

A Technician's Guide to Washington Pharmacy Law

William E. Fassett, Ph.D., R.Ph.

Professor of Pharmacy Law & Ethics
Department of Pharmacotherapy
College of Pharmacy
Washington State University
Revised December 2, 2008

A Technician's Guide to Washington Pharmacy Law

BECOMING AND REMAINING A TECHNICIAN

What is a technician? A technician is a person registered with the Board of Pharmacy who is trained to perform non-discretionary manipulative functions related to the practice of pharmacy while under the supervision of a licensed pharmacist.	RCW 18.64A.030(1)
You must be registered separately in each state in which you want to work as a technician.	
You may be issued a license as a technician upon completion of a Board-approved training program. While in training, technicians are licensed as Pharmacy Assistants. The training may be a formal academic program or an on-the-job training program. You must have a high school diploma or a GED prior to entering a technician training program. The initial license fee is \$50.	WAC 246-901-020(1); 907-030(13)
Technician and assistant registration forms are available from the Board's web site at https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/forms.htm#persons As part of the application, you will be asked to disclose any medical conditions, including specific learning disabilities, which may affect your ability to practice. You are required to disclose these even if you personally don't think they pose a problem.	WAC 246-901-060; 080
As part of the application, you will be asked whether you've been convicted or have entered a plea of guilty or of "no contest" to any crime other than minor traffic infractions. DUI, MIP, and reckless driving are not considered minor traffic offenses, and must be reported.	
If not otherwise included in your training program, you must complete 4 hours of AIDS/HIV education prior to registration as an assistant or technician.	WAC 246-901-130

Background Checks Required Because any convictions will be revealed by a background check required by the Board, false statements or omissions will be detected and could cause the Board to refuse to issue a technician license. Note that when you fill out the form, you agree to notify the Board of any future convictions or changes in your situation, and you agree that you have read RCW 18.130.170 and RCW 18.130.080 of the Uniform Disciplinary Act.	RCW 18.64.165; RCW 43.43.832
License Renewal, Address Changes, Display of License Where you Work Note that you are also practicing without a license if you fail to pay your annual renewal fee, which is due on or before your birthday. The current renewal fee is \$40. A penalty fee of \$40 is charged for late renewal. You are required to maintain your current address on file with the Department of Health/Board of Pharmacy. A copy of your technician license must be displayed to the public in any pharmacy in which you are working. If you work at multiple locations, you should have a copy (photocopy is ok) at each location. You may obscure your address (but not your name or other information on the license) on the copy displayed to the public.	WAC 246-907-030(13); 246-12-310; 246-901-060; RCW 18.64.140

National Certification Exam Current Board rules provide that the technician applicant must provide "proof of successful completion of a certification examination approved by the board." Currently, the Board approves individual exams for each training program. Effective January 1, 2009, all new applicants will need to have passed an examination developed by an agency certified by the National Commission for Certifying Agencies (NCCA). Two exams are currently certified and meet Washington's requirement	WAC WAC 246-901-060 (2)
<ul style="list-style-type: none"> Pharmacy Technicians Certifying Exam (PTCE) – offered by the Pharmacy Technicians Certifying Board - www.ptcb.org Examination for Certification of Pharmacy Technicians (ExCPT) – offered by the Institute for Certification of Pharmacy Technicians - www.nationaltechexam.org <p>Although it is desirable, WA does not require technicians, once licensed, to maintain CPhT status from either PTCB or ICPT.</p>	

THE PRACTICE OF PHARMACY AND INTERNS

<p>Engaging in the Practice of Pharmacy – What may interns do? Interns may “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 is 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.”</p>	<p>WAC 246-858-040(2); RCW 18.64; RCW 18.64A</p>
<p>The practice of pharmacy includes:</p> <ul style="list-style-type: none"> • Interpreting prescription orders; • Compounding, dispensing, labeling, administering, and distribution of drugs and devices; • The monitoring of drug therapy and use (see WAC 246-863-110 for the Board’s definition of monitoring of drug therapy); • 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; • The participating in drug utilization reviews and drug product selection; • The proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; • 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. 	<p>RCW 18.64.011(11)</p>
<p>The statute that allows pharmacists to use technicians or assistants, and to supervise them, does not mention interns. Thus, interns should not supervise technicians.</p>	
<p>Board rules do allow interns to participate with technicians in “tech-check-tech” activities when dispensing limited quantities of unit-dose medications in institutional settings.</p>	<p>WAC 246-901-035(2)</p>

WHAT MAY TECHNICIANS AND ASSISTANTS DO?

