Drugs, 104
Omnibus Budget Reconciliation Act of 1987. See OBRA-87
Omnibus Budget Reconciliation Act of 1990. See OBRA-90
Online pharmacy, 221
Optometrists. See OD
Oral contraceptives
  PPI requirements, 134
Orange Book, 162
Orphan Drug Act, 109
OSHA, 336
OTC Drugs, 104, 122
  7-point label, 123
  Cracs required, 124
Drug Facts label, 123
  Imprints required in WA, 116
Prescription required in WA for,
  113
Tamper-proof packaging, 126
  Dispensing by prescription, 126
  Imprints required, 123
Non-pharmacy sales, 127
Spanish labeling, 124
Out-of-state prescriptions
  Generic substitution, 164
P2C2
  Compounding lawsuit, 196
PA-C, 139
Package insert
  See Labeling, professional, 132
Partial filling
  Legend drugs, 173
Partner packs, 146
Partnership, general, 63
Partnership, limited, 63
Partnership, Limited Liability (LLP), 63
PAs, 139
Patent rights, 159
Patient counseling, 271
  Documentation of, 273
  Patient Information Leaflets, 134
  Refusal to be counseled, 273
Patient medication record system, 260
  Data security, 265
  Use of, required, 268
Patient profiles
  Home IV Therapy, 96
Patient Safety and Quality Improvement Act of 2005, 291
Patients
  Disposal of drugs by, 193
  Right to see medical records, 281
PDMA
  Samples, restrictions on, 207
Percentage rents, 360
PGY1, 54
PGY2, 55
Pharmaceutical services committee, 85
Pharmaceutical Services Committee, 76
Pharmacies
  Ambulatory. See Pharmacies, Community
  Application to utilize ancillary personnel, 64
Discipline of, 45
Board denial of higher ratios, 50
License fees, 48
Pharmacist-technician ratios allowed with a utilization plan, 50
Specialized function, medication histories, 48
Specialized function, stocking automated distribution devices, 48
Specialized function, unit-dose checking, 47
Specialized functions, 47
Specialized functions, described in utilization plan, 49
Specialized function, IV admixtures, 47
Training programs, 43
Pharmacy Technicians and Assistants
Board of Pharmacy rules, 45
ID badges required, 49
Prior approval required to utilize, 45
Utilization fee, 45
Utilization plan elements, 49
Phase I, 116
Phase II, 116
Phase III, 116
Phase IV. See Post-marketing surveillance
Phenmetrazine
Limits on use in WA, 235
Phenylpropanolamine, 126, 244
Physical therapists
Administration of drugs, 139
Physician’s Assistants. See pas
Pilot projects
Board may approve, 51
PILs, 134
Plan B
Lawsuit against WA BOP, 67
Pharmacies must fill, 66
Poison centers, national number, 71
Poison Information, 116

