

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 Repealed by Order 110, filed 6/15/72.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 Repealed by Order 124, filed 10/31/74.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 Repealed by Order 110, filed 6/15/72.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 Repealed by Order 124, filed 10/31/74.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 Repealed by Order 110, filed 6/15/72.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 Repealed by Order 120, filed 3/11/74.
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 Repealed by Order 110, filed 6/15/72.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 Repealed by 80-05-074 (Order 154, Resolution 4/80), filed 4/28/80.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 Order 120, filed 3/11/74, extended effective date to October 31, 1974 (Repealed before implementation date).] Repealed by Order 124, filed 10/31/74.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 Order 120, filed 3/11/74, extended effective date to October 31, 1974 (Repealed before implementation date).] Repealed by Order 124, filed 10/31/74.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 Order 120, filed 3/11/74, extended effective date to October 31, 1974 (Repealed before implementation date).] Repealed by Order 124, filed 10/31/74.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 360-34

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 Repealed second time by Order 121, filed 8/8/74.

Chapter 360-08 WAC PRACTICE AND PROCEDURE

WAC

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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.]

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, eluded, 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.]

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.]

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 of \$1.00.

(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. [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 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 6/80), § 360-11-010, filed 6/26/80. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution 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, bio-chemistry, 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 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 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 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 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 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 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 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.
360-12-130	Registered pharmacists—Reinstatement.
360-12-140	Pharmacist prescriptive authority—Prior board approval required.

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. [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 one retake of the jurisprudence portion at a time and place to be specified by the board.

(5) An examinee failing the retake of the jurisprudence examination shall be required to retake the full board examination. [Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution 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 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 who wish to register as pharmacists in the state of Washington shall complete such additional academic work, if necessary, so as to be qualified to receive a baccalaureate degree in pharmacy or doctor of pharmacy degree from an accredited college or school of pharmacy recognized by the state board of pharmacy.

(2) In addition, before registration can be extended to them, they shall pass successfully 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 up to 800 hours of the required 1500 hours. [Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution 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 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 9/79), § 360-12-120, filed 9/6/79; Regulation 8, filed 3/23/60.]

WAC 360-12-130 Registered pharmacists—Reinstatement. (1) A pharmacist who desires to reinstate 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 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 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 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 his or her license must complete such continuing education credits as the board may specify in each individual case. [Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution 3-79), § 360-12-130, filed 3/27/79; Regulation 2, filed 3/23/60.]

WAC 360-12-140 Pharmacist prescriptive authority—Prior board approval required. A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW 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 shall make application through, and receive approval from, the board prior to commencement of this aspect of the practice of pharmacy. [Statutory Authority: RCW 18.64.005(4) and (11). 80-08-035 (Order 155, Resolution 6/80), § 360-12-140, filed 6/26/80, effective 9/30/80.]

Chapter 360-13 WAC EXTENDED CARE FACILITY

WAC

360-13-010	Promulgation.
360-13-020	Emergency kits.
360-13-030	Supplemental use dose kits.
360-13-045	Definitions.
360-13-055	Drug facilities.
360-13-065	Pharmaceutical services.

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.

360-13-070 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 department of health 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. [Order 104, § 360-13-010, filed 12/5/69; Order 50 (part), filed 3/28/67.]

WAC 360-13-020 Emergency kits. (1) The contents and quantity thereof of the emergency kit shall be determined by the "Pharmacy and Therapeutics Committee" of the nursing home or a committee consisting of the consulting pharmacist to the extended care facility and at least one licensed physician.

(2) The "Pharmacy and Therapeutics Committee" or a committee consisting of the consulting pharmacist to the nursing home and at least one licensed physician and the pharmacist supplying the emergency kit shall sign the list of medications to be contained in the emergency kit. Signed copies of the list shall be on file in the extended care facility and in the supplying pharmacy.

(3) The emergency kit shall contain only those items listed on the emergency kit list.