<p>Only a pharmacist, an intern, or a technician may</p> <ul style="list-style-type: none"> • Enter a new prescription into the computer; • Retrieve the drug product to fill a prescription. 	<p>WAC 246-901-020(4)</p>
<p>Pharmacy assistants may not remove the bottle from the shelf to fill a prescription, but may return used bottles to the shelf. They may count, pour, and label for individual prescriptions. They may also be assigned to do bulk counting of pre-count containers.</p>	<p>WAC 246-901-070</p>
<p>A pharmacist may NOT delegate any of the following functions to a pharmacy technician or assistant (although interns may perform these functions):</p> <ul style="list-style-type: none"> • Receipt of a verbal prescription other than a refill authorization • Consultation with the patient regarding the prescription and/or regarding any information in the patient medication record • Consultation with the prescriber regarding the patient and the patient’s prescription • Extemporaneous compounding of the prescription, except for bulk compounding • Interpretation of the data in the patient medication record system • Ultimate responsibility for the correctness of a dispensed prescription • Providing patient information as required by WAC 246-869-120 • Signing of documents or registry books that require a pharmacist’s signature • Professional communications with physicians, dentists, nurses, and other health care practitioners 	<p>WAC 246-863-095</p>

SPECIALIZED FUNCTIONS

Technicians may perform specialized functions if they have particular training to perform those functions:	WAC 246-901-035
<ul style="list-style-type: none"> • Prepare parenteral admixtures. • Participate in Tech-check-Tech unit dose filling. • Checking and stocking of automated drug distribution devices 	
<p>Parenteral Admixtures</p> <ul style="list-style-type: none"> • Training must include testing showing 100% accuracy in preparing a representative sample of IV admixtures using aseptic technique • A “licensed pharmacist” must check each parenteral product produced by a technician. Note: the Board’s rule is ambiguous about whether an intern can be a “licensed pharmacist” for this purpose. I advise my students not to perform these final checks. 	WAC 246-901-035 (2)
<p>Unit Dose Medication Checking</p> <p>This function may be performed by technicians filling unit dose cassettes for hospitals, residential habitation centers, or nursing homes.</p> <ul style="list-style-type: none"> • Training must include testing demonstrating 99% accuracy in checking unit-dose medications. Following verification of the drug order by a licensed pharmacist, a pharmacy technician may check unit-dose cassettes filled by another pharmacy technician or by an intern. Note that this rule allows techs to check cassettes filled by interns, but doesn’t mention interns checking techs. • No more than a 48-hour supply may be placed in the cassette • A licensed health professional must check the drug before it is administered to the patient. 	WAC 246-901-035 (1)
<p>Automated Drug Distribution Devices. These are for both inpatient distribution outside central pharmacies, and remote distribution.</p> <ul style="list-style-type: none"> • Checking and stocking of medications in ADDDs is reserved to a pharmacist, pharmacy intern, or pharmacy technician • Pharmacy technicians checking accuracy of medications must meet Specialized Functions requirements with documentation of training on file in the pharmacy. <p>Note: the Nursing Quality Assurance Commission believes that checking of drugs in ADDDs is within an RN’s scope of practice.</p>	WAC 246-872-030

TECHNICIAN AND ASSISTANT UTILIZATION PLANS

Pharmacies wishing to employ technicians or assistants (virtually all pharmacies) must apply to the Board and file a Utilization Plan. Plan elements must include:	WAC 246-901-100
<ul style="list-style-type: none"> • A description of how technicians will be utilized and supervised • Job descriptions for technician positions • Task analyses or similar documents that define <ul style="list-style-type: none"> ○ Duties performed and conditions under which they are performed ○ Number of positions in each category • If technicians will be utilized for specialized functions, the plan must include: <ul style="list-style-type: none"> ○ Criteria for selections of technicians ○ Description of methods of training and testing ○ A copy of the section of the pharmacy’s quality assurance plan related to specialized functions 	
<p>Pharmacists to Technician Ratios:</p> <p>For each pharmacy, a standard ratio is for no more than 3 technicians per supervising pharmacist.</p> <ul style="list-style-type: none"> • Each supervising pharmacist must be actively practicing pharmacy (i.e., the Director of Pharmacy in his or her office doesn’t count) • When the pharmacy provides services to inpatients, pharmacists who are practicing pharmacy outside the confines of the pharmacy (e.g., inspecting nursing units, reviewing charts, consulting with professional staff) may be included in the ratio if: <ul style="list-style-type: none"> ○ There are sufficient numbers of pharmacists within the pharmacy to supervise the work of technicians; ○ The pharmacy is not open to the public; ○ The medications are being checked by another health professional before being given to the patient; and ○ Drug orders are not dispensed from the pharmacy without being checked by a licensed pharmacist or intern except for board-approved 	WAC 246-901-130

