

Title 360 WAC

PHARMACY, BOARD OF

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DISPOSITION OF CHAPTERS FORMERLY CODIFIED IN THIS TITLE

**Chapter 360-24
PROHIBITED ADVERTISING**

360-24-010	Price advertising of drugs requiring prescriptions prohibited. [Emergency Rule 41, effective 10/21/60; Permanent Rule 41A, effective 11/20/60.] Repealed by Order 110, filed 6/15/72.
360-24-020	Advertising or mail order solicitation of sale or distribution of prescription drugs prohibited. [Emergency Rule 40, effective 10/21/60; Permanent Rule 40A, effective 11/20/60.] Repealed by Order 124, filed 10/31/74.
360-24-030	Prohibition on advertising exempt narcotic products. [Order 100 (part), § 360-24-030, filed 6/25/68; Regulation 42, filed 3/23/64.] Repealed by Order 110, filed 6/15/72.
360-24-035	Prohibition on advertising controlled substances. [Order 110, § 360-24-035, filed 6/15/72.] Repealed by Order 124, filed 10/31/74.
360-24-040	Full disclosure in drug advertisements. [Regulation 43, filed 3/23/64.] Repealed by Order 110, filed 6/15/72.
360-24-045	Prohibition on advertising legend or prescription drugs. [Order 110, § 360-24-045, filed 6/15/72.] Repealed by Order 120, filed 3/11/74.

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360-24-050 Misleading advertising of drug prices. [Regulation 44, filed 3/23/64.] Repealed by Order 110, filed 6/15/72.

**Chapter 360-25
DRUG PRICE DISCLOSURE OF PRESCRIPTION DRUGS**

360-25-001	Drug price disclosure implementation delay. [Order 120, § 360-25-001, filed 3/11/74.] Repealed by 80-05-074 (Order 154, Resolution No. 4/80), filed 4/28/80. Statutory Authority: RCW 18.64.005 (4) and (11).
360-25-005	Drug price disclosure policy. [Order 119, § 360-25-005, filed 1/2/74, effective 4/1/74. Order 120, filed 3/11/74, extended effective date to October 31, 1974 (Repealed before implementation date).] Repealed by Order 124, filed 10/31/74.
360-25-010	Drug price disclosure defined. [Order 119, § 360-25-010, filed 1/2/74, effective 4/1/74; Order 112, § 360-25-010, filed 8/21/72; Order 110, § 360-25-010, filed 6/15/72. Order 120, filed 3/11/74, extended effective date to October 31, 1974 (Repealed before implementation date).] Repealed by Order 124, filed 10/31/74.
360-25-020	Drug price disclosure conditions. [Order 119, § 360-25-020, filed 1/2/74, effective 4/1/74; Order 112, § 360-25-020, filed 8/21/72; Order 110, § 360-25-020, filed 6/15/72. Order 120, filed 3/11/74, extended effective date to October 31, 1974 (Repealed before implementation date).] Repealed by Order 124, filed 10/31/74.
360-25-025	Drug price disclosure—Required. [Order 112, § 360-25-025, filed 8/21/72.] Repealed by Order 124, filed 10/31/74.
360-25-030	Drug price discount defined. [Order 110, § 360-25-030, filed 6/15/72.] Repealed by Order 124, filed 10/31/74.
360-25-040	Drug discounts—Conditions. [Order 110, § 360-25-040, filed 6/15/72.] Repealed by Order 124, filed 10/31/74.

**Chapter 360-30
HYPODERMIC SYRINGES, NEEDLES AND DEVICES**

360-30-010	Hypodermic devices sale registrations. [Order 134, § 360-30-010, filed 9/7/77.] Repealed by 81-19-086 (Order 163, Resolution No. 8/81), filed 9/17/81. Statutory Authority: RCW 18.64.005(11).
360-30-020	Hypodermic devices destruction. [Order 137, § 360-30-020, filed 11/8/77.] Repealed by 81-19-086 (Order 163, Resolution No. 8/81), filed 9/17/81. Statutory Authority: RCW 18.64.005(11).
360-30-030	Enforcement. [Order 137, § 360-30-030, filed 11/8/77.] Repealed by 81-19-086 (Order 163, Resolution No. 8/81), filed 9/17/81. Statutory Authority: RCW 18.64.005(11).

**Chapter 360-34
DRUG TREATMENT AND MAINTENANCE PROGRAMS**

360-34-010	Methadone maintenance program. [Order 106, § 360-34-010, filed 6/3/71.] Repealed by Order 114, filed 6/28/73. Repealed second time by Order 121, filed 8/8/74.
360-34-020	Methadone withdrawal programs. [Order 106, § 360-34-020, filed 6/3/71.] Repealed by Order 114, filed 6/28/73.

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6/28/73. Repealed second time by Order 121, filed 8/8/74.

Chapter 360-08 WAC

PRACTICE AND PROCEDURE

WAC

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- 360-08-030 Appearance and practice before board—Solicitation of business unethical.
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WAC 360-08-010 Appearance and practice before board—Who may appear. No person may appear in a representative capacity before the board or its designated hearing officer other than the following:

(1) Attorneys at law duly qualified and entitled to practice before the supreme court of the state of Washington.

(2) Attorneys at law duly qualified and entitled to practice before the highest court of record of any other state, if the attorneys at law of the state of Washington are permitted to appear in a representative capacity before administrative agencies of such other state, and if not otherwise prohibited by our state law.

(3) A bona fide officer, partner, or full-time employee of an individual firm, association, partnership, or corporation who appears for such individual firm, association, partnership, or corporation.

[Regulation .08.010, filed 1/10/63; Regulation .08.010, filed 3/23/60.]

WAC 360-08-030 Appearance and practice before board—Solicitation of business unethical. It shall be unethical for persons acting in a representative capacity before the board to solicit business by circulars, advertisements or by personal communication or interviews not warranted by personal relations, provided that such representatives may publish or circulate business cards. It is equally unethical to procure business indirectly by solicitors of any kind.

[Regulation .08.020, filed 1/10/63; Regulation .08.030, filed 3/23/60.]

WAC 360-08-040 Appearance and practice before board—Standards of ethical conduct. All persons appearing in proceedings before the board in a representative capacity shall conform to the standards of ethical conduct required of attorneys before the courts of Washington. If any such person does not conform to such standards, the board may decline to permit such person to appear in a representative capacity in any proceeding before the board.

[Regulation .08.030, filed 1/10/63; Regulation .08.040, filed 3/23/60.]

WAC 360-08-050 Appearance and practice before board—Appearance by former employee of board or former member of attorney general's staff. No former

employee of the board or member of the attorney general's staff may at any time after severing his employment with the board or the attorney general appear, except with the written permission of the board, in a representative capacity on behalf of other parties in a formal proceeding wherein he previously took an active part as a representative of the board.

[Regulation .08.040, filed 1/10/63; Regulation .08.050, filed 3/23/60.]

WAC 360-08-060 Appearance and practice before board--Former employee as expert witness. No former employee of the board shall at any time after severing his employment with the board appear, except with the written permission of the board, as an expert witness on behalf of other parties in a formal proceeding wherein he previously took an active part in the investigation as a representative of the board.

[Regulation .08.050, filed 1/10/63; Regulation .08.060, filed 3/23/60.]

WAC 360-08-070 Computation of time. In computing any period of time prescribed or allowed by the board rules, by order of the board or by any applicable statute, the day of the act, event, or default after which the designated period of time begins to run is not to be included. The last day of the period so computed is to be included, unless it is a Saturday, Sunday or a legal holiday, in which event the period runs until the end of the next day which is neither a Saturday, Sunday nor a holiday. When the period of time prescribed or allowed is less than seven days, intermediate Saturdays, Sundays and holidays shall be excluded in the computation.

[Regulation .08.060, filed 1/10/63; Regulation .08.070, filed 3/23/60.]

WAC 360-08-080 Notice and opportunity for hearing in contested cases. In any contested case, all parties shall be served with a notice at least 10 days before the date set for the hearing. The notice shall state the time, place, and issues involved, as required by RCW 34.04.090(1).

[Regulation .08.070, filed 1/10/63; Regulation .08.080, filed 3/23/60.]

WAC 360-08-090 Service of process--By whom served. The board shall cause to be served all orders, notices and other papers issued by it, together with any other papers which it is required by law to serve. Every other paper shall be served by the party filing it.

[Regulation .08.080, filed 1/10/63; Regulation .08.090, filed 3/23/60.]

WAC 360-08-100 Service of process--Upon whom served. All papers served by either the board or any party shall be served upon all counsel of record at the time of such filing and upon parties not represented by counsel or upon their agents designated by them or by law. Any counsel entering an appearance subsequent to the initiation of the proceeding shall notify all other

counsel then of record and all parties not represented by counsel of such fact.

[Regulation .08.090, filed 1/10/63; Regulation .08.100, filed 3/23/60.]

WAC 360-08-110 Service of process--Service upon parties. The final order, and any other paper required to be served by the board upon a party, shall be served upon such party or upon the agent designated by him or by law to receive service of such papers, and a copy shall be furnished to counsel of record.

[Regulation .08.100, filed 1/10/63; Regulation .08.110, filed 3/23/60.]

WAC 360-08-120 Service of process--Method of service. Service of papers shall be made personally or, unless otherwise provided by law, by first class, registered, or certified mail; or by telegraph.

[Regulation .08.110, filed 1/10/63; Regulation .08.120, filed 3/23/60.]

WAC 360-08-130 Service of process--When service complete. Service upon parties shall be regarded as complete: By mail, upon deposit in the United States mail properly stamped and addressed; by telegraph, when deposited with a telegraph company properly addressed and with charges prepaid.

[Regulation .08.120, filed 1/10/63; Regulation .08.130, filed 3/23/60.]

WAC 360-08-140 Service of process--Filing with the board. Papers required to be filed with the board shall be deemed filed upon actual receipt by the board at the place specified in its rules accompanied by proof of service upon parties required to be served.

[Regulation .08.130, filed 1/10/63; Regulation .08.140, filed 3/23/60.]

WAC 360-08-230 Depositions and interrogatories in contested cases--Right to take. Except as may be otherwise provided, any party may take the testimony of any person, including a party, by deposition upon oral examination or written interrogatories for use as evidence in the proceeding.

[Regulation .08.230, filed 1/10/63; Regulation .08.230, filed 3/23/60.]

WAC 360-08-240 Depositions and interrogatories in contested cases--Scope. Unless otherwise ordered, the deponent may be examined regarding any matter not privileged, which is relevant to the subject matter involved in the proceeding.

[Regulation .08.240, filed 1/10/63; Regulation .08.240, filed 3/23/60.]

WAC 360-08-250 Depositions and interrogatories in contested cases--Officer before whom taken. Within the United States or within a territory or insular possession subject to the dominion of the United States depositions shall be taken before an officer authorized to administer oaths by the laws of the state of Washington

or of the place where the examination is held; within a foreign country, depositions shall be taken before a secretary of an embassy or legation, consul general, vice consul or consular agent of the United States, or a person designated by the board or agreed upon by the parties by stipulation in writing filed with the board. Except by stipulation, no deposition shall be taken before a person who is a party or the privy of a party, or a privy of any counsel of a party, or who is financially interested in the proceeding.

[Regulation .08.250, filed 1/10/63; Regulation .08.250, filed 3/23/60.]

WAC 360-08-260 Depositions and interrogatories in contested cases—Authorization. A party desiring to take the deposition of any person upon oral examination shall give reasonable notice of not less than three days in writing to the board and all parties. The notice shall state the time and place for taking the deposition, the name and address of each person to be examined, if known, and if the name is not known, a general description sufficient to identify him or the particular class or group to which he belongs. On motion of a party upon whom the notice is served, the hearing officer may for cause shown, enlarge or shorten the time. If the parties so stipulate in writing, depositions may be taken before any person, at any time or place, upon any notice, and in any manner and when so taken may be used as other depositions.

[Regulation .08.260, filed 1/10/63; Regulation .08.260, filed 3/23/60.]

WAC 360-08-270 Depositions and interrogatories in contested cases—Protection of parties and deponents. After notice is served for taking a deposition, upon its own motion or upon motion reasonably made by any party or by the person to be examined and upon notice and for good cause shown, the board or its designated hearing officer may make an order that the deposition shall not be taken, or that it may be taken only at some designated place other than that stated in the notice, or that it may be taken only on written interrogatories, or that certain matters shall not be inquired into, or that the scope of the examination shall be limited to certain matters, or that the examination shall be limited to certain matters, or that the examination shall be held with no one present except the parties to the action and their officers or counsel, or that after being sealed, the deposition shall be opened only by order of the board, or that business secrets or secret processes, developments, or research need not be disclosed, or that the parties shall simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the board; or the board may make any other order which justice requires to protect the party or witness from annoyance, embarrassment, or oppression. At any time during the taking of the deposition, on motion of any party or of the deponent and upon a showing that the examination is being conducted in bad faith or in such manner as unreasonably to annoy, embarrass, or oppress

the deponent or party, the board or its designated hearing officer may order the officer conducting the examination to cease forthwith from taking the deposition, or may limit the scope and manner of the taking of the deposition as above provided. If the order made terminates the examination, it shall be resumed thereafter only upon the order of the board. Upon demand of the objecting party or deponent, the taking of the deposition shall be suspended for the time necessary to make a motion for an order.

[Regulation .08.270, filed 1/10/63; Regulation .08.270, filed 3/23/60.]

WAC 360-08-280 Depositions and interrogatories in contested cases—Oral examination and cross-examination. Examination and cross-examination shall proceed as at an oral hearing. In lieu of participating in the oral examination, any party served with notice of taking a deposition may transmit written cross interrogatories to the officer who, without first disclosing them to any person, and after the direct testimony is complete, shall propound them seriatim to the deponent and record or cause the answers to be recorded verbatim.

[Regulation .08.280, filed 1/10/63; Regulation .08.280, filed 3/23/60.]

WAC 360-08-290 Depositions and interrogatories in contested cases—Recordation. The officer before whom the deposition is to be taken shall put the witness on oath and shall personally or by someone acting under his direction and in his presence, record the testimony by typewriter directly or by transcription from stenographic notes, wire or record recorders, which record shall separately and consecutively number each interrogatory. Objections to the notice, qualifications of the officer taking the deposition, or to the manner of taking it, or to the evidence presented or to the conduct of the officer, or of any party, shall be noted by the officer upon the deposition. All objections by any party not so made are waived.

[Regulation .08.290, filed 1/10/63; Regulation .08.290, filed 3/23/60.]

WAC 360-08-300 Depositions and interrogatories in contested cases—Signing attestation and return. When the testimony is fully transcribed the deposition shall be submitted to the witness for examination and shall be read to or by him, unless such examination and reading are waived by the witness and by the parties. Any changes in form or substance which the witness desires to make shall be entered upon the deposition by the officer with a statement of the reasons given by the witness for making them. The deposition shall then be signed by the witness, unless the parties by stipulation waive the signing or the witness is ill or cannot be found or refuses to sign. If the deposition is not signed by the witness, the officer shall sign it and state on the record the fact of the waiver or of the illness or absence of the witness or the fact of the refusal to sign together with the reason, if any, given therefor; and the deposition may then be used as fully as though signed, unless on a motion to suppress the board holds that the reasons

given for the refusal to sign require rejection of the deposition in whole or in part.

The officer shall certify on the deposition that the witness was duly sworn by him and that the deposition is a true record of the testimony given by the witness. He shall then securely seal the deposition in an envelope indorsed with the title of proceeding and marked "Deposition of (here insert name of witness)" and shall promptly send it by registered or certified mail to the board, or its designated hearing officer, for filing. The party taking the deposition shall give prompt notice of its filing to all other parties. Upon payment of reasonable charges therefor, the officer shall furnish a copy of the deposition to any party or to the deponent.

[Regulation .08.300, filed 1/10/63; Regulation .08.300, filed 3/23/60.]

WAC 360-08-310 Depositions and interrogatories in contested cases—Use and effect. Subject to rulings by the hearing officer upon objections a deposition taken and filed as provided in this rule will not become a part of the record in the proceeding until received in evidence by the hearing officer upon his own motion or the motion of any party. Except by agreement of the parties or ruling of the hearing officer, a deposition will be received only in its entirety. A party does not make a party, or the privy of a party, or any hostile witness his witness by taking his deposition. Any party may rebut any relevant evidence contained in a deposition whether introduced by him or any other party.

[Regulation .08.310, filed 1/10/63; Regulation .08.310, filed 3/23/60.]

WAC 360-08-320 Depositions and interrogatories in contested cases—Fees of officers and deponents. Deponents whose depositions are taken and the officers taking the same shall be entitled to the same fees as are paid for like services in the superior courts of the state of Washington, which fees shall be paid by the party at whose instance the depositions are taken.

[Regulation .08.320, filed 1/10/63; Regulation .08.320, filed 3/23/60.]

WAC 360-08-330 Depositions upon interrogatories—Submission of interrogatories. Where the deposition is taken upon written interrogatories, the party offering the testimony shall separately and consecutively number each interrogatory and file and serve them with a notice stating the name and address of the person who is to answer them and the name or descriptive title and address of the officer before whom they are to be taken. Within 10 days thereafter a party so served may serve cross-interrogatories upon the party proposing to take the deposition. Within five days thereafter, the latter may serve redirect interrogatories upon the party who served cross-interrogatories.

[Regulation .08.330, filed 1/10/63; Regulation .08.330, filed 3/23/60.]

(1986 Ed.)

WAC 360-08-340 Depositions upon interrogatories—Interrogation. Where the interrogatories are forwarded to an officer authorized to administer oaths as provided in WAC 360-08-250 the officer taking the same after duly swearing the deponent, shall read to him seriatim, one interrogatory at a time and cause the same and the answer thereto to be recorded before the succeeding interrogatory is asked. No one except the deponent, the officer and the court reporter or stenographer recording and transcribing it shall be present during the interrogation.

[Regulation .08.340, filed 1/10/63; Regulation .08.340, filed 3/23/60.]

WAC 360-08-350 Depositions upon interrogatories—Attestation and return. The officer before whom interrogatories are verified or answered shall (1) certify under his official signature and seal that the deponent was duly sworn by him, that the interrogatories and answers are a true record of the deponent's testimony, that no one except deponent, the officer and the stenographer were present during the taking, and that neither he nor the stenographer, to his knowledge, is a party, privy to a party, or interested in the event of the proceedings, and (2) promptly send by registered or certified mail the original copy of the deposition and exhibits with his attestation to the board, or its designated hearing officer, one copy to the counsel who submitted the interrogatories and another copy to the deponent.

[Regulation .08.350, filed 1/10/63; Regulation .08.350, filed 3/23/60.]

WAC 360-08-360 Depositions upon interrogatories—Provisions of deposition rule. In all other respects, depositions upon interrogatories shall be governed by the previous deposition rule.

[Regulation .08.360, filed 1/10/63; Regulation .08.360, filed 3/23/60.]

WAC 360-08-370 Official notice—Matters of law. The board or its hearing officer, upon request made before or during a hearing, will officially notice:

(1) **Federal law.** The Constitution; congressional acts, resolutions, records, journals and committee reports; decisions of federal courts and administrative agencies; executive orders and proclamations; and all rules, orders and notices published in the Federal Register;

(2) **State law.** The Constitution of the state of Washington, acts of the legislature, resolutions, records, journals and committee reports; decisions of administrative agencies of the state of Washington, executive orders and proclamations by the governor; and all rules, orders and notices filed with the code reviser.

(3) **Governmental organization.** Organization, territorial limitations, officers, departments, and general administration of the government of the state of Washington, the United States, the several states and foreign nations;

(4) **Board organization.** The board's organization, administration, officers, personnel, official publications, and practitioners before its bar.

[Regulation .08.370, filed 1/10/63; Regulation .08.370, filed 3/23/60.]

WAC 360-08-380 Official notice--Material facts.

In the absence of controverting evidence, the board and its hearing officers, upon request made before or during a hearing, may officially notice:

(1) **Board proceedings.** The pendency of, the issues and position of the parties therein, and the disposition of any proceeding then pending before or theretofore concluded by the board.

(2) **Business customs.** General customs and practices followed in the transaction of business;

(3) **Notorious facts.** Facts so generally and widely known to all well-informed persons as not to be subject to reasonable dispute, or specific facts which are capable of immediate and accurate demonstration by resort to accessible sources of generally accepted authority, including but not exclusively, facts stated in any publication authorized or permitted by law to be made by any federal or state officer, department, or agency;

(4) **Technical knowledge.** Matters within the technical knowledge of the board as a body of experts, within the scope or pertaining to the subject matter of its statutory duties, responsibilities or jurisdiction;

(5) **Request or suggestion.** Any party may request, or the hearing officer or the board may suggest, that official notice be taken of a material fact, which shall be clearly and precisely stated, orally on the record, at any pre-hearing conference or oral hearing or argument, or may make such request or suggestion by written notice, any pleading, motion, memorandum, or brief served upon all parties, at any time prior to a final decision;

(6) **Statement.** Where an initial or final decision of the board rests in whole or in part upon official notice of a material fact, such fact shall be clearly and precisely stated in such decision. In determining whether to take official notice of material facts, the hearing officer of the board may consult any source of pertinent information, whether or not furnished as it may be, by any party and whether or not admissible under the rules of evidence;

(7) **Controversion.** Any party may controvert a request or a suggestion that official notice of a material fact be taken at the time the same is made if it be made orally, or by a pleading, reply or brief in response to the pleading or brief or notice in which the same is made or suggested. If any decision is stated to rest in whole or in part upon official notice of a material fact which the parties have not had a prior opportunity to controvert, any party may controvert such fact by appropriate exceptions if such notice be taken in an initial or intermediate decision or by a petition for reconsideration if notice of such fact be taken in a final report. Such controversion shall concisely and clearly set forth the sources, authority and other data relied upon to show the existence or nonexistence of the material fact assumed or denied in the decision;

(8) **Evaluation of evidence.** Nothing herein shall be construed to preclude the board or its authorized agents from utilizing their experience, technical competence,

and specialized knowledge in the evaluation of the evidence presented to them.

[Regulation .08.380, filed 1/10/63; Regulation .08.380, filed 3/23/60.]

WAC 360-08-390 Presumptions. Upon proof of the predicate facts specified in the following six subdivisions hereof without substantial dispute and by direct, clear, and convincing evidence, the board, with or without prior request or notice, may make the following presumptions, where consistent with all surrounding facts and circumstances:

(1) **Continuity.** That a fact of a continuous nature, proved to exist at a particular time, continues to exist as of the date of the presumption, if the fact is one which usually exists for at least that period of time;

(2) **Identity.** That persons and objects of the same name and description are identical;

(3) **Delivery.** Except in a proceeding where the liability of the carrier for nondelivery is involved, that mail matter, communications, express or freight, properly addressed, marked, billed and delivered respectively to the post office, telegraph, cable or radio company, or authorized common carrier of property with all postage, tolls and charges properly prepaid, is or has been delivered to the addressee or consignee in the ordinary course of business;

(4) **Ordinary course.** That a fact exists or does not exist, upon proof of the existence or nonexistence of another fact which in the ordinary and usual course of affairs, usually and regularly coexists with the fact presumed;

(5) **Acceptance of benefit.** That a person for whom an act is done or to whom a transfer is made has, does or will accept same where it is clearly in his own self-interest so to do;

(6) **Interference with remedy.** That evidence, with respect to a material fact which in bad faith is destroyed, elojned, suppressed or withheld by a party in control thereof, would if produced, corroborate the evidence of the adversary party with respect to such fact.

[Regulation .08.390, filed 1/10/63; Regulation .08.390, filed 3/23/60.]

WAC 360-08-400 Stipulations and admissions of record. The existence or nonexistence of a material fact, as made or agreed in a stipulation or in an admission of record, will be conclusively presumed against any party bound thereby, and no other evidence with respect thereto will be received upon behalf of such party, provided:

(1) **Upon whom binding.** Such a stipulation or admission is binding upon the parties by whom it is made, their privies and upon all other parties to the proceeding who do not expressly and unequivocally deny the existence or nonexistence of the material fact so admitted or stipulated, upon the making thereof, if made on the record at a prehearing conference, oral hearing, oral argument or by a writing filed and served upon all parties within five days after a copy of such stipulation or admission has been served upon them;

(2) **Withdrawal.** Any party bound by a stipulation or admission of record at any time prior to final decision may be permitted to withdraw the same in whole or in part by showing to the satisfaction of the hearing officer or the board that such stipulation or admission was made inadvertently or under a bona fide mistake of fact contrary to the true fact and that its withdrawal at the time proposed will not unjustly prejudice the rights of other parties to the proceeding.

[Regulation .08.400, filed 1/10/63; Regulation .08.400, filed 3/23/60.]

WAC 360-08-410 Form and content of decisions in contested cases. Every decision and order, whether proposed, initial, or final, shall:

- (1) Be correctly captioned as to name of agency and name of proceeding;
- (2) Designate all parties and counsel to the proceeding;
- (3) Include a concise statement of the nature and background of the proceeding;
- (4) Be accompanied by appropriate numbered findings of fact and conclusions of law;
- (5) Whenever practical, the conclusions of law shall include the reason or reasons for the particular order or remedy afforded;
- (6) Wherever practical, the conclusions and/or order shall be referenced to specific provisions of the law and/or regulations appropriate thereto, together with reasons and precedents relied upon to support the same.

[Regulation .08.410, filed 1/10/63; Regulation .08.410, filed 3/23/60.]

WAC 360-08-420 Definition of issues before hearing. In all proceedings the issues to be adjudicated shall be made initially as precise as possible, in order that hearing officers may proceed promptly to conduct the hearings on relevant and material matter only.

[Regulation .08.420, filed 1/10/63; Regulation .08.420, filed 3/23/60.]

WAC 360-08-430 Prehearing conference rule--Authorized. In any proceeding the board or its designated hearing officer upon its or his own motion, or upon the motion of one of the parties or their qualified representatives, may in its or his discretion direct the parties or their qualified representatives to appear at a specified time and place for a conference to consider

- (1) The simplification of the issues;
- (2) The necessity of amendments to the pleadings;
- (3) The possibility of obtaining stipulations, admissions of facts and of documents;
- (4) The limitation of the number of expert witnesses;
- (5) Such other matters as may aid in the disposition of the proceeding.

[Regulation .08.430, filed 1/10/63; Regulation .08.430, filed 3/23/60.]

WAC 360-08-440 Prehearing conference rule--Record of conference action. The board or its designated hearing officer shall make an order or statement which

recites the action taken at the conference, the amendments allowed to the pleadings and the agreements made by the parties or their qualified representatives as to any of the matters considered, including the settlement or simplification of issues, and which limits the issues for hearing to those not disposed of by admissions or agreements; and such order or statement shall control the subsequent course of the proceeding unless modified for good cause by subsequent order.

[Regulation .08.440, filed 1/10/63; Regulation .08.440, filed 3/23/60.]

WAC 360-08-450 Submission of documentary evidence in advance. Where practicable the board or its designated hearing officer may require:

- (1) That all documentary evidence which is to be offered during the taking of evidence be submitted to the hearing examiner and to the other parties to the proceeding sufficiently in advance of such taking of evidence to permit study and preparation of cross-examination and rebuttal evidence;
- (2) That documentary evidence not submitted in advance, as may be required by subsection (1), be not received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the evidence sooner;
- (3) That the authenticity of all documents submitted in advance in a proceeding in which such submission is required, be deemed admitted unless written objection thereto is filed prior to the hearing, except that a party will be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

[Regulation .08.450, filed 1/10/63; Regulation .08.450, filed 3/23/60.]

WAC 360-08-460 Excerpts from documentary evidence. When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the hearing examiner and to the other parties. Only the excerpts, so prepared and submitted, shall be received in the record. However, the whole of the original document shall be made available for examination and for use by all parties to the proceeding.

[Regulation .08.460, filed 1/10/63; Regulation .08.460, filed 3/23/60.]

WAC 360-08-470 Expert or opinion testimony and testimony based on economic and statistical data--Number and qualifications of witnesses. That the hearing examiner or other appropriate officer in all classes of cases where practicable make an effort to have the interested parties agree upon the witness or witnesses who are to give expert or opinion testimony, either by selecting one or more to speak for all parties or by limiting the number for each party; and, if the interested parties cannot agree, require them to submit to him and to the other parties written statements containing the names,

addresses and qualifications of their respective opinion or expert witnesses, by a date determined by him and fixed sufficiently in advance of the hearing to permit the other interested parties to investigate such qualifications.

[Regulation .08.470, filed 1/10/63; Regulation .08.470, filed 3/23/60.]

WAC 360-08-480 Expert or opinion testimony and testimony based on economic and statistical data—Written sworn statements. That the hearing examiner or other appropriate officer, in all classes of cases in which it is practicable and permissible, require, and when not so permissible, make every effort to bring about by voluntary submission, that all direct opinion or expert testimony and all direct testimony based on economic or statistical data be reduced to written sworn statements, and, together with the exhibits upon which based, be submitted to him and to the other parties to the proceeding by a date determined by the hearing officer and fixed a reasonable time in advance of the hearing; and that such sworn statements be acceptable as evidence upon formal offer at the hearing, subject to objection on any ground except that such sworn statements shall not be subject to challenge because the testimony is not presented orally, and provided that witnesses making such statements shall not be subject to cross-examination unless a request is made sufficiently in advance of the hearing to insure the presence of the witnesses.

[Regulation .08.480, filed 1/10/63; Regulation .08.480, filed 3/23/60.]

WAC 360-08-490 Expert or opinion testimony and testimony based on economic and statistical data—Supporting data. That the hearing examiner or other appropriate officer, in his discretion but consistent with the rights of the parties, cause the parties to make available for inspection in advance of the hearing, and for purposes of cross-examination at the hearing, the data underlying statements and exhibits submitted in accordance with WAC 360-08-480, but, wherever practicable that he restrict to a minimum the placing of such data in the record.

[Regulation .08.490, filed 1/10/63; Regulation .08.490, filed 3/23/60.]

WAC 360-08-500 Expert or opinion testimony and testimony based on economic and statistical data—Effect of noncompliance with WAC 360-08-470 or 360-08-480. Whenever the manner of introduction of opinion or expert testimony or testimony based on economic or statistical data is governed by requirements fixed under the provisions of WAC 360-08-470 or 360-08-480, such testimony not submitted in accordance with the relevant requirements shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to conform to such requirements.