(4) The emergency kit shall apply only for bonafide emergencies and shall not be used when medication can be obtained from a pharmacy.

(5) The emergency kit being available only for bonafide emergencies shall contain small quantities of individual items. The "small quantities" are to be considered in light of the number of residents in the extended care facility and their potential needs for the emergency medication.

(6) Whenever medications requiring a prescription are used from the emergency kit, the following must be reduced to writing and be kept with the emergency kit:

- Name of the resident
- Name and quantity of medication
- Nature of the emergency
- Time and date of administration
- Name of person administering medication
- Name of physician authorizing medication:

Provided however, The pharmacy record will be a prescription on file in the pharmacy.

(7) The pharmacist supplying the emergency kit shall keep a record for each extended care facility of the name and quantity of medication supplied to the emergency kit and the date of supply or replenishment.

(8) Record keeping must conform to existing federal and state laws, rules, and regulations.

(9) The contents of the emergency kit, the approved list of contents, and all records relating to the emergency kit shall be made freely available and open for inspection to representatives of the Board of Pharmacy.

(10) The emergency kit shall be kept in a locked cabinet or be locked itself.

(11) The emergency kit shall at all times remain the responsibility of the pharmacist supplying the emergency kit.

(12) The emergency kit shall have a list of contents on the outside of the kit. [Order 104, § 360-13-020, filed 12/5/69; Order 50, subsection 1-12, filed 3/28/67.]

WAC 360-13-030 Supplemental use dose kits. 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 unit dose kit for supplemental non-emergency drug therapy if the necessary drug is not timely available from the pharmacy. The supplemental unit dose kit may contain up to four single unit doses of each drug approved by the pharmacy and therapeutics committee. The supplemental use dose kit shall remain the property of the supplying pharmacy and said pharmacy shall be responsible for proper storage, security and accountability. [Order 114, § 360-13-030, filed 6/28/73.]

WAC 360-13-045 Definitions. (1) "Department" means the state department of social and health services.

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

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

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

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

(6) "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.

(7) "Nursing home" means any home, place or institution which operates or maintains facilities providing convalescent or chronic care, or both, for a period in excess of twenty-four consecutive hours for three or more patients not related by blood or marriage to the operator, who, by reason of illness or infirmity, are unable properly to care for themselves. Convalescent and chronic care may include, but not be limited to, any or all procedures commonly employed in waiting on the sick, such as administration of medicines, preparation of special diets, giving of bedside nursing care, application of dressings and bandages, and carrying out of treatment prescribed by a duly licensed practitioner of the healing arts. It may also include care of mentally incompetent persons. Nothing in this definition shall be construed to include general hospitals or other places which provide care and treatment for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both. Nothing in this definition shall be construed to include any boarding home, guest home, hotel or related institution which is held forth to the public as providing, and which is operated to give only board, room and laundry to persons not in need of medical or nursing treatment or

supervision except in the case of temporary acute illness. The mere designation by the operator of any place or institution as a hospital, sanitarium, or any other similar name, which does not provide care for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both, shall not exclude such place or institution from the provisions of this chapter.

(8) "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.

(9) "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.

(10) "p.r.n. drug" means a drug which a physician has ordered to be administered only when needed under certain circumstances.

(11) "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.

(12) "Single unit" means one, discrete pharmaceutical dosage form (e.g., one tablet or one capsule) of a drug. A single unit becomes a unit-dose, if the physician orders that particular amount of the drug for a person.

(13) "Stop order" means a written policy that definitely prescribes the number of doses or the period of time after which administration of the drug to a patient must be stopped automatically, unless the physician's order for the drug specified the number of doses or the period of time the order was to be in effect.

(14) "Unit-dose" means the ordered amount of a drug 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 whereby a pharmacist dispenses drugs in unit doses so the selection and issuance of individual doses of drugs for administration are pharmacy based and controlled. [Order 121, § 360-13-045, filed 8/8/74.]