UNIFORM DISCIPLINARY ACT

Technicians are subject to the same laws regarding discipline as are pharmacists, nurses, physicians, or other health care providers. These laws are set forth in the Uniform Disciplinary Act. Some provisions that have been used to discipline technicians include:	RCW 18.130.180
<ul style="list-style-type: none"> • Conviction of a crime related to the practice of one’s profession. <ul style="list-style-type: none"> ○ Theft, including credit card theft, shoplifting, or fraud ○ Controlled substances act violations • Misrepresentation or concealment of a material fact in obtaining a license • Incompetence or negligence which harms a patient • Suspension or revocation of a license in another state • Possession, use, or distribution of controlled substances in any way other than for legitimate or therapeutic purposes • Aiding or abetting an unlicensed person to practice when a license is required • Practicing beyond the scope of practice allowed by law or regulation • Current misuse of alcohol, controlled substances, or legend drugs • Abuse of a client or patient, or sexual contact with a client or patient 	

Reporting of Unprofessional Conduct or Impairment	WAC 246-16-200 thru 250
Technicians, like all other licensees of the Department of Health, are now required to report to the Board when they have knowledge of unprofessional conduct by another license holder, or of the inability of another license holder to practice safely due to mental or physical impairment. They must also self-report certain events	
<p>Unprofessional Conduct by another licensee. If you are aware that another licensee (e.g., pharmacist or technician) has been convicted or been subject to a determination by a hospital to have committed unprofessional conduct, you are required to notify the Board.</p> <ul style="list-style-type: none"> • Conviction means by a court, and includes a plea of guilty or “no contest.” • A final determination by the hospital that terminates a licensee’s service or restricts the licensee’s privileges must be reported if it was based on unprofessional conduct, incompetence or negligence. 	

<p>Impairment of another licensee. If you are aware that another licensee is not able to safely practice due to mental or physical impairment, such as by use of drugs or alcohol, you must report that to the Board. Unless a patient has been harmed by the other licensee, it is permitted to report impairment due to alcohol or substance abuse to WRAPP. Generally, you will want to discuss these matters with an appropriate supervisor.</p>
<p>Self-reporting. The rules require you to report to the Board any of the following regarding yourself:</p> <ul style="list-style-type: none"> • Any conviction (including a plea of “no contest”) or hospital employer adverse action based on a finding of unprofessional conduct. • Information that you are unable to practice safely due to physical or mental impairment. In most cases, you may self-refer to WRAPP, unless your impairment has resulted in harm to a patient. • If you are declared to be disqualified from participating in Medicaid or Medicare. <p>Prior to completing a self-report, I recommend that you consult an attorney knowledgeable about administrative law. This should be done promptly, however, as all reports must be made within 30 days after a person has actual knowledge of the event.</p>

PRESCRIPTIONS AND REQUIREMENTS OF PRESCRIPTION IN WASHINGTON

<p>Is the prescription valid?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Is it issued for a specific patient? <input type="checkbox"/> Is it issued by an authorized prescriber? <input type="checkbox"/> Was it issued in the DUE COURSE of the prescriber’s practice? (Is it within the scope of practice of the prescriber? Did the prescriber have a <i>bona fide</i> prescriber-patient relationship?) <input type="checkbox"/> Is it for a legitimate medical purpose? 	<p>RCW 69.41.040</p>
<p>Elements that must be present in a prescription before it is filled and dispensed to a patient:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Prescriber’s name, address <input type="checkbox"/> Patient name <input type="checkbox"/> Patient’s address (on Rx or in the patient information system) <input type="checkbox"/> Date written <input type="checkbox"/> Name of drug, dosage form, strength, and quantity or duration of therapy <input type="checkbox"/> Complete directions for use <ul style="list-style-type: none"> o Cannot indicate “as directed” in an automated patient record <input type="checkbox"/> Signature of prescriber if it is a written Rx <input type="checkbox"/> Prescriber’s DEA number if it is for a controlled substance <input type="checkbox"/> Specification regarding generic substitution (using a 2-line Rx blank if a written Rx) <input type="checkbox"/> Any refill information <input type="checkbox"/> Any additional instructions <input type="checkbox"/> A serial number placed by the pharmacist <input type="checkbox"/> The date filled <input type="checkbox"/> The initials of the responsible pharmacist who filled the Rx <input type="checkbox"/> The identity of the actual drug dispensed (e.g., NDC number) if product interchange has occurred. <input type="checkbox"/> The prescription must be typewritten, hand printed (not cursive) or electronically transmitted. <input type="checkbox"/> If the patient is a Medicaid recipient in an outpatient setting, the prescription must be telephoned, faxed, e-prescribed, or written on a “tamper-resistant” prescription pad. 	<p>WAC 246-869-100; RCW 69.41.120; RCW 69.41.010(13);FDCA; PL 110-28</p>