[Regulation .08.500, filed 1/10/63; Regulation .08.500, filed 3/23/60.]

[Title 360 WAC—p 8]

WAC 360-08-510 Continuances. Any party who desires a continuance shall, immediately upon receipt of notice of a hearing, or as soon thereafter as facts requiring such continuance come to his knowledge, notify the board or its designated hearing officer of said desire, stating in detail the reasons why such continuance is necessary. The board or its designated hearing officer, in passing upon a request for continuance, shall consider whether such request was promptly and timely made. For good cause shown, the board or its designated hearing officer may grant such a continuance and may at any time order a continuance upon its or his own motion. During a hearing, if it appears in the public interest or in the interest of justice that further testimony or argument should be received, the examiner or other officer conducting the hearing may in his discretion continue the hearing and fix the date for introduction of additional evidence or presentation of argument. Such oral notice shall constitute final notice of such continued hearing.

[Regulation .08.510, filed 1/10/63; Regulation .08.510, filed 3/23/60.]

WAC 360-08-520 Rules of evidence—Admissibility criteria. Subject to the other provisions of these rules, all relevant evidence is admissible which, in the opinion of the officer conducting the hearing, is the best evidence reasonably obtainable, having due regard for its necessity, availability and trustworthiness. In passing upon the admissibility of evidence, the officer conducting the hearing shall give consideration to, but shall not be bound to follow, the rules of evidence governing civil proceedings, in matters not involving trial by jury, in the superior court of the state of Washington.

[Regulation .08.520, filed 1/10/63; Regulation .08.520, filed 3/23/60.]

WAC 360-08-530 Rules of evidence—Tentative admission—Exclusion—Discontinuance—Objections.

When objection is made to the admissibility of evidence, such evidence may be received subject to a later ruling. The officer conducting the hearing may, in his discretion, either with or without objection, exclude inadmissible evidence or order cumulative evidence discontinued. Parties objecting to the introduction of evidence shall state the precise grounds of such objection at the time such evidence is offered.

[Regulation .08.530, filed 1/10/63; Regulation .08.530, filed 3/23/60.]

WAC 360-08-540 Petitions for rule making, amendment or repeal—Who may petition. Any interested person may petition the board requesting the promulgation, amendment, or repeal of any rule.

[Regulation .08.540, filed 1/10/63; Regulation .08.540, filed 3/23/60.]

WAC 360-08-550 Petitions for rule making, amendment or repeal—Requisites. Where the petition requests the promulgation of a rule, the requested or proposed rule must be set out in full. The petition must

also include all the reasons for the requested rule together with briefs of any applicable law. Where the petition requests the amendment or repeal of a rule presently in effect, the rule or portion of the rule in question must be set out as well as a suggested amended form, if any. The petition must include all reasons for the requested amendment or repeal of the rule.

[Regulation .08.550, filed 1/10/63; Regulation .08.550, filed 3/23/60.]

WAC 360-08-560 Petitions for rule making, amendment or repeal--Agency must consider. All petitions shall be considered by the board and the board may, in its discretion, order a hearing for the further consideration and discussion of the requested promulgation, amendment, repeal, or modification of any rule.

[Regulation .08.560, filed 1/10/63; Regulation .08.560, filed 3/23/60.]

WAC 360-08-570 Petitions for rule making, amendment or repeal--Notice of disposition. The board shall notify the petitioning party within a reasonable time of the disposition, if any, of the petition.

[Regulation .08.570, filed 1/10/63; Regulation .08.570, filed 3/23/60.]

WAC 360-08-580 Declaratory rulings. As prescribed by RCW 34.04.080, any interested person may petition the board for a declaratory ruling. The board shall consider the petition and within a reasonable time the board shall:

- (1) Issue a nonbinding declaratory ruling; or
- (2) Notify the person that no declaratory ruling is to be issued; or
- (3) Set a reasonable time and place for hearing argument upon the matter, and give reasonable notification to the person of the time and place for such hearing and of the issues involved.

If a hearing as provided in subsection (3) is conducted, the board shall within a reasonable time:

- (1) Issue a binding declaratory rule; or
- (2) Issue a nonbinding declaratory ruling; or
- (3) Notify the person that no declaratory ruling is to be issued.

[Regulation .08.580, filed 1/10/63; Regulation .08.580, filed 3/23/60.]

WAC 360-08-590 Forms. Any interested person petitioning the board for a declaratory ruling pursuant to RCW 34.04.080, shall generally adhere to the following form for such purpose.

At the top of the page shall appear the wording "Before the board of pharmacy." On the left side of the page below the foregoing the following caption shall be set out: "In the matter of the petition of (name of petitioning party) for a declaratory ruling." Opposite the foregoing caption shall appear the word "petition."

The body of the petition shall be set out in numbered paragraphs. The first paragraph shall state the name and address of the petitioning party. The second paragraph shall state all rules or statutes that may be

brought into issue by the petition. Succeeding paragraphs shall set out the state of facts relied upon in form similar to that applicable to complaints in civil actions before the superior courts of this state. The concluding paragraphs shall contain the prayer of the petitioner. The petition shall be subscribed and verified in the manner prescribed for verification of complaints in the superior courts of this state.

The original and two legible copies shall be filed with the board. Petitions shall be on white paper either 8 1/2" x 11" or 8 1/2" x 13" in size.

Any interested person petitioning the board requesting the promulgation, amendment or repeal of any rules shall generally adhere to the following form for such purpose.

At the top of the page shall appear the wording "Before the board of pharmacy." On the left side of the page below the foregoing the following caption shall be set out: "In the matter of the petition of (name of petitioning party) for (state whether promulgation, amendment or repeal) of rule (or rules)." Opposite the foregoing caption shall appear the word "petition."

The body of the petition shall be set out in numbered paragraphs. The first paragraph shall state the name and address of the petitioning party and whether petitioner seeks the promulgation of new rule or rules, or amendment or repeal of existing rule or rules. The second paragraph, in case of a proposed new rule or amendment of an existing rule, shall set forth the desired rule in its entirety. Where the petition is for amendment, the new matter shall be underscored and the matter proposed to be deleted shall appear in double parentheses. Where the petition is for repeal of an existing rule, such shall be stated and the rule proposed to be repealed shall either be set forth in full or shall be referred to by board rule number. The third paragraph shall set forth concisely the reasons for the proposal of the petitioner and shall contain a statement as to the interest of the petitioner in the subject matter of the rule. Additional numbered paragraphs may be used to give full explanation of petitioner's reason for the action sought.

Petitions shall be dated and signed by the person or entity named in the first paragraph or by his attorney. The original and two legible copies of the petition shall be filed with the board. Petitions shall be on white paper, either 8 1/2" x 11" or 8 1/2" x 13" in size.

[Regulation .08.590, filed 1/10/63; Regulation .08.590, filed 3/23/60.]

Chapter 360-10 WAC INTERNSHIP REQUIREMENTS

WAC

360-10-010	General requirements.
360-10-020	Registration of interns and preceptors.
360-10-030	Rules for the pharmacy intern.
360-10-040	Training reports.
360-10-050	Requirements for preceptor certification.
360-10-060	Rules for preceptors.
360-10-070	Repeal of prior regulations.
360-10-080	Special internship approval.

WAC 360-10-010 General requirements. (1) RCW 18.64.080(5) states: "Any person enrolled as a student of pharmacy in an accredited college may file with the state board of pharmacy an application for registration as a pharmacy intern——." A student of pharmacy shall be defined as any person enrolled in a college of pharmacy accredited by the board of pharmacy or any person enrolled in a prepharmacy program at an accredited college, and whose credits are acceptable for transfer by accredited colleges of pharmacy.

(2) As provided for in RCW 18.64.080(3) the board may specify not more than one year of internship requirement. The board of pharmacy hereby establishes fifteen hundred hours for the internship requirement. Credit may be allowed for up to three hundred hours for the completion of approved clinically oriented classes within a college of pharmacy; provided further that an additional five hundred hours of credit for the internship shall be granted to graduates of schools or colleges of pharmacy approved by the board.

(3) An applicant for licensure as a pharmacist who has completed seven hundred internship hours will be permitted to take the state board examination for licensure; however, no pharmacist license will be issued to the applicant until the fifteen hundred internship hours have been completed.

(4) Credit for up to five hundred hours at the rate of no more than fifteen hours per week may be allowed for part-time experience gained during the period while a student is regularly enrolled in a college; and full-time experience allowed while a student is enrolled for less than six quarter credit hours or four semester credit hours. This shall not exclude experience gained during regular student holiday and vacation periods.

(5) To retain a certificate as a pharmacy intern for the six year period prescribed by law, the intern must make continuing satisfactory progress in completing the pharmacy course.

(6) Experience must be obtained under the guidance of a preceptor who has met certification requirements prescribed in WAC 360-10-050 except as hereinafter provided for experience gained outside the state of Washington.

(7) Experience obtained in another state may be accepted toward the fulfillment of the fifteen hundred hour requirement provided that a letter is received from the board of pharmacy of that state in which the experience is gained and such letter indicates the experience gained would have been acceptable internship experience to the board of pharmacy in that state.

(8) A pharmacy intern shall not receive credit for any hours which predate his enrollment in a school of pharmacy, which does not include enrollment in a prepharmacy educational program: *Provided however*, That any pharmacy internship hours which predate this amendatory regulation shall be acceptable for any intern taking the state pharmacy board examination prior to July 1, 1972.

[Order 139, § 360-10-010, filed 12/9/77; Order 106, § 360-10-010, filed 6/3/71; Regulation 48, § I, filed 6/17/66.]

[Title 360 WAC—p 10]

WAC 360-10-020 Registration of interns and preceptors. (1) In order to be registered as a pharmacy intern, the qualified applicant in WAC 360-12-010 must file with the board of pharmacy an application for registration as a pharmacy intern as provided for in RCW 18.64.080. The application shall be accompanied by a fee as specified in WAC 360-18-020.

(2) A pharmacist who has met the certification requirements prescribed in WAC 360-10-050 and presented proper application to, and has been accepted by the board of pharmacy shall be certified as a preceptor. The board shall issue a certificate to qualified applicants and the certificate shall be in the pharmacy during the period that the intern is receiving training in the pharmacy.

(3) Registration as a preceptor shall be valid until July 31 of the odd-numbered year following registration. Said registration can be renewed by filing a renewal registration form supplied by the board of pharmacy no later than July 31st of the odd-numbered year. Said form shall indicate that the renewal applicant has the necessary qualifications to continue as a preceptor.

[Statutory Authority: RCW 18.64.005 and 18.64A.020, 83-18-021 (Order 175), § 360-10-020, filed 8/30/83; Order 106, § 360-10-020, filed 6/3/71; Regulation 48, § II, filed 6/17/66.]

WAC 360-10-030 Rules for the pharmacy intern.

(1) The intern shall send notification to the board of pharmacy on or before the first day of beginning of his training. Such notification shall consist of the date, the name of the pharmacy, and the name of the preceptor where the intern expects to begin his internship. The board of pharmacy shall promptly notify the intern of the acceptability of the preceptor under whom the intern expects to gain experience. Internship credit will not be accepted until the preceptor has been certified.

(2) The pharmacy intern shall engage in the compounding and dispensing of pharmaceutical preparations, and the selling of items restricted to sale under the supervision of a registered pharmacist, only while he is under the direct and personal supervision of a certified preceptor.

[Regulation 48, § III, filed 6/17/66.]

WAC 360-10-040 Training reports. (1) The intern shall file on forms provided by the board an internship evaluation report with the board at the completion of internship training and at the termination of any employment. The evaluation report shall include the following: Evaluation of:

- (a) The preceptors under whom internship was served.
- (b) Evaluation of the entire program.

(2) Upon completion of the intern's fifteen hundred hours of experience, the last preceptor under whom this experience was obtained shall file a report with the board. Such report shall briefly describe the type of professional experience received under the preceptor's supervision and the preceptor's opinion on the ability of the intern to practice pharmacy.

(3) The board of pharmacy shall provide the necessary affidavit forms to certify hours of experience, which

shall only include hours under the personal supervision of a preceptor. Affidavits must be certified and recorded in the office of the board of pharmacy not later than thirty days prior to examination and the termination of any employment.

(4) The intern's report and all or part of the hours covered by the period of the report can be rejected by the board if for the period involved the pharmacy intern has not performed adequate pharmaceutical services.

[Order 106, § 360-10-040, filed 6/3/71; Order 102, § 360-10-040, filed 12/5/69; Regulation 48, § IV, filed 6/17/66.]

WAC 360-10-050 Requirements for preceptor certification. (1) A pharmacist who is registered and actively engaged in practice in a Class A pharmacy in the state of Washington, and who has met certification requirements prescribed in this section of the regulation and who has been certified by the board of pharmacy shall be known as a "pharmacy preceptor."

(2) The pharmacy preceptor must have completed twelve months as a registered pharmacist engaged in the compounding and dispensing of pharmaceuticals.

(3) Any preceptor or preceptor applicant who has been found guilty of a drug or narcotic violation or whose pharmacist license has been revoked or suspended by the state board of pharmacy shall not be eligible for certification as a preceptor, unless special permission is obtained from the board of pharmacy.

(4) The pharmacy preceptor shall subscribe the following professional standards:

(a) The preceptor shall use every precaution to safeguard the public when dispensing any drugs or preparations; he shall make no attempt to prescribe for or to treat disease.

(b) The preceptor shall keep his pharmacy clean, neat, and sanitary, and well equipped with accurate measuring and weighing devices and other apparatus suitable for the proper performance of his professional duties.

(c) The preceptor shall be a good citizen and uphold and defend the laws of the states and nation; he shall keep himself informed concerning pharmacy and drug laws, and other laws pertaining to health and sanitation, and shall cooperate with the enforcement authorities.

(d) The preceptor shall willingly make available his expert knowledge of drugs to the intern and other health professions.

(e) The preceptor shall strive to perfect and enlarge his professional knowledge. He shall keep himself informed regarding professional matters by reading current pharmaceutical, scientific, and medical literature, attending seminars and other means.

(f) The preceptor shall seek to attract to his profession, youth of good character and intellectual capacity and aid in their instruction.

(g) The preceptor shall be responsible for the quality of the internship training under his supervision and he shall insure that the intern actually engages in pharmaceutical activities during that training period.

(5) The board of pharmacy shall withdraw a preceptor's certification upon proof that the preceptor failed to meet requirements as stated in this section.

[Order 106, § 360-10-050, filed 6/3/71; Regulation 48, § V, filed 6/17/66.]

WAC 360-10-060 Rules for preceptors. (1) The pharmacy preceptor shall supervise the pharmacy intern and shall be responsible for the compounding and dispensing of pharmaceuticals dispensed by an intern.

(2) The pharmacy 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 preceptor. This is to say that two interns may dispense and record internship experience in the same day under one preceptor's direct supervision; however, they may not dispense and record internship experience during the same hour of the day.

[Order 102, § 360-10-060, filed 12/5/69; Regulation 48, § VI, filed 6/17/66.]

WAC 360-10-070 Repeal of prior regulations. Except as provided for in WAC 360-10-010 (7) and (8) of this regulation, WAC 360-12-030 and 360-12-040 shall be repealed upon the effective date of this regulation.

[Regulation 48, § VII, filed 6/17/66.]

WAC 360-10-080 Special internship approval. (1) The board will consider applications for approval of special internship programs. Such programs may be approved when the board determines that they offer a significant educational opportunity.

(2) Applications for special internship approval must be submitted at least fifteen days prior to the next board meeting which will afford the board an opportunity to review the program.

[Order 114, § 360-10-080, filed 6/28/73.]

Chapter 360-11 WAC

PROFESSIONAL PHARMACEUTICAL EDUCATION

WAC

360-11-010	Continuing education.
360-11-020	Continuing education programs.
360-11-023	Applications for approval as a provider of continuing education—Post-approval of continuing education credits.
360-11-027	Continuing education program providers' responsibilities.
360-11-030	Instructors' credit toward continuing education unit.
360-11-033	Credit for continuing education.
360-11-037	Credit for individual study programs.
360-11-040	Amount of continuing education.
360-11-045	Pharmacist audits—Disallowed credit.
360-11-060	Advisory committee on continuing education.
360-11-070	Waiver of the continuing education requirement.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-11-050	Application of excess continuing education units. [Order 116, § 360-11-050, filed 11/9/73.] Repealed by 80-08-036 (Order 156, Resolution No. 6/80), filed 6/26/80. Statutory Authority: RCW 18.64.005(12).
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WAC 360-11-010 Continuing education. (1) No renewal certificate of licensure shall be issued by the

board of pharmacy until the applicant submits satisfactory proof to the board that during the twelve months preceding his or her application for renewal he or she has participated in courses of continuing professional pharmaceutical education of the types and number of continuing education credits specified by the board. Such continuing education is hereby declared to be a mandatory requirement for license renewal, except that pharmacists applying for the first annual renewal of their license following graduation shall be exempt from the provisions of this regulation.

(2) Continuing education requirements must be submitted along with the license application and fee. If the continuing education requirements are not complete the license renewal application will be returned with an explanatory note. The license renewal will not be processed until complete.

(3) Each individual pharmacist is responsible for maintaining records which verify the continuing education requirements which are submitted in support of annual renewal of license. Records shall be retained for a minimum of two years.

(4) A pharmacist who desires to reinstate his or her license after having been unlicensed for over one year shall, as a condition to reinstatement of his or her license, complete such continuing education credits as may be specified by the board in each individual case.

[Statutory Authority: RCW 18.64.005(12). 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-010, filed 6/26/80. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-11-010, filed 3/27/79; Order 116, § 360-11-010, filed 11/9/73.]

WAC 360-11-020 Continuing education programs.

The continuing professional pharmaceutical education courses may consist of post-graduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses or such other forms of continuing professional pharmaceutical education as may be approved by the board. Policies for such approvals will be set by the board to allow full consideration for those pharmacists residing in areas where local continuing education programs, seminars and meetings are not available. Such courses shall consist of subject matter pertinent to the following general areas of professional pharmaceutical education:

(1) Socio-economic and legal aspects of health care;

(2) The properties and actions of drugs and dosage forms;

(3) The etiology, characteristics and therapeutics of the disease state;

(4) Such other areas of professional pharmaceutical education as shall be designated by the board.

The specific subject matter of such courses may include but shall NOT BE LIMITED TO THE FOLLOWING: Pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable disease, pharmaceutical marketing, professional practice management and such other subject matter as may from time to time be represented in a curriculum of an accredited college of pharmacy or as may otherwise be selected by the board.

[Order 116, § 360-11-020, filed 11/9/73.]

WAC 360-11-023 Applications for approval as a provider of continuing education—Post-approval of continuing education credits. (1) Applications for approval as a provider of continuing education or for post-approval of continuing education credit shall be made on the form provided for this purpose by the Washington state board of pharmacy.

(2) In the case of an application for provider approval, the application form shall be submitted 30 days prior to the date the program will be held: *Provided, however,* That the board may waive the requirement that an application be filed 30 days prior to the date of the program on good cause shown in an individual case.

(3) In the case of an application for post-approval of continuing education credits for a pharmacist who has attended a worthy program for which the provider has not obtained approval, the pharmacist must file application for this approval within 30 days following the program.

(4) All programs approved by the American Council on Pharmaceutical Education are accepted for continuing education credit and do not require that an individual provider approval be obtained in each case.

[Statutory Authority: RCW 18.64.005(12). 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-023, filed 6/26/80.]

WAC 360-11-027 Continuing education program providers' responsibilities.

(1) A continuing education provider shall supply each attendee or subscriber with a written program description which lists the topic(s) covered, number of speakers or authors, time devoted to the program topic(s), and the instructional objectives of the program. The program description must also bear a statement of the number of hours of continuing education credit assigned by the provider.

(2) The provider must make available to each attendee or subscriber proof of attendance or participation suitable for verifying to the board the completion of continuing education requirements.

(3) The provider shall retain, for a period of two years, a list of persons to whom proof of attendance or participation as specified in (2) above was supplied. Providers of nonevaluated self-instruction units shall be exempt from this requirement.

[Statutory Authority: RCW 18.64.005(12). 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-027, filed 6/26/80.]

WAC 360-11-030 Instructors' credit toward continuing education unit.

Any pharmacist whose primary responsibility is *not* the education of health professionals, who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy-related topics in organized continuing education or in-service programs shall be granted continuing education credit for such time expended during actual presentation, upon adequate documentation to the board of pharmacy.

Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instruction or lecturing to groups of physicians, pharmacists, nurses or others on pharmacy related topics outside his/her formal course responsibilities in a learning institution.

[Order 116, § 360-11-030, filed 11/9/73.]

WAC 360-11-033 Credit for continuing education.

(1) One hour of continuing education credit will be awarded for each hour of proven attendance at lectures, short courses, workshops, or conferences given by academic institutions or by professional associations utilizing either faculty from academic institutions or recognized experts on the subject under discussion.

(2) One hour of continuing education credit will be awarded for each hour of proven attendance at those portions of regularly scheduled meetings of professional pharmacy groups, associations, or societies where speakers make presentations on topics of professional importance. Only those portions of meetings actually devoted to the presentation by the speaker may be used for credit. Such programs may be presented by any qualified speaker, including pharmacy school faculty, physicians, pharmacists or other appropriate professional persons.

(3) Programs which are acceptable for meeting continuing education requirements of other states will normally be acceptable to meet continuing education requirements in the state of Washington but credit for such programs will be subject to the limitations contained in these rules relating to evaluation and maximum hour allotments.

[Statutory Authority: RCW 18.64.005(12), 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-033, filed 6/26/80.]

WAC 360-11-037 Credit for individual study programs.

(1) Individual study programs of various types may be counted for continuing education credit. The amount of such credit which can be applied toward meeting the annual continuing education requirement will depend on whether the provider evaluates the users' mastery of the subject material.

(2) Self-instruction units such as audio tapes, video cassettes or audio tapes/slides may be counted on the basis of one hour of credit for each hour of actual viewing or listening time, provided there is a procedure conducted by the provider which evaluates learning and retention of information by the user. To obtain such credit, the pharmacist must be able to provide a certificate supplied by the program provider that he or she has satisfactorily achieved the goals of the learning unit.

(3) Correspondence courses available from recognized academic institutions which cover appropriate topics will be awarded continuing education credit on the basis of ten hours per unit credit awarded by the institution. It is also required that such correspondence courses evaluate the users learning and retention of information provided by the course.

(4) In cases where a user evaluation is not included as part of the self-instruction unit, credit will be accepted only to the extent of five hours of the total annual hours of continuing education requirement. Nonevaluated self-instruction includes programs such as audio tapes, video tapes, slide/tape programs, texts or journals. To obtain credit for a nonevaluated self-instruction program, a form approved by the Washington state board of pharmacy must be filled out and returned to the board office. For articles, tapes, and related types of learning units, one hour of credit may be claimed for each hour of reading, viewing, or listening time. The board may waive the five hours maximum credit allowable on good cause shown in an individual case.

[Statutory Authority: RCW 18.64.005(12), 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-037, filed 6/26/80.]

WAC 360-11-040 Amount of continuing education.

Effective with the 1982 renewals the equivalent of one and 1/2 continuing education unit (1.5 continuing education unit or 15 hours) of professional continuing education shall have been completed and shall be required annually of each applicant for renewal of licensure. One continuing education unit is the equivalent of ten hours of participation in continuing education programs approved by the board of pharmacy.

[Statutory Authority: RCW 18.64.005(12), 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-040, filed 6/26/80; Order 116, § 360-11-040, filed 11/9/73.]

WAC 360-11-045 Pharmacist audits--Disallowed credit.

(1) The board may audit the documentation submitted by a pharmacist in support of continuing education requirements and may disallow credit for that portion which does not meet the requirements of these rules.

(2) Since individual pharmacist audits will usually be retrospective, it is recognized that disallowed credit may work hardship on the pharmacist involved. In cases where a pharmacist is audited and some or all credit is disallowed, the continuing education requirement for the following year will be increased by the amount of hours disallowed.

(3) A pharmacist who is audited and has credit disallowed will automatically be audited for three consecutive years. Failure to satisfy the continuing education requirement as a result of disallowed credit in two consecutive years will be considered a violation of these regulations and will be good and sufficient cause for imposition of disciplinary action by the board.

[Statutory Authority: RCW 18.64.005(12), 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-045, filed 6/26/80.]

WAC 360-11-060 Advisory committee on continuing education.

There is under the jurisdiction of the board of pharmacy an advisory committee on continuing education consisting of ten members appointed by the board of pharmacy. The membership shall consist of two members from the state board of pharmacy, two members from the faculties of colleges of pharmacy in the state and six practicing pharmacists within the state.

The two board members shall be nonvoting members. The advisory committee shall meet a minimum of once a year.

It shall be the duty of the advisory committee to recommend to the board the standards and specifications to be required of programs that may be acceptable for approval by the board to fulfill the continuing education requirement, the approval of the programs fulfilling the standards and specifications adopted, the number of continuing education units to be awarded for the satisfactory completion of approved programs, and such other matters that will assist the board in the implementation of the continuing education requirements for the relicensure of pharmacists.

[Statutory Authority: RCW 18.64.005(12), 80-08-036 (Order 156, Resolution No. 6/80), § 360-11-060, filed 6/26/80; Order 116, § 360-11-060, filed 11/9/73.]

WAC 360-11-070 Waiver of the continuing education requirement. The board of pharmacy may, at its discretion, waive the requirements of this regulation for due cause.

[Order 116, § 360-11-070, filed 11/9/73.]

Chapter 360-12 WAC PHARMACISTS

WAC

360-12-010	Applicants—Citizenship.
360-12-015	Examinations.
360-12-020	Applicants—Application forms—Fees.
360-12-050	Applicants—Reciprocity applicants.
360-12-065	Foreign-trained applicants.
360-12-110	Licensed pharmacists—Change of home address.
360-12-120	Licensed pharmacists—Employed as responsible managers—Duty to notify board.
360-12-125	Inactive pharmacist license.
360-12-128	Retired pharmacist license.
360-12-130	Pharmacists—Reinstatement or reactivation of license.
360-12-140	Pharmacist prescriptive authority—Prior board notification of written guideline or protocol required.
360-12-150	Monitoring of drug therapy by pharmacists.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-12-030	Applicants—Experience requirements. [Regulation 29, filed 3/23/60.] Repealed with saving clause as to prior experience (WAC 360-10-070). WAC 360-12-070 is repealed by Order 109, filed 5/23/72.
360-12-040	Applicants—Reciprocal registration—Experience. [Regulation 20, filed 3/23/60.] Repealed with saving clause as to prior experience (WAC 360-10-070). WAC 360-12-070 is repealed by Order 109, filed 5/23/72.
360-12-060	Applicants—From foreign countries. [Regulation 21, filed 3/23/60.] Repealed by Order 122, filed 9/30/74.
360-12-070	Applicants—Pharmacy graduates of U.W. and W.S.U. [Regulation 3, filed 3/23/60.] Repealed by Order 109, filed 5/23/72.

WAC 360-12-010 Applicants—Citizenship. All applicants for license to practice as registered pharmacists in Washington must be citizens or resident aliens of the United States.

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[Order 121, § 360-12-010, filed 8/8/74; Regulation 1, filed 3/23/60.]

WAC 360-12-015 Examinations. (1) The examination for licensure as a pharmacist shall be known as the full board examination and shall consist of both theoretical and practical sections in such form as may be determined by the board.

(2) The score required to pass the overall examination shall be 75 percent. In addition, the scores achieved in the jurisprudence and written practice of pharmacy sections of the exam shall be no lower than 75 percent and the scores achieved on the other sections of the exam shall be no lower than 60 percent.

(3) An examinee failing any portion of the examination other than the jurisprudence section shall retake the regularly scheduled full board examination.

(4) An examinee failing the jurisprudence portion of the full board examination shall be allowed to retake the jurisprudence portion at a time and place to be specified by the board.

(5) An examinee who fails the jurisprudence examination three times shall not be eligible for further examination until he or she has satisfactorily completed additional preparation as directed and approved by the board.

[Statutory Authority: RCW 18.64.005(1) and 18.64.080, 84-04-029 (Order 183), § 360-12-015, filed 1/25/84. Statutory Authority: RCW 69.50.201, 79-04-048 (Order 147, Resolution No. 3-79), § 360-12-015, filed 3/27/79.]

WAC 360-12-020 Applicants—Application forms—Fees. Any person who has graduated from an accredited school of pharmacy in another state, wishing to become registered in the state of Washington by taking the full examination, shall make application to the board for examination before he or she shall be allowed to work as a pharmacist. (Forms will be supplied by the board. Submission of a fee is required by RCW 18.64.080(8).)

[Order 109, § 360-12-020, filed 5/23/72; Regulation 19 (part), filed 3/23/60.]

WAC 360-12-050 Applicants—Reciprocity applicants. (1) Applicants for license by reciprocity whose applications have been approved for the purpose of taking the jurisprudence examination may appear before the board at the time designated for examination.

(2) An applicant for reciprocity licensing shall be required to take and pass the jurisprudence examination given by the board prior to being issued his or her license. The jurisprudence examination shall be offered at least once in every two months.

(3) An applicant for reciprocity licensing who has been out of the active practice of pharmacy for between three and five years must take and pass the jurisprudence examination and additionally must either serve an internship of 300 hours or take and pass such additional practical examinations as may be specified by the board in each individual case.

(4) An applicant for reciprocity licensing who has been out of the active practice of pharmacy for over five years must take and pass the full board examination and serve an internship of 300 hours.

[Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-12-050, filed 3/27/79; Order 121, § 360-12-050, filed 8/8/74; Regulation 4, filed 3/23/60.]

WAC 360-12-065 Foreign-trained applicants. (1) Applicants whose academic training in pharmacy has been obtained from institutions in foreign countries, wishing to be licensed as pharmacists in the state of Washington shall take and pass the foreign pharmacy graduate equivalency examination prepared by the foreign pharmacy graduate education commission and shall have received an educational equivalency certificate from that commission.

(2) In addition, prior to licensure they shall pass the Washington state board of pharmacy full board examination and meet its internship requirements.

(3) Applicants whose academic training in pharmacy has been obtained from institutions in foreign countries and whose credentials are such that no further education is necessary must earn a total of 1500 intern hours before licensure. The applicant must earn at least 1200 intern hours before taking the full board examination: *Provided*, That the board may, for good cause shown, waive the required 1500 hours.