WAC 360-13-055 Drug facilities. (1) There shall be adequate drug facilities to provide for locked storage of all drugs without crowding and for the observance of safe procedures and techniques in the preparation of medicines for administration.

(a) Any room or area which serves as a drug facility shall serve clean functions only and shall be well illuminated and ventilated. When any mobile drug storage cabinet is not being used in the administration of medicines to patients, it shall be stored in a room which meets this requirement.

(b) Each drug facility shall include a sink with hot and cold running water, a work counter and drug storage cabinets, by June 1, 1975.

(c) All drug storage cabinets (stationary or mobile) shall be designed and arranged so drug containers are readily accessible and shall be closed, locked cabinets unless they are stationary cabinets in a locked room

which serves exclusively for storage of drugs and supplies and equipment used in the administration of drugs. Any mobile drug storage cabinet shall be a closed cabinet with locks to prevent access to drugs when the cabinet is unattended.

(d) Drug storage cabinets, except those for schedule II controlled substances, within the same drug facility may be keyed alike. Locks and keys for one drug facility shall be different from those for any other drug facility and from any other locks and keys within the nursing home so that only the keys to a particular drug facility can be used to gain access to drugs stored within that drug facility.

(2) All drug storage shall be designed and finished so it can be cleaned easily and shall be kept clean.

(3) A metric-apothecary conversion chart and a poison antidote chart shall be posted conspicuously at each drug facility. [Order 121, § 360-13-055, filed 8/8/74.]

WAC 360-13-065 Pharmaceutical services. (1) Administration of Pharmaceutical Services.

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

(b) Unless the nursing home operates a pharmacy which is licensed by the Washington state board of pharmacy, the nursing home shall have a written agreement with a licensed pharmacist which provides for him to serve as a consultant on pharmaceutical services. A staff pharmacist or the consultant pharmacist shall regularly visit all nursing units and any other areas of the nursing home in which drugs are kept to review and make recommendations regarding methods and practices in ordering, storing, record keeping and disposing of drugs and biologicals. The pharmacist shall make such on-site reviews at least monthly. Signed, dated records of the pharmacist's on-site reviews with his recommendations shall be kept on file in the nursing home.

(c) There shall be a pharmaceutical and therapeutics committee, whose membership includes a staff or consultant pharmacist and at least one physician and the director of nursing or her designee, responsible for advising and assisting in the formulation of written policies and procedures pertinent to pharmaceutical services and for the review and approval of such policies and procedures.

(d) There shall be written policies and procedures which provide for the procurement, storage, control, use, retention, release and disposal of drugs and biologicals in accordance with applicable federal and state laws and regulations. Written policies and procedures shall be kept current and followed in practice, shall be reviewed at least annually by the pharmaceutical and therapeutics committee, and shall be dated and signed by members of the committee.

(e) If an emergency drug kit is provided, the nursing home shall comply with the rules and regulations adopted by the Washington state board of pharmacy establishing minimum standards for emergency kits which are found in WAC 360-13-010 and WAC 360-13-020.

(2) Storage, Labeling and Control of Drugs.

(a) All drugs shall be stored in an orderly fashion in locked cabinets or in cabinets in a locked room which serves exclusively for storage of drugs and supplies and equipment used in the administration of drugs. Drugs shall be accessible only to persons who are legally authorized to dispense or administer drugs and shall be kept in locked storage at any time such a legally authorized person is not in immediate attendance.

(b) Schedule III controlled substances shall be stored apart from other drugs on a separate shelf or in a separate compartment or cabinet: *Provided, however,* That schedule III controlled substances may be stored with schedule II controlled substances.

(c) 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.

(d) All drugs requiring refrigeration shall be stored in a separate, locked box or compartment within a refrigerator, or in a separate refrigerator which is locked or in a locked room and shall be accessible only to persons legally authorized to dispense or administer drugs. In each refrigerator in which drugs are stored, there shall be a thermometer located so it can be read easily. The inside temperature of a refrigerator in which drugs are stored shall be maintained within a 35° fahrenheit to 50° fahrenheit range.