<p>Who may prescribe which drugs?</p>	<p>RCW 69.41.030; RCW 69.50.101(w)(1)</p>
<ul style="list-style-type: none"> • Physicians (MD or DO) – All drugs, all classes for human patients, regardless of where the prescriber is licensed. • Dentists (DDS or DMD) – All drugs, all classes, for human patients for head and neck conditions, regardless of where the prescriber is licensed. • Podiatrists (DPM or PodD) – All drugs, all classes, for human patients, for conditions of the ankles and feet, regardless of where the prescriber is licensed. • Veterinarians (DVM) – All drugs, all classes, for non-human animals, regardless of where the prescriber is licensed. • Physicians Assistants (PA, PA-C) – All drugs, all classes approved by supervising physician, only if PA is licensed in WA • Nurse Practitioners (ARNP) – All drugs, including CSA Schedule II, III, IV, or V, if appropriate to the ARNP’s specialty, only if ARNP is licensed in WA. • Nurse Anesthetists – a specialty form of Nurse Practitioner in WA • Nurse Midwife – a specialty form of Nurse Practitioner in WA • Optometrists (OD) – Topical ophthalmic drugs, and certain other drugs contained on a listed in WAC 246-851-580 and -590, only if licensed in WA. Controlled substances in Schedules III, IV, or V are limited to a maximum of 7 days’ supply; Schedules III, IV, to a maximum of 30 doses. Benzodiazepines intended for anti-anxiety associated with procedures are limited to single doses. • Naturopaths (ND) – Drugs used in naturopathic practice, including testosterone and codeine products in CSA Schedules III , IV, or V. • Midwife (not an ARNP) – may use certain drugs for delivery or neonatal care, may administer certain drugs, and may prescribe diaphragms, only if licensed in WA • Pharmacist – may prescribe all classes and types of drugs in accordance with a prescriptive authority protocol, limited to the scope of the authorizing prescriber, only if the pharmacist is licensed in WA. 	

INTERPRETING PRESCRIPTION ABBREVIATIONS

The use of abbreviations in prescriptions and patient orders is NOT RECOMMENDED by most patient safety authorities, but they are still widely used. Here's a short list of the most common abbreviations (the original Latin phrase is shown in parentheses):

- a.c. – before meals (ante cibos)
- ad – [to make] up to
- a.d. – right ear (aurio dextra)
- ad Lib. – at will (ad libitum)
- a.m. – before noon, i.e., morning (ante meridian)
- aq. – water (aqua)
- a.s. – left ear (aurio sinister)
- a.u. – each ear (aures utrae)
- b.i.d. – twice a day (bis in die)
- BP – blood pressure
- Caps – capsules (capsulae)
- d – day (diem)
- d/c – discontinue or discharge (DANGEROUS)
- EAC – external auditory canal
- et (&) – and
- gtt. (gtts.) – drop (drops) (gutta, guttae)
- h or ° – hour (hora)
- HA – headache
- h.s. – bedtime (hora somni – hour of sleep)
- I.M. – intramuscular
- I.V. – intravenous
- NKA – no known allergies
- noc – night (nocturnal)
- NPO – nothing by mouth (see p.o.)
- non rep. (NR) – do not repeat or no refills (non repetatur)
- o.d. – once daily (DANGEROUS)
- o.d. – right eye (oculus dexter)
- o.s. – left eye (oculus sinister)
- o.u. – each eye (oculo utro)
- p.c. – after meals (post cibos)
- p.o. – by mouth (per os)
- p.r. – rectally (per rectum)
- p.m. – evening (afternoon) (post-meridian)