[Statutory Authority: RCW 18.64.005. 84-03-015 (Order 180), § 360-12-065, filed 1/9/84. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-12-065, filed 3/27/79; Order 122, § 360-12-065, filed 9/30/74.]

WAC 360-12-110 Licensed pharmacists change of home address. All licensed pharmacists shall notify the state board of pharmacy of any change of home address.

[Statutory Authority: RCW 18.64.005(11). 79-10-007 (Order 151, Resolution No. 9/79), § 360-12-110, filed 9/6/79; Regulation 5, filed 3/23/60.]

WAC 360-12-120 Licensed pharmacists--Employed as responsible managers--Duty to notify board. Licensed pharmacists employed as responsible managers for a pharmacy shall at once notify the state board of pharmacy of such employment and shall comply with such instructions as may be received. A pharmacist shall also at once notify the state board of pharmacy of termination of employment as a responsible manager. Please refer to WAC 360-16-050 for additional information.

[Statutory Authority: RCW 18.64.005(11). 79-10-007 (Order 151, Resolution No. 9/79), § 360-12-120, filed 9/6/79; Regulation 8, filed 3/23/60.]

WAC 360-12-125 Inactive pharmacist license. Any pharmacist who desires to leave the active practice of pharmacy in the state of Washington may request an inactive license from the board. The request for an inactive license must be submitted on a form provided by the board. It must be renewed in the same manner as an active license upon payment of a fee as specified by the board.

The holder of an inactive license shall not practice pharmacy in the state of Washington. The holder of an inactive license need not comply with the continuing education requirements contained in chapter 360-11 WAC.

(1986 Ed.)

In order to reactivate an inactive license, the holder of the inactive license must comply with the provisions of WAC 360-12-130.

[Statutory Authority: RCW 18.64.140. 85-06-010 (Order 193), § 360-12-125, filed 2/22/85.]

WAC 360-12-128 Retired pharmacist license. (1) Any pharmacist who has been licensed in the state for twenty-five consecutive years, who wishes to retire from the practice of pharmacy, may apply to the board of pharmacy for a retired pharmacist license.

(2) The holder of a retired pharmacist license shall not be authorized to practice pharmacy and need not comply with the continuing education requirements of chapter 360-11 WAC.

(3) A retired pharmacist license shall be granted to any qualified applicant and shall entitle such person to receive mailings from the board of pharmacy: *Provided*, That lawbook updates shall not be mailed without charge.

(4) In order to reactivate a retired pharmacist license, the holder must comply with the provision of WAC 360-12-130.

(5) The annual renewal fee for a retired pharmacist license shall be twenty dollars.

[Statutory Authority: RCW 18.64.005(11). 86-24-057 (Order 203), § 360-12-128, filed 12/2/86.]

WAC 360-12-130 Pharmacists--Reinstatement or reactivation of license. (1) A pharmacist who desires to reinstate or reactivate his or her license after having been out of the active practice of pharmacy must meet the following requirements, as applicable, in addition to paying the fee required by RCW 18.64.140.

(a) If the pharmacist has been unlicensed or the holder of an inactive license for three years or less, he or she must take and pass the jurisprudence examination given by the board.

(b) If the pharmacist has been unlicensed or the holder of an inactive license for between three and five years, he or she must take and pass the jurisprudence examination given by the board and either serve an internship of 300 hours or take and pass such further written practical examinations as are specified by the board in each individual case.

(c) If the pharmacist has been unlicensed or the holder of an inactive license for over five years, he or she must take and pass the full board examination and serve an internship of 300 hours.

(2) A pharmacist desiring to reinstate or reactivate his or her license must complete such continuing education credits as the board may specify in each individual case.

[Statutory Authority: RCW 18.64.140. 85-06-010 (Order 193), § 360-12-130, filed 2/22/85. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-12-130, filed 3/27/79; Regulation 2, filed 3/23/60.]

WAC 360-12-140 Pharmacist prescriptive authority--Prior board notification of written guideline or protocol required. (1) A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW

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18.64.011(11)) by initiating or modifying 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 must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy.

(2) For purposes of pharmacist prescriptive authority under RCW 18.64.011(11), a written guideline or protocol is defined as an agreement in which any practitioner authorized to prescribe legend drugs delegates to a pharmacist or group of pharmacists authority to conduct specified prescribing functions. Any modification of the written guideline or protocol shall be treated as a new protocol. It shall include:

(a) A statement identifying the practitioner authorized to prescribe and the pharmacist(s) who are party to the agreement. The practitioner authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' current practice.

(b) A time period not to exceed 2 years during which the written guideline or protocol will be in effect.

(c) A statement of the type of prescriptive authority decisions which the pharmacist(s) is (are) authorized to make, which includes:

(i) A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case.

(ii) A general statement of the procedures, decision criteria, or plan the pharmacist(s) is (are) to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved.

(d) A statement of the activities pharmacist(s) is (are) to follow in the course of exercising prescriptive authority, including documentation of decisions made, and a plan for communication or feedback to the authorizing practitioner concerning specific decisions made. Documentation may occur on the prescription record, patient drug profile, patient medical chart, or in a separate log book.

[Statutory Authority: RCW 18.64.005(11), 81-19-086 (Order 163, Resolution No. 8/81), § 360-12-140, filed 9/17/81. Statutory Authority: RCW 18.64.005(4) and (11), 80-08-035 (Order 155, Resolution No. 6/80), § 360-12-140, filed 6/26/80, effective 9/30/80.]

WAC 360-12-150 Monitoring of drug therapy by pharmacists. 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.

[Statutory Authority: RCW 18.64.005 and 69.41.075, 83-20-053 (Order 176), § 360-12-150, filed 9/29/83. Statutory Authority: RCW 18.64.005 and 69.41.240, 83-10-013 (Order 174), § 360-12-150, filed 4/26/83.]

Reviser's note: RCW 28B.19.077 requires the use of underlining and deletion marks to indicate amendments to existing rules. The bracketed material in the above section does not appear to conform to this rule.

Chapter 360-13 WAC EXTENDED CARE FACILITY

WAC

360-13-010	Promulgation.
360-13-020	Emergency kit.
360-13-030	Supplemental dose kits.
360-13-045	Definitions.
360-13-055	Drug facilities.
360-13-066	Pharmaceutical services.
360-13-100	Provision for continuity of drug therapy for residents.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-13-040	Drug storage. [Order 109, § 360-13-040, filed 5/23/72.] Repealed by Order 121, filed 8/8/74.
360-13-050	Poisons and other nonmedicinal chemical agents. [Order 109, § 360-13-050, filed 5/23/72.] Repealed by Order 121, filed 8/8/74.
360-13-060	Record requirements. [Order 109, § 360-13-060, filed 5/23/72.] Repealed by Order 121, filed 8/8/74.
360-13-065	Pharmaceutical services. [Order 121, § 360-13-065, filed 8/8/74.] Repealed by 82-06-042 (Order 165), filed 3/2/82. Statutory Authority: RCW 18.64.005(11) and 69.41.075.
360-13-070	Medications. [Order 109, § 360-13-070, filed 5/23/72.] Repealed by Order 121, filed 8/8/74.

WAC 360-13-010 Promulgation. In the interests of protecting public health the Washington state board of pharmacy shall hereby allow the use of an emergency drug kit in any nursing home holding a valid Washington state nursing home license. The emergency drug kit shall be considered to be a physical extension of the pharmacy supplying the emergency drug kit and shall at all times remain under the ownership of the supplying pharmacy.

[Statutory Authority: RCW 18.64.005(11), 81-10-027 (Order 159), § 360-13-010, filed 4/28/81; Order 104, § 360-13-010, filed 12/5/69; Order 50 (part), filed 3/28/67.]

WAC 360-13-020 Emergency kit. (1) The contents and quantity of drugs and supplies in the emergency kit

shall be determined by the pharmaceutical services committee as defined in WAC 360-13-045(9) which shall consider the number of residents to be served and their potential need for emergency medications.

(2) A copy of the approved list of contents shall be conspicuously posted on or near the kit.

(3) The emergency kit shall be used only for bonafide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner.

(4) Records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the nursing home and the supplying pharmacy.

(5) The pharmaceutical services committee shall be responsible for ensuring proper storage, security and accountability of the emergency kit

(a) The emergency kit shall be stored in a locked area or be locked itself;

(b) Emergency kit drugs shall be accessible only to licensed nurses as defined in WAC 360-13-045(6).

(6) The contents of the emergency kit, the approved list of contents, and all related records shall be made freely available and open for inspection to representatives of the board of pharmacy and the department.

[Statutory Authority: RCW 18.64.005(11), 81-06-077 (Order 158), § 360-13-020, filed 3/4/81; Order 104, § 360-13-020, filed 12/5/69; Order 50, subsection 1-12, filed 3/28/67.]

WAC 360-13-030 Supplemental dose kits. (1) In addition to an emergency kit, each institution holding a valid Washington state nursing home license, and which employs a unit dose drug distribution system, may maintain a supplemental dose kit for supplemental non-emergency drug therapy if the necessary drug is not available from the pharmacy in a timely manner.

(2) The pharmaceutical services committee shall determine the quantities of drugs in the supplemental dose kit in light of the number of residents in the facility and their potential needs for supplemental doses.

(3) The supplemental dose kit shall remain the property of the supplying pharmacy.

(4) The supplying pharmacy and the facility's pharmaceutical services committee shall be responsible for proper storage, security and accountability of the kit.

[Statutory Authority: RCW 18.64.005(11), 81-06-077 (Order 158), § 360-13-030, filed 3/4/81; Order 114, § 360-13-030, filed 6/28/73.]

WAC 360-13-045 Definitions. (1) "Board" means the Washington state board of pharmacy.

(2) "Department" means the state department of social and health services.

(3) "Dose" means the amount of drug to be administered at one time.

(4) "Drug facility" means a room or area designed and equipped for drug storage and the preparation of drugs for administration.

(5) "Legend drug" means a drug bearing the legend, "Caution, federal law prohibits dispensing without a prescription."

(6) "Licensed nurse" means either a registered nurse or a licensed practical nurse.

(7) "Licensed practical nurse" means a person duly licensed under the provisions of the licensed practical nurse act of the state of Washington, chapter 18.78 RCW.

(8) "Nursing home" means any home, place or institution licensed as a nursing home under chapter 18.51 RCW.

(9) "Pharmaceutical services committee" means a committee which develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice. The pharmaceutical services committee shall consist of a staff or consultant pharmacist, a physician, the director of nursing or his/her designee and the administrator or his/her designee.

(10) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy under the provisions of chapter 18.64 RCW.

(11) "Pharmacy" means a place where the practice of pharmacy is conducted, properly licensed under the provisions of chapter 18.64 RCW by the Washington state board of pharmacy.

(12) "Practitioner" means a physician under chapter 18.71 RCW; and osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW; a dentist under chapter 18.32 RCW; a podiatrist under chapter 18.22 RCW; an osteopathic physician's assistant under chapter 18.57A RCW when authorized by the committee of osteopathic commissioners; a physician's assistant under chapter 18.71A RCW when authorized by the board of medical examiners; a registered nurse when authorized by the board of nursing under chapter 18.88 RCW, or a pharmacist under chapter 18.64 RCW.

(13) "Registered nurse" means a person duly licensed under the provisions of the law regulating the practice of registered nursing in the state of Washington, chapter 18.88 RCW.

(14) "Unit-dose" means the ordered amount of a drug in [an individually sealed package and in] a dosage form ready for administration to a particular person by the prescribed route at the prescribed time.

(15) "Unit-dose drug distribution system" means a system of drug dispensing and control that is characterized by the dispensing of the majority of drugs in unit doses, ready to administer form, and for most drugs, not more than a 48-hour supply of doses is available at the residential care unit at any time.

[Statutory Authority: RCW 18.64.005(11), 81-06-077 (Order 158), § 360-13-045, filed 3/4/81; Order 121, § 360-13-045, filed 8/8/74.]

Reviser's note: RCW 34.04.058 requires the use of underlining and deletion marks to indicate amendments to existing rules, and deems ineffectual changes not filed by the agency in this manner. The bracketed material in the above section does not appear to conform to the statutory requirement.

WAC 360-13-055 Drug facilities. (1) There shall be facilities for drug preparation and storage near the nurses' station on each unit.

(2) The drug facilities shall be well illuminated, ventilated and equipped with a work counter, sink with hot and cold running water and drug storage units.

(3) The drug storage units shall provide:

(a) Locked storage for all drugs,
 (b) Separately keyed storage for Schedule II and III controlled substances,

(c) Segregated storage of different resident's drugs.

(4) There shall be a refrigerator for storage of thermolabile drugs in the drug facility.

(5) Locks and keys, for drug facilities shall be different from other locks and keys within the nursing home.

(6) Poisons and other nonmedicinal chemical agents in containers bearing a warning label shall be stored in separate locked storage apart from drugs used for medicinal purposes.

[Statutory Authority: RCW 18.64.005(11), 81-06-077 (Order 158), § 360-13-055, filed 3/4/81; Order 121, § 360-13-055, filed 8/8/74.]

WAC 360-13-066 Pharmaceutical services. (1) Administration of pharmaceutical services.

(a) There shall be provision for timely delivery of drugs and biologicals from a pharmacy so a practitioner's orders for drug therapy can be implemented without undue delay.

(b) Unless the nursing home operates a licensed pharmacy and employs a director of pharmaceutical services, the nursing home shall have a written agreement with one or more licensed pharmacists who provide for pharmaceutical consultant services. The staff pharmacist or consultant pharmacist supervises the entire spectrum of pharmaceutical services in the nursing home.

(c) There shall be a pharmaceutical services committee whose membership includes at least a staff or consultant pharmacist, a physician, the director of nursing or his/her designee, and the administrator or his/her designee. The pharmaceutical services committee develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice.

(d) Reference material regarding the use of medication, adverse reactions, toxicology, and poison control center information shall be available to facility staff.

(e) There shall be procedures established for the reporting and recording of medication errors and adverse drug reactions.

(2) A staff pharmacist of consultant pharmacist shall be responsible for coordinating pharmaceutical services which include:

(a) Provision of pharmaceutical services evaluations and recommendations to the administrative staff.

(b) On-site reviews to ensure that drug handling and utilization procedures are carried out in conformance with recognized standards of practice.

(c) Regularly reviewing each resident's therapy to screen for potential or existing drug therapy problems and documenting recommendations.

(d) Provision of drug information to the nursing home staff and physicians as needed.

(e) Planning and participating in the nursing home staff development program.

(f) Consultation regarding resident care services with other departments.

(3) Security and storage of drugs.

(a) The nursing home shall store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security as defined by regulation and accepted standards of practice.

(b) All drugs shall be stored in locked cabinets, rooms, or carts, and shall be accessible only to personnel licensed to administer or dispense drugs.

(c) Schedule III controlled substances shall be stored apart from other drugs on a separate shelf or in a separate compartment or cabinet, provided, however, Schedule III controlled substances may be stored with Schedule II controlled substances. Schedule III controlled substances can be stored with other drugs when distributed in a unit dose drug distribution system.

(d) Drugs for external use shall be stored apart from drugs for internal use, on a separate shelf or in a separate compartment or cabinet. Any shelf, compartment, or separate cabinet used for storage of external drugs shall be clearly labeled to indicate it is to be used for external drugs only.

(e) At all times, all keys to drug boxes, cabinets, and rooms shall be carried by persons legally authorized to administer drugs and on duty on the premises.

(f) If a supplemental dose kit within a unit dose drug distribution system is provided it must comply with WAC 360-13-030.

(g) If an emergency kit is provided, it shall comply with Washington state board of pharmacy regulations WAC 360-13-010 and 360-13-020.

(4) Labeling of drugs.

(a) The label for each legend drug which is not dispensed in a unit dose shall have the name and address of the pharmacy from which the drug was dispensed; the prescription number; the physician's name; the resident's full name; the date of issue; the initials of the dispensing pharmacist; the name and strength of the drug; a controlled substances schedule, if any; the amount (e.g., number of tablets or cc's) of the drug dispensed, and the expiration date. In the case of a compounded drug which contains Schedule II or III controlled substances, the quantity of each controlled substance per cc or teaspoonful shall be shown on the label.

(b) In a unit dose drug distribution system, a clear, legible label shall be printed or affixed securely to each unit dose package. Each unit dose drug label shall include: the name, strength and, for each unit dose package, the dosage amount of the drug; the expiration date for any time-dated drug; the lot or control number; and controlled substances schedule number, if any. Each individual drug compartment shall be labeled with the full name of the resident whose drug the compartment contains and the name of the resident's physician.

(c) Nonlegend drugs shall be clearly labeled with at least the patient's name, date of receipt by the facility, as well as display a manufacturer's original label or a pharmacy label if repackaged by the pharmacist.

(d) A label on a container of drugs shall not be altered or replaced except by the pharmacist. Drug containers having soiled, damaged, incomplete, or makeshift labels shall be returned to the pharmacy for relabeling or disposal. Drugs in containers having no labels or illegible labels shall be destroyed.

(5) Control and accountability.

(a) The nursing home shall maintain and follow written procedures which provide for the accurate control and accountability of all drugs in the nursing home.

(b) No drugs may be returned from the nursing home to a pharmacy except as provided in paragraph (4)(d) or if the drug is returned in unopened unit dose packages.

(c) Drugs shall be released to a resident upon discharge only on specific written authorization of the attending physician. A receipt containing information sufficient to document the drug's destination, the person who received the drug, and the name and quantity of drugs released shall be entered in the resident's health record.

(d) All of an individual resident's drugs including Schedule III, IV and V controlled substances, that are discontinued by the physician and remain unused, shall be destroyed by a licensed nurse employee of the nursing home in the presence of a witness within 90 days after having been discontinued, and accurate records of destruction maintained except from drugs which are sealed in unit dose packages.

(e) Outdated, unapproved, contaminated, deteriorated, adulterated, or recalled drugs shall not be available for use in the nursing home.

(f) Except in the case of Schedule II controlled substances and drugs which are sealed in unit dose packages, drugs which remain in the nursing home after the patient has died or been discharged, and drugs in containers with illegible or missing labels, shall be immediately and irretrievably disposed of by a licensed nurse employee in the presence of a witness and proper records maintained of such disposal. Destruction of Schedule II drugs shall be handled in accordance with (6)(g). Unit dose packages may be returned to the pharmacy.

(6) Special requirements for controlled substances.

(a) All Schedule II controlled substances shall be stored in separately keyed and locked secure storage within a drug facility.

(b) Schedule III controlled substances shall be stored apart from other drugs and may be stored on a separate shelf, drawer, or compartment with Schedule II controlled substances.

(c) There shall be a record book for Schedule II and Schedule III controlled substances which shall be a bound book with consecutively numbered pages in which complete records of receipt and withdrawal of Schedule II and III controlled substances are maintained.

(d) At least once each 24 hours, the amount of all Schedule II controlled substances stored in the facility shall be counted by at least two persons who are legally authorized to administer drugs. A similar count shall be made of all Schedule III controlled substances at least weekly. Records of counts shall be entered in the Schedule II and III controlled substances book(s).

(e) When a resident is discharged, a record of release for any Schedule II or III controlled substances released shall be entered on the appropriate page for the given drug in the controlled substances record book.

(f) Any discrepancy in actual count of Schedule II or III controlled substances and the record shall be documented in the Schedule II or III controlled substances books and reported immediately to the responsible supervisor who shall investigate the discrepancy. Any discrepancy which has not been corrected within seven calendar days shall be reported to the consultant pharmacist and the Washington state board of pharmacy.

(g) Discontinued Schedule II controlled substances and all Schedule II controlled substances which remain after the discharge or death of residents shall:

(i) Be destroyed at the nursing home within 30 days by a registered pharmacist and the director or nursing or a registered nurse designee with appropriate documentation maintained, or

(ii) Be destroyed at the nursing home by a representative of the Washington state board of pharmacy if so requested by the board or the nursing home.

(h) A nursing home may establish procedures which vary from those paragraphs (6)(a)(g) if they are using a unit dose drug distribution system and if that system provides for the accurate accounting, by the nursing home and the supplying pharmacy, of the receipt and disposition of all Schedule II and III controlled substances.

(7) Drug administration.

(a) Staff shall follow written procedures which provide for the safe handling and administration of drugs to residents.

(i) Drugs shall be administered only by persons licensed to administer drugs.

(ii) The resident shall be identified prior to administration.

(b) All drugs shall be identified up to the point of administration.

(c) Drugs shall be prepared immediately prior to administration and administered by the same person who prepares them except under a unit dose system.

(d) Drug administration shall be documented as soon as possible after the act of administration, and shall include:

(i) Verification of administration

(ii) Reasons for ordered doses not taken

(iii) Reasons for administration of, and response to drugs given on and as needed basis (PRN).

(e) Drug orders shall be received only by a licensed nurse and administered only on the written or verbal order of a practitioner. Verbal orders shall be signed by the prescribing practitioner in a timely manner.

(f) The self-administration of medication program shall provide evidence of:

(i) Assessment of the resident's capabilities

(ii) Instructions for administration

(iii) Monitoring of progress and compliance with orders

(iv) Safe storage of drugs.

[Statutory Authority: RCW 18.64.005(11), 81-14-055 (Order 161), § 360-13-066, filed 6/30/81.]

WAC 360-13-100 Provision for continuity of drug therapy for residents. When a resident of a long term care facility has the opportunity for an unscheduled therapeutic leave that would be precluded by the lack of an available pharmacist to dispense drugs prescribed by an authorized practitioner, a registered nurse designated by the facility and its consultant or staff pharmacist and who agrees to such designation, may provide the resident or a responsible person with up to a 72-hour supply of a prescribed drug or drugs for use during that leave from the resident's previously dispensed package of such drugs. The drugs shall only be provided in accordance with protocols developed by the pharmaceutical services committee and the protocols shall be available for inspection. These protocols shall include the following:

(1) Criteria as to what constitutes an unscheduled therapeutic leave requiring the provision of drugs by the registered nurse;

(2) Procedures for repackaging and labeling the limited supply of previously dispensed drugs by the designated registered nurse that comply with all state and federal laws concerning the packaging and labeling of drugs;

(3) Provision to assure that none of the medication provided to the resident or responsible person may be returned to the resident's previously dispensed package of such drug or to the facility's stock.

(4) A record-keeping mechanism that will provide for the maintenance of a permanent log that includes the following information:

(a) The name of the person to whom the drug was provided;

(b) The drug and quantity provided;

(c) The date and time that the request for the drug was made;

(d) The date and time that the drug was provided;

(e) The name of the registered nurse that provided the drug;

(f) The conditions or circumstances that precluded a pharmacist from providing the drug.

Refer to WAC 308-120-270 for related regulations on this practice.

[Statutory Authority: RCW 18.64.005 and 69.41.240, 83-10-013 (Order 174), § 360-13-100, filed 4/26/83.]

Chapter 360-16 WAC PHARMACIES

WAC

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DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-16-010	Notice of opening new drug store. [Regulation 34, effective 5/28/59, filed 3/23/60.] Repealed by Order 114, filed 6/28/73.
360-16-030	Change of ownership or location. [Order 109, § 360-16-030, filed 5/23/72; Regulation 33, effective 5/28/59, filed 3/23/60.] Repealed by Order 114, filed 6/28/73.
360-16-060	Responsible manager—Responsibility. [Regulation 7, filed 3/23/60.] Repealed by 79-10-007 (Order 151, Resolution No. 9/79), filed 9/6/79. Statutory Authority: RCW 18.64.005(11).
360-16-080	Prescription department grading. [Regulation 22, filed 3/23/60.] Repealed by Order 51 (part), filed 8/15/67.
360-16-090	Equipment. [Regulation 11, amended 5/28/59, filed 3/23/60.] Repealed by Order 51 (part), filed 8/15/67.
360-16-095	Narcotic register book—Exempt narcotics. [Regulation 31, effective 6/12/58, filed 3/23/60.] See WAC 360-28-070 and 360-28-075.
360-16-097	Record requirements—Dangerous drugs. [Order 100 (part), § 360-16-097, filed 6/25/68.] Repealed by Order 109, filed 5/23/72.
360-16-100	Maintenance of pharmaceutical supplies. [Regulation 32, effective 5/28/59, filed 3/23/60.] Repealed by Order 51 (part), filed 8/15/67. For later reenactment, see WAC 360-16-230.
360-16-110	Hospital pharmacy standards. [Regulation 35, effective 10/2/59, filed 3/23/60, subsection (4)(b), as corrected, filed 12/8/60.] Repealed by 82-12-024 (Order 167), filed 5/25/82. Statutory Authority: RCW 18.64.005(11).
360-16-160	Sale of inhalers over the counter. [Regulation 13, filed 3/23/60.] Repealed by 79-10-007 (Order 151, Resolution No. 9/79), filed 9/6/79. Statutory Authority: RCW 18.64.005(11).
360-16-170	Drug vending machine for over-the-counter drugs. [Statutory Authority: RCW 18.64.005(11), 79-10-007 (Order 151, Resolution No. 9/79), § 360-16-170, filed 9/6/79; Regulation 17, filed 3/23/60.] Repealed by 85-11-066 (Order 194), filed 5/21/85. Statutory Authority: RCW 18.64.005.
360-16-260	Patient medication record system. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290, 83-01-083 (Order 171), § 360-16-260, filed 12/17/82; Order 125, § 360-16-260, filed 1/28/75, effective 7/1/75.] Repealed by 84-03-016 (Order 181), filed 1/9/84. Statutory Authority: RCW 18.64.005.

WAC 360-16-005 Pharmacies and differential hours. (1) A pharmacy must provide adequate security for its drug supplies and records and in the absence of a pharmacist the pharmacy must be closed and access

limited to persons authorized by the pharmacist; for example, janitorial services, inventory services, etc. If a pharmacy is located within a larger mercantile establishment which is open to the public for business at times when a pharmacist is not present then the pharmacy must be enclosed by solid partitions at least seven feet in height, from the floor, which are sufficient to provide adequate security for the pharmacy. In the absence of a pharmacist such pharmacies must be locked and secured so that only persons authorized by the pharmacist can gain access, provided however that employees of the mercantile establishment cannot be authorized to enter the closed pharmacy during those hours that the mercantile establishment is open to the public for business.

(2) All equipment and records referred to in WAC 360-16-230 and all drugs, devices, poisons and other items or products which are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area.

(3) Written prescription orders and refill request can be delivered to a pharmacy at any time. But if no pharmacist is present then the prescription orders must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a "mail slot" or "drop box" such that the prescription order is stored in the pharmacy area. The times that the pharmacy is open for business must be so displayed that they are prominently visible to the person depositing the prescription orders.

(4) Prescriptions shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place.

(5) No drugs, devices, poisons and other items or products which are restricted to sale either by or under the personal supervision of a pharmacist can be sold or delivered without a pharmacist being present in the pharmacy.

(6) Any pharmacy having hours differing from the remainder of an establishment shall have a separate and distinct telephone number from that business establishment. The phone shall not be answerable in the remainder if the establishment unless all conversations, when the pharmacist is absent, are recorded and played back by the pharmacist.

(7) Oral prescriptions cannot be taken if a pharmacist is not present unless it is taken on a recording which must inform the caller as to the times the pharmacy is open.

(8) A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the times that it is open for business. If a pharmacy is located within a larger mercantile establishment having hours of operation different from the pharmacy then the pharmacy times of being open for business shall be prominently displayed in a permanent manner at the pharmacy area and on or adjacent to the entrance to the mercantile establishment.

(9) Any advertising by the mercantile establishment which makes reference to the pharmacy or those products which are sold only in the pharmacy which in such advertising sets forth the days and hours that the mercantile establishment is open to the public for business must also indicate the days and hours that the pharmacy is open to the public for business.

(10) Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy must notify the board of pharmacy at least thirty days prior to commencing such differential hours. In order to constitute notification the applicant must complete the file forms provided by the board providing the required information. Board inspection and approval must be completed prior to the commencing of such differential hours. Such inspection and approval or disapproval shall be within 10 days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and pharmacy standards under chapter 360-16 WAC.

[Order 106, § 360-16-005, filed 9/11/70.]

WAC 360-16-011 Pharmacy license notice requirements. (1) Applications for a new pharmacy license must be submitted at least thirty days prior to the next regularly scheduled board meeting and the board shall require the submission of proof of the applicant's identity, and qualifications and such other information as may be necessary to properly evaluate the application, and, at its option, the board may require a personal interview at the next scheduled board meeting.

(2) In case of change of ownership or location of a pharmacy, the original license comes void and must be returned with a new application, as set forth in paragraph (1) above, and the statutorily required fees.

[Order 114, § 360-16-011, filed 6/28/73.]

WAC 360-16-020 New pharmacy registration. The state board of pharmacy shall issue no new pharmacy registrations after December 1, 1976 unless:

(1) The pharmacy will operate a bona fide prescription department, with such equipment, facilities, supplies and pharmaceuticals as are specified by state board regulations;

(2) The pharmacy passes inspection with a minimum of an "A" grade;

(3) The pharmacy in a new or remodeled building can produce evidence of being built or remodeled in accordance with all building, health and fire codes required for the particular area.

[Order 130, § 360-16-020, filed 11/10/76; Regulation 10, filed 3/23/60.]

WAC 360-16-025 Pharmacy license renewal. The state board of pharmacy will not renew any pharmacy license after June 1, 1984 unless the following are submitted:

(1) A complete renewal application form;

(2) A completed self-inspection form; and

(3) The fee as established by WAC 360-18-020.

[Statutory Authority: RCW 18.64.043. 84-12-019 (Order 186), § 360-16-025, filed 5/25/84.]

WAC 360-16-040 Employers to require evidence of pharmacist's qualifications. It shall be the duty of every employer to require suitable evidence of qualifications to practice pharmacy before they permit anyone to be in charge, compound or dispense drugs on their premises.

[Regulation 19 (part), filed 3/23/60.]

WAC 360-16-050 Responsible manager—Appointment. Every nonlicensed proprietor of one or more pharmacies shall place in charge of each pharmacy a licensed pharmacist who shall be known as the "responsible manager." The nonlicensed proprietor shall immediately report to the state board of pharmacy the name of the "responsible manager," who shall ensure that the pharmacy complies with all the laws, rules and regulations pertaining to the practice of pharmacy. 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. A now-licensed proprietor shall at once notify the board of pharmacy of the termination of employment of a responsible manager. Please refer to WAC 360-12-120 for additional information.