(e) At all times, all keys to drug boxes, cabinets and rooms shall be carried by persons who are legally authorized to administer drugs and on duty on the premises. All drug administration shall be by persons legally authorized to administer drugs. This shall not be interpreted to preclude the keeping of one set of reserve, duplicate keys to drug storage facilities, provided such a set is kept in a secure location that is known and available to only the nursing home administrator or a responsible person designated by the administrator.

(f) All drugs shall be obtained and kept in containers which have been labeled securely and legibly by a pharmacist, or in their original containers labeled by their manufacturers and shall not be transferred from the container in which they were obtained except for preparation of a dose for administration.

(g) The label for each legend drug which is not dispensed in a unit-dose in accordance with WAC 248-14-280(4) shall have: The name and address of the pharmacy from which the drug was dispensed; the prescription number, the physician's name; the patient's full name; the date of issue; the initials of the dispensing pharmacist; the name and strength of the drug; the controlled substances schedule, if any; the amount (e.g., number of tablets or cc's) of the drug dispensed; and the expiration date, if a time-dated drug. 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.

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.

(h) No drugs may be returned from the nursing home to a pharmacy except as provided in the preceding subsection (g) and the following subsection WAC 248-14-280(4) pertaining to unit dose drug distribution system.

(i) Drugs shall be released to a patient upon discharge only on written authorization of a physician. A receipt shall be secured for all legend drugs released to a patient or a responsible person who accepts the drug(s) for the patient. The patient, or other responsible person to whom the drugs are released, shall acknowledge receipt of the drugs by signing a statement in which the following data are included: The name of the patient; the date of the release of the drugs; the prescription number, name, strength, and amount of each drug; the signature of the person releasing the drugs and the signature of the person receiving the drugs. Signed acknowledgements of receipt of drugs shall be kept in the patient's record. The release record for any schedule II and III controlled substance shall be entered on the appropriate page for the given drug in the bound controlled substance record book. This entry shall include the date, the amount of the drug, the location to which the patient is going, the signature of the person releasing the drug, and the signature of the person receiving the drug.

(j) There shall be written policies establishing a reasonable period of time after which the administration of drugs must be stopped automatically unless a physician's order for a drug specified the number of doses or a definite period of time the order was to be in effect. Such automatic stop order times shall not exceed: Three days for narcotics and anticoagulants; seven days for amphetamines, antibiotics, anti-inflammatories, antiemetics, antihistamines, antineoplastics, barbiturates, cold preparations, cortisones, cough preparations, sulfonamides and tranquilizers; and thirty days for all other drugs.

(i) Patients' attending physicians shall be informed of stop order policies.

(ii) Prior to the time administration of a drug would be stopped automatically in accordance with policy, a licensed nurse shall notify the physician and review the patient's condition in conference with the physician so continuity in the patient's drug therapy will not be interrupted should the physician decide to renew the order. A statement about this notification of the physician and review of the patient's condition with the physician shall be entered in the patient's clinical record, dated and signed by the licensed nurse.

(k) All of an individual patient'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 within 90 days after having been discontinued.

Any drug having an expiration date shall be removed from usage and destroyed immediately after the expiration date.

All of an individual patient's drugs, except those released to the patient on discharge and schedule II controlled substances, shall be destroyed by a licensed nurse immediately after discharge or death of the patient: *Provided, however,* That the nursing home may, for a period not to exceed one month, retain the individual drugs of a nursing home patient who has been hospitalized and may return directly to the nursing home upon discharge from the hospital.

(i) Drugs shall be destroyed by a licensed nurse in the presence of a witness in such a manner that they cannot be retrieved, salvaged, or used; they shall not be discarded with garbage or refuse.