- p.r.n. – as needed (pro re nata – as the occasion arises)
- q – every (quaque)
- q. a.m. – every morning
- q.d. – every day (DANGEROUS)
- q.h. – every hour
- q4h – every 4 hours (also q4°)
- q8h – every 8 hours (also q8°)
- q6h – every 6 hours (also q6°)
- q12h – every 12 hours (also q12°)
- q h.s. – every [day at] bedtime
- q.i.d. – four times a day (quater in die)
- q.i.d pc & hs – 4 doses per day, either after a meal or at bedtime (4 total doses per day)
- q.n. – every night (DANGEROUS)
- q. noc. – every night
- q.o.d. – every other day (DANGEROUS)
- q.s. – sufficient quantity
- q.s. ad – enough [to make] up to ___ mL
- rep. – repeat (repetatur)
- S.C. (SubQ or SQ) – subcutaneous
- sig. – label to patient (signa)
- stat. – immediately (statim)
- supp. – suppository (suppositorium)
- tab. – tablet (tabella)
- t/o – telephone order (might look like t.i.d.)
- t.i.d. – three times a day (ter in die)
- t.i.d. pc & hs – three times a day, after meals, and at bedtime (4 doses total per day)
- u.d. or ut. dict. – as directed (ut dictum)
- ung. – ointment (unguentum)
- v.o. – verbal order
- w.a. – while awake (e.g., “q4-6h w.a.” – means every 4 to 6 hours during waking hours)
- 1X, 2X, 3X, etc. – 1 time, 2 times, 3 times (DANGEROUS – confused with strengths or sizes)
- x 3 d, x 10 d, etc. – for 3 days, for 10 days (DANGEROUS may be confused with doses)

The following usually have a line drawn above them:

- aa – of each (ana)
- a – before (ante), e.g., “Take 1 hr ā appointment.”
- c – with (cum), e.g., “Take c water”
- p – after (post), e.g., “Apply p bathing”
- s – without (sine), e.g., “Apply s bandaging”
- ss – one-half (semis)

Prescriptions must be legible Pharmacists who fill illegible prescriptions are responsible to the patient for injuries that result from illegible prescriptions. Prescriptions must be hand printed (not cursive), typewritten, or electronically transmitted..	RCW 69.41.120; RCW 69.41.010(13)
---	----------------------------------

NEW AND REFILL PRESCRIPTIONS

New Prescriptions are any original orders written, phoned, or faxed to a pharmacy other than instructions to refill a previous prescription.

- New prescriptions are given a unique serial number by the pharmacy
- Orders to continue refilling a prescription that is over 1 year old (or 6 months old for C-3 or C-4 drugs) must be treated as if they were new prescriptions.

Refills are dispensings of a drug that use the same prescription number as a previously-filled prescription. A prescription may be refilled if authorized by the prescriber, either at the time the prescription was first written, or later, as long as the prescription has not expired (1 year in WA for legend drugs other than C-3 or C-4).

WA regulations do not make any exceptions regarding drug utilization review or patient counseling based upon whether an order is a new prescription or a refill.

Transfer of Refill Information to other Pharmacies by pharmacists or interns. If a prescription has refills remaining, and has not expired, one may transfer the prescription and its refill information to another pharmacy, who may fill the remaining refills. Once transferred to another pharmacy, the prescription may not be filled in your pharmacy. When transferring a prescription to another pharmacy, one must do the following:	WAC 246-869-090; 21 CFR § 1306.25
<ul style="list-style-type: none"> • Record that the prescription has been transferred in the medication record system • Record the name and address of the pharmacy to whom it was transferred • Record the full name of the pharmacist or intern to whom the transfer was made. 	
If the prescription is for a C-3, C-4, or C-5 drug, one must also do the following:	
<ul style="list-style-type: none"> • Locate the original HARD COPY of the prescription, and write “VOID” on its face • Record the name, address and DEA number of the pharmacy to whom the prescription was transferred. 	
When receiving a transferred prescription from the other pharmacy, one must record the following on the copy of the prescription:	
<ul style="list-style-type: none"> • Write the word “TRANSFER” on the copy of the prescription • Record the name and address of the other pharmacy • Record the full name of the pharmacist or intern who is providing the transfer information (first and last name) • Record the other pharmacy’s prescription number • Record all the necessary prescription information, including patient name and address, doctor name and address, drug, strength, quantity, and directions • Record the date that the prescription was first written • Record the date it was last filled • Record the number of refills allowed • Record the number of refills remaining 	

If the prescription is for a **C-3, C-4, or C-5** drug, one must also obtain and record the following information:

- The DEA number of the prescriber
- The DEA number of the transferring pharmacy
- Dates and locations of all previous fillings of the prescription
- The name, address, DEA number and serial number of the original prescription and pharmacy, if it is different from the transferring pharmacy.

If you work for a chain that shares a common database among all its pharmacies, you only need to fill the refillable prescription at your pharmacy, and allow the system to keep track of the location and date.

DRUG CLASSES

Legend Drugs – Also known as Prescription Drugs.	RCW 69.41
---	-----------

Their labels indicate “**R** only” or “Caution: Federal law prohibits dispensing without prescription.” May be telephoned, faxed, or written prescriptions, and may be filled or refilled (if authorized by prescriber) for up to 1 year from the date written in WA.

Over-the-Counter or OTC Drugs – Also known as Nonprescription Drugs. Their labels bear directions for use that lay persons can understand. May be prescribed (e.g., omeprazole capsules) and filled as if they were prescription drugs, using a valid prescription and label.