[Statutory Authority: RCW 18.64.005(11). 79-10-007 (Order 151, Resolution No. 9/79), § 360-16-050, filed 9/6/79; Regulation 6, filed 3/23/60.]

WAC 360-16-070 Clinic dispensaries. The clinics of this state shall place their dispensaries in charge of a registered pharmacist, or the dispensing must be done by each prescribing physician in person.

[Regulation 9, filed 3/23/60.]

WAC 360-16-096 Prescription record requirements. Records for the original prescription and refill records shall be maintained on the filled prescription or in a separate record book or patient medication record. Such records must be maintained for a period of at least five years and shall be made available for inspection to representatives of the board of pharmacy: *Provided*, That after two years a complete and accurate copy of the original and refill records may be maintained on microfilm, electromagnetic tape, or other board-approved record storage and retrieval system.

The pharmacist shall be required to insure that the following information be recorded:

Original prescription—At the time of dispensing, a serial number, date of dispensing, and the initials of the responsible pharmacist shall be placed on the face of the prescription. The patient's address must be readily available to the pharmacist, either from the face of the prescription, a record book, patient medication record, or hospital or clinic record.

Refill prescription authorization—Refills for prescription for legend drugs must be authorized by the prescriber prior to the dispensing of the refill prescription.

Refill prescription—At the time of dispensing, the date of refilling, quantity of the drug (if other than

original), the name of authorizing person (if other than original), and the initials of the responsible pharmacist shall be recorded on the back side of the prescription, or in a separate record book or patient medication record.

Prescription refill limitations—No prescription may be refilled for a period longer than one year from the date of the original prescription. "PRN" prescriptions shall expire at the end of one year. Expired prescriptions require authorization before filling. If granted a new prescription shall be written and placed in the files.

Prescription copies—Prescription copies and prescription labels presented for filling must be considered as informational only, and may not be used as the sole document. The prescriber shall be contacted for complete information and authorization. If granted, a new prescription shall be written and placed on file. Copies of prescriptions must be clearly identified as such on the face of the prescription.

Emergency refills—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.

[Order 131, § 360-16-096, filed 2/4/77; Order 126, § 360-16-096, filed 5/21/75; Order 117, § 360-16-096, filed 11/9/73; Regulation 49, filed 12/1/65.]

WAC 360-16-098 Refusal to permit inspection. The refusal to permit an authorized representative of the Washington state board of pharmacy to examine during normal business hours the premises, inventory and/or records relating to drugs of licensed wholesalers, manufacturers, pharmacies and shopkeepers constitutes grounds for the suspension or revocation of the establishment's license and/or that of the pharmacist refusing such requested examination.

[Order 109, § 360-16-098, filed 5/23/72; Order 103, § 360-16-098, filed 12/5/69.]

WAC 360-16-120 Mechanical devices in hospitals. Mechanical devices for storage of floor stock, shall be limited to hospitals and shall comply with all the following provisions:

(1) All drugs and medicines to be stocked in the device shall be prepared for use in the device by or under the direct supervision of a registered pharmacist in the employ of the hospital and shall be prepared in the hospital from the hospital stock in which the drug is to be administered. "Hospital" shall mean any hospital licensed by the state department of health or under the direct supervision of the state department of institutions.

(2) Such device shall be stocked with drugs and medicines only by a registered pharmacist in the employ of the hospital.

(3) A registered pharmacist in the employ of the hospital shall be personally responsible for the inventory and stocking of drugs and medicines in the device and he shall be personally responsible for the condition of the drugs and medicines stored in the device.

(4) A registered pharmacist in the employ of the hospital shall be the only person having access to that portion, section, or part of the device in which the drugs or medicines are stored.

(5) All containers of drugs or medicines to be stored in the device shall be correctly labeled to include: Name, strength, route of administration and if applicable, the expiration date.

(6) At the time the removal of any drug or medicine from the device, the device shall automatically make a written record showing the name, strength, and quantity of the drug or medicine removed, the name of the patient for whom the drug or medicine was ordered, and the identification of the nurse removing the drug or medicine from the device. The record must be maintained for five years by the hospital and shall be accessible to the pharmacist.

(7) Medical practitioners authorized to prescribe, pharmacists authorized to dispense, or nurses authorized to administer such drugs shall be the only persons authorized to remove any drug or medicine from the device and such removal by a nurse or medical practitioner shall be made only pursuant to a chart order. An identification mechanism, required to operate the device shall be issued permanently to each operator while the operator is on the staff of, or employed by the hospital. Such mechanism must imprint the operator's name or number if it permits the device to operate.

(8) The device shall be used only for the furnishing of drugs or medicines for administration in the hospital to registered in-patients or emergency patients in the hospital.

(9) Every hospital seeking approval to use any device shall, prior to installation of the device, register with the board by filing an application. Such application shall contain: The name and address of the hospital; the name of the registered pharmacist who is to be responsible for stocking the device; the manufacturer's name and model, description, and the proposed location of each device in the hospital.

(10) No such device shall be used until approval has been granted by the board, and no change in the location of the device or in the registered pharmacist responsible for stocking the device shall be made without prior written notice to the board. No such device shall be removed from the licensed premises without prior approval of the board.

(11) As used in this section, a "pharmacist in the employ of the hospital" shall not include any pharmacist who is, or is employed by, a manufacturer, wholesaler, distributor, or itinerant vendor of drugs or medicines.

(12) Each and every device approved by the board shall be issued a certificate of location. Such certificate must be conspicuously displayed on the device and contain the following:

- (a) Name and address of the hospital
- (b) Name of the registered pharmacist who is to be responsible for stocking the device
- (c) Location of the device in the hospital
- (d) Manufacturer's name of the device and the serial number of the device.

(13) Upon any malfunction the device shall not be used until the malfunction has been corrected.

(14) A copy of this regulation shall be attached to each and every device certified by the board of pharmacy.

[Regulation 47, filed 12/1/65.]

WAC 360-16-150 Return or exchange of drugs. Except as provided in this rule, prescriptions, drugs, medicines, sick room supplies and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescriptions, drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.

(1) Those drugs and sick room supplies legally dispensed by prescription in unit dose forms or in sealed single or multiple dose ampoules or vials in which the pharmacist can readily determine that entry or attempted entry by any means has not been made and which, in the pharmacist's professional judgment, meet the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability may be returned.

(2) Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards based on the following criteria;

(a) The pharmacist can readily determine that entry or attempt at entry to the unit dose package or blister card has not been made;

(b) In the pharmacist's professional judgment, the unit dose package or full or partial multiple dose medication card meets the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability;

(c) The drug has been stored in such a manner as to prevent contamination by a means that would affect the efficacy and toxicity of the drug;

(d) The drug has not come into physical possession of the person for whom it was prescribed and control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs;

(e) The drug labeling or packaging has not been altered or defaced so that the identity of the drug, its potency, lot number, and expiration date is retrievable.

(f) If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug.

(3) This rule shall not include items such as orthopedic appliances, crutches, canes, wheelchairs and other similar items unless otherwise prohibited.

(4) Controlled substances shall not be returned to a pharmacy except for destruction in accordance with rules of the drug enforcement administration or the Washington state board of pharmacy.

[Statutory Authority: RCW 18.64.005. 84-12-020 (Order 187), § 360-16-150, filed 5/25/84; Regulation 28, filed 3/23/60.]

WAC 360-16-180 Prescription department--Conversing with pharmacist prohibited. Henceforth the prescription department of every licensed pharmacy in the state of Washington shall be protected against trespass by the lay public. No person shall be permitted to converse with a registered pharmacist while he or she is engaged in compounding a prescription, except nothing in this promulgation shall prevent one pharmacist from consulting with another pharmacist, a physician, a dentist or a veterinary surgeon, regarding the contents or technique connected with or pertaining to, the prescription being compounded.

[Regulation 37, filed 11/23/60.]

WAC 360-16-200 Physical standards for pharmacies--Adequate stock. (1) The pharmacy must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients.

(2) Dated items--All merchandise which has exceeded its expiration date must be removed from stock.

(3) All stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration.

(4) All stock and materials must be properly labeled according to federal and state statutes, rules and regulations.

(5) Devices that are not fit or approved by the FDA for use by the ultimate consumer shall not be offered for sale and must be removed from stock.

(6) All drugs shall be stored in accordance with USP standards and shall be protected from excessive heat or freezing except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed.

[Statutory Authority: RCW 18.64.005. 85-11-066 (Order 194), § 360-16-200, filed 5/21/85; Order 131, § 360-16-200, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 360-16-210 Physical standards for pharmacies--Adequate facilities. (1) The prescription department shall be well lighted (adequately to allow any person with normal vision to read a label without strain, 30-50 foot candles).

(2) The prescription department shall be well ventilated. There shall be a constant flow of air through the area.

(3) There shall be a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(4) The prescription counter shall be uncluttered and clean at all times. Only those items necessary to the filling of prescriptions shall be thereon. (Profile systems are excepted.)

(5) There shall be a sink with hot and cold running water in the prescription compounding area.

(6) There shall be refrigeration facilities with a thermometer in the prescription compounding area for the

storage of pharmaceutical items requiring refrigeration. USP standards of refrigeration require that the temperature be maintained between two degrees and eight degrees centigrade (36 degrees and 46 degrees fahrenheit). A locked refrigerator in the immediate vicinity of the prescription department will meet the requirements of this paragraph.

(7) 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.

[Order 131, § 360-16-210, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 360-16-220 Physical standards for pharmacies--Sanitary conditions. (1) The walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order.

(2) Adequate trash receptacles shall be available, both in the prescription compounding and in the retail areas.

(3) If a restroom is provided, there must be a sink with hot and cold running water, soap and towels, and the toilet must be clean and sanitary.

(4) All equipment must be kept in a clean and orderly manner. That equipment used in the compounding of prescriptions (counting, weighing, measuring, mixing and stirring equipment) must be clean and in good repair.

(5) All professional personnel and staff, while working in the pharmacy, shall keep themselves and their apparel neat and clean.

[Order 131, § 360-16-220, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 360-16-230 Physical standards for pharmacies--Adequate equipment. (1) All pharmacies shall have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment shall be in good repair and shall be available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

(2) All pharmacies will have in their possession:

(a) One up-to-date copy of the state of Washington statutes, rules and regulations governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines maintained in a binder.

(3) All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs.

[Statutory Authority: RCW 18.64.005. 85-11-066 (Order 194), § 360-16-230, filed 5/21/85; 84-03-015 (Order 180), § 360-16-230, filed 1/9/84; Order 131, § 360-16-230, filed 2/4/77; Order 118, § 360-16-230, filed 1/2/74; Order 51 (part), filed 8/15/67.]

WAC 360-16-240 General. (1) A list of antidotes for poisoning shall be posted or otherwise readily available for reference. The telephone number of the nearest poison control center shall be readily available.

(2) The Washington state board of pharmacy shall set standards for the grading of pharmacies in the state of Washington. There shall be three classifications: A, 100-90; B, 89-80; and C, below 80. Each pharmacy being inspected shall receive either a Class A, Class B, or Class C certificate, depending on the extent of compliance with the set standards.

(3) Any pharmacy receiving a Class C rating will have 60 days to raise its standards to a Class B or better. If after 60 days the pharmacy has failed to raise its standards to a Class B or better, a hearing will be conducted to consider disciplinary action.

(4) Any pharmacy receiving two consecutive B grades will be subject to a hearing to consider disciplinary action.

(5) The certificate of inspection must be posted on the front of the prescription case in conspicuous view of the general public and shall not be removed or defaced.

(6) Noncompliance with the provisions of RCW 18.64A.010 - 900 (Pharmacy assistants) and WAC 360-52-010 - 100 (Pharmacy assistants) shall result in an automatic "C" grade regardless of point scores as found (2) above. Refer to (3) above for specific information on "C" grades.

[Statutory Authority: RCW 18.64.043. 84-12-019 (Order 186), § 360-16-240, filed 5/25/84. Statutory Authority: RCW 18.64.005(9) and 69.50.201. 79-02-060 (Order 146, Resolution No. 2-79), § 360-16-240, filed 2/1/79; Order 131, § 360-16-240, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 360-16-245 Poison control. Each pharmacy shall maintain at least one ounce bottle of Ipecac syrup in stock at all times.

[Order 120, § 360-16-245, filed 3/11/74.]

WAC 360-16-250 Patient information required. (1) With each new prescription dispensed after January 1, 1974, the pharmacist, in addition to labeling the prescription in accordance with the requirements of RCW 18.64.246, 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.

[Order 118, § 360-16-250, filed 1/2/74; Order 116, § 360-16-250, filed 11/9/73.]

WAC 360-16-255 Prescription labeling. To every prescription container, there shall be fixed a label or labels bearing the following information:

(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a

patient after its dispensing, the dispenser shall take the following factors into account:

- (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) Any other relevant factors.

The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use date or discard by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.

(2) The quantity of drug dispensed, for example the volume or number of dosage units.

(3) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed."

(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 360-16-250.

[Statutory Authority: RCW 18.64.246. 85-06-010 (Order 193), § 360-16-255, filed 2/22/85. Statutory Authority: RCW 18.64.005. 84-22-027 (Order 191), § 360-16-255, filed 11/1/84.]

WAC 360-16-270 Child-resistant containers. (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including CFR Part 1700 of Title 16, unless:

- (a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.
- (b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant.

(2) Authorization from the patient to the pharmacist to use a regular container (nonchild-resistant) shall be verified in one of the following ways:

(a) The patient or his agent may sign a statement on the back of the prescription requesting a container that is not child-resistant.

(b) The patient or his agent may sign a statement on a patient medication record requesting containers that are not child-resistant.

(c) The patient or his agent may sign a statement on any other permanent record requesting containers that are not child-resistant.

(3) No pharmacist or pharmacy employee may designate himself or herself as the patient's agent.

[Order 126, § 360-16-270, filed 5/21/75.]

WAC 360-16-290 Pharmacist's professional responsibilities. (1) A pharmacist cannot delegate the following professional responsibilities:

- (a) Receipt of a verbal prescription other than refill authorization from a prescriber.

(b) 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.

(c) Interpretation and identification of the contents of the prescription.

(d) Consultation with the prescriber regarding the patient and his prescription.

(e) Determination of the product required for the prescription.

(f) Extemporaneous compounding of the prescription.

(g) Interpretation of data in a patient medication record system.

(h) FINAL CHECK on ALL aspects of the completed prescription and assumption of the responsibility for the filled prescription, including but not limited to: Accuracy of drug, strength, labeling, proper container and other requirements.

(i) Dispense prescriptions to patient with proper patient information as required by WAC 360-16-250.

(j) Signing of the poison register and the Schedule V controlled substance registry book at the time of sale in accordance with RCW 18.64.243 and WAC 360-36-020 and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.

(k) Professional communications with physicians, dentists, nurses and other health care practitioners.

(l) Any duty required by law, court order in Thurston County Cause No. 53812, rule or regulation to be performed only by a registered pharmacist.

(2) Utilizing personnel to assist the pharmacist.

(a) The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his 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 supervisory and professional responsibilities.

(b) Pharmacy interns and externs are excluded from provisions of this regulation.

[Order 129, § 360-16-290, filed 7/13/76; Order 127, § 360-16-290, filed 12/1/75.]

WAC 360-16-300 Closing a pharmacy. (1) Whenever a pharmacy ceases to operate, the owner shall notify the pharmacy board of the pharmacy's closing not later than fifteen days prior to the anticipated date of closing. This notice shall be submitted in writing and shall contain all of the following information:

(a) The date the pharmacy will close;

(b) The names and addresses of the persons who shall have custody of the prescription files, the bulk compounding records, the repackaging records, and the controlled substances inventory records of the pharmacy to be closed;

(c) The names and addresses of any persons who will acquire any of the legend drugs from the pharmacy to be closed, if known at the time the notification is filed.

(2) Not later than 15 days after the pharmacy has closed, the owner shall submit to the pharmacy board the following documents:

(a) The license of the pharmacy that closed; and

(b) A written statement containing the following information;

(i) Confirmation that all legend drugs have been transferred to an authorized person (or persons) or destroyed. If the legend drugs were transferred, the names and addresses of the person(s) to whom they were transferred;

(ii) If controlled substances were transferred, a list of the names and addresses to whom the substances were transferred, the substances transferred, the amount of each substance transferred, and the date on which the transfer took place;

(iii) Confirmation that the drug enforcement administration (DEA) registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(iv) Confirmation that all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed;

(v) Confirmation that all signs and symbols indicating the presence of the pharmacy have been removed.

[Statutory Authority: RCW 18.64.005 and 69.41.240. 83-10-013 (Order 174), § 360-16-300, filed 4/26/83.]

Chapter 360-17 WAC

HOSPITAL PHARMACY STANDARDS

WAC

360-17-010	Definitions.
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WAC 360-17-010 Definitions. For the purpose of these rules and regulations, the following definitions apply:

(1) "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.

(2) "Controlled substance" means those drugs, substances or immediate precursors listed in Schedule I through V, chapter 69.50 RCW, State Uniform Controlled Substance Act, as now or hereafter amended.

(3) "Drug" means any product referenced in RCW 18.64.011(3) as now or hereafter amended.

(4) "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.

(5) "Drug dispensing" means an act entailing the interpretation of an order for a drug or biological and, pursuant to that order, proper selection, measuring, labeling, packaging, and issuance of the drug for a patient or for a service unit of the facility.

(6) "Hospital" means any institution licensed pursuant to chapters 70.41 or 71.12 RCW or designated pursuant to RCW 72.23.020.

(7) "Hospital pharmacy" means that portion of a hospital which is engaged in the manufacture, production, preparation, dispensing, sale, and/or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases; and which is licensed by the state board of pharmacy pursuant to the Washington State Pharmacy Practice Act, chapter 18.64 RCW.

(8) "Immediate supervision" means visual and/or physical proximity that insure adequate safety and controls.

(9) "Investigational drug" means any article which has not been approved for use in the United States, but for which an investigational drug application (IND) has been approved by the FDA.

(10) "Nurse" means a registered nurse or a licensed practical nurse licensed pursuant to chapters 18.88 or 18.78 RCW.

(11) "Practitioner" means any person duly authorized by law or rule in the state of Washington to prescribe drugs in RCW 18.64.011(9).

(12) "Pharmacist" means a person duly licensed by the state board of pharmacy to engage in the practice of pharmacy.

(13) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(14) "Pharmacy Assistant Level A and Level B" means persons certified under chapter 18.64A RCW.

(15) "Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice in the state of Washington.

(16) "Practice of pharmacy" means the definition given in RCW 18.64.011(11) now or hereafter amended.

(17) "Protocol" means a written set of guidelines.

(18) "Registered nurse" means an individual licensed under the provisions of chapter 18.88 RCW, regulating the practice of registered nursing in the state of Washington.

(19) "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.

(20) "Shall" means that compliance with regulation is mandatory.

(21) "Should" means that compliance with a regulation or standard is recommended.

[Statutory Authority: RCW 18.64.005(12), 82-12-041 (Order 168), § 360-17-010, filed 5/28/82. Statutory Authority: RCW 18.64.005(11), 81-16-036 (Order 162), § 360-17-010, filed 7/29/81.]

WAC 360-17-020 Applicability. The following rules and regulations are applicable to all facilities licensed pursuant to chapters 70.41 and 71.12 RCW or designated pursuant to RCW 72.23.020.

[Statutory Authority: RCW 18.64.005(12), 82-12-041 (Order 168), § 360-17-020, filed 5/28/82. Statutory Authority: RCW 18.64.005(11), 81-16-036 (Order 162), § 360-17-020, filed 7/29/81.]

WAC 360-17-030 Licensure. Hospital pharmacists shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW.

[Statutory Authority: RCW 18.64.005(11), 81-16-036 (Order 162), § 360-17-030, filed 7/29/81.]

WAC 360-17-040 Personnel. (1) Director of pharmacy. The pharmacy, organized as a separate department or service, shall be directed by a licensed pharmacist appropriately qualified by education, training, and experience to manage a hospital pharmacy. The patient care and management responsibilities of the director of pharmacy shall be clearly delineated in writing and shall be in accordance with currently accepted principles of management, safety, adequate patient care and treatment. The responsibilities shall include the establishment and maintenance of policies and procedures, ongoing monitoring and evaluation of pharmaceutical service, use and control of drugs, and participation in relevant planning, policy and decision making activities. Hospitals which do not require, or are unable to obtain the services of a fulltime director shall be held responsible for the principles contained herein and shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services. Where the director of pharmacy is not employed fulltime, then the hospital shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services described herein. The director of pharmacy shall be responsible to the chief executive officer of the hospital or his/her designee.

(2) Supportive personnel. The director of pharmacy shall be assisted by sufficient numbers of additional pharmacists and/or pharmacy assistants and clerical personnel required to operate safely and efficiently to meet the needs of the patients.

(3) Supervision. All of the activities and operations of each hospital pharmacy shall be professionally managed by the director or a pharmacist designee. Functions and activities shall be under the immediate supervision of a pharmacist and shall be performed according to written policies and procedures. When the hospital pharmacy is decentralized, each decentralized section(s) or separate organizational element(s) shall be under the immediate supervision of a pharmacist responsible to the director.

[Statutory Authority: RCW 18.64.005(11), 81-16-036 (Order 162), § 360-17-040, filed 7/29/81.]

WAC 360-17-050 Absence of a pharmacist. (1) General. Pharmaceutical services shall be available on a 24-hour basis. If round-the-clock services of a pharmacist are not feasible, arrangements shall be made in advance by the director of pharmacy to provide reasonable assurance of pharmaceutical services.

(2) Access to the pharmacy. Whenever a drug is required to treat an immediate need and not available from floor stock when the pharmacy is closed, the drug may be obtained from the pharmacy by a designated registered nurse, who shall be accountable for his/her actions. One registered nurse shall be designated in each hospital shift for removing drugs from the pharmacy.

(a) The director of pharmacy shall establish written policy and recording procedures to assist the registered nurse who may be designated to remove drugs from the pharmacy, when a pharmacist is not present, in accordance with Washington State Pharmacy Practice Act, RCW 18.64.255(2), which states that the director of pharmacy and the hospital be involved in designating the nurse.

(b) The stock container of the drug or similar unit dose package of the drug removed shall be left with a copy of the order of the authorized practitioner to be checked by a pharmacist, when the pharmacy reopens, or as soon as is practicable.

(c) Only a sufficient quantity of drugs shall be removed in order to sustain the patient until the pharmacy opens.

(d) All drugs removed shall be completely labeled in accordance with written policy and procedures, taking into account state and federal rules and regulations and current standards.

[Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-050, filed 7/29/81.]

WAC 360-17-055 Emergency outpatient medications. The director of pharmacy of a hospital shall, in concert with the appropriate committee of the hospital medical staff, develop policies and procedures, which shall be implemented, to provide emergency pharmaceuticals to outpatients during hours when normal community or hospital pharmacy services are not available. The delivery of a single dose for immediate administration to the patient shall not be subject to this regulation. Such policies shall allow the designated registered nurse(s) to deliver medications other than controlled substances, pursuant to the policies and procedures which shall require that:

(1) An order of a practitioner authorized to prescribe a drug is presented. Oral or electronically transmitted orders must be verified by the prescriber in writing within 72 hours.

(2) The medication is prepackaged by a pharmacist and has a label that contains:

(a) Name, address, and telephone number of the hospital.

(b) The name of the drug (as required by chapter 360-49 WAC), strength and number of units.

(c) Cautionary information as required for patient safety and information.

(d) An expiration date after which the patient should not use the medication.

(3) No more than a 24-hour supply is provided to the patient except when the pharmacist has informed appropriate hospital personnel that normal services will not be available within 24 hours.

(4) The container is labeled by the designated registered nurse(s) before presenting to the patient and shows the following:

(a) Name of patient;

(b) Directions for use by the patient;

(c) Date;

(d) Identifying number;

(e) Name of prescribing practitioner;

(f) Initials of the registered nurse;

(5) The original or a direct copy of the order by the prescriber is retained for verification by the pharmacist after completion by the designated registered nurse(s) and shall bear:

(a) Name and address of patient;

(b) Date of issuance;

(c) Units issued;

(d) Initials of designated registered nurse.

(6) The medications to be delivered as emergency pharmaceuticals shall be kept in a secure place in or near the emergency room in such a manner as to preclude the necessity for entry into the pharmacy.

(7) The procedures outlined in this rule may not be used for controlled substances.

[Statutory Authority: RCW 18.64.005. 83-23-109 (Order 179), § 360-17-055, filed 11/23/83.]

WAC 360-17-060 Physical requirements. (1) Area. The pharmacy facilities shall include:

(a) Appropriate transportation and communications systems for the distribution and control of drugs within the hospital.

(b) Sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies.

(2) In order to meet the medical services' need for drugs throughout the hospital, the pharmacy facilities should include:

(a) Space for the management and clinical functions of the pharmaceutical service.

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

(c) Other equipment necessary.

(3) Access to unattended areas. All areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel. The director of pharmacy shall designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations.

(4) Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

(a) It is the joint responsibility of the director of pharmacy and the director of nursing to ensure that drug handling, storage, and preparation are carried out in conformance with established policies, procedures, and accepted standards.

(b) Locked storage or locked medication carts shall be provided for use on each nursing service area or unit.

(5) Flammable storage. All flammable material shall be stored and handled in accordance with applicable local and state fire regulations, and there shall be written policy and procedures for the destruction of these flammable materials.

[Statutory Authority: RCW 18.64.005, 85-11-066 (Order 194), § 360-17-060, filed 5/21/85. Statutory Authority: RCW 18.64.005(11), 81-16-036 (Order 162), § 360-17-060, filed 7/29/81.]

WAC 360-17-070 Drug procurement, distribution and control. (1) General. Pharmaceutical service shall include:

(a) Procurement, preparation, storage, distribution and control of all drugs throughout the hospital.

(b) A monthly inspection of all nursing care units or other areas of the hospital where medications are dispensed, administered or stored. Inspection reports shall be maintained for one year.

(c) Monitoring the drug therapy.

(d) Provisions for drug information to patients, physicians and others.

(e) Surveillance and reporting of adverse drug reactions and drug product defect(s).

(2) Additional pharmaceutical services should include:

(a) Obtaining and recording comprehensive drug histories and participation in discharge planning in order to affect appropriate drug use.

(b) Preparation of all sterile products (e.g., IV admixtures, piggybacks, irrigation solutions), except in emergencies.

(c) Distribution and control of all radiopharmaceuticals.

(d) Administration of drugs.

(e) Prescribing.

(3) The director shall be responsible for establishing specifications for procurement, distribution and the maintenance of a system of accountability for drugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy.

(4) The director shall establish, annually review and update when necessary comprehensive written policies and procedures governing the responsibilities and functions of the pharmaceutical service. Policies affecting patient care and treatment involving drug use shall be established by the director of pharmacy with the cooperation and input of the medical staff, nursing service and the administration.

(5) Labeling:

(a) Inpatient. All drug containers in the hospital shall be labeled clearly, legibly and adequately to show the drug's name (generic and/or trade) and strength when applicable. Accessory or cautionary statements and the expiration date shall be applied to containers as appropriate.

(b) Outpatients. Labels on medications used for outpatients, emergency room, and discharge drug orders shall meet the requirements of RCW 18.64.246.

(c) Parenteral and irrigation solutions. When drugs are added to intravenous solutions, a suitable label shall be affixed to the container. As a minimum the label shall indicate name and location of the patient, name and amount of drug(s) added, appropriate dating, initials of the personnel who prepared and checked the solution.

(6) Medication orders. Drugs are to be dispensed and administered only upon orders of authorized practitioners. A pharmacist shall review the original order or direct copy thereof, prior to dispensing any drug, except for emergency use or as authorized in WAC 360-17-050.

(7) Controlled substance accountability. The director of pharmacy shall establish effective procedures and maintain adequate records regarding use and accountability of controlled substances, and such other drugs as appropriate, in compliance with state and federal laws and regulations.

(a) Complete, accurate, and current records shall be kept of receipt of all controlled substances and in addition, a Schedule II perpetual inventory shall be maintained.

(b) The pharmacy shall maintain records of Schedule II drugs issued from the pharmacy to other hospital units which include:

(i) Date

(ii) Name of the drug

(iii) Amount of drug issued

(iv) Name and/or initials of the pharmacist who issued the drug

(v) Name of the patient and/or unit to which the drug was issued.

(c) Records shall be maintained by any unit of the hospital which utilizes Schedule II drugs indicating:

(i) Date

(ii) Time of administration

(iii) Name of the drug (if not already indicated on the records

(iv) Dosage of the drug which was used which shall include both the amount administered and any amount destroyed.

(v) Name of the patient to whom the drug was administered

(vi) Name of the practitioner who authorized the drug

(vii) Signature of the licensed individual who administered the drug.

(d) When it is necessary to destroy small amounts of controlled substances following the administration of a dose by a nurse, the destruction shall be witnessed by a second nurse who shall countersign the records of destruction.

(e) The director of the pharmacy shall develop written procedures for the proper destruction of controlled substances not covered by (d) above conforming with federal and state statutes. A copy of the procedures shall be forwarded to the Drug Enforcement Administration

(DEA) and the state board of pharmacy. As a minimum, procedures shall include the following:

(i) All destructions shall render the drugs unrecoverable.

(ii) Destruction shall be accomplished by the pharmacist and one other licensed health professional.

(iii) Records of all destructions shall be maintained by the pharmacy. Quarterly summary reports shall be mailed to the DEA with copies to the state board of pharmacy.

(iv) A copy of the destruction record shall be maintained in the pharmacy for five years.

(f) Periodic monitoring of controlled substances records shall be performed by a nurse or a pharmacist to determine whether the drugs recorded on usage records have also been recorded on the patient's chart.

(g) Use of multiple dose vials of controlled substances shall be discouraged.

(h) Controlled substances, Schedule II and III, which are floor stocked, in any hospital patient or nursing service area shall be checked by actual count at the change of each shift by two authorized persons licensed to administer drugs.

(i) All controlled substance records shall be kept for five years.

(j) Hospitals wishing to use record systems other than that described above shall make application and receive written approval from the board of pharmacy prior to implementation.

(k) Significant losses or disappearances of controlled substances and the facts surrounding the discrepancy shall be reported to the board of pharmacy, the drug enforcement agency, the chief executive officer of the hospital and other appropriate authorities.