(ii) For any drug which is destroyed or any drug which is retained for a hospitalized patient, there shall be an entry in the patient's record which shall include the following: The date; the name, strength, and quantity of the drug; a statement as to whether the drug was destroyed or retained; the signature of the licensed nurse who destroyed or retained the drug; and, for any drug destruction, the signature of the witness. In addition, a record of the destruction of any schedule III controlled substance shall be entered on the page for the particular prescription in the schedule III record book.

(3) 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. This may be accomplished by maintaining a separately keyed and locked secure cabinet or metal lined drawer or separately keyed and locked metal box securely fastened down within a locked drug cabinet.

(b) There shall be a schedule II controlled substances record book which shall be a bound book with numbered pages, in which each receipt and withdrawal of a schedule II controlled substance is recorded. The record for each prescription of a schedule II controlled substance shall be on a separate page. For each receipt of a schedule II controlled substance the following shall be recorded: The patient's full name; the prescription number; the name of the pharmacy; the name of the prescribing physician; the name, strength and number of dosage units of the drug received; the method of administration; the date of receipt and the signature of the licensed nurse who received the drug. For each withdrawal from a prescription container of a schedule II controlled substance, the following shall be recorded: The date and time, the signature of the nurse who withdrew the drug, the amount of the drug withdrawn, and the balance of the drug in the container after the withdrawal.

At least once a day, the amount (e.g., number of tablets, ampules or cc's) of the drug in each container of a schedule II controlled substance (including any for which a physician has ordered discontinuance of administration) shall be counted simultaneously by at least two persons who are legally authorized to administer drugs. A record of each count shall be entered on the page for the particular prescription in the schedule II controlled substance record book and signed by persons who made

the count, or the daily count may be entered in the separate bound record book and signed by persons who made the count.

(c) There shall be a schedule III controlled substances record book which shall be a bound book with numbered pages in which each receipt and withdrawal of a schedule III controlled substance shall be recorded in the same manner as that required for schedule II controlled substances.

At least once a week, the amount (e.g., number of tablets, ampules or cc's) of the drug in each container of a schedule III controlled substance (including any for which a physician has ordered discontinuance of administration) shall be counted simultaneously by at least two persons who are legally authorized to administer drugs. A record of each count shall be entered on the page for the particular prescription in the schedule III controlled substance record book and signed by persons who make the count or the weekly count may be entered in a separate bound record book and signed by persons who made the count.

(d) For any discrepancy between actual count and the record for any schedule II or schedule III controlled substance prescription, a signed entry describing the discrepancy shall be made on the record page for the particular prescription in which the discrepancy was found. The discrepancy shall be reported in writing immediately to the responsible supervisor who shall investigate. Any discrepancy which has not been corrected within seven calendar days shall be reported to the department of the Washington state board of pharmacy.

(e) Unused schedule II controlled substances for which a physician has ordered discontinuance of administration shall be returned to the drug enforcement administration within 60 days after having been discontinued.

(f) All schedule II controlled substances which remain after the discharge or the death of patients shall be returned to the drug enforcement administration at least once each month. They may be delivered in person by an authorized representative of the nursing home or sent by registered mail to:

District Supervisor
Drug Enforcement Administration
221 First Avenue West, Room 200
Seattle, Washington 98119

Appropriate forms will be furnished by the drug enforcement administration. Receipts for drugs from the drug enforcement administration shall be kept on file in the nursing home, and readily accessible to authorized representatives of the department and the Washington state board of pharmacy.

(4) Unit Dose Drug Distribution System.

The following additional requirements shall apply to any unit dose drug distribution system:

(a) The nursing home shall have in effect a current written agreement with the pharmacy which supplies drugs for the unit dose drug distribution system. The agreement shall delineate the functions, responsibilities

and services of both the nursing home and the pharmacy, shall provide assurance of compliance with applicable federal and state laws and regulations and shall be dated and signed by individuals authorized to execute such an agreement on behalf of the nursing home and the pharmacy.

(b) There shall be policies and procedures, as required under WAC 248-14-280(1)(d), which are specific to the unit dose drug distribution system as well as policies and procedures pertaining to other components of the pharmaceutical services.