Methamphetamine precursors – OTC sales of drugs containing	RCW 69.43.110-170; WAC 246-889-070
---	------------------------------------

pseudoephedrine, ephedrine, or phenylpropanolamine must be recorded in a log by the pharmacy or retailer unless they are combination products in liquid, or pediatric formulations. A person may purchase no more than 2 packages per 24 hours containing no more than 3 gm per package or more than 3.6 gm total. Sales pursuant to a prescription do not need to be recorded in the log. Sales that must be recorded are restricted to persons 18 yrs or older. The log must record the patient name, address, photo ID number, type of photo ID, date of birth, date and time of sale, drug name and strength, and number of packages and tablets sold. Products subject to the record requirement may not be accessible to the public. Any person selling these products must have completed an on-line training program.

Controlled Substances – CSAs. Have potential for abuse, and may be either legend (most of them) or OTC (a selected few drugs). CSAs are divided into five schedules, depending on potential for abuse:	RCW 69.50; DEA’s Pharmacist Manual, available online (http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/2pharm_manual.pdf)
---	--

- Schedule I (C-1): Heroin, LSD, etc. May not be prescribed.
- Schedule II (C-2): Require written prescriptions, may not be refilled. May be filled for up to 1 year from the date written in WA. Includes meperidine, oxycodone, etc. (Faxed Rxs are allowed in limited circumstances)
- Schedule III (C-3): Mostly narcotics in combination. May be telephoned, and may be filled and/or refilled up to 5 times within 6 months from the date written. Acetaminophen (APAP) with codeine, and hydrocodone/APAP are examples.
- Schedule IV (C-4): Non-narcotic combinations mostly. Same rules as C-3, includes benzodiazepines.
- Schedule V (C-5): No refill limitations, includes legend drugs such as Lomotil®, and OTC products such as Robitussin-AC®.

The schedule of a CSA drug must be printed on the package. Persons who prescribe CSA drugs must be registered with the US Drug Enforcement Administration (DEA) and place their DEA number on all prescriptions. Prescriptions for C-2 drugs must be filed separately from files for legend drugs or other CSA drugs. Special order forms must be used by the pharmacy to order C-2 drugs from suppliers.

No person may prescribe controlled substances for his or her own use.	RCW 18.130.180 (6); 69.50.308 (e)
--	-----------------------------------

This is considered unprofessional conduct in WA. As a result, it cannot be for a “legitimate medical purpose,” so a pharmacist may not fill such a prescription. Prescribers may write prescriptions or orders for controlled substances for family members, however.

GENERIC DRUGS AND DRUG PRODUCT SELECTION

Brand Name -- Also known as Proprietary Name. Usually indicated by being capitalized, and followed by a symbol such as ® or ™. Example: Prozac®. Specifies a product made by a specific manufacturer or distributor. Must be labeled with the official name as well, e.g., Prozac® (fluoxetine hydrochloride).

Official Name – Also known as generic name or nonproprietary name. Approved by the government for all approved drugs and shows both the primary compound and the salt form, if applicable. Usually not capitalized. Example: fluoxetine hydrochloride.

Single source – When only one company markets a drug, it is called a single source drug. Most products are single source during the time that their manufacturer holds patent rights to market the product exclusively.

Multisource – After the patent expires, drugs become multisource products when they are marketed by several distributors.

Generic substitution. RCW 69.41.100-190

Washington law permits the pharmacist to substitute a less costly multisource drug instead of the drug prescribed by brand name. This is called **generic substitution**. All of the following conditions must be met in order to substitute the generic equivalent:

- The substituted product must be less expensive.
 - The substituted product must be the same chemical entity and same salt, given in the same dosage form.
 - The product must be therapeutically equivalent, as indicated by an ‘AB’ rating in the Orange Book, or based upon other reliable information available to the pharmacist that indicates that, when administered, the substituted product (1) produces the same peak blood level at the same time as the prescribed product, when administered in the same dose; and (2) produces the same area under the curve (AUC) as the prescribed product, when given in the same dose and regimen.
 - The prescriber does not indicate “DAW” or sign on the Dispense as Written line; or
 - The patient does not request the brand name.
 - The pharmacist passes at least 60% of the savings on to the patient.
- The pharmacist must label the product with the generic name, or the brand name of the product actually used, not the brand that was prescribed.

Therapeutic substitution occurs when the pharmacist is allowed to substitute a different chemical entity or salt in place of the drug prescribed. This can be done with prior authorization of the prescriber, often as part of formulary-based practices such as Washington’s Preferred Drug List.