(8) Drug recall. The director shall develop and implement a recall procedure to assure that potential harm to patients within the hospital is prevented and that all drugs included on the recall are returned to the pharmacy for proper disposition.

(9) All medications administered to inpatients shall be recorded in the patient's medical record.

(10) Adverse drug reactions. All adverse drug reactions shall be appropriately recorded in the patient's record and reported to the prescribing practitioner and to the pharmacy.

(11) Drug errors. All drug errors shall upon discovery be recorded in an incident report and reported to the prescribing practitioner and to the pharmacy.

[Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-070, filed 7/29/81.]

WAC 360-17-080 Administration of drugs. (1) General. Drugs shall be administered only upon the order of a practitioner who has been granted clinical privileges to write such 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.

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(2) Administration. Drugs shall be administered only by appropriately licensed personnel in accordance with state and federal laws and regulations governing such acts and in accordance with medical staff approved hospital policy.

(3) Patient's drugs. The hospital shall develop written policies and procedures for the administration of drugs brought into the hospital by or for patients.

(a) Drugs brought into the hospital by or for the patient shall be administered only when there is a written order by a practitioner. Prior to use, such drugs shall be identified and examined by the pharmacist to ensure acceptable quality for use in the hospital.

(b) Drugs from outside the hospital which are not used during the patient's hospitalization shall be packaged and sealed, if stored in the hospital, and returned to the patient at time of discharge or given to the patient's family.

(c) Return of drugs may be prohibited due to possible jeopardy of the patient's health.

(d) Written procedures shall be developed for the disposal of unreturned drugs.

(4) Self-administration. Self-administration of drugs shall occur only within approved protocols in accordance with a program of self-care or rehabilitation. Policy and specific written procedures, approved by the appropriate medical staff, nursing service and administration shall be established by the director of pharmacy.

[Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-080, filed 7/29/81.]

WAC 360-17-090 Investigational drugs. (1) Distribution. Storage, distribution, and control of approved investigational drugs used in the institution shall be the responsibility of the director of pharmacy or his designee. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs.

(2) General. Investigational drugs shall be properly labeled and stored for use only under the explicit direction of the authorized principal investigator or coinvestigator(s). Such drugs shall be approved by an appropriate medical staff committee.

(3) Administration. On approval of the principal investigator or coinvestigator(s), those authorized to administer drugs may administer these drugs after they have been given basic pharmacological information about the drug. Investigational drugs shall be administered in accordance with approved written protocol that includes any requirements for the patient's appropriate informed consent.

[Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-090, filed 7/29/81.]

WAC 360-17-100 Additional responsibilities of pharmacy service. (1) General. The pharmacy service shall participate in other activities and committees within the hospital affecting pharmaceutical services, drugs and drug use.

(2) Quality assurance. The pharmaceutical service shall establish a pharmacy quality assurance program.

(1986 Ed.)

(3) Clinical activities. The director of pharmacy should develop clinically oriented programs, including but not limited to obtaining and recording comprehensive drug histories and participation in discharge planning to affect appropriate drug use, a formal drug information service, prescribing, and administration of drugs.

[Statutory Authority: RCW 18.64.005(11), 81-16-036 (Order 162), § 360-18-100, filed 7/29/81.]

**Chapter 360-18 WAC
LICENSING PERIODS AND FEES**

WAC
360-18-010 Licensing periods.
360-18-020 Fees.

**DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS
CHAPTER**

360-18-030 Intern registration fee. [Statutory Authority: RCW 18.64.005 (4) and (11), 80-05-074 (Order 154, Resolution No. 4/80), § 360-18-030, filed 4/28/80.] Repealed by 83-18-021 (Order 175), filed 8/30/83. Statutory Authority: RCW 18.64.005 and 18.64A.020.

WAC 360-18-010 Licensing periods. (1) The following are established by the board of pharmacy as the licensing periods for each license specified:

(a) Pharmacist licenses will expire on February 1 of each year.

(b) Pharmacy location, CSA (retail), prophylactic (retail pharmacy), pharmacy assistant utilization, shopkeeper and shopkeeper differential hours licenses will expire on June 1 of each year.

(c) CSA (sodium pentobarbital), Level A assistant, physician assistant, wholesaler (full line), wholesaler (OTC only), intern, manufacturer, CSA wholesaler, CSA manufacturer, prophylactic (vending machine), and prophylactic wholesaler licenses will expire on October 1 of each year.

(2) Any license that is not renewed on or before the expiration date established herein shall expire and shall no longer be a valid license to practice or conduct the activity for which it is issued. Any license that has not been renewed within sixty days of the expiration date shall be renewed only upon payment of the renewal fee and penalty fee as specified in WAC 360-18-020.

[Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-18-010, filed 12/17/82. Statutory Authority: RCW 18.64.005 (4) and (11), 80-05-074 (Order 154, Resolution No. 4/80), § 360-18-010, filed 4/28/80.]

WAC 360-18-020 Fees. The following fees shall be charged by the board of pharmacy:

(a) PHARMACY LOCATION & CSA	
Original pharmacy fee	\$165.00
Original pharmacy assistant utilization fee	35.00
Renewal pharmacy fee	85.00
Renewal pharmacy assistant utilization fee	35.00
Penalty pharmacy fee	165.00
(b) VENDOR	
Original fee	40.00
Renewal fee	40.00
Penalty fee	40.00
(c) PHARMACIST	
Exam fee (full exam)	125.00
Reexamination fee (jurisprudence portion)	25.00
Original license fee	75.00
Renewal fee, active and inactive license	60.00
Penalty fee	60.00
Reciprocity fee	250.00
Certification of license status to other states	10.00
(d) SHOPKEEPER	
(i) SHOPKEEPER - sixteen or more drugs	
Original fee	10.00
Renewal fee	10.00
Penalty fee	5.00
(ii) SHOPKEEPER - with differential hours	
Original fee	10.00
Renewal fee	10.00
Penalty fee	5.00
(e) DRUG MANUFACTURER	
Original fee	250.00
Renewal fee	250.00
Penalty fee	250.00
(f) DRUG WHOLESALER - full line	
Original fee	250.00
Renewal fee	250.00
Penalty fee	250.00
(g) DRUG WHOLESALER - OTC only	
Original fee	150.00
Renewal fee	150.00
Penalty fee	150.00
(h) DRUG WHOLESALER - export	
Original fee	250.00
Renewal fee	250.00
Penalty	250.00
(i) PHARMACY ASSISTANT - Level "A"	
Original fee	30.00
Renewal fee	20.00
(j) PHARMACY INTERN	
Original registration fee	15.00
Renewal registration fee	15.00

(k) CONTROLLED SUBSTANCES ACT (CSA) REGISTRATIONS

Dispensing registration fee (i.e. pharmacies)	35.00
Dispensing renewal fee (i.e. pharmacies)tr	30.00
Distributors registration fee (i.e. wholesalers)	50.00
Distributors renewal fee (i.e. wholesalers)	50.00
Manufacturers registration fee	50.00
Manufacturers renewal fee	50.00
Physician assistant registration fee	15.00
Physician assistant renewal fee	10.00
CRN with prescriptive authorization registration fee	15.00
CRN with prescriptive authorization renewal fee	10.00
Sodium pentobarbital for animal euthanization registration fee	20.00
Sodium pentobarbital for animal euthanization renewal fee	15.00

[Statutory Authority: RCW 18.64.005(4), 85-22-033 (Order 196), § 360-18-020, filed 10/31/85; 85-06-010 (Order 193), § 360-18-020, filed 2/22/85. Statutory Authority: RCW 18.64.005, 84-17-142 (Order 189), § 360-18-020, filed 8/22/84; 84-04-030 (Order 184), § 360-18-020, filed 1/25/84; 83-22-034 (Order 177), § 360-18-020, filed 10/26/83. Statutory Authority: RCW 18.64.005 and 18.64A.020, 83-18-021 (Order 175), § 360-18-020, filed 8/30/83. Statutory Authority: RCW 18.64.005(12), 82-12-041 (Order 168), § 360-18-020, filed 5/28/82. Statutory Authority: RCW 18.64.005 (4) and (11), 80-08-035 (Order 155, Resolution No. 6/80), § 360-18-020, filed 6/26/80, effective 9/30/80; 80-05-074 (Order 154, Resolution No. 4/80), § 360-18-020, filed 4/28/80.]

**Chapter 360-19 WAC
PATIENT MEDICATION RECORD SYSTEMS**

WAC	
360-19-010	Purpose.
360-19-020	Definitions.
360-19-030	Minimum required information in an automated patient medication record system.
360-19-040	Minimum required information in a manual patient medication record system.
360-19-050	Minimum procedures for utilization of a patient medication record system.
360-19-060	Auxiliary recordkeeping procedure.
360-19-070	Retrieval of information from an automated system.
360-19-080	Confidentiality and security of data.
360-19-090	Extension of time for compliance.
360-19-100	Effective date.

WAC 360-19-010 Purpose. The purpose of this chapter shall be to insure that a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place, in order to insure the health and welfare of the patients served. This system will consist of certain patient and prescription information, and shall provide the pharmacist within the pharmacy means to retrieve all new prescription and refill prescription information relevant to patients of the pharmacy. It shall be designed to provide adequate safeguards against the improper manipulation or alteration of records, and to provide an audit trail. It may be either

a manual system or an automated data processing system for the storage and retrieval of prescription and patient information. If an automated data processing system is utilized, an auxiliary recordkeeping procedure shall be available for documentation of new and refill prescriptions in case the automated system is inoperative for any reason. Establishment of a patient medication record system is intended 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.

[Statutory Authority: RCW 18.64.005, 84-03-016 (Order 181), § 360-19-010, filed 1/9/84.]

WAC 360-19-020 Definitions. Terms used in this chapter shall have the meaning set forth in this section unless the context clearly indicates otherwise:

- (1) "Address" means the place of residence of the patient.
- (2) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription order, and authorization of subsequent modifications of that order.
- (3) "Auxiliary recordkeeping procedure" means a back-up procedure used to record medication record system data in case of scheduled or unscheduled downtime of an automated data processing system.
- (4) "Hard copy of the original prescription" shall include the prescription as defined in RCW 18.64.011(8) and/or the medical records or chart.
- (5) "Therapeutic duplication" means two or more drugs in the same pharmacological or therapeutic category which when used together may have an additive or synergistic effect.

[Statutory Authority: RCW 18.64.005, 84-03-016 (Order 181), § 360-19-020, filed 1/9/84.]

WAC 360-19-030 Minimum required information in an automated patient medication record system. An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system.

- (1) All automated patient medication record systems must maintain the following information with regard to ambulatory patients:
 - (a) Patient's full name and address.
 - (b) A serial number assigned to each new prescription.
 - (c) The date of all instances of dispensing a drug.
 - (d) The identification of the dispenser who filled the prescription.
 - (e) The name, strength, dosage form and quantity of the drug dispensed.
 - (f) Any refill instructions by the prescriber.
 - (g) The prescriber's name, address, and DEA number where required.

(h) The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050.

(i) Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(j) Authorization for other than child-resistant containers pursuant to WAC 360-16-270, if applicable.

(2) All automated patient medication record systems must maintain the following information with regard to institutional patients:

(a) Patient's full name.

(b) Unique patient identifier.

(c) Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(d) Patient location.

(e) Patient status, for example, active, discharge, or on-pass.

(f) Prescriber's name, address, and DEA number where required.

(g) Minimum prescription data elements:

(i) Drug name, dose, route, form, directions for use, prescriber.

(ii) Start date and time when appropriate.

(iii) Stop date and time when appropriate.

(iv) Amount dispensed when appropriate.

(h) The system shall indicate any special medication status for an individual prescription, for example, on hold, discontinued, self-administration medication, investigational drugs, patient's own medications, special administration times, restrictions, controlled substances.

(i) The system shall indicate on the labeling, and in the system, (for the pharmacist, nursing and/or physician alert) any special cautionary alerts or notations deemed necessary by the dispenser for the patient safety.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-030, filed 1/9/84.]

WAC 360-19-040 Minimum required information in a manual patient medication record system. A manual patient medication record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.

(1) All manual patient medication record systems must maintain the following information with regard to ambulatory patients:

(a) Patient's full name and address.

(b) A serial number assigned to each new prescription.

(c) The date of all instances of dispensing a drug.

(d) The identification of the dispenser who filled the prescription.

(e) The name, strength, dosage form and quantity of the drug dispensed.

(f) The prescriber's name, address and DEA number where appropriate.

(g) Any patient allergies, idiosyncrasies or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(2) All manual patient medication record systems must maintain the following information with regard to institutional patients:

(a) Patient's full name.

(b) Unique patient identifier.

(c) Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(d) Patient location.

(e) Patient status, for example, active, discharge, or on-pass.

(f) Prescriber's name, address and DEA number where required.

(g) Minimum prescription data elements:

(i) Drug name, dose, route, form, directions for use, prescriber.

(ii) Start date and time when appropriate.

(iii) Stop date and time when appropriate.

(iv) Amount dispensed when appropriate.

(h) The system shall indicate any special medication status for an individual prescription, for example, on hold, discontinued, self-administration medication, investigational drugs, patient's own medications, special administration times, restrictions, controlled substances.

(i) The system shall indicate on the labeling, and in the system, (for the pharmacist, nursing and/or physician alert) any special cautionary alerts or notations deemed necessary by the dispenser for the patient safety.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-040, filed 1/9/84.]

WAC 360-19-050 Minimum procedures for utilization of a patient medication record system. Upon receipt of a prescription or drug order, a dispenser must examine visually or via an automated data processing system, the patient's medication record to determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication, and to determine improper utilization of the drug and to consult with the prescriber if needed. Any order modified in the system must carry in the audit trail the unique identifier of the person who modified the order. Any change in drug name, dose, route, dose form or directions for use which occurs after an initial dose has been given requires that a new order be entered into the system and the old order be discontinued, or that the changes be accurately documented in the record system, without destroying the original record or its audit trail.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-050, filed 1/9/84.]

WAC 360-19-060 Auxiliary recordkeeping procedure. If an automated data processing system is used to maintain a patient's medication record, an auxiliary recordkeeping procedure must be available for use when the automated data system is temporarily inoperative due to scheduled or unscheduled system interruption. The auxiliary recordkeeping procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. Upon restoration of operation of the automated system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. This section does not require that a permanent dual recordkeeping system be maintained.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-060, filed 1/9/84.]

WAC 360-19-070 Retrieval of information from an automated system. All automated patient medication record systems must provide within 72 hours, via CRT or hard copy printout, the information required by WAC 360-19-030 and by 21 CFR § 1306.22(b) as amended July 1, 1980. Any data purged from an automated patient medication record system must be available within 72 hours.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-070, filed 1/9/84.]

WAC 360-19-080 Confidentiality and security of data. (1) Information contained in patient medication record systems shall be considered to be a part of prescription records maintained in accordance with RCW 18.64.245 and shall be maintained for a period of at least five years in the same manner as provided for all prescription records (see WAC 360-16-096).

(2) The information in the patient medication record system which identifies the patient shall be deemed confidential and may be released to persons other than the patient or a pharmacist, or a practitioner authorized to prescribe only on written release of the patient. If in the judgment of the dispenser, the prescription presented for dispensing is determined to cause a potentially harmful drug interaction or other problem due to a drug previously prescribed by another practitioner, the dispenser may communicate this information to the prescribers.

(3) Security codes or systems must be established on automated medication record systems to prevent unauthorized modification of data.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-080, filed 1/9/84.]

WAC 360-19-090 Extension of time for compliance. The rules regarding patient medication record systems contained in chapter 360-19 WAC shall apply to all pharmacists practicing pharmacy in the state of Washington upon the effective date of the chapter unless an extension is granted by the board pursuant to this rule. In order to seek an extension that will allow compliance with this chapter to be delayed, good cause for granting such extension must be shown. The board shall

consider requests for extensions and if, in the board's judgment good cause is shown, the board may grant an extension for a period of time, specifying those portions of the rules with respect to which an extension is being granted.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-090, filed 1/9/84.]

WAC 360-19-100 Effective date. The effective date of this rule shall be March 1, 1984. All pharmacies must be in compliance after that date unless an extension has been granted by the board.

[Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-100, filed 1/9/84.]

Chapter 360-20 WAC SALES PROHIBITED

WAC

- 360-20-100 Drug sample prohibitions.
360-20-210 Unsealed hard gelatin capsule restrictions.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

- 360-20-010 Sulfa bandages. [Regulation 16, filed 3/23/60.] Repealed by Order, filed 8/24/67.
360-20-020 Exempt narcotics to minors. [Regulation 36, filed 3/23/60.] Repealed by Order 108, filed 10/26/71.
360-20-030 Ozone manufacturing devices. [Regulation 27, filed 3/23/60.] Repealed by Order 106, filed 9/11/70 and Order 108, filed 10/26/71.
360-20-035 Hypodermic syringes and needles. [Order 106, § 360-20-035, filed 9/11/70.] Repealed by Order 109, filed 5/23/72.
360-20-040 Dihydrocodeinone or any of its salts. [Emergency Regulation 38, filed 6/15/60 and Permanent Order 39, filed 6/15/60.] Repealed by Order 108, filed 10/26/71.
360-20-070 Exempt narcotics—Narcotic register books. [Order 105, § 360-20-070, filed 12/5/69, effective 3/1/70.] Repealed by Order 109, filed 5/23/72.
360-20-200 Hard gelatin capsule restrictions. [Statutory Authority: RCW 18.64.005(11). 86-18-023 (Order 201), § 360-20-200, filed 8/26/86.] Repealed by 86-21-033 (Order 202), filed 10/9/86. Statutory Authority: RCW 18.64.005(11).

WAC 360-20-100 Drug sample prohibitions. (1) The possession, distribution or dispensing of legend drug samples by a pharmacy is hereby prohibited.

(2) This shall not apply to any pharmacy owned and operated by a licensed hospital which is nonprofit and charitable and which is entitled to receive a declaration of current tax exempt status from the government of the United States under section 501(c) of the Internal Revenue Code.

[Order 114, § 360-20-100, filed 6/28/73.]

WAC 360-20-210 Unsealed hard gelatin capsule restrictions. (1) No pharmacy or shopkeeper may sell in the state of Washington any nonprescription drug which is manufactured in unsealed, two piece, hard gelatin capsules unless:

(a) The drug product is restricted to sale only by prescription; or

- (b) The drug product is marketed:
- (i) In packaging utilizing a minimum of two tamper evident packing features; and
 - (ii) The manufacturer uses consistent tamper evident features within each product line; and
 - (iii) The manufacturer places on its principal display panel each product's tamper evident features or places an alerting statement regarding the package location of those features; and,
 - (iv) The package contains a color depiction of the drug product.

(2) For the purpose of this regulation the following features will not be considered as acceptable tamper evident features: Glued carton flaps, cellophane wrappers with overlapping end flaps, or cellulose wet shrink seals.

(3) A tamper evident package must have an indicator or a barrier to entry which if breached or missing can reasonably be expected to provide evidence to consumers that tampering has occurred.

[Statutory Authority: RCW 18.64.005(11), 86-21-033 (Order 202), § 360-20-210, filed 10/9/86.]

Chapter 360-21 WAC WHOLESALEERS

WAC

360-21-010	Definitions.
360-21-020	Minimum standards for wholesalers.
360-21-030	Inspections.
360-21-040	Records.
360-21-050	Security.
360-21-060	Unauthorized sales.
360-21-070	Application for full line wholesaler license and over-the-counter only wholesaler license.
360-21-080	Application for controlled substance wholesaler license.
360-21-090	Export wholesaler.

WAC 360-21-010 Definitions. (1) "Full line wholesaler" means any wholesaler authorized by the board to possess and sell legend drugs, controlled substances (additional registration required) and nonprescription drugs (over-the-counter - OTC) to a licensed pharmacy or other legally licensed or authorized person.

(2) "Over-the-counter only wholesaler" means any wholesaler authorized by the board to possess and sell nonprescription (OTC) drugs to any outlets licensed for resale.

(3) "Controlled substances wholesaler" means a licensed wholesaler authorized by the board to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

(4) "Export wholesaler" means any wholesaler authorized by the board to export legend drugs and nonprescription (OTC) drugs to foreign countries.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-010, filed 3/2/82.]

WAC 360-21-020 Minimum standards for wholesalers. The following minimum standards shall apply to all wholesale outlets for which licenses have been issued by the board:

(1) Light and ventilation: All wholesale outlets including all storage areas, shall be well lighted, well ventilated and properly heated.

(2) Sanitary facilities: All wholesale outlets shall have sanitary facilities constructed in accordance with the laws and ordinances applying thereto. Facilities shall include a restroom for employees which shall be provided with a wash basin supplied with hot and cold running water and toilet.

(3) All drugs and chemicals shall be stored at appropriate temperatures according to label requirements to maintain stability.

(4) A residence shall not be considered to be an acceptable location for issuance of a wholesaler's license unless the wholesaler's business is operated in a separate space within the residence which otherwise meets the requirements of this section.

(5) Adequate space shall be provided consistent with the wholesale drug outlet operation.

(6) Minimum equipment shall be maintained consistent with the wholesale drug outlet's operation and shall be in proper working order at all times.

(7) Adequate security shall be provided as specified in WAC 360-21-050.

(8) Surrounding environmental conditions shall be adequate to prevent contamination of stored products.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-020, filed 3/2/82.]

WAC 360-21-030 Inspections. Inspections shall be performed by representatives of the board of pharmacy to ensure compliance with chapter 360-21 WAC. The following items shall be included in these inspections:

(a) The walls, ceilings, windows, and floors of the premises shall be clean and maintained in good repair and order.

(b) The licensee's premises shall be free from obnoxious odors.

(c) All persons working in premises are required to keep themselves and their apparel in a clean and sanitary condition.

(d) Other areas of inspection include, but are not limited to housekeeping, sanitation, record keeping, accountability, security, types of outlets sold to and sources of drugs purchased.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-030, filed 3/2/82.]

WAC 360-21-040 Records. Invoices shall be maintained for a period of five years, and show the source of supply for all drugs and to whom they were sold or distributed. Lack of such records shall be grounds for suspension or revocation of wholesaler license. These records shall be available during regular business hours for inspection by any authorized representative of the board of pharmacy. In those instances in which records are stored in a location other than the wholesaler's premises, the records must be available for inspection within 72 hours.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-040, filed 3/2/82.]

WAC 360-21-050 Security. (1) Every wholesaler shall take security precautions to ensure that access from outside the premises is reduced to a minimum and that internal security equipment (alarm systems) are used to detect entry after hours.

(2) Legend drug storage areas shall be constructed in such a manner as to prevent illegal entry.

(3) Adequate lighting shall be provided at the outside perimeter of the premises to reduce the possibility of illegal entry.

(4) All applicants for a license as a controlled substances wholesaler must comply with the security requirements as found in 21 CFR 1301.02, 1301.71 through 1301.74 and 1301.90 through 1301.92.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-050, filed 3/2/82.]

WAC 360-21-060 Unauthorized sales. No wholesaler shall sell or distribute any drugs or devices except to an individual, corporation, or entity who is authorized by law or regulation to possess such drugs or devices. No wholesaler shall sell any drugs or devices to an ultimate consumer.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-060, filed 3/2/82.]

WAC 360-21-070 Application for full line wholesaler license and over-the-counter only wholesaler license. No person shall act as a wholesaler unless he/she has obtained a license from the board.

(1) All application for licensure of a new or relocated wholesaler shall be accompanied by the required fee as set forth in WAC 360-18-020.

(2) Applications shall specify the location of the wholesaler premises. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or person holding the three largest interests shall be indicated on the application.

(b) If the owner is a corporation, the name filed shall be the same as filed with the secretary of state. The name of the corporation, and the names of the corporation officers shall be indicated on the application.

(3) All license renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (2) of this rule.

(4) A change of ownership or location requires a new license.

(5) The license is issued to a person or firm and is nontransferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.

(6) The license fee cannot be prorated.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-070, filed 3/2/82.]

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WAC 360-21-080 Application for controlled substance wholesaler license. No person shall act as a controlled substance wholesaler unless he/she has obtained a controlled substance wholesaler license from the board.

(1) He/she must be licensed as a full line wholesaler.

(2) He/she must meet all security requirements as set forth in WAC 360-21-050(4).

(3) He/she must meet additional requirements for registration and fees as set forth in WAC 360-36-010.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-080, filed 3/2/82.]

WAC 360-21-090 Export wholesaler. (1) Upon application the board may issue a wholesaler license for the primary business of exporting drugs to foreign countries.

(2) Such license authorizes the holder to export non-controlled drugs to persons in a foreign jurisdiction that have legitimate reasons to possess such drugs.

(3) Letters from consulate of the country to which drugs are exported should verify consignee receiving such drugs is legally entitled in that country to receive them, if applicable. These letters shall be made available to the board upon its request.

(4) Records to be kept by export wholesaler:

(a) Complete description of drug, including, name, quantity, strength, and dosage unit.

(b) Name and address of purchaser.

(c) Name and address of consignee in the country of destination.

(d) Name and address of forwarding agent.

(e) Proposed export date.

(f) Shippers involved and methods of shipment.

(5) The issuance of an export wholesaler license does not authorize delivery of drugs in the United States.

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-090, filed 3/2/82.]

Chapter 360-23 WAC

PRESCRIPTION DRUG PRICE ADVERTISING

WAC

360-23-010	Drug price advertising defined.
360-23-020	Drug price advertising conditions.
360-23-030	Prohibition on advertising controlled substances.
360-23-050	Drug price disclosure—Required.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-23-040	Advertising or mail order solicitation of sale or distribution of prescription drugs prohibited. [Order 124, § 360-23-040, filed 10/31/74.] Repealed by 83-10-013 (Order 174), filed 4/26/83. Statutory Authority: RCW 18.64.005 and 69.41.240.
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WAC 360-23-010 Drug price advertising defined. Drug price advertising is the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

[Order 124, § 360-23-010, filed 10/31/74; Order 120, § 360-23-010, filed 3/11/74.]

WAC 360-23-020 Drug price advertising conditions. A pharmacy may advertise legend or prescription drug prices provided:

(1) The advertising complies with all state and federal laws, including regulations of the United States Food and Drug Administration and the Washington State Consumer Protection Act, chapter 19.86 RCW.

(2) The advertising is solely directed towards providing consumers with drug price information and does not promote the use of a prescription drug or drugs to the public.

(3) The drug price advertising shall contain all the following information for all drug products or brand names used in the advertisement:

(a) The proprietary name of the drug product advertised, if any,

(b) The generic name of the drug product advertised, if any,

(c) The strength of the drug product advertised. If the drug product advertised contains more than one active ingredient and a relevant strength can be associated with it without indicating each active ingredient, the generic name and quantity of each active ingredient is not required.

(d) The dosage form of the drug product advertised, and

(e) The price charged for a specified quantity of the drug product.

(4) Advertising of any generic drug that in any way compares a generic drug to a brand name drug may not in any manner imply that the brand name drug is the product offered for sale.

[Statutory Authority: RCW 18.64.005(11), 79-10-007 (Order 151, Resolution No. 9/79), § 360-23-020, filed 9/6/79; Order 124, § 360-23-020, filed 10/31/74; Order 120, § 360-23-020, filed 3/11/74.]

WAC 360-23-030 Prohibition on advertising controlled substances. No person, partnership, corporation, association or agency shall advertise controlled substances for sale to the general public in any manner that promotes or tends to promote the use or abuse of those drugs. Controlled substances shall not be physically displayed to the public.

[Order 124, § 360-23-030, filed 10/31/74.]

WAC 360-23-050 Drug price disclosure--Required. No pharmacy shall refuse to disclose the retail price of a prescription drug upon request.

[Order 124, § 360-23-050, filed 10/31/74.]

Chapter 360-28 WAC

SALES REQUIRING A PHARMACIST'S SUPERVISION

WAC
360-28-010 Pharmacist supervised sales—General.

(1986 Ed.)

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-28-011	Hypodermic syringes and needles. [Order 109, § 360-28-011, filed 5/23/72.] Repealed by Order 137, filed 11/8/77.
360-28-020	Pharmacist supervised sales—Bromide preparations. [Regulation 14, filed 3/23/60.] Repealed by Order 106, filed 9/11/70.
360-28-030	Pharmacist supervised sales—Antihistamine products. [Regulation 18, adopted 5/28/59, filed 3/23/60.] Repealed by Order 106, filed 9/11/70.
360-28-040	Pharmacist supervised sales—Dangerous medicinal preparation. [Regulation 12, filed 3/23/60.] Repealed by Order 106, filed 9/11/70.
360-28-050	Pharmacist supervised sales—Vitamin contained compounds labeled with a therapeutic dosage. [Regulation 30, filed 3/23/60.] Repealed by Order 106, filed 9/11/70.
360-28-060	Pharmacist supervised sales—Legend type preparations. [Regulation 26, filed 3/23/60.] Repealed by Order 106, filed 9/11/70.
360-28-070	Exempt narcotics register book. [Order 100 (part), § 360-28-070, filed 6/25/68; Regulation 31 (part), filed 11/6/64.] Repealed by Order 108, filed 10/26/71.
360-28-075	Exempt narcotics—Pharmacist's responsibilities. [Order 100 (part), § 360-28-075, filed 6/25/68; Regulation 31 (part), filed 11/6/64.] Repealed by Order 108, filed 10/26/71.
360-28-080	Requirements for purchasers of exempt narcotics. [Order 100 (part), § 360-28-080, filed 6/25/68.] Repealed by Order 108, filed 10/26/71.
360-28-085	Maximum quantity of an exempt narcotic in a forty-eight-hour period. [Order 100 (part), § 360-28-085, filed 6/25/68.] Repealed by Order 108, filed 10/26/71.
360-28-100	Exempt narcotics—Signature of dispensing pharmacist. [WAC 360-28-100 (reference section to WAC 360-32-020).] Repealed by Order 109, filed 5/23/72.

WAC 360-28-010 Pharmacist supervised sales—General. The state board of pharmacy, pursuant to authority vested in it by the legislature, and for the protection of public health, will issue from time to time as deemed necessary by said board, a list of ingredients or preparations as may be sold only under the direct supervision of a licensed pharmacist. The failure to include in such listings any ingredient or preparation will not authorize the sale thereof by other than a licensed pharmacist where the statutes of this state or other valid regulations, require such sale to be made only under the direct supervision of a licensed pharmacist.

[Regulation 15, filed 3/23/60.]