(c) Policies shall specify the kinds of drugs which will and the kinds of drugs which will not be dispensed under the unit dose drug distribution system.

(i) In specifying the kinds of drugs to be included or excluded, consideration shall be given to all forms of drugs such as liquids, injectables, tablets, capsules, powders, ointments, drops, and suppositories.

(ii) Schedule II and III controlled substances may be included in the unit dose drug distribution system only if the methods of incorporating such drugs into the system are in compliance with applicable federal and state laws, rules and regulations and an accurate written description of such methods has been reviewed and approved in writing by the state board of pharmacy. A copy of this written description upon which the state board of pharmacy has recorded its approval shall be kept on file in the nursing home.

(d) There shall be a system for transmitting physicians' orders for administration of drugs from the nursing home to the pharmacist which ensures the transmission of orders is complete, accurate, and timely. This shall include provision for timely transmission of orders for newly admitted patients, changes in orders, discontinuance of orders and orders to be carried out immediately ("Stat").

(i) A direct copy (carbon copy, photocopy, or facsimile) of each physician's order for administration of drugs shall be sent to the pharmacy.

(ii) Any telephone transmittal of a physician's order by nursing home staff shall be by a licensed nurse to a licensed pharmacist and shall be followed by transmittal of a direct copy of the physician's order.

(e) Both the pharmacist and the nursing home shall maintain a complete, up-to-date, accurate record (drug profile) of each patient's drug orders.

(i) Each record (drug profile) shall include the following for each drug order which is currently in effect: The date of the order, the name and dose of the drug, the route or method of administration, the time or frequency of administration, and the number of doses to be administered or the date and time at which the administration of the drug is to be stopped according to the physician's order or stop-order policy.

For a drug which is ordered to be given only when necessary (p.r.n.) and not on a regular basis, the record (drug profile) shall clearly indicate the following instead of time and frequency: The minimum interval of time between doses, the maximum number of doses which may be administered, and the specific condition for which the drug is to be given.

(ii) The drug profile in the nursing home shall be designed and used for recording all administration of drugs to the patient.

(f) Each single unit or unit dose of a drug shall be packaged in a manner which protects the drug from contamination or deterioration and prevents escape of the drug until the time the package is opened deliberately.

(g) A clear, legible label shall be printed on or affixed securely to each package of a single unit or unit dose of a drug. Each drug label shall include: The name; strength and, for each unit dose package, the dosage amount or the drug; the expiration date for any time-dated drug; the lot of control number; and controlled substance schedule number, if any.

(h) Packages of single units or unit doses of drugs shall be placed, transported and kept in individual compartments so that drugs for one patient are segregated from drugs for another patient.

(i) Each individual drug compartment shall be labeled with the full name of the patient whose drug the compartment contains and the name of the patient's physician.

(ii) Packages of drugs shall be placed systematically in individual compartments so they may be located readily at the proper time for administration.

(i) Cabinets, carts and other equipment used to transport or store individual compartments of drugs for patients shall be designed to prevent loss or intermixing of drugs for different patients.

(j) After delivery of drugs to a nursing home, no single unit or unit dose package of a drug shall be removed from an individual patient's drug compartment and no single unit or unit dose package shall be opened until the time a nurse is ready to administer the drug to the patient.

(k) The schedule for drug delivery shall ensure that drugs are on nursing units ready for administration in accordance with physicians' orders at the established time for drug administration. Definite provision shall be made for timely delivery of drugs, drug orders for newly admitted patients, and orders for immediate administration of drugs ("Stat" orders).

If a supplemental use dose kit is provided, the nursing home shall comply with the rules and regulations adopted by the Washington state board of pharmacy establishing minimum standards for supplemental use dose kits which are found in WAC 360-13-030.

(l) There shall be an established system for receipting and for reporting to the pharmacist any patient's untoward reaction to a drug and any errors, omissions or other variations in drug administration.