LABELS AND PACKAGING OF DRUGS DISPENSED DIRECTLY TO PATIENTS

Labels on prescription containers dispensed by pharmacists must contain the following: RCW 18.64.246; WAC 246-869-210; 21 CFR §§ 209.1-209.11

- Name and address of pharmacy (phone number not required)
- Name of patient
- Serial number
- Date dispensed
- Complete directions for use
- Drug name, strength, and quantity dispensed. (The prescriber may request that the drug name and strength be omitted, but the pharmacist need not comply.)
- An “expiration date”
- Necessary auxiliary labels (e.g., SHAKE WELL, MAY CAUSE DROWSINESS)
- “Caution: State or federal law prohibits transfer of this medication to any person other than the person for whom it was prescribed.”
- The pharmacist’s initials must be either on the label or maintained in the patient medication record system.
- The label, container cap, PIL, Med Guide, or a separate sheet of paper provided to the patient must state “Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.”

Labels on ambulatory custom packaging (e.g., bingo cards) must contain the same information as above, for each medication in the package, but note that the pharmacist’s initials must be on the package. Also note that they cannot contain more than 31 days’ supply. The pharmacist’s initials must be on the package. Since these containers do not meet the standards for child-resistant containers, the pharmacy must have on file a written request for non-CRCs. RCW 18.64.246; WAC 246-869-255

Labels on parenteral products delivered to a patient's home must contain the following	RCW 18.64.246; WAC 246-871-050
Information in addition to that required for other ambulatory prescriptions:	
<input type="checkbox"/> Telephone number of the pharmacy <input type="checkbox"/> A 24-hour phone number that will connect to a pharmacist. <input type="checkbox"/> Directions must include infusion rate <input type="checkbox"/> Date the medication was compounded <input type="checkbox"/> Expiration date must include a time, if applicable <input type="checkbox"/> Compounder's or pharmacist's initials <input type="checkbox"/> Storage requirements <input type="checkbox"/> Antineoplastic auxiliary labels, where applicable	
Labels on legend drugs dispensed by a prescriber directly to patients must contain the following:	RCW 69.41.050
<input type="checkbox"/> Name of patient <input type="checkbox"/> Name and strength of the drug <input type="checkbox"/> Date dispensed <input type="checkbox"/> Name of prescriber <input type="checkbox"/> Complete directions for use	
<p>Exceptions:</p> <p>Prescriber may omit drug name and directions if it is judged appropriate for the particular patient under the circumstances. Sample packages in their original manufacture's package need only contain the name of the patient and name of the prescriber.</p>	
All containers dispensed directly to patients must meet USP and Poison Prevention Packaging Act requirements:	15 USC § 1471; 16 CFR § 1700.14;
<input type="checkbox"/> Containers must be tight, light-resistant <input type="checkbox"/> Must meet requirements for child-resistant-containers (CRC) unless the patient requests a non-CRC container. For dispensing by pharmacists, the patient request for a non-CRC must be in writing, with a note placed in the computer.	

LABELS FOR INPATIENT DRUGS

Hospital Inpatient Drugs	WAC 246-873-080(5)(a)
<input type="checkbox"/> Drug name <input type="checkbox"/> Strength <input type="checkbox"/> Expiration date, if applicable <input type="checkbox"/> Auxiliary labeling as applicable	
Hospital Parenteral Drugs	WAC 246-873-080(5)(c)
<input type="checkbox"/> Name and concentration of base solution <input type="checkbox"/> Name and amount of added drugs <input type="checkbox"/> Name and location of patient <input type="checkbox"/> Appropriate expiration dating <input type="checkbox"/> Initials of personnel who prepared the solution	
Nursing Home Non-Unit Dose Drugs	WAC 246-865-060(4)(a)
<input type="checkbox"/> Pharmacy name and address <input type="checkbox"/> Prescription number <input type="checkbox"/> Physician's name <input type="checkbox"/> Resident's full name <input type="checkbox"/> Date of issue <input type="checkbox"/> Initials of dispensing pharmacist <input type="checkbox"/> Name and strength of drug <input type="checkbox"/> Quantity of drug dispensed <input type="checkbox"/> CSA schedule number, if applicable <input type="checkbox"/> Expiration date <input type="checkbox"/> If compounded C-II or C-III drug, must show quantity of controlled substance per mL or teaspoonful.	
Note: directions for use are not required, and child-resistant containers are not required.	
Nursing Home Unit Dose Drugs	WAC 246-865-060(4)(b)
<input type="checkbox"/> Name of drug <input type="checkbox"/> Strength <input type="checkbox"/> Dosage amount <input type="checkbox"/> Expiration date <input type="checkbox"/> Lot or control number <input type="checkbox"/> CSA schedule number, if applicable	
Each resident's drug compartment must be labeled with the resident's full name, the physician's name, and the contents of the compartment	