Chapter 360-32 WAC

SALES REQUIRING PRESCRIPTIONS

WAC	
360-32-050	Identification of legend drugs for purposes of chapter 69.41 RCW.
360-32-055	Ephedrine prescription restrictions.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-32-010	Home fluoridation preparations. [Regulation 23, filed 3/23/60.] Repealed by 79-09-138 (Order 149, Resolution No. 9/79), filed 9/5/79. Statutory Authority: RCW 18.64.005(11).
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- 360-32-020 Oral narcotic prescription list. [Order 101, § 360-32-020, filed 12/5/69; Regulation 24, filed 3/23/60.] Repealed by Order 108, filed 10/26/71.
- 360-32-030 Inhalers containing analeptic substances. [Regulation 25, filed 3/23/60.] Repealed by Order 106, filed 9/11/70.
- 360-32-035 Inhalers having directions to be sold under direction of a physician. [Regulation 13 (part), filed 3/23/60.] Repealed by 79-09-138 (Order 149, Resolution No. 9/79), filed 9/5/79. Statutory Authority: RCW 18.64.005(11).
- 360-32-040 Hallucinogenic drugs. [Regulation 46, filed 12/1/65 and Emergency Order 46, filed 10/5/65.] Repealed by Order 108, filed 10/26/71.
- 360-32-045 Ephedrine prescription restrictions. [Order 132, § 360-32-045, filed 5/4/77; Order 128, § 360-32-045, filed 5/19/76.] Repealed by 79-09-138 (Order 149, Resolution No. 9/79), filed 9/5/79. Statutory Authority: RCW 18.64.005(11).

WAC 360-32-050 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) In accordance with chapter 69.41 RCW, the board of pharmacy hereby finds that those drugs which have been determined by the food and drug administration, pursuant to the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law for the reasons that their toxicity or other potentiality for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are not safe for use except under the supervision of a practitioner.

(2) The board of pharmacy hereby specifically identifies as legend drugs, for purposes of chapter 69.41 RCW, those drugs which have been designated as legend drugs under federal law and are listed as such in the 1985-86 edition of the *American Druggist Blue Book*. Copies of the list of legend drugs as contained in the *American Druggist Blue Book* shall be available for public inspection at the headquarters office of the State Board of Pharmacy, 319 East 7th Avenue, Olympia, Washington 98504. Copies of this list shall be available from the board of pharmacy at the above address upon request made and upon payment of a fee in the amount of \$20 per copy.

(3) There may be changes in the marketing status of drugs after the publication of the above reference. Upon application of a manufacturer or distributor, the board may grant authority for the over the counter distribution of certain drugs which had been designated as legend drugs in this reference. Such determinations will be made after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-32-050, filed 9/4/85. Statutory Authority: RCW 18.64.005 and 69.41.075. 83-20-053 (Order 176), § 360-32-050, filed 9/29/83. Statutory Authority: RCW 69.41.075. 81-10-025 (Order 160), § 360-32-050, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution No. 9/79), § 360-32-050, filed 9/5/79.]

WAC 360-32-055 Ephedrine prescription restrictions. (1) The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies ephedrine, or any of its salts in a solid or aqueous form normally intended for oral

administration, in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.

(2) The following products containing ephedrine or its salts are exempted from the provisions of this regulation:

- | | |
|---|---|
| 1. AMORDRINE tablet
(Searle) | 25 mg (as racemic hydrochloride) |
| 2. BRONITIN tablet
(Whitehall) | 24 mg ephedrine |
| 3. BRONKAID tablet
(Breon) | 24 mg (as sulfate) |
| 4. BRONKOTABS tablet
(Breon) | 24 mg (as sulfate) |
| 5. CALCIDRINE SYRUP
(Abbott) | 4.2 mg/5cc HCl |
| 6. HISTADYL EC
(Lilly) | ephedrine hydrochloride, 30 mg/30 ml |
| 7. HISTIVITE-D
(Vitarine) | ephedrine sulfate, 30 mg/30 ml |
| 8. NYQUIL
(Vicks) | ephedrine sulfate, 8 mg/30 ml |
| 9. PRIMATINE M tablet
(Whitehall) | 24 mg (as hydrochloride) |
| 10. QUELIDRINE
(Abbott) | ephedrine hydrochloride, 5 mg/5 ml |
| 11. QUIET-NITE
(Rexall) | ephedrine sulfate, 10 mg/30 ml |
| 12. VERAQUAD tablet -
suspension (Knoll) | 24 mg tablet, 12 mg/5 ml (as hydrochloride) |

[Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-32-055, filed 3/2/82. Statutory Authority: RCW 69.41.075. 81-10-025 (Order 160), § 360-32-055, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution No. 9/79), § 360-32-055, filed 9/5/79.]

Chapter 360-33 WAC

IDENTIFICATION OF LEGEND DRUGS-- IMPRINTS, MARKINGS, AND LABELING

WAC

360-33-050 Drug imprint information provided by manufacturers and distributors.

WAC 360-33-050 Drug imprint information provided by manufacturers and distributors. Each manufacturer and distributor who manufactures or commercially distributes any legend drug in the state of Washington shall provide written information to the board identifying all current imprints used. This information shall be submitted on a form provided by the board and shall be updated annually, or as changes in imprints occur.

[Statutory Authority: RCW 18.64.005 and 69.41.240. 83-10-013 (Order 174), § 360-33-050, filed 4/26/83.]

Chapter 360-36 WAC

REGULATIONS IMPLEMENTING THE UNIFORM CONTROLLED SUBSTANCES ACT

WAC

360-36-010	Uniform Controlled Substances Act.
360-36-020	Dispensing Schedule V controlled substances.
360-36-115	Designation of nonnarcotic stimulant drugs for purposes of RCW 69.50.402 (a)(3).
360-36-210	Eligibility.
360-36-220	Product restrictions.
360-36-240	Storage.
360-36-250	Drug administration.
360-36-260	Records and reports.
360-36-270	Penalties.
360-36-400	Authority to control.
360-36-410	Schedule I.
360-36-411	Adding MPPP to Schedule I.
360-36-412	Adding PEPAP to Schedule I.
360-36-413	Adding MDMA to Schedule I.
360-36-420	Schedule II.
360-36-430	Schedule III.
360-36-440	Schedule IV.
360-36-450	Schedule V.
360-36-451	Adding buprenorphine to Schedule V.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-36-100	Additional Schedule I substances. [Order 142, § 360-36-100, filed 12/9/77; Order 126, § 360-36-100, filed 5/21/75.] Repealed by 80-14-012 (Order 157, Resolution No. 9/80), filed 9/22/80. Statutory Authority: RCW 69.41.180.
360-36-110	Additional Schedule II substances. [Statutory Authority: RCW 18.64.005(9) and 69.50.201. 79-02-060 (Order 146, Resolution No. 2-79), § 360-36-110, filed 2/1/79; Order 142, § 360-36-110, filed 12/9/77.] Repealed by 80-14-012 (Order 157, Resolution No. 9/80), filed 9/22/80. Statutory Authority: RCW 69.41.180.
360-36-120	Additional Schedule III substances. [Statutory Authority: RCW 18.64.005(9) and 69.50.201. 79-02-060 (Order 146, Resolution No. 2-79), § 360-36-120, filed 2/1/79; Order 142, § 360-36-120, filed 12/9/77.] Repealed by 80-14-012 (Order 157, Resolution No. 9/80), filed 9/22/80. Statutory Authority: RCW 69.41.180.
360-36-130	Additional Schedule IV substances. [Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-36-130, filed 3/27/79. Statutory Authority: RCW 18.64.005(9) and 69.50.201. 79-02-060 (Order 146, Resolution No. 2-79), § 360-36-130, filed 2/1/79; Order 142, § 360-36-130, filed 12/9/77.] Repealed by 80-14-012 (Order 157, Resolution No. 9/80), filed 9/22/80. Statutory Authority: RCW 69.41.180.
360-36-140	Additional Schedule V substances. [Statutory Authority: RCW 18.64.005(9) and 69.50.201. 79-02-060 (Order 146, Resolution No. 2-79), § 360-36-140, filed 2/1/79; Order 142, § 360-36-140, filed 12/9/77.] Repealed by 80-14-012 (Order 157, Resolution No. 9/80), filed 9/22/80. Statutory Authority: RCW 69.41.180.
360-36-150	Rescheduled substances. [Order 142, § 360-36-150, filed 12/9/77.] Repealed by 79-02-060 (Order 146, Resolution No. 2-79), filed 2/1/79. Statutory Authority: RCW 18.64.005(9) and 69.50.201.
360-36-160	Placement of phencyclidine in Schedule II. [Statutory Authority: RCW 69.50.201. 78-05-048 (Order 144, Resolution No. 12-78), § 360-36-160, filed 4/24/78.] Repealed by 79-02-060 (Order 146, Resolution No. 2-79), filed 2/1/79. Statutory Authority: RCW 18.64.005(9) and 69.50.201.

360-36-170	Placement of lorazepam in Schedule IV. [Statutory Authority: RCW 69.50.201. 78-05-048 (Order 144, Resolution No. 12-78), § 360-36-170, filed 4/24/78.] Repealed by 79-02-060 (Order 146, Resolution No. 2-79), filed 2/1/79. Statutory Authority: RCW 18.64.005(9) and 69.50.201.
360-36-230	Registration. [Statutory Authority: RCW 69.50.301. 80-05-074 (Order 154, Resolution No. 4/80), § 360-36-230, filed 4/28/80. Statutory Authority: RCW 18.64.005(11) and 69.50.301. 79-10-006 (Order 150, Resolution No. 9/79), § 360-36-230, filed 9/6/79; Order 138, § 360-36-230, filed 11/8/77.] Repealed by 85-06-010 (Order 193), filed 2/22/85. Statutory Authority: RCW 18.64.005.

WAC 360-36-010 Uniform Controlled Substances Act. (1) Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 CFR), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW 69.50.306. Although those regulations are automatically applicable to registrants in this state, the board is nevertheless adopting as its own regulations the existing regulations of the federal government published in the code of federal regulations revised as of April 1, 1979, and all references made therein to the director or the secretary shall have reference to the board of pharmacy, and the following sections are not applicable: Section 1301.11-13, section [1301.31] [131.31], section 1301.43-57, section 1303, section 1308.41-48, and section 1316.31-67. The following specific rules shall take precedence over the federal rules adopted herein by reference, and therefore any inconsistencies shall be resolved in favor of the following specific rules.

(2) Registrations under chapter 69.50 RCW shall be for an annual period with the registration period ending on a date to coincide with those license renewal dates as found in rules promulgated under chapter 18.64 RCW.

(3) A separate registration is required for each place of business (as defined in section 1301.23) where controlled substances are manufactured, distributed or dispensed. Application for registration must be made on forms supplied by the pharmacy board, and all information called for thereon must be supplied unless the information is not applicable, in which case it must be indicated. An applicant for registration must hold the appropriate wholesaler, manufacturer or pharmacy license provided for in chapter 18.64 RCW.

(4) Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference [by] [to] Rule 1) and must maintain said inventory records for a period of five years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include:

(a) Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;

(b) Distribution records; i.e., invoices, etc. from wholesalers and manufacturers and prescriptions records for dispensers;

(c) In the event of a loss by theft or destruction, two copies of DEA 106 (report of theft or loss of controlled

substances) must be transmitted to the federal authorities and a copy must be sent to the board;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to and from whom. Said record must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to section 1307.11 (federal rules).

(5) The records must be maintained separately for Schedule II drugs. The records for Schedule III, IV and V drugs may be maintained either separately or in a form that is readily retrievable from the business records of the registrant. Prescription records will be deemed readily retrievable if the prescription has been stamped in red ink in the lower right hand corner with the letter "C" no less than one inch high, and said prescriptions are filed in a consecutively numbered prescription file which includes prescription and noncontrolled substances.

(6) A federal order form is required for each distribution of a Schedule I or II controlled substance, and said forms along with other records required to be kept must be made readily available to authorized employees of the board.

(7) Schedule II drugs require that a dispenser have a signed prescription in his possession prior to dispensing said drugs. An exception is permitted in an "emergency." An emergency exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the physician to provide a written prescription for the drug at that time. If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within 72 hours, and further he must note on the prescription that it was filled on an emergency basis.

[Statutory Authority: RCW 18.64.005(4), 85-06-010 (Order 193), § 360-36-010, filed 2/22/85. Statutory Authority: RCW 69.50.301, 80-05-074 (Order 154, Resolution No. 4/80), § 360-36-010, filed 4/28/80; 79-10-007 (Order 151, Resolution No. 9/79), § 360-36-010, filed 9/6/79. Statutory Authority: RCW 69.50.301 and chapter 69.50 RCW. 78-02-070 (Order 140), § 360-36-010, filed 1/25/78; Order 132, § 360-36-010, filed 5/4/77; Order 108, § 360-36-010, filed 10/26/71.]

Reviser's note: RCW 34.04.058 requires the use of underlining and deletion marks to indicate amendments to existing rules, and deems ineffectual changes not filed by the agency in this manner. The bracketed material in the above section does not appear to conform to the statutory requirement.

WAC 360-36-020 Dispensing Schedule V controlled substances. (1) Those drugs classified in Schedule V of the Uniform Controlled Substances Act (RCW 69.50-.212) which can be dispensed without a prescription can be so distributed only for the medical purpose(s) indicated on the manufacturer's label (e.g., cough syrups may only be dispensed for the treatment of coughs) and shall be dispensed in accordance with the following rules.

(2) Only a licensed pharmacist or a pharmacy intern may dispense a Schedule V drug. The pharmacist or

pharmacy intern making the sale is responsible for the recording of the required information in the Schedule V register book. The pharmacist or pharmacy intern shall not sell a Schedule V drug to a person below the age of 21 and shall require the purchaser to supply identification so that the purchaser's true name, address and age can be verified. The pharmacist must keep the Schedule V drugs in a safe place not accessible to members of the public. The name and address of the pharmacy must be placed on the bottle or vial of each Schedule V drug sold and the pharmacist or pharmacy intern dispensing the product must place the date of sale and his/her initials on the label at the time of sale. The pharmacist or pharmacy intern is required to show every purchaser of a Schedule V product a copy of subsections (3) and (4) of this rule (sections relating to purchaser(s) of Schedule V drugs).

(3) No person shall obtain a Schedule V drug without a practitioner's prescription unless he/she complies with the following:

(a) The product must be purchased as a medicine for its indicated medical use only;

(b) The purchaser must sign the Schedule V register book with his/her true name and address and supply proof of identification.

(c) The purchaser cannot purchase more than 120 mls (four fluid ounces) of Schedule V cough preparations, nor more than 240 mls (eight fluid ounces) of Schedule V anti-diarrheal preparations.

(4) In the absence of a practitioner's prescription, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain, within a ninety-six hour period, more than the maximum quantity set forth in subsection (3)(c) of this rule. Further, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain more than twice the maximum quantity set forth in (3)(c) above in any sixty-day period.

(5)(a) Every pharmacy handling Schedule V drugs must keep a Schedule V register book in which the following statement must appear at the top of each page: "I have not obtained any Schedule V preparations within the last ninety-six hours, nor obtained Schedule V preparations more than twice within the last sixty days. This is my true name and address." All sales of Schedule V preparations without a practitioner's prescription shall be recorded in the Schedule V register book and the following information must be recorded therein:

(i) Printed name of purchaser

(ii) Signature of purchaser

(iii) Address of purchaser

(iv) Name of the Schedule V preparation sold

(v) Quantity of Schedule V preparation sold

(vi) Date of sale

(vii) Initials or name of pharmacist or pharmacy intern who sold the Schedule V drug

(viii) Proof of identification: A unique identification number from a driver's license or from other state or federally issued photo identification card.

(b) All register books used to record the sale of Schedule V preparations shall conform to the following standards:

(i) The book shall be 8 1/2 inches wide, 11 inches long.

(ii) The book shall be securely bound, not loose leaf or spiral bound.

(iii) The book shall have its pages consecutively numbered with a unique number assigned to each book and identified on each page.

(iv) Each page shall consist of an original and duplicate. If any sales are recorded, the duplicate sheet must be mailed to the board of pharmacy when completed or on the last day of each month, whichever is earlier.

(3) All pharmacy records relating to Schedule V drugs shall be open to examination by state board of pharmacy investigators during normal business hours. The refusal to permit such examination shall constitute grounds for the suspension or revocation of the pharmacist's license.

[Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-36-020, filed 12/17/82. Statutory Authority: RCW 18.64.005 and 69.41.075. 82-19-022 (Order 169), § 360-36-020, filed 9/8/82; Order 108, § 360-36-020, filed 10/26/71.]

WAC 360-36-115 Designation of nonnarcotic stimulant drugs for purposes of RCW 69.50.402 (a)(3). The board of pharmacy hereby designates, the following Schedule II controlled substances as nonnarcotic stimulants for purposes of RCW 69.50.402 (a)(3):

(1) Amphetamine sulfate in any of its generic forms and under the following brand names:

- (a) Benzedrine (SKF);
- (b) Benzedrine spansules (SKF);

(2) Dextroamphetamine sulfate in any of its generic forms and under the following brand names:

- (a) Dexampex (Lemmon);
- (b) Dexedrine (SKF);
- (c) Ferndex (Ferndale);
- (d) Dexedrine spansules (SKF);
- (e) Diphylets (Tutag).

(3) Dextroamphetamine HCL in any of its generic forms and under the following brand names:

- (a) Daro (Fellows).

(4) Dextroamphetamine tannate in any of its generic forms and under the following brand names:

- (a) Obotan (Mallinckrodt);
- (b) Obotan forte (Mallinckrodt).

(5) Methamphetamine HCL (Desoxyephedrine HCL) in any of its generic forms and under the following brand names:

- (a) Desoxyn (Abbott);
- (b) Methampex (Lemmon);
- (c) Obedrin-LA (Beecham Labs.).

(6) Amphetamine complex in any of its generic forms and under the following brand names:

- (a) Biphetamine 7 1/2 (Pennwalt);
- (b) Biphetamine 12 1/2 (Pennwalt);
- (c) Biphetamine 20 (Pennwalt).

(7) Combined amphetamines sold under the following brand names:

- (a) Amphaplex-10 and 20 (Palmedico);
- (b) Obetrol-10 and 20 (Obetrol);
- (c) Delcobese-5, 10, 15, and 20mg. (Delco);

(d) Dexamyl (SKF);

(e) Eskatrol (SKF).

(8) Phenmetrazine HCL in any of its generic forms and under the following brand name:

(a) Preludin (Boehringer-Ingelheim).

(9) Methylphenidate HCL in any of its generic forms and under the following brand name:

(a) Ritalin (Cd,25).

[Statutory Authority: RCW 69.50.201. 79-08-069 (Order 148, Resolution No. 7-79), § 360-36-115, filed 7/24/79.]

WAC 360-36-210 Eligibility. Any humane society or animal control agency who designates a responsible individual under WAC 360-36-260 may apply to the Washington state board of pharmacy for a limited registration under chapter 69.50 RCW (Controlled Substances Act) to purchase, possess and administer sodium pentobarbital. The sodium pentobarbital will be used only to euthanize injured, sick, homeless or unwanted domestic pets and domestic or wild animals.

[Order 138, § 360-36-210, filed 11/8/77.]

WAC 360-36-220 Product restrictions. Sodium pentobarbital obtained under this limited registration shall be labeled "For veterinary use only." The board will make available a list of approved products.

[Statutory Authority: RCW 18.64.005(11) and 69.50.301. 79-10-006 (Order 150, Resolution No. 9/79), § 360-36-220, filed 9/6/79; Order 138, § 360-36-220, filed 11/8/77.]

WAC 360-36-240 Storage. The registered location supply of sodium pentobarbital shall be kept or stored in a safe or a substantial well-built double-locked drawer or cabinet.

(1) Registrants may designate only the following agents to possess and administer sodium pentobarbital at locations other than the registered location:

- (a) Humane officer;
- (b) Animal control enforcement officer;
- (c) Animal control authority;
- (d) Peace officer authorized by police chief, sheriff or county commissioners.

(2) Specially designated agents of the registrant may possess a supply of sodium pentobarbital for emergency field use. Such emergency supply shall be stored in a locked metal box securely attached to the vehicle. The designated agent shall be responsible to insure that the sodium pentobarbital is present at the beginning and is present or accounted for at the end of each shift. A log book shall be kept in which all receipts and use of sodium pentobarbital from the emergency supply shall be recorded.

[Order 138, § 360-36-240, filed 11/8/77.]

WAC 360-36-250 Drug administration. All agencies so registered under the chapter will establish written policies and procedures to insure that any of their agents or personnel which administer sodium pentobarbital have received sufficient training in its handling and administration, and have demonstrated adequate knowledge of the potentials and hazards, and proper

techniques to be used in administering the drug. A copy of the written policies and procedures shall be filed with the board at the time of initial application for registration. The board shall be notified in writing of any individuals who have qualified to administer sodium pentobarbital or of any amendments or deletions to the policies and procedures.

[Order 138, § 360-36-250, filed 11/8/77.]

WAC 360-36-260 Records and reports. (1) Each agency or society shall designate an individual as the registrant who shall be responsible for maintaining all records and submitting all reports required by applicable federal or state law or regulation, including chapter 360-36 WAC.

(2) This responsible individual shall also be responsible for the ordering, possession, safe storage and utilization of the sodium pentobarbital.

[Order 138, § 360-36-260, filed 11/8/77.]

WAC 360-36-270 Penalties. In addition to any criminal or civil liabilities that may occur, the board may deny, suspend, or revoke registration upon determination that (1) the registration was procured through fraud or misrepresentation, (2) the registrant or any agent or employee of the registrant has violated any of the federal or state laws related to drugs, or has violated any of the rules or regulations of the board of pharmacy.

[Order 138, § 360-36-270, filed 11/8/77.]

WAC 360-36-400 Authority to control. Pursuant to the authority granted to the board of pharmacy in RCW 69.50.201, the board has considered the following factors with regards to each of the substances listed in this chapter and in chapter 69.50 RCW:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the substance;
- (4) The history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) The risk to the public health;
- (7) The potential of the substance to produce psychic or psychological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under the Uniform Controlled Substances Act (chapter 69.50 RCW).

[Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-400, filed 11/7/84.]

WAC 360-36-410 Schedule I. The board finds that the following substances have high potential for abuse and have no accepted medical use in treatment in the United States or that they lack accepted safety for use in treatment under medical supervision. The board, therefore, places each of the following substances in Schedule I.

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(a) The controlled substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name, are included in Schedule I.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Acetylmethadol;
- (2) Alfentanil;
- (3) Allylprodine;
- (4) Alphacetylmethadol;
- (5) Alphameprodine;
- (6) Alphamethadol;
- (7) Alpha-methylfentanyl (N-[1-alpha-methyl-beta-phenyl] ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);
- (8) Benzethidine;
- (9) Betacetylmethadol;
- (10) Betameprodine;
- (11) Betamethadol;
- (12) Betaprodine;
- (13) Clonitazene;
- (14) Dextromoramide;
- (15) Diampromide;
- (16) Diethylthiambutene;
- (17) Difenoxin;
- (18) Dimenoxadol;
- (19) Dimepheptanol;
- (20) Dimethylthiambutene;
- (21) Dioxaphetyl butyrate;
- (22) Dipipanone;
- (23) Ethylmethylthiambutene;
- (24) Etonitazene;
- (25) Etoxidine;
- (26) Furethidine;
- (27) Hydroxypethidine;
- (28) Ketobemidone;
- (29) Levomoramide;
- (30) Levophenacymorphan;
- (31) Morpheridine;
- (32) Noracymethadol;
- (33) Norlevorphanol;
- (34) Normethadone;
- (35) Norpipanone;
- (36) Phenadoxone;
- (37) Phenampromide;
- (38) Phenomorphan;
- (39) Phenoperidine;
- (40) Piritramide;
- (41) Propheptazine;
- (42) Properidine;
- (43) Propiram;
- (44) Racemoramide;
- (45) Tilidine;
- (46) Trimeperidine.

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following

opium derivatives, their salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Acetorphine;
- (2) Acetyldihydrocodeine;
- (3) Benzylmorphine;
- (4) Codeine methylbromide;
- (5) Codeine-N-Oxide;
- (6) Cyprenorphine;
- (7) Desomorphine;
- (8) Dihydromorphine;
- (9) Drotebanol;
- (10) Etorphine (except hydrochloride salt);
- (11) Heroin;
- (12) Hydromorphenol;
- (13) Methyl-desorphine;
- (14) Methyl-dihydromorphine;
- (15) Morphine methylbromide;
- (16) Morphine methylsulfonate;
- (17) Morphine-N-Oxide;
- (18) Myrophine;
- (19) Nicocodeine;
- (20) Nicomorphine;
- (21) Normorphine;
- (22) Pholcodine;
- (23) Thebacon.

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of paragraph (d) of this section, only, the term "isomer" includes the optical, position, and geometric isomers.):

- (1) 3,4-methylenedioxy amphetamine;
- (2) 5-methoxy-3,4-methylenedioxy amphetamine;
- (3) 3,4,5-trimethoxy amphetamine;
- (4) 4-bromo-2,5-dimethoxy-amphetamine: Some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA;
- (5) 2,5-dimethoxyamphetamine: Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA;
- (6) 4-methoxyamphetamine: Some trade or other names: 4-methoxy-alpha-methylphenethylamine; paramethoxyamphetamine; PMA;
- (7) 4-methyl-2,5-dimethoxyamphetamine: Some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; "STP";
- (8) Bufotenine: Some trade or other names: 3-(beta-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;
- (9) Diethyltryptamine: Some trade or other names: N,N-Diethyltryptamine; DET;
- (10) Dimethyltryptamine: Some trade or other names: DMT;

(11) Ibogaine: Some trade or other names: 7-Ethyl-6,6 beta,7,8,9,10,12,13,-octahydro-2-methoxy-6,9-methano-5H-pyrido (1',2'1,2) azepino (5,4-b) indole; Tabernanthe iboga;

- (12) Lysergic acid diethylamide;
- (13) Marihuana;
- (14) Mescaline;
- (15) Parahexyl-7374; some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo[b,d]pyran; synhexyl;
- (16) Peyote, meaning all parts of the plant presently classified botanically as *Lophophora Williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds, or extracts; (interprets 21 USC § 812 (c), Schedule I (c)(12))

(17) N-ethyl-3-piperidyl benzilate;

(18) N-methyl-3-piperidyl benzilate;

(19) Psilocybin;

(20) Psilocyn;

(21) Tetrahydrocannabinols, synthetic equivalents of the substances contained in the plant, or in the resinous extractives of *Cannabis*, specifically, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

- (i) Delta 1 - cis - or trans tetrahydrocannabinol, and their optical isomers, excluding dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration;
- (ii) Delta 6 - cis - or trans tetrahydrocannabinol, and their optical isomers;
- (iii) Delta 3.4 - cis - or trans tetrahydrocannabinol, and its optical isomers; (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(22) Ethylamine analog of phencyclidine: Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl)ethylamine; cyclohexamine; PCE;

(23) Pyrrolidine analog of phencyclidine: Some trade or other names: 1-(1-phenylcyclohexyl)pyrrolidine; PCPy; PHP;

(24) Thiophene analog of phencyclidine: Some trade or other names: 1-(1-[2-thenyl]-cyclohexyl)-piperidine; 2-thienylanalog of phencyclidine; TCP; TCP;

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of mecloqualone having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

- (i) Mecloqualone;
- (ii) Methaqualone.

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

- (i) Fenethyline;
- (ii) N-ethylamphetamine.

[Statutory Authority: RCW 65.50.201 [69.50.201]. 86-16-057 (Order 200), § 360-36-410, filed 8/1/86. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-410, filed 11/7/84.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency and appear herein pursuant to the requirements of RCW 34.08.040.

WAC 360-36-411 Adding MPPP to Schedule I. The Washington state board of pharmacy finds that 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-411, filed 9/4/85.]

WAC 360-36-412 Adding PEPAP to Schedule I. The Washington state board of pharmacy finds that 1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-412, filed 9/4/85.]

WAC 360-36-413 Adding MDMA to Schedule I. The Washington state board of pharmacy finds that 3,4-methylenedioxymethamphetamine (MDMA) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

[Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-413, filed 9/4/85.]

WAC 360-36-420 Schedule II. The board finds that the following substances have a high potential for abuse and have currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions and that the abuse of the following substances may lead to severe psychic or psychological dependence. The board, therefore, places each of the following substances in Schedule II.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule II.

(b) Substances. (Vegetable origin or chemical synthesis.) Unless specifically excepted, any of the following substances, except those listed in other schedules,

whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, naloxone, and naltrexone, and their respective salts, but including the following:

- (i) Raw opium;
- (ii) Opium extracts;
- (iii) Opium fluid extracts;
- (iv) Powdered opium;
- (v) Granulated opium;
- (vi) Tincture of opium;
- (vii) Codeine;
- (viii) Ethylmorphine;
- (ix) Etorphine hydrochloride;
- (x) Hydrocodone;
- (xi) Hydromorphone;
- (xii) Metopon;
- (xiii) Morphine;
- (xiv) Oxycodone;
- (xv) Oxymorphone; and
- (xvi) Thebaine.

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b)(1) of this section, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (The crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy.)

(c) Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

- (1) Alphaprodine;
- (2) Anileridine;
- (3) Bezitramide;
- (4) Bulk dextropropoxyphene (nondosage forms);
- (5) Dihydrocodeine;
- (6) Diphenoxylate;
- (7) Fentanyl;
- (8) Isomethadone;
- (9) Levomethorphan;
- (10) Levorphanol;
- (11) Metazocine;
- (12) Methadone;
- (13) Methadone—Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

(14) Moramide—Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;

(15) Pethidine (meperidine);

(16) Pethidine—Intermediate—A, 4-cyano-1-methyl-4-phenylpiperidine;

(17) Pethidine—Intermediate—B, ethyl-4-phenylpiperidine-4-carboxylate;

(18) Pethidine—Intermediate—C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(19) Phenazocine;

(20) Piminodine;

(21) Racemethorphan;

(22) Racemorphan;

(23) Sufentanil.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) Methamphetamine, its salts, isomers, and salts of its isomers;

(3) Phenmetrazine and its salts;

(4) Methylphenidate.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital;

(2) Pentobarbital;

(3) Phencyclidine;

(4) Phencyclidine immediate precursors;

(i) 1-phenylcyclohexylamine;

(ii) 1-piperidinocyclohexanecarbonitrile (PCC);

(5) Secobarbital.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(2) Phenylacetone: Some trade or other names phenyl-2-propanone, P2P, benzyl methyl ketone, methyl benzyl ketone.