Poison Prevention Packaging Act, 180
Poison Sales, 115
Poison-prevention packaging, 124
Poisons, 115
Post-marketing surveillance, 117
PPIs, 134
Practice of Pharmacy, defined, 29
Preemption
Conflicts, 11
Explicit, 11
Field, 12
US Supreme Court Cases, 13
Preemption preamble, FDA, 12
Preferred Drug List, WA, 167
Pregnancy Discrimination Act, 331
Prescriber-patient relationship, 145
Prescribers
Authorized in WA, 138
Authorized in WA (Table), 141
Dispensing by, 137
Prescribing Information, 132
Prescription Drug Benefits
Overview of, 339
Prescription Drug Marketing Act, 109
Prescription Monitoring Program, 243
Prescription Only Drugs. See Legend Drugs
Prescription pads
Tamper-resistant, 149
Washington tamper resistant requirement, 150
Prescriptions
"UD" not allowed, 152
Complete directions required, 152
Copies, 176
Electronic, 156
FAX requirements, 155
Home IV Therapy, 96
Internet, 145
Legibility, 149
Oral, 154
Out-of-State, generic substitution of, 164
Partial filling, legend drugs, 171-173
For partners of patients with stds, 146
Pharmacist judgment, 174
Refills, 171
Recorded on voice message systems, 154
Required elements, 138
Telephoned, 154
Time limits on dispensing, 151
Transfers between pharmacies, legend drugs, 176
Two-line blank required, 153
Verbal, Best practices, 154
Washington Tamper-Resistant Pad Requirements, 150
Written by deceased prescriber, 144
Prescriptive authority, pharmacists
Approved protocol, 140
Presumed to Know the Law, 5
Price fixing, 341
Price Posting, 342
Private vs. Government Contracts, 344
Products liability, 312
Prospective drug use review, 268
Protected Health Information, 278
Allowed disclosures, 284
Minors' rights to control, 286
Use for health care operations, 279
Use for payment, 279
Use for treatment, 279
Protocol, defined, 77
Pseudoephedrine, 126, 127, 244
Public health center, defined, 76
Pure Food and Drug Act, 103
Quality Assurance
Required for hospitals, 289
Qui tam suit, 367
RBRVS, 353
Recalls, 186
Classes of, 186
Levels of, 186
Recalls, of drugs. See also Drugs, recalls
Reciprocity. See Pharmacists, license transfer
Records
Controlled substances, minimum retention, 65
Regulations, 14
Regulations, defined, 14
Remote Dispensing, 92
Remote processing of medication orders
WA BOP Guidelines, 94
REMS, 110
Reporters, of legal opinions, 19
Reproductive Privacy Act, 55
Residencies, 54
Residential care facilities, 84
Resource Conservation and Recovery Act of 1976 (RCRA), 189
Resource-based relative value scale, 353
Responsible pharmacist manager, 65
And Ancillary personnel, 65
Overall authority, 65
Restatement of Contracts, 19
Restatement of Torts, 19
Restatements of Common Law, 19
Restraint of trade, 341
Restricted Devices, 119
Retired or Inactive pharmacists, 31
Retirement communities, 84
Return or Exchange
Legend drugs, 185
Reverse distributors, 192
Revised Code of Washington, 18
Revocable Privilege, 5
Riegel v. Medtronic, 13
Right of Conscience rule
DHHS, 56
Risk Evaluation and Mitigation Strategies. See REMS
RPM. See Responsible pharmacist manager
Rx symbol, 130
Rx-to-OTC Switches, 112
Ryan Haight Online Pharmacy
  Consumer Protection Act of 2008, 145, 221
SAMHSA, 23, 252
Sample packages
  Required labeling for patients, 137
Samples. See Legend Drugs, samples
Sanction Schedules, 304
Sanctioning Guidelines, 302
Sanctioning process, 303
See Orange Books.
Self-administration of drugs, defined, 77
Self-administration of medication, 81
Senior apartments, 84
Sexual contact with clients or patients, 60
Shopkeepers, 128
Shopkeepers and Itinerant Vendors, 99
Side Effects Statement
  Required by FDAAA, 112
Single Convention on Narcotic Drugs, 215
Slander and libel, 6
Social Security number, required, 62
Sole Proprietorship, 63
Sovereign Immunity, 15
Standard of evidence
  Agency law, 6
Stark Act, 362
State v. Clausing, 145
Stormans, Inc. Et al. V. Selecky et al, 68
Structure of Government, 21
Student of pharmacy
  Defined, 38
Suboxone. See Buprenorphine
Subutex. See Buprenorphine
Sulfanilamide Elixir, 103
Supplemental ndas, 117
Supplemental New Drug Application, 158

Supreme Courts, 9
Syringes, 119
Tablet splitting programs, 175
Tamper Resistant Prescription Pads, 389
Tech-check-tech programs, 47
The Combat Methamphetamine Epidemic Act of 2005, 247
Theophylline, 113
Therapeutic Interchange Program, 167
Therapeutic Substitution, 158, 166
Thermometers, 121
Thimerosol
  In vaccines, 183
Third Party Contracts, 344
Timely manner rule
  Exceptions, 66
Torts, 6, 313
Trade names, 158
Transfers of prescriptions, 176
Treatment, Payment, Healthcare Operations
  Defined, 278
Trial Courts, 8
True out-of-pocket expense, 343
UD
  Not allowed in directions, 152
Unapproved Drugs, 106
Unemployment compensation, 335
Unfair or deceptive practice, 341
Uniform Disciplinary Act, 60, 293
Uniformed Services Employment and Reemployment Act, 337
Unlabeled uses
  OTC drugs, 126
Unlicensed Practice, prohibited, 35
Unprofessional conduct, 294
USA PATRIOT Act, 248
USAN
  United States Adopted Name. See Official Name
Use Before Dates, 137
USP <795>, 203
USP <797>, 206
USP Compounding Chapters, 202
Vaccines
  - Mercury-containing, 183
Verbal orders. See Pharmacies, hospital; verbal orders
Verification, defined, 45
Veterinarians
  - Dispensing by, 138
Warranties, 311
Washington Administrative Code, 18
Washington Board of Pharmacy
  - Powers & Responsibilities, 25
  - Staff Contact Phone Numbers, 26
Washington Controlled Substances Act, 215

Washington Recovery Assistance Program for Pharmacy. See WRAPP
Waxman-Hatch Amendment, 109
*Western States Medical Ctr v. Shalala*, 197
Westlaw, 20
Whistle blowers, 338
Wholesalers and Manufacturers, 100
Wiley Law. See Pure Food and Drug Act
WISHA, 336
WRAPP, 253
*Wyeth v. Levine*, 13