(m) There shall be an established system for determining the number of unit doses of each p.r.n. drug to be delivered for a particular patient each day so each p.r.n. drug is available when needed by a patient.

(n) Unopened single unit or unit dose packages of drugs which were not administered shall be left in the patient's individual drug compartments and returned to the pharmacy at the time of the next drug delivery. Single unit or unit dose packages of drugs which have been

opened but not administered to the patient shall be destroyed. There shall be an established system for sending written reports to the pharmacist regarding each loss or destruction of a drug. [Order 121, § 360-13-065, filed 8/8/74.]

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 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.
360-16-160	Sale of inhalers over the counter. [Regulation 13, filed 3/23/60.] Repealed by 79-10-007 (Order 151, Resolution 9/79), filed 9/6/79. Statutory Authority: RCW 18.64.005(11).

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 360-16-040 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 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 360-16-110 Hospital pharmacy standards.

(1) **Pharmacy.** The hospital shall provide for the proper handling and storage of drugs.

(2) Definitions.

(a) "Pharmacy" refers to the central area in a hospital where drugs are stored and are issued to hospital departments or where prescriptions are filled.

(b) "Pharmacist" refers to one currently registered as a pharmacist in the state of Washington under the provisions of chapter 18.64 RCW.

(c) "Prescription" means an order for drugs for a specific patient given by a duly licensed physician, dentist or other person legally authorized to write prescriptions transmitted to a pharmacist for dispensing to the specific patient.

(d) "Legend drugs" are those drugs bearing the manufacturer's legend, "Federal law prohibits dispensing without a prescription".

(3) **Functions of pharmacy.** The functions of the hospital pharmacy shall include:

(a) Distributing routine drug supplies to hospital departments and issuing drugs on prescriptions or special orders for individual patients.

(b) Bulk compounding of sterile and nonsterile pharmaceuticals as determined by hospital policy and regulations.

(c) Dispensing and/or compounding drugs for home use for patients as necessary in compliance with federal, state and local laws.

(d) Purchasing, accounting for, storing, labeling, issuing and controlling drugs.

(e) Maintaining records on narcotics, tax free alcohol and other pharmaceuticals as are required by federal, state and local laws.

(f) Complying with federal and state laws controlling drugs and pharmacy operation.

(4) Organization, administration and staffing.

(a) The hospital pharmacy shall be under the supervision of a pharmacist.

(b) Drugs located in other areas of the hospital shall also be under the supervision of the pharmacist who shall keep adequate records in accordance with subsections (8)(f), (8)(g) and (9)(a) through (9)(h).

(c) The responsibility and authority of the pharmacist shall be clearly defined in writing by hospital authorities.

(d) Adequate, properly trained personnel shall be available to fulfill the functions of the pharmacy.

(e) Hospital pharmacy services shall be available often enough to provide drugs, supplies and prescriptions without undue delay.

(f) It is recommended that there should be a pharmacy and therapeutic committee composed of representatives of the medical staff, hospital administration, the nursing department and the pharmacist. The pharmacist should serve as secretary to the committee. The committee should meet at least semi-annually. The committee should:

(i) Develop and maintain an up-to-date formulary of accepted drugs for use in the hospital.

(ii) Serve as an advisory group to the hospital pharmacist on matters pertaining to choice of drugs to be stocked.

(iii) Evaluate clinical data concerning drugs requested for use in the hospital.

(iv) Add to and delete from the list of drugs accepted for use in the hospital.

(v) Prevent unnecessary duplication in the stock of the same basic drug and its preparation.

(vi) Make recommendations concerning drugs to be stocked on the nursing units and other services.

(g) Every hospital shall have its pharmacy policies, rules and regulations and procedures in writing. These should be developed by the pharmacy and therapeutic committee.

(5) Pharmacy facilities.

(a) An adequate area which is properly lighted and ventilated and suitably equipped to carry out all pharmacy operations, including proper storage of all pharmaceuticals, shall be provided.