(3) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine;

(ii) 1-piperidinocyclohexanecarbonitrile (PCC).

(g) Hallucinogenic substances. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product. (Some other names for dronabinol [6aR-trans]-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-i-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.)

[Statutory Authority: RCW 65.50.201 [69.50.201]. 86-16-057 (Order 200), § 360-36-420, filed 8/1/86. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-420, filed 11/7/84.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency and appear herein pursuant to the requirements of RCW 34.08.040.

WAC 360-36-430 Schedule III. The board finds that the following substances have a potential for abuse less than the substances listed in Schedules I and II, and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to moderate or low physical dependency or high psychological dependency. The board, therefore, places each of the following substances in Schedule III.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations are referred to as excepted compounds in Schedule III as published in 21 CFR 1308.13(b)(1) as of April 1, 1984, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances;

(2) Benzphetamine;

(3) Chlorphentermine;

(4) Clortermine;

(5) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing:

(i) Amobarbital;

(ii) Secobarbital;

(iii) Pentobarbital;

or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;

(2) Any suppository dosage form containing:

(i) Amobarbital;

(ii) Secobarbital;

(iii) Pentobarbital;

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid;

- (4) Chlorhexadol;
- (5) Glutethimide;
- (6) Lysergic acid;
- (7) Lysergic acid amide;
- (8) Methyprylon;
- (9) Sulfondiethylmethane;
- (10) Sulfonethylmethane;
- (11) Sulfonmethane.

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof calculated as the free anhydrous base or alkaloid, in limited quantities as set forth in paragraph (e) of this section:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) Not more than 300 milligrams of dihydrocodeine per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

(4) Not more than 300 milligrams of dihydrocodeine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

[Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-430, filed 11/7/84.]

WAC 360-36-440 Schedule IV. The board finds that the following substances have a low potential for abuse relative to substances in Schedule III and have currently accepted medical use in treatment in the United States and that the abuse of the substances may

lead to limited physical dependence or psychological dependence relative to the substances in Schedule III. The board, therefore, places each of the following substances in Schedule IV.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule IV.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)- ϵ -dimethylamino-1,2-diphenyl-3-methyl-2 propionoxybutane).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Alprazolam;
- (2) Barbitol;
- (3) Chloral betaine;
- (4) Chloral hydrate;
- (5) Chlordiazepoxide;
- (6) Clonazepam;
- (7) Clorazepate;
- (8) Diazepam;
- (9) Ethchlorvynol;
- (10) Ethinamate;
- (11) Flurazepam;
- (12) Halazepam;
- (13) Lorazepam;
- (14) Mebutamate;
- (15) Meprobamate;
- (16) Methohexital;
- (17) Methylphenobarbital (mephobarbital);
- (18) Oxazepam;
- (19) Paraldehyde;
- (20) Petrichloral;
- (21) Phenobarbital;
- (22) Prazepam;
- (23) Temazepam;
- (24) Triazolam.

(d) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position or geometric), and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible.

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers

(whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Diethylpropion;
- (2) Mazindol;
- (3) Pemoline (including organometallic complexes and chelates thereof);
- (4) Phentermine;
- (5) Pipradrol;
- (6) SPA ((-)-1-dimethylamino-1, 2-dephenylethane.
- (f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:

- (1) Pentazocine.

[Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-440, filed 11/7/84.]

WAC 360-36-450 Schedule V. The board finds that the following substances have low potential for abuse relative to substances in Schedule IV and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. The board, therefore, places each of the following substances in Schedule V.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth in this section, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

[Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. 84-22-062 (Order 190), § 360-36-450, filed 11/7/84.]

WAC 360-36-451 Adding buprenorphine to Schedule V. The Washington state board of pharmacy finds that buprenorphine has a low potential for abuse relative to substances in Schedule IV; has currently accepted medical use in treatment in the United States; and the substance has limited physical dependence or psychological dependence liability relative to the substances in Schedule IV, and hereby places that substance in Schedule V.

[Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-36-451, filed 9/4/85.]

Chapter 360-40 WAC PROPHYLACTICS

WAC

360-40-010	Definitions.
360-40-040	Sale of condoms prohibited.
360-40-070	Condom standards.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-40-020	Application for license. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-020, filed 12/17/82.] Repealed by 85-06-010 (Order 193), filed 2/22/85. Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730].
360-40-030	Display of licenses and identification. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-030, filed 12/17/82.] Repealed by 85-06-010 (Order 193), filed 2/22/85. Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730].
360-40-050	List of approved condoms. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-050, filed 12/17/82.] Repealed by 85-06-010 (Order 193), filed 2/22/85. Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730].
360-40-060	Submission of condoms for testing. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-060, filed 12/17/82.] Repealed by 85-06-010 (Order 193), filed 2/22/85. Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730].
360-40-080	Suspension or revocation of prophylactic licenses. [Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-080, filed 12/17/82.] Repealed by 85-06-010 (Order 193), filed 2/22/85. Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730].

WAC 360-40-010 Definitions. (1) The following definitions shall be applicable to these rules.

(1) "Board" shall mean the Washington state board of pharmacy;

(2) "Condom" shall mean a prophylactic consisting of a very thin sheath designed to be placed over the penis to prevent conception or venereal disease during coitus, and is commonly made of rubber, parchment skins, plastic or similar materials;

(3) "Prophylactic" shall mean any device or medical preparation or compound which is or may be used, designed, intended or which has or may have special utility, for the prevention and/or treatment of venereal diseases;

(4) "Sell" and "sale" shall, in addition to their usual and ordinary meanings, include possession in violation of the intent of this chapter, exchange, give away or gift, or any disposal.

[Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730]. 85-06-010 (Order 193), § 360-40-010, filed 2/22/85. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-010, filed 12/17/82; Order 108, § 360-40-010, filed 10/26/71.]

WAC 360-40-040 Sale of condoms prohibited. No condoms shall be sold in this state unless the following conditions are met:

(1) All condoms shall be individually sealed in plastic, foil or a comparable type seal to protect the product from deterioration due to exposure to air.

(2) The container in which the condom is sold to the purchaser shall bear the date of manufacture and the condom may not be sold in this state three years after the date of manufacture.

[Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730]. 85-06-010 (Order 193), § 360-40-040, filed 2/22/85. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-040, filed 12/17/82.]

WAC 360-40-070 Condom standards. All condoms shall meet the following standards:

(1) Rubber condoms (elastic material) shall be capable of withstanding inflation with one cubic foot of air. They shall be free from holes, imperfect rings and blisters.

(2) Nonrubber condoms (nonelastic material) shall be of suitable length, not patched, and shall be free from grease or any foreign substances that may be used as a filler for hiding imperfections or discolorations.

[Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730]. 85-06-010 (Order 193), § 360-40-070, filed 2/22/85. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-40-070, filed 12/17/82.]

Chapter 360-44 WAC

PUBLIC RECORDS ACCESS PURSUANT TO INITIATIVE 276

WAC	Purpose.
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360-44-040	Operations and procedures.
360-44-050	Public records available.
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360-44-080	Requests for public records.
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360-44-120	Protection of public records.
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360-44-140	Address where requests to be directed.
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WAC 360-44-010 Purpose. The purpose of this chapter shall be to ensure compliance by the

Washington state board of pharmacy with the provisions of chapter 1, Laws of 1973 (Initiative 276), Disclosure—Campaign finances—Lobbying—Records; and in particular with sections 25-32 of that act, dealing with public records.

[Order 113, § 360-44-010, filed 4/27/73.]

WAC 360-44-020 Definitions. (1) "Public record" includes any writing containing information relating to the conduct of government or the performance of any governmental or proprietary function prepared, owned, used or retained by any state or local agency regardless of physical form or characteristics.

(2) "Writing" means handwriting, typewriting, printing, photostating, photographing and every other means of recording any form of communication or representation, including letters, words, pictures, sounds, or symbols or combination thereof, and all papers, maps, magnetic or paper tapes, photographic films and prints, magnetic or punched cards, discs, drums and other documents.

(3) The "Washington state board of pharmacy" is the board whose members are appointed by the governor, pursuant to RCW 18.64.001. The Washington state board of pharmacy shall hereinafter be referred to as the "board." Where appropriate, the term "board" also refers to the staff and employees of the Washington state board of pharmacy.

[Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-44-020, filed 12/17/82; Order 113, § 360-44-020, filed 4/27/73.]

WAC 360-44-030 Description of central and field organization of the board. The board is a drug control agency. The administrative office of the board and its staff are located at 319 East 7th Avenue, Olympia, Washington 98504.

[Order 113, § 360-44-030, filed 4/27/73.]

WAC 360-44-040 Operations and procedures. (1) The board of pharmacy consists of five members, one of whom is designated as a chairman. The members are appointed by the governor for staggered four year terms.

(2) The board meets approximately once a month in various places throughout the state. The time and place of the meeting can be learned by writing or calling the administrative office of the board.

(3) The executive secretary is the board's chief executive. He is responsible for carrying out the board's directions and for directing the board's staff.

(4) It is the board's duty to administer the law in chapters 18.64, 18.64A, 18.81, 69.04, 69.40, 69.41, 69.50, and 70.54 RCW.

(a) Chapter 18.64 RCW - Pharmacy Act - creation of board of pharmacy, definition of terms used in pharmacy act, examination and licensing of pharmacists, interns, wholesalers, shopkeepers and vendors, grounds for license suspension or revocation, unlawful practices, prescription labels and records.

(b) Chapter 18.64A RCW - Pharmacy Assistants Law - creation of pharmacy assistants, definition of

terms, regulation of classifications and services, limitations on practice, grounds for certificate suspension or revocation, applications, fees, employment of pharmacy assistants, and pharmacists liability and responsibility.

(c) Chapter 18.81 RCW – Prophylactic Law – regulation and licensing of prophylactics and distributors.

(d) Chapter 69.04 RCW – Food, Drug and Cosmetic Act. Board has joint responsibility with director of department of agriculture. Board regulates only the drug and devices portion of the act. DMSO sales and use provisions are contained in this law.

(e) Chapter 69.40 RCW – Poison Act – labeling of drugs incorrectly and selling poisons without labeling.

(f) Chapter 69.41 RCW – Legend Drug Act – definition of terms, prohibited acts, regulation of sale, delivery, or possession of legend drugs, requirements for prescriptions and labels, search and seizure procedures. Penalties for violations are created and rules regarding legend drugs are authorized. The procedures and requirements for substitution of legend drugs, manufacturing standards and liability of pharmacists are outlined. Requirements for identification and labeling marking of legend drugs are created.

(g) Chapter 69.50 RCW – Controlled Substances Act – places all narcotics, barbiturates, amphetamines, hallucinogenics and marijuana into five schedules. Sets standards and definitions for the five schedules. Regulates the manufacture, distribution and dispensing of controlled substances. Sets forth offenses, penalties and prohibited acts. Enforcement and administrative provisions include administrative and criminal search warrants.

(h) Chapter 70.54 RCW – Laetrile – board given authority to sample and test laetrile and promulgate rules regarding it.

(5) Information concerning all licenses or registrations issued by the board may be obtained by writing or calling the administrative office of the board.

[Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. 83-01-083 (Order 171), § 360-44-040, filed 12/17/82; Order 113, § 360-44-040, filed 4/27/73.]

WAC 360-44-050 Public records available. All public records of the board, as defined in WAC 360-44-020 are deemed to be available for public inspection and copying pursuant to these rules, except as otherwise provided by section 31, chapter 1, Laws of 1973 and WAC 360-44-100.

[Order 113, § 360-44-050, filed 4/27/73.]

WAC 360-44-060 Public records officer. The board's public records shall be in the charge of the public records officer designated by the board. The person so designated shall be located in the administrative office of the board. The public records officer shall be responsible for the following: The implementation of the board's rules and regulations regarding release of public records, coordinating the staff of the board in this regard, and generally insuring compliance by the staff with the public records disclosure requirements of chapter 1, Laws of 1973.

(1986 Ed.)

[Order 113, § 360-44-060, filed 4/27/73.]

WAC 360-44-070 Office hours. Public records shall be available for inspection and copying during the customary hours of the board. For the purposes of this chapter, the customary office hours shall be from 9 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday, excluding legal holidays.

[Order 113, § 360-44-070, filed 4/27/73.]

WAC 360-44-080 Requests for public records. In accordance with requirements of chapter 1, Laws of 1973 that agencies prevent unreasonable invasions of privacy, protect public records from damage or disorganization, and prevent excessive interference with essential functions of the agency, public records may be inspected or copied or copies of such records may be obtained, by members of the public, upon compliance with the following procedures:

(1) A request shall be made in writing upon a form prescribed by the board which shall be available at its administrative office. The form shall be presented to the public records officer; or to any member of the board's staff, if the public records officer is not available, at the administrative office of the board during customary office hours. The request shall include the following information:

(a) The name of the person requesting the record;

(b) The time of day and calendar date on which the request was made;

(c) The nature of the request;

(d) If the matter requested is referenced within the current index maintained by the records officer, a reference to the requested record as it is described in such current index;

(e) If the requested matter is not identifiable by reference to the board's current index, an appropriate description of the record requested.

(2) In all cases in which a member of the public is making a request, it shall be the obligation of the public records officer or staff member to whom the request is made, to assist the member of the public in appropriately identifying the public record requested.

[Order 113, § 360-44-080, filed 4/27/73.]

WAC 360-44-090 Copying. No fee shall be charged for the inspection of public records. The board shall charge a fee of twenty-five cents per page of copy for providing copies of public records and for the use of the board's copy equipment. This charge is the amount necessary to reimburse the board for its actual costs incident to such copying. The copy machine will be operated by staff persons only.

[Order 113, § 360-44-090, filed 4/27/73.]

WAC 360-44-100 Exemptions. (1) The board reserves the right to determine that a public record requested in accordance with the procedures outlined in WAC 360-44-080 is exempt under provisions of section 31, chapter 1, Laws of 1973.

[Title 360 WAC—p 49]

(2) In addition, pursuant to section 26, chapter 1, Laws of 1973, the board reserves the right to delete identifying details when it makes available or publishes any public record, in any cases when there is reason to believe that disclosure of such details would be an invasion of personal privacy protected by chapter 1, Laws of 1973. The public records officer will fully justify such deletion in writing.

(3) All denials of requests for public records must be accompanied by a written statement specifying the reason for the denial, including a statement of the specific exemption authorizing the withholding of the record and a brief explanation of how the exemption applies to the record withheld.

[Order 113, § 360-44-100, filed 4/27/73.]

WAC 360-44-110 Review of denials of public records requests. (1) Any person who objects to the denial of a request for a public record may petition for prompt review of such decision by tendering a written request for review. The written request shall specifically refer to the written statement by the public records officer or other staff member which constituted or accompanied the denial.

(2) Immediately after receiving a written request for review of a decision denying a public record, the public records officer or other staff member denying the request shall refer it to the executive secretary of the board. The executive secretary shall immediately consider the matter and either affirm or reverse such denial or call a special meeting of the board as soon as legally possible to review the denial. In any case, the request shall be returned with a final decision, within two business days following the original denial.

(3) Administrative remedies shall not be considered exhausted until the board has returned the petition with a decision or until the close of the second business day following denial of inspection, whichever occurs first.

[Order 113, § 360-44-110, filed 4/27/73.]

WAC 360-44-120 Protection of public records. No record shall be removed from the board office except by written permission of the public records officer under such conditions as are required to protect the records from damage or disorganization. No record may be marked, folded or damaged in any way nor may any record be removed from any file to which it is attached nor may the record's filing order be damaged in any way.

[Order 113, § 360-44-120, filed 4/27/73.]

WAC 360-44-130 Index of public records available. (1) The board has available to all persons:

- (a) A current index which provides identifying information concerning all licenses issued by the board;
- (b) A current index to all rules and regulations adopted by the board;
- (c) A current list of the results of all scientific tests of prophylactics conducted by the board.

[Title 360 WAC—p 50]

(2) Final orders in the adjudication of cases are filed in the investigative file of the subject licensee.

(3) Correspondence and materials referred to therein by and with the board relating to any regulatory, supervisory or enforcement responsibilities of the agency, whereby the agency determines, or opines upon, or is about to determine or opine upon, the rights of the state, the public, a subdivision of state government, or of any private party is filed chronologically, with one copy also filed in a licensee's file, if applicable.

(4) The board has determined that it would be unduly burdensome to maintain an index, except as set forth herein, due to fiscal and personnel limitations and to the general nature and large volume of correspondence of the board.

(5) The board shall not give, sell or provide access to lists of individuals requested for commercial purposes.

[Order 113, § 360-44-130, filed 4/27/73.]

WAC 360-44-140 Address where requests to be directed. All communications with the board including but not limited to the submission of materials pertaining to its operations and/or the administration or enforcement of chapter 1, Laws of 1973 and these rules; requests for copies of the board's decisions and other matters, shall be addressed as follows: Washington State Board of Pharmacy, c/o Public Records Officer, 319 East 7th Avenue, Olympia, Washington 98504.

[Order 113, § 360-44-140, filed 4/27/73.]

WAC 360-44-150 Adoption of form. The board hereby adopts for use by all persons requesting inspection and/or copying or copies of its records, the form attached hereto as Appendix A entitled "Request for public record."

[Order 113, § 360-44-150, filed 4/27/73.]

WAC 360-44-990 Appendix A--Form.

WASHINGTON STATE BOARD OF PHARMACY
319 East Seventh Avenue — WEA Bldg.
Olympia, Washington 98504

REQUEST FOR PUBLIC RECORDS

1. -----
Name

Street City State Zip
2. ----- day of ----- 19-- at ----- O'clock -----
Date and Time of Request
3. Nature of Request:

4. Current Index Reference -----

- 5. Record Description if not Indexed -----

- 6. Signature of Requestor -----

FOR AGENCY USE ONLY

Received by ----- Staff Time Expended -----
Request: Time Completed -----
No. Pages Copied ----- @25¢ a copy — Total -----

[Order 113, Appendix A (codified as WAC 360-44-990), filed 4/27/73.]

**Chapter 360-45 WAC
STATE ENVIRONMENTAL POLICY ACT
EXEMPTION**

WAC
360-45-010 SEPA exemption.

WAC 360-45-010 SEPA exemption. The board of pharmacy has reviewed its authorized activities and has found them to be exempt pursuant to WAC 197-10-040(2), 197-10-150 through 197-10-190 and the State Environmental Policy Act, chapter 43.21C RCW.

[Order 128, § 360-45-010, filed 5/19/76.]

**Chapter 360-46 WAC
GOOD MANUFACTURING PRACTICE FOR
FINISHED PHARMACEUTICALS**

WAC
360-46-010 Definitions.
360-46-020 Finished pharmaceuticals—Manufacturing practice.
360-46-030 Personnel.
360-46-040 Buildings or facilities.
360-46-050 Equipment.
360-46-060 Production and control procedures.
360-46-070 Components.
360-46-080 Product containers and their packaging material.
360-46-090 Laboratory controls.
360-46-100 Stability.
360-46-110 Expiration dating.
360-46-120 Packaging and labeling.
360-46-130 Master production and control records—Batch production and control records.
360-46-140 Distribution records.
360-46-150 Complaint files.

WAC 360-46-010 Definitions. (1) As used in these regulations, "act" means the Uniform Food, Drug and Cosmetic Act, chapter 69.04 RCW.

(2) The definitions and interpretations contained in the act shall be applicable to such terms used in these regulations.

(3) As used in these regulations:

(a) The term "component" means any ingredient intended for use in the manufacture of drugs in dosage

form, including those that may not appear in the finished product.

(b) The term "batch" means a specific quantity of a drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(c) The term "lot" means a batch or any portion of a batch of a drug or, in the case of a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality within specified limits.

(d) The terms "lot number" or "control number" mean any distinctive combination of letters, numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a batch or lot of drug can be determined.

(e) The term "active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term shall include those components which may undergo chemical change in the manufacture of the drug and be present in the finished drug product in a modified form intended to furnish the specified activity or effect.

(f) The term "inactive ingredient" means any component other than an "active ingredient" present in a drug.

(g) The term "materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

(h) The term "strength" means:

(i) The concentration of the drug substance (for example, w/w, w/v, or unit dose/volume basis) and/or

(ii) The potency, that is, the therapeutic activity of the drug substance as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

[Order 133, § 360-46-010, filed 8/4/77.]

WAC 360-46-020 Finished pharmaceuticals—Manufacturing practice.

(1) The criteria in WAC 360-46-040 through 360-46-150, inclusive, shall apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug conform to or are operated or administered in conformity with current good manufacturing practice to assure that a drug meets the requirements of the act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess as required by the act.

(2) The regulations in this part permit the use of precision automatic, mechanical, or electronic equipment in

the production and control of drugs when adequate inspection and checking procedures are used to assure proper performance.

[Order 133, § 360-46-020, filed 8/4/77.]

WAC 360-46-030 Personnel. (1) The personnel responsible for directing the manufacture and control of the drug shall be adequate in number and background of education, training, and experience, or combination thereof, to assure that the drug has the safety, identity, strength, quality, and purity that it purports to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing or control operations they perform, the necessary training or experience, and adequate information concerning the reason for application of pertinent provisions of this part to their respective functions.

(2) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drugs shall be excluded from direct contact with drug products until the condition is corrected. All employees shall be instructed to report to supervisory personnel any conditions that may have such an adverse effect on drug products.

[Order 133, § 360-46-030, filed 8/4/77.]

WAC 360-46-040 Buildings or facilities. Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operations in the manufacturing, processing, packing, labeling, or holding of a drug. The buildings shall:

(1) Provide adequate space for:

(a) Orderly placement of equipment and materials to minimize any risk of mixups between different drugs, drug components, in-process materials, packaging materials, or labeling, and to minimize the possibility of contamination.

(b) The receipt, storage, and withholding from use of components pending sampling, identification, and testing prior to release by the materials approval unit for manufacturing or packaging.

(c) The holding of rejected components prior to disposition to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable.

(d) The storage of components, containers, packaging materials, and labeling.

(e) Any manufacturing and processing operations performed.

(f) Any packaging or labeling operations.

(g) Storage of finished products.

(h) Control and production-laboratory operations.

(2) Provide adequate lighting, ventilation, and screening and, when necessary for the intended production or control purposes, provide facilities for adequate air-pressure, microbiological, dust humidity, and temperature controls to:

(a) Minimize contamination of products by extraneous adulterants, including cross-contamination of one

product by dust or particles of ingredients arising from the manufacture, storage, or handling of another product.

(b) Minimize dissemination of micro-organisms from one area to another.

(c) Provide suitable storage conditions for drug components, in-process materials, and finished drugs in conformance with stability information as derived under WAC 360-46-100.

(3) Provide adequate locker facilities and hot and cold water washing facilities, including soap or detergent, air drier or single service towels, and clean toilet facilities near working areas.

(4) Provide an adequate supply of potable water under continuous positive pressure in a plumbing system free of defects that could cause or contribute to contamination of any drug. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

(5) Provide suitable housing and space for the care of all laboratory animals.

(6) Provide for safe and sanitary disposal of sewage, trash, and other refuse within and from the buildings and immediate premises.

[Order 133, § 360-46-040, filed 8/4/77.]

WAC 360-46-050 Equipment. Equipment used for the manufacture, processing, packing, labeling, holding, testing, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate cleaning, maintenance, and operation for its intended purpose. The equipment shall:

(1) Be so constructed that all surfaces that come into contact with a drug product shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(2) Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not contact drug products so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(3) Be constructed and installed to facilitate adjustment, disassembly cleaning and maintenance to assure the reliability of control procedures, uniformity of production and exclusion from the drugs of contaminants from previous and current operations that might affect the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(4) Be of suitable type, size and accuracy for any testing, measuring, mixing, weighing, or other processing or storage operations.

[Order 133, § 360-46-050, filed 8/4/77.]

WAC 360-46-060 Production and control procedures. Production and control procedures shall include all reasonable precautions, including the following, to

assure that the drugs produced have the safety, identity, strength, quality, and purity they purport to possess:

(1) Each significant step in the process, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, weighing and measuring during various stages of the processing, and the determination of the finished yield, shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or if such steps in the processing are controlled by precision automatic, mechanical, or electronic equipment, their proper performance is adequately checked by one or more competent individuals. The written record of the significant steps in the process shall be identified by the individual performing these tests and by the individual charged with checking these steps. Such identifications shall be recorded immediately following the completion of such steps.

(2) All containers, lines, and equipment used during the production of a batch of a drug shall be properly identified at all times to accurately and completely indicate their contents and, when necessary, the stage of processing of the batch.

(3) To minimize contamination and prevent mixups, equipment, utensils, and containers shall be thoroughly and appropriately cleaned and properly stored and have previous batch identification removed or obliterated between batches or at suitable intervals in continuous production operations.

(4) Appropriate precautions shall be taken to minimize microbiological and other contamination in the production of drugs purporting to be sterile or which by virtue of their intended use should be free from objectionable micro-organisms.

(5) Appropriate procedures shall be established to minimize the hazard of cross-contamination of any drugs while being manufactured or stored.

(6) To assure the uniformity and integrity of products, there shall be adequate in-process controls, such as checking the weights and disintegration times of tablets, the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions. In-process sampling shall be done at appropriate intervals using suitable equipment.

(7) Representative samples of all dosage form drugs shall be tested to determine their conformance with the specifications for the product before distribution.

(8) Procedures shall be instituted whereby review and approval of all production and control records, including packaging and labeling, shall be made prior to the release or distribution of a batch. A thorough investigation of any unexplained discrepancy or the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has already been distributed. This investigation shall be undertaken by a competent and responsible individual and shall extend to other batches of the same drug and other drugs that may have been associated with the specific failure. A written record of the investigation shall be made and shall include the conclusions and followup.

(9) Returned goods shall be identified as such and held. If the conditions under which returned goods have

been held, stored, or shipped prior to or during their return, or the condition of the product, its container, carton, or labeling as a result of storage or shipping, cast doubt on the safety, identity, strength, quality, or purity of the drug, the returned goods shall be destroyed or subjected to adequate examination or testing to assure that the material meets all appropriate standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to stock, it may be reprocessed provided the final product meets all its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date, and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of paragraph (8) of this section.

(10) Filters used in the manufacture, processing, or packaging of components of drug products for parenteral injection in humans shall not release fibers into such products. No asbestos-containing or other fiber-releasing filter may be used in the manufacture, processing, or packaging of such products. Filtration, as needed, shall be through a non-fiber-releasing filter. For the purpose of this regulation a non-fiber-releasing filter is defined as a non-asbestos filter that, after any appropriate pretreatment, such as washing or flushing, will not continue to release fibers into the drug product or component that is being filtered. A fiber is defined as any particle with length at least three times greater than its width.

[Order 133, § 360-46-060, filed 8/4/77.]

WAC 360-46-070 Components. All components and other materials used in the manufacture, processing, and packaging of drug products, and materials necessary for building and equipment maintenance, upon receipt shall be stored and handled in a safe, sanitary, and orderly manner. Adequate measures shall be taken to prevent mixups and cross-contamination affecting drugs and drug products. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications and are released by a materials approval unit. Control of components shall include the following:

(1) Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals when indicated.

(2) An adequate number of samples shall be taken from a representative number of component containers from each lot and shall be subjected to one or more tests to establish the specific identity.

(3) Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.

(4) Representative samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with appropriate specifications.

(5) Representative samples of components liable to micro-biological contamination shall be subjected to

microbiological tests prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.

(6) Approved components shall be appropriately identified and retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality, and purity at time of use. This requires the following:

(a) Approved components shall be handled and stored to guard against contaminating or being contaminated by other drugs or components.

(b) Approved components shall be rotated in such a manner that the oldest stock is used first.

(c) Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

(7) Appropriate records shall be maintained, including the following:

(a) The identity and quantity of the component, the name of the supplier, the supplier's lot number, and the date of receipt.

(b) Examinations and tests performed and rejected components and their disposition.

(c) An individual inventory and record for each component used in each batch of drug manufactured or processed.

(8) An appropriately identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, shall be retained for at least two years after distribution of the last drug lot incorporating the component has been completed or one year after the expiration date of this last drug lot, whichever is longer.

[Order 133, § 360-46-070, filed 8/4/77.]

WAC 360-46-080 Product containers and their packaging material. Suitable specifications, test methods, cleaning procedures, and, when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use. Containers for parenteral drugs, drug products or drug components shall be cleansed with water which has been filtered through a non-fiber-releasing filter equivalent to that indicated in WAC 360-46-060(10). Product containers and their components shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or established requirements and shall provide adequate protection against external factors that can cause deterioration or contamination of the drug.

[Order 133, § 360-46-080, filed 8/4/77.]

WAC 360-46-090 Laboratory controls. Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality and purity. Laboratory controls shall include:

(1) The establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers, and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such records shall also provide for appropriate retesting of drug components, product containers, and their components subject to deterioration.

(2) A reserve sample of all active ingredients as required by WAC 360-46-070(2).

(3) The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process drug preparations. Such samples shall be adequately representative and properly identified.

(4) The establishment of master records containing a description of sampling procedures and appropriate specifications for finished drug products. Such samples shall be adequately representative and properly identified.

(5) Adequate provisions for checking the identity and strength of drug products for all active ingredients and for assuring:

(a) Sterility of drugs purported to be sterile and freedom from objectionable micro-organisms for those drugs which should be so by virtue of their intended use.

(b) The absence of pyrogens for those drugs purported to be pyrogen-free.

(c) Minimal contamination of ophthalmic ointments by foreign particles and harsh or abrasive substances.

(d) That the drug release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.

(6) Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.

(7) A properly identified reserve sample of the finished product (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least two years after the drug distribution has been completed or one year after the drug's expiration date, whichever is longer.

(8) Provision for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least two years after distribution has been completed or one year after the drug's expiration date, whichever is longer.

(9) Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.

(10) Provision that firms which manufacture nonpenicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products,

or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such nonpenicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration, or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.

[Order 133, § 360-46-090, filed 8/4/77.]

WAC 360-46-100 Stability. There shall be assurance of the stability of finished drug products. This stability shall be:

- (1) Determined by reliable, meaningful, and specific test methods.
- (2) Determined on products in the same container-closure system in which they are marketed.
- (3) Determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling), as well as on the reconstituted product.
- (4) Recorded and maintained in such manner that the stability data may be utilized in establishing product expiration dates.