PATIENT MEDICATION RECORDS AND THEIR USE

<p>Each pharmacy must maintain patient medication records. The record must be unique for each patient; may not combine records into a “family profile.”</p> <p>Elements in the record must include:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Patient name <input type="checkbox"/> Address <input type="checkbox"/> Age or date of birth (DOB) <input type="checkbox"/> A current list of any allergies or chronic conditions. If no allergies are known to the patient, must put “none” or “NKA,” not just leave the field blank <input type="checkbox"/> Record of all medications dispensed by the pharmacy OR USED BY PATIENT <input type="checkbox"/> Pharmacist’s notes regarding therapy <input type="checkbox"/> A note in the record if the patient wants non-child-resistant containers 	<p>RCW 18.64.245; 69.41.042; WAC 246-875-020; OBRA-90</p>
<p>Prior to dispensing new or refill prescriptions, pharmacists must review the profile to determine if any of the following exist:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Known contraindications to the requested drug <input type="checkbox"/> Therapeutic duplications <input type="checkbox"/> Drug-drug and/or drug-disease interactions <input type="checkbox"/> Allergies <input type="checkbox"/> Improper use, such as <ul style="list-style-type: none"> o Early filling o Late filling o Overdosing o Underdosing o Confusion about medications (such as overuse of albuterol inhaler and not refilling inhaled steroid) <p>If any of these are detected, the pharmacist must take steps to correct the situation.</p>	<p>WAC 246-875-040, OBRA-90</p>

<p>Confidentiality of Patient Records Information about a patient’s medical conditions that identifies the patient is called Protected Health Information (PHI).</p>	<p>HIPAA, RCW 70.02; RCW 18.64.245; RCW 69.41.044; RCW 69.41.055; WAC 246-875-070(2)</p>
<p>The pharmacy must distribute a Notice of Privacy Practices to each new patient, and obtain his or her written acknowledgement of its receipt. Questions from patients concerning PHI or their records should be referred to the pharmacist and/or the pharmacy’s Information Officer.</p>	
<p>PHI may not be used or disclosed without the patient’s written permission, except for</p> <ul style="list-style-type: none"> • Treatment of the patient; • Obtaining payment from the patient or third party payers for the pharmacy’s services; or • Necessary use in the healthcare operations of the pharmacy 	
<p>PHI may be generally disclosed by a pharmacist to</p> <ul style="list-style-type: none"> • Another healthcare provider known to be providing care to the patient (e.g., the prescriber of the prescription, or another pharmacy to transfer the prescription) • Another healthcare provider who has treated the patient in the past, unless the patient has previously instructed the pharmacist not to disclose to that provider • Any person if the pharmacist has a reasonable belief that the disclosure is necessary to avoid or minimize danger to the patient or another person • Anyone for whom the patient has given consent • An immediate family member or other person with whom the patient is known to have a close relationship, in accordance with good pharmacy practice, if <ul style="list-style-type: none"> o The information is provided ORALLY, and o The patient has not previously instructed the pharmacist in writing not to make disclosures to that person 	

PATIENT INFORMATION AND COUNSELING

Each patient (or his or her agent) who receives medication in a pharmacy	WAC 246-869-220; OBRA-90; RCW 18.130.180(13)
must be provided with information needed to assure its proper use (whether the prescription is new or a refill). <ul style="list-style-type: none">• This must be done by the pharmacist or intern.• If the patient refuses, the refusal should be documented. It is improper and unprofessional conduct for a technician to select the “counseling denied” option on a point-of-sale device unless the patient has explicitly refused counseling.• Washington does not allow an “offer to counsel”• Asking the patient “have you had this before?” as a basis for not counseling them is not allowed	
If the medication is being delivered to the patient outside the confines of the pharmacy, the important information must be provided by a written insert, and must include a written notice that a pharmacist is available to the patient for counseling, and must provide a phone number to reach the pharmacist.	
Important information to be included in counseling includes: <ul style="list-style-type: none"><input type="checkbox"/> Name and nature of the drug<input type="checkbox"/> Intended use of the drug<input type="checkbox"/> Directions for use, and special instructions on how to administer or use safely and effectively<input type="checkbox"/> Major side effects and how to avoid them<input type="checkbox"/> Special storage requirements<input type="checkbox"/> How to obtain refills<input type="checkbox"/> What to do if a dose is missed<input type="checkbox"/> Any drugs/food, etc., to avoid while taking the drug	

12/2/08 – non-booklet layout