[Order 133, § 360-46-100, filed 8/4/77.]

WAC 360-46-110 Expiration dating. To assure that drug products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use, the label of all such drugs shall have suitable expiration dates which relate to stability tests performed on the product.

- (1) Expiration dates appearing on the drug labeling shall be justified by readily available data from stability studies such as described in WAC 360-46-100.
- (2) Expiration dates shall be related to appropriate storage conditions stated on the labeling wherever the expiration date appears.
- (3) When the drug is marketed in the dry state for use in preparing a liquid product, the labeling shall bear expiration information for the reconstituted product as well as an expiration date for the dry product.

[Order 133, § 360-46-110, filed 8/4/77.]

WAC 360-46-120 Packaging and labeling. Packaging and labeling operations shall be adequately controlled: To assure that only those drug products that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mixups between drugs during filling, packaging, and labeling operations; to assure that correct labels and labeling are employed for the drug; and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. An hour, day, or

shift code is appropriate as a lot or control number for drug products manufactured or processed in continuous production equipment. Packaging and labeling operations shall:

(1) Be separated (physically or spatially) from operations on other drugs in a manner adequate to avoid mixups and minimize cross-contamination. Two or more packaging or labeling operations having drugs, containers, or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated either physically or spatially.

(2) Provide for an inspection of the facilities prior to use to assure that all drugs and previously used packaging and labeling materials have been removed.

(3) Include the following labeling controls:

(a) The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual to assure that they are accurate regarding identity, content, and conformity with the approved copy before release to inventory.

(b) The maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms, or quantity of contents in such a manner as to prevent mixups and provide proper identification.

(c) A suitable system for assuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.

(d) Restriction of access to labels and package labeling to authorized personnel.

(e) Avoidance of gang printing of cut labels, cartons, or inserts when the labels, cartons, or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format and/or color schemes. If gang printing is employed, packaging and labeling operations shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting, and handling during and after printing.

(4) Provide strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the batch production record. Said record shall identify the labeling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of drug finished and the quantities of labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In event of any significant unexplained discrepancy, an investigation should be carried out according to WAC 360-46-060(8).

(5) Provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all specified tests have been met.

[Order 133, § 360-46-120, filed 8/4/77.]

WAC 360-46-130 Master production and control records--Batch production and control records. (1) To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of drug product shall be prepared, dated, and signed or initialed by a competent and responsible individual and shall be independently checked, reconciled, dated, and signed or initialed by a second competent and responsible individual. The master production and control record shall include:

(a) The name of the product, description of the dosage form, and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialed and dated by the person or persons responsible for approval of such labeling.

(b) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished drug and a statement of the total weight or measure of any dosage unit.

(c) A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; and accurate statement of the weight or measure of each ingredient regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form provided that provisions for such variations are included in the master production and control record; an appropriate statement concerning any calculated excess of an ingredient; an appropriate statement of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

(d) A description of the containers, closures, and packaging and finishing materials.

(e) Manufacturing and control instructions, procedures, specifications special notations, and precautions to be followed.

(2) The batch production and control record shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two years after the batch distribution is complete or at least one year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch and shall be readily available during such retention period. The batch record shall include:

(a) An accurate reproduction of the appropriate master formula record checked, dated, and signed or initialed by a competent and responsible individual.

(b) A record of each significant step in the manufacturing, processing, packaging, labeling testing, and controlling of the batch, including: Dates; individual major equipment and lines employed; specific identification of each batch of components used; weights and measures of components and products used in the course of processing; in-process and laboratory control results; and identifications of the individual(s) actively performing and the individual(s) directly supervising or checking each significant step in the operation.

(c) A batch number that identifies all the production and control documents relating to the history of the batch and all lot or control numbers associated with the batch.

(d) A record of any investigation made according to WAC 360-46-060(8).

[Order 133, § 360-46-130, filed 8/4/77.]

WAC 360-46-140 Distribution records. (1) Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the drug. Records shall be retained for at least two years after the distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.

(2) To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest approved stock is distributed whenever possible.

[Order 133, § 360-46-140, filed 8/4/77.]

WAC 360-46-150 Complaint files. Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with WAC 360-46-060(8). The record of each investigation shall be maintained for at least two years after distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.

[Order 133, § 360-46-150, filed 8/4/77.]

Chapter 360-47 WAC AMYGDALIN (LAETRILE)

WAC	
360-47-010	Availability.
360-47-020	License.
360-47-030	License application.
360-47-040	Good manufacturing practices.
360-47-050	Identity.

WAC 360-47-010 Availability. Amygdalin (laetrile) shall be available in intrastate commerce to the citizens of the state of Washington in accordance with all applicable state laws and regulations. Amygdalin (laetrile) imported into the state of Washington shall be so imported in conformity with federal regulations and/or court decisions.

[Order 135, § 360-47-010, filed 10/5/77.]

WAC 360-47-020 License. Manufacturers and/or wholesale distributors of amygdalin (laetrile) shall be licensed by the state board of pharmacy, as provided in RCW 18.64.045.

[Order 135, § 360-47-020, filed 10/5/77.]

WAC 360-47-030 License application. Applications for the production of amygdalin (laetrile) for use pursuant to chapter 122, Laws of 1977, 1st ex. sess., shall be filed with the board of pharmacy. Such applications shall include:

- (1) A full list of the articles used as components of such drug;
- (2) A full statement of the composition of such drug;
- (3) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
- (4) Such samples of such drug and of the articles used as components thereof as the board may require; and
- (5) Specimen of the labeling proposed to be used for such drug. Labels must include the name of the drug (amygdalin or laetrile), its strength per unit, manufacturer's name and address, lot number, and expiration date, if any.

[Order 135, § 360-47-030, filed 10/5/77.]

WAC 360-47-040 Good manufacturing practices. Manufacturers of amygdalin (laetrile) shall conform to the standards for good manufacturing practices of finished pharmaceuticals, as provided in WAC 360-46-010 through 360-46-150.

[Order 135, § 360-47-040, filed 10/5/77.]

WAC 360-47-050 Identity. Certification of batches of amygdalin (laetrile) shall be made under the direction of the state board of pharmacy, with the costs for required testing, including purity and potency, to be borne by the manufacturer and/or wholesale distributor. The manufacturer and/or wholesale distributor shall be held totally responsible for the quality of the drug product, in accordance with RCW 18.64.270.

[Order 135, § 360-47-050, filed 10/5/77.]

Chapter 360-48 WAC DIMETHYL SULFOXIDE (DMSO)

WAC	
360-48-010	Availability.
360-48-020	License.
360-48-030	License application.
360-48-040	Good manufacturing practices.
360-48-050	Purity.
360-48-060	Contents.
360-48-070	Labeling.
360-48-080	Other forms of DMSO.

WAC 360-48-010 Availability. DMSO for topical use (i.e., for application to the skin) shall be available in intrastate commerce to the citizens of the state of Washington in accordance with all applicable state laws and regulations.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-010, filed 11/2/81.]

(1986 Ed.)

WAC 360-48-020 License. Manufacturers and/or wholesale distributors of DMSO must have a license issued by the state board of pharmacy, as provided in RCW 18.64.045 and/or RCW 18.64.046.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-020, filed 11/2/81.]

WAC 360-48-030 License application. Applications for the manufacture of DMSO for use pursuant to chapter 69.04 RCW shall be filed with the board of pharmacy. Such applications shall include:

- (1) A full list of the articles used as components of such drug;
- (2) A full statement of the composition of such drug;
- (3) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing in such drug;
- (4) Such samples of such drug and of the articles used as components thereof as the board may require; and
- (5) Specimen of the labeling proposed to be used for such drug;
- (6) Specific information under the following section headings and in the following order:
 - (a) Description.
 - (b) Clinical pharmacology.
 - (c) Indications and usage.
 - (d) Contraindications.
 - (e) Warnings.
 - (f) Precautions.
 - (g) Adverse reactions.
 - (h) Overdosage.
 - (i) Dosage and administration.
 - (j) How supplied.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-030, filed 11/2/81.]

WAC 360-48-040 Good manufacturing practices. Manufacturers of DMSO shall conform to the standards for good manufacturing practices of finished pharmaceuticals, as provided in WAC 360-46-010 through 360-46-150. Further, manufacturers shall comply with the state Food, Drug, and Cosmetic Act, chapter 69.04 RCW.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-040, filed 11/2/81.]

WAC 360-48-050 Purity. (1) Certification of batches of DMSO shall be made as required by the state board of pharmacy, with the costs for required testing, including purity and potency, to be borne by the manufacturer and/or wholesale distributor. The manufacturer and/or wholesale distributor shall be held totally responsible for the quality of the drug product, in accordance with RCW 18.64.270.

Such batch testing shall be required upon commencement of manufacture of DMSO and thereafter as the state board of pharmacy shall require.

(2) DMSO shall be packaged in tightly closed light resistant glass containers. Such containers, including lids, caps, or other closures, shall have been tested by the DMSO manufacturer and shown not to interact with the

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contents. Such test results must be submitted to the state board of pharmacy upon request.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-050, filed 11/2/81.]

WAC 360-48-060 Contents. DMSO made available to the public for topical use, must contain purified dimethyl sulfoxide (meeting or exceeding FDA approved drug grade) and in addition may contain one or more of the following ingredients:

- Carboxypolymethylene (pharmaceutical grade)
- Sodium Carbonate, USP
- Sodium Chloride, USP
- Urea, USP
- Purified water, USP

Any batch found to contain any ingredient not on the above list shall result in the product being declared to be adulterated in accordance with RCW 69.04.430.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-060, filed 11/2/81.]

WAC 360-48-070 Labeling. (1) The labeling of topical DMSO shall include the following:

(a) The name and place of business of the manufacturer, the packer, and the distributor. (Each one must appear and be identified.)

(b) Adequate directions for use under which a lay person can safely use the drugs, including "Warning -Be sure that the skin is clean before using this product."

(c) Statements of those conditions, purposes, or uses for which such drug is intended, recommended, or suggested in any oral, written, printed, or graphic advertising, except that no such statement shall refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(d) The dosage for each of the uses for which it is intended and usual quantities for persons of different physical conditions.

(e) Frequency of application.

(f) Duration of application.

(g) The proprietary name of the drug.

(h) The established name of the drug.

(i) An identifying lot or control number.

(j) The date of manufacture.

(k) The strength of the solution expressed as a percentage weight in volume at 68°F. (20°C.).

(l) Net contents of container.

(m) Warnings: The labeling shall describe serious adverse reactions and potential safety hazards, limitations in use, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with the drug; a casual relationship need not have been provided. In addition to any warning labeling developed by the manufacturer, all immediate containers of DMSO must prominently show the following warnings:

- (i) "FOR EXTERNAL USE ONLY"
- (ii) "Warning -Use only as directed. Keep out of reach of children."
- (iii) "Caution -Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes."
- (iv) "Caution -If symptoms persist for more than 10 days, consult a physician."
- (v) "In conditions affecting children under 6 years of age consult a physician."
- (vi) "In case of accidental ingestion, contact a physician immediately."
- (vii) "There is no evidence that this product may be safely used by pregnant women or nursing mothers."
- (viii) "Warning -Be sure that skin is clean before using this product, which is a powerful solvent. Grease, chemicals, or any other substance could be absorbed into the skin along with the DMSO."

(o) Disclaimer. Each label must state:

"DMSO has not been approved under federal law for use in interstate commerce in the treatment of any condition or disease state in humans other than interstitial cystitis. Testing for safety and efficacy has not been performed by any agency of the state of Washington. Persons using this product do so at their own risk."

(p) Label locations. The immediate container label must show items: a, b, e, g, h, i, j, k, l, m, i, ii, and v. All other information specified in this section shall be shown in the patient package insert which must be attached to the container when sold.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-070, filed 11/2/81.]

WAC 360-48-080 Other forms of DMSO. The board of pharmacy hereby declares that all forms of DMSO intended for medical use, for other than topical application, are legend drugs as defined in chapter 69.41 RCW.

Such other forms shall meet all of the other requirements of this chapter.

[Statutory Authority: RCW 69.41.075 and 1981 c 50 § 1. 81-22-048 (Order 164), § 360-48-080, filed 11/2/81.]

Chapter 360-49 WAC DRUG PRODUCT SUBSTITUTION

WAC

- 360-49-010 Dispensing responsibilities.
- 360-49-020 Product selection responsibilities.
- 360-49-040 Manufacturers, wholesalers, distributors, pharmacy location, requirement that drug products offered for sale comply with 21 USC 355—Immediate suspension and subsequent revocation of licenses authorized for violation.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

- 360-49-030 Manufacturer requirements. [Order 143, § 360-49-030, filed 12/9/77.] Repealed by 79-12-063 (Order 152), filed 11/29/79. Statutory Authority: RCW 69.41.180.

WAC 360-49-010 Dispensing responsibilities. When the pharmacist dispenses, with the practitioner's authorization, a therapeutically equivalent drug product, the following information shall be noted:

(a) On oral prescriptions, the pharmacist shall indicate on the permanent prescription record, if substitution is permitted.

(b) The manufacturer or distributor of the drug product actually dispensed or its national drug code number or short name code or trade name shall be noted on the permanent record, or on the patient medication record if this document is utilized for providing and recording refills. This requirement shall also apply to refill prescriptions when a different distributor or manufacturer's product is used.

(c) The generic or trade name of the drug actually dispensed shall be noted on the prescription label or package label. For combination drug products, the generic names of the drugs combined or the trade name of the manufacturer or distributor shall be noted on the prescription label. For prescriptions compounded with multiple ingredients, the label designation will be left to the discretion of the pharmacist.

(d) For institutionalized and closed system patients, the pharmacist may identify the manufacturer or distributor of the product actually dispensed through pharmacy purchasing records or packaging records, and a published formulary designation may be used on the label.

[Statutory Authority: RCW 69.41.180. 79-12-063 (Order 152), § 360-49-010, filed 11/29/79; Order 143, § 360-49-010, filed 12/9/77.]

WAC 360-49-020 Product selection responsibilities.

(1) The determination of the drug product to be dispensed on a prescription is a professional responsibility of the pharmacist, and the pharmacist shall not dispense any product that in his/her professional opinion does not meet adequate standards.

(2) Pharmacists may utilize as the basis for their decisions on therapeutically equivalent drug products:

(a) Available drug product information from federal and state agencies, official compendia, and drug manufacturers, or

(b) Other scientific or professional resources, or

(c) The federal food and drug administration "approved drug products" as a board approved reference for a positive formulary of therapeutically equivalent products within the limitations stipulated in that publication.

(3) Those pharmacies that fill prescriptions based on prior authorization for therapeutically equivalent drug substitution must have available for inspection and review such authorization documentation in the institutional records or in the pharmacy.

[Statutory Authority: RCW 69.41.180. 79-12-063 (Order 152), § 360-49-020, filed 11/29/79; Order 143, § 360-49-020, filed 12/9/77.]

(1986 Ed.)

WAC 360-49-040 Manufacturers, wholesalers, distributors, pharmacy location, requirement that drug products offered for sale comply with 21 USC 355—Immediate suspension and subsequent revocation of licenses authorized for violation. (1) In order to provide for enforcement of RCW 69.41.100 through 69.41.180 and to protect the public health and safety when generic drugs are substituted for brand name drugs pursuant to chapter 110, Laws of 1979, drug products which are offered for sale by, or stored at the premises of, any manufacturer, distributor, wholesaler or pharmacy location must have an approved new drug application (NDA) or abbreviated new drug application (ANDA) designation by the Federal Food and Drug Administration pursuant to 21 USC 355 unless they are exempt from the requirements for such a designation.

[(2)][(3)] In order to provide for enforcement of RCW 69.41.100 through 69.41.180 and to protect the public health and safety drug products offered for sale by, or stored at the premises of, a manufacturer, wholesaler, distributor or pharmacy location which do not have the required NDA or ANDA, or exemption therefrom referenced in paragraph (1) above, are hereby declared to be contraband and subject to surrender to and destruction by the Washington state board of pharmacy. This surrender and destruction shall take place as specified below.

(3) The board shall publish in its newsletter the source from which the current list compiled by the Federal Food and Drug Administration of generic drugs which do not have an NDA or ANDA and are not exempt from such a requirement and are therefore contraband as provided in paragraph (2) above may be obtained. The board shall also respond to both written and telephone inquiries from any source regarding the status of any generic drug.

(4) Whenever it is made to appear to the board that a manufacturer, wholesaler, distributor or pharmacy location within the state of Washington is in possession of a stock of drugs which are contraband as defined in paragraph (2) above, a representative of the board shall confirm with the Federal Food and Drug Administration, by telephone, that the particular drug or drugs involved do not have the required NDA or ANDA and that they are not exempt from this requirement. Upon receipt of this confirmation, the board shall direct such of its investigative personnel as it deem necessary to proceed to the premises of the manufacturer, wholesaler, distributor or pharmacy location and to then inform the owner, or person in charge, of the contraband status of the drugs in question.

(5) The pharmacy board investigative personnel shall offer the owner, or person in charge, of the premises at which the drug products are being kept the opportunity to immediately voluntarily surrender to the board all stocks of the drug products whether kept at the premises of the manufacturer, wholesaler, distributor, or pharmacy location, or at any separate storage facility under the control of the manufacturer, wholesaler, distributor or retailer, which are contraband under subsection (2)

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above. A receipt shall be given to the owner, or person in charge, for all drug products voluntarily surrendered.

(6) All drug products voluntarily surrendered pursuant to subsection (5) above shall be destroyed by the board of pharmacy unless they are ordered returned to the manufacturer, wholesaler, distributor or pharmacy location by order of a court of competent jurisdiction. No destruction of any drug products surrendered will be accomplished until 30 days after the date of their surrender to the board.

(7) Retention, dispensing, promotion or advertisement, of any drug products by a manufacturer, wholesaler, distributor or pharmacy location, either at their business premises or at any separate storage facility after notification of their contraband status under subsection (2) above shall constitute a direct and immediate danger to the public health and safety and will be good and sufficient cause for the immediate summary suspension and subsequent revocation of any license issued by the board of pharmacy to the manufacturer, wholesaler, distributor or pharmacy location and will also constitute good and sufficient cause for revocation of any license issued by the board of pharmacy to the owner of any manufacturer, wholesaler, distributor or pharmacy location or any person in charge thereof who knowingly retains, dispenses, promotes or advertises, any drug products which are contraband under subsection (2) above after notification of their status.

[Statutory Authority: RCW 69.41.180, 80-14-012 (Order 157, Resolution No. 9/80), § 360-49-040, filed 9/22/80; 80-02-113 (Order 153, Resolution No. 1/80), § 360-49-040, filed 1/28/80.]

Reviser's note: RCW 34.04.058 requires the use of underlining and deletion marks to indicate amendments to existing rules, and deems ineffectual changes not filed by the agency in this manner. The bracketed material in the above section does not appear to conform to the statutory requirement.

Chapter 360-52 WAC PHARMACY ASSISTANT

WAC

360-52-010	Level A pharmacy assistants utilization.
360-52-020	Level A education and training.
360-52-030	Limitations, trainees.
360-52-040	Level A program approval.
360-52-050	Level A certification.
360-52-060	Level B pharmacy assistants utilization.
360-52-070	Level B certification programs.
360-52-080	Identification.
360-52-090	Board approval of pharmacies utilizing pharmacy assistants.
360-52-100	Level A experience equivalency.

WAC 360-52-010 Level A pharmacy assistants utilization. (1) Level A pharmacy assistants may assist in performing, under the immediate supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy.

(2) Immediate supervision shall include visual and/or physical proximity that will insure adequate safety controls, except that the board of pharmacy may apply the standards of the joint commission on accreditation of

hospitals for facilities licensed pursuant to chapters 70.41 or 71.12 RCW.

(3) The following shall not be considered to be manipulative and nondiscretionary functions associated with the practice of pharmacy:

(a) Consultation with the prescriber regarding the patient and his prescription.

(b) Receipt of a verbal prescription other than refill approval or denial from a prescriber.

(c) 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.

(d) Interpretation and identification of the contents of the prescription document.

(e) Determination of the product required for the prescription.

(f) Extemporaneous compounding of the prescription, except in accordance with written policies and procedures in accordance with WAC 360-52-090(2), whereby the accuracy, correct procedure and preparation, and safety of pharmaceutical constituents can be verified by the pharmacist.

(g) Interpretation of data in a patient medication record system.

(h) Final check on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including but not limited to accuracy of drug, strength, labeling, and proper container.

(i) Dispense prescriptions to patient with proper patient information as required by WAC 360-16-250.

(j) Any duty required by law, rule or regulation to be performed only by a registered pharmacist.

[Order 141, § 360-52-010, filed 12/9/77.]

WAC 360-52-020 Level A education and training.

(1) The education and/or training of Level A pharmacy assistants shall be obtained in one of the following manners:

(a) Formal academic program for pharmacy assistant training approved by the board.

(b) On-the-job training program following guidelines approved by the board.

(2) The minimum educational requirement shall be high school graduation or G.E.D.

[Order 141, § 360-52-020, filed 12/9/77.]

WAC 360-52-030 Limitations, trainees. An individual enrolled in a training program for Level A pharmacy assistants will perform Level A functions only under the immediate supervision of a pharmacist preceptor or a delegated alternate pharmacist.

[Order 141, § 360-52-030, filed 12/9/77.]

WAC 360-52-040 Level A program approval. (1) Program standards. The board will establish standards by which programs designed to train Level A pharmacy assistants shall be judged.

(2) Approval. In order for a program for training pharmacy assistants to be considered for approval by the

board, the director of the program, who shall be a pharmacist, shall submit to the board a description of the course of training offered, including subjects taught, method of teaching, and practical experience provided. The director of the program shall also advise the board concerning the skills and knowledge which are obtained in such course, and the method by which the proficiency of the pharmacy assistant in those skills and knowledge was tested or ascertained. The board may require such additional information from program sponsors as it desires.

(3) Program change. The board shall be informed and shall grant approval before any significant change in program can be implemented.

(4) Reapproval. Each approved program will be reexamined at intervals to be determined by the board. Approval will be continued or withdrawn following each reexamination.

(5) Registry. A registry of approved programs shall be maintained by the board which shall be available upon request to interested persons.

[Order 141, § 360-52-040, filed 12/9/77.]

WAC 360-52-050 Level A certification. Any person completing an approved pharmacy assistant training program and who wishes to perform in that capacity shall apply to the board for certification as a Level A pharmacy assistant, on forms to be supplied by the board, which shall include a verification of program competency by a notarized statement of the program director and a declaration by the applicant that he has never been found guilty by any court of competent jurisdiction of any violation of any laws relating to drugs or the practice of pharmacy.

The fee for annual certification shall be ten dollars.

[Order 141, § 360-52-050, filed 12/9/77.]

WAC 360-52-060 Level B pharmacy assistants utilization. Level B pharmacy assistants may perform, under the general supervision of a licensed pharmacist, duties including but not limited to typing of prescription labels, filing, refiling, bookkeeping, pricing or determination of cost or charge, stocking, delivery, nonprofessional phone inquiries, and documentation of third party reimbursements.

[Statutory Authority: RCW 18.64.005(11) and 18.64A.030. 80-02-113 (Order 153, Resolution No. 1/80), § 360-52-060, filed 1/28/80. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-52-060, filed 3/27/79; Order 141, § 360-52-060, filed 12/9/77.]

WAC 360-52-070 Level B certification programs.

(1) Training. No formal training or educational program will be required by the board, and there will be no age or educational restrictions. The supervising pharmacist shall thoroughly instruct the Level B pharmacy assistant in the limitations of the functions he may perform.

(2) Record of certifications. All pharmacies employing Level B pharmacy assistants shall complete a certification application on a form approved by the board, such form to include a declaration by the applicant that

he or she has never been found guilty by any court of competent jurisdiction of any violation of any laws relating to drugs or the practice of pharmacy, for each Level B pharmacy assistant employed. The completed form will be witnessed by the responsible pharmacist for the pharmacy and will be produced for inspection on the request of the board or its agents. The fee for certification will be included in the fee for authorization to utilize the services of pharmacy assistants.

[Order 141, § 360-52-070, filed 12/9/77.]

WAC 360-52-080 Identification. All Level A pharmacy assistants must wear badges or tags clearly identifying them as Level A pharmacy assistants while on duty. Those pharmacy assistants working within the pharmacy and having contact with patients or the general public shall wear badges or tags clearly identifying their status.

[Order 141, § 360-52-080, filed 12/9/77.]

WAC 360-52-090 Board approval of pharmacies utilizing pharmacy assistants. (1) Application. All licensed pharmacies may apply on a form supplied by the board for permission to utilize the services of pharmacy assistants. The fee for such application or annual renewal shall be twenty-five dollars.

(2) Utilization plan for Level A pharmacy assistants. The application for approval must describe the manner in which the pharmacy assistants will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the board. The board will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy.

(3) Utilization plan for Level B pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant.

(4) The board may give conditional approval for pilot or demonstration projects for innovative applications in the utilization of pharmacy assistants.

[Order 141, § 360-52-090, filed 12/9/77.]

WAC 360-52-100 Level A experience equivalency. Individuals who are employed in a pharmacy and who were performing as Level A pharmacy assistants prior to May 28, 1977 and have been continuously employed as Level A assistants since that date, or who have 1,040 hours employment performing Level A pharmacy assistant functions within the last eighteen months, shall be considered to have met the educational and/or training requirements upon verification to the board, in a notarized statement by the appropriate supervising or director pharmacist(s), as to the skill and knowledge of the individual, taking into consideration the approved guidelines. The Level A assistant may, under these conditions apply for certification to the board.

[Order 141, § 360-52-100, filed 12/9/77.]

Chapter 360-54 WAC

NUCLEAR PHARMACIES AND PHARMACISTS

WAC

360-54-010	Purpose and scope.
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360-54-040	Nuclear pharmacists.
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WAC 360-54-010 Purpose and scope. (1) No person may lawfully provide radiopharmaceutical services unless he or she is a nuclear pharmacist, or is performing radiopharmaceutical services under the supervision of a nuclear pharmacist, and is acting in accordance with the state board of pharmacy and state radiation control agency regulations.

(2) These regulations shall not apply to anyone who is an "authorized practitioner" as that term is defined in section 2 of these regulations.

(3) The requirements imposed by these nuclear pharmacy regulations shall apply in addition to, and not in place of, any other requirements contained in regulations of the state board of pharmacy, the state radiation control agency, or any other state or federal agency.

[Statutory Authority: RCW 18.64.005(9), 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-010, filed 2/1/79.]

WAC 360-54-020 Definitions. (1) A "nuclear pharmacy" is a class A pharmacy providing radiopharmaceutical services.

(2) "Nuclear pharmacist" means a licensed pharmacist who has submitted evidence to the board of pharmacy that he or she meets the requirements of WAC 360-54-040 of these regulations regarding training, education, and experience, and who has received notification by letter from the board of pharmacy that, based on the evidence submitted, he or she is recognized by the board of pharmacy as qualified to provide radiopharmaceutical services.

(3) "Radiopharmaceutical service" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(4) A "radiopharmaceutical" is any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such

substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(6) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

(7) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

(8) "Authorized practitioner" means a practitioner duly authorized by law to possess, use, and administer radiopharmaceuticals.

[Statutory Authority: RCW 18.64.005(9), 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-020, filed 2/1/79.]

WAC 360-54-030 Nuclear pharmacies. (1) A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

(2) Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel. A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy and the state radiation control agency before approval of the license.

(3) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with accepted professional standards of radiopharmaceutical quality assurance.

(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the state board of pharmacy, the state radiation control agency and other state and federal agencies.

(5) For nuclear pharmacies handling radiopharmaceuticals exclusively, the state board of pharmacy may waive regulations pertaining to the pharmacy permits for

nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(6) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(7) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(8) In addition to any labeling requirements of the state board of pharmacy for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: 1) Standard radiation symbol; 2) the words "caution-radioactive material"; 3) the name of the radiopharmaceutical; 4) the amount of radioactive material contained, in millicuries or microcuries; 5) if a liquid, the volume in milliliters; 6) the requested calibration time for the amount of radioactivity contained; 7) expiration data, if applicable; and 8) specific concentration of radioactivity.

(9) The immediate container shall be labeled with: 1) The standard radiation symbol; 2) the words "caution-radioactive material"; 3) the name of the nuclear pharmacy; 4) the prescription number; 5) the name of the radiopharmaceutical; (6) the date; and (7) the amount of radioactive material contained in millicuries or microcuries.

(10) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(11) Nuclear pharmacies may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(12) The nuclear pharmacy shall have the current revisions of state laws and regulations of the state board of pharmacy and state radiation control agency.

(13) The nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided. A detailed library listing shall be submitted to the state board of pharmacy and state radiation control agency before approval of the license.

[Statutory Authority: RCW 18.64.005(9), 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-030, filed 2/1/79.]

WAC 360-54-040 Nuclear pharmacists. In order for a pharmacist to qualify under these regulations as a nuclear pharmacist, he or she must:

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the state radiation control agency; and,

(2) Be a pharmacist licensed to practice in Washington; and,

(3) Submit to the board of pharmacy either:

(a) Certification that he or she has completed a minimum of 6 months on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services, or

(b) Certification that he or she has completed a nuclear pharmacy training program in an accredited college of pharmacy or

(c) That upon application to the board in affidavit form, and upon the furnishing of such other information as the board may require, the board may grant partial or equivalent credit for education and experience gained in programs not sponsored by an accredited college of pharmacy, if, in the opinion of the board, the education and experience gained by participants in these programs would provide the same level of competence as participation in a program at an accredited college of pharmacy; and

(4) Receive a letter of notification from the board of pharmacy that the evidence submitted that the pharmacist meets the requirements of subsections 1, 2, and 3 above has been accepted by the board and that, based thereon, the pharmacist is recognized by the board as a nuclear pharmacist.

[Statutory Authority: RCW 18.64.005(9), 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-040, filed 2/1/79.]

WAC 360-54-050 Minimum equipment requirements. (1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the state board of pharmacy and radiation control agency before approval of the license.

(2) The state board of pharmacy may, for good cause shown, waive regulations pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

[Statutory Authority: RCW 18.64.005(9), 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-050, filed 2/1/79.]