(b) A library including the current U.S. Pharmacopeia, National Formulary, New and Nonofficial Drugs, and U.S. Dispensatory, and such other references as are needed for effective pharmacy operation is required.

(c) Special locked storage for narcotics and barbiturates and special additional storage for flammables shall be provided.

(d) The pharmacy shall be arranged in an orderly fashion and be kept clean, and all mechanical equipment shall be in good repair.

(6) Purchase, storage, labeling and control of drugs.

(a) The pharmacist should furnish specifications for the purchase of all pharmacy drugs, chemicals and pharmaceutical preparations even though a purchasing agent may do the actual procurement through a centralized department.

(b) Physicians' advice should be sought through the pharmacy and therapeutic committee in setting up any standards for specifications of drugs.

(c) Purchase, storage and control of drugs shall be such as to prevent having outdated, deteriorated, impure or improperly standardized drugs in the hospital.

(d) Purchase of narcotics shall be in compliance with state and federal laws and regulations.

(e) Purchase, storage and control of tax free alcohol shall be accordance with applicable state and federal laws and regulations.

(f) All flammable materials shall be stored and handled in accord with applicable local and state fire regulations.

(g) All drug containers in the pharmacy or in other areas of the hospital shall be clearly and legibly labeled to show drug's name (generic and trade) and strength.

(h) Poisonous external and caustic drugs shall show proper warning or poison labels and shall be stored separately from other drugs.

(i) The pharmacist shall be completely responsible for all labeling of drugs.

(j) All medicines, poisons and stimulants kept in any hospital department shall be plainly labeled and stored in a specially designated, well illuminated cabinet, closet or store room, and made accessible only to authorized personnel.

(k) The pharmacist shall regularly and periodically visit all departments of the hospital and check all drugs and pharmaceuticals as to the proper name, strength, storage condition, expiration date and warning label, and should remove at once any unlabeled or incorrectly labeled drug item. It shall be the responsibility of the pharmacist to confer with department heads regarding abnormal or erratic use of drugs and to make necessary adjustments in the approved maximum quantities of drugs issued to departments with proper approval. (See WAC 360-16-110(8)(a).)

(7) Bulk compounding of pharmaceuticals.

(a) A pharmacist shall be in charge of bulk compounding of pharmaceuticals. This does not prohibit the registered nurse from making weaker aqueous solutions from concentrated solutions or pre-weighed units (such as tablets) which are properly labeled by the pharmacist or manufacturer with specific directions for dilution. Neither does it prohibit the registered nurse from adding prepared sterile additives to parenteral solutions as specifically directed by the physician.

(b) All hospital pharmacies in which any compounding is done shall have proper instruments of measure available in accord with the state board of pharmacy regulations.

(c) All drugs used in compounding shall be handled to avoid contamination through contact with measuring devices, transporting devices or weighing devices.

(d) Sterilization of pharmaceuticals shall conform to the standards set by the U.S. Pharmacopeia.

(e) All drugs compounded or manufactured in the hospital shall be carefully labeled as to strength, content and, if need be, expiration date.

(8) Distribution or issuance of drugs.

(a) The hospital shall have lists of drugs (including narcotics, barbiturates and emergency drugs) indicating the approved maximum amounts of each drug generally to be issued to hospital departments. These lists should be developed by the pharmacy and therapeutics committee.

(b) Drugs may be given to patients in the hospital only on the order of a physician, dentist or other person legally authorized to write prescriptions. No change in order for drugs shall be made except with the approval of the physician, dentist or other person legally authorized to write prescriptions.

(c) Antidotes should be available for emergency cases involving poisoning. The stock of antidotes to be maintained should be determined by the pharmacy and therapeutic committee.

(d) A prescription is required for all legend drugs and narcotics issued to employees or to a patient for use outside the hospital.

(e) Only a pharmacist may compound and/or dispense drugs.

(f) Records of prescriptions filled by the pharmacist shall be properly filed and kept for five years.

(g) The pharmacy shall keep proper records of issue of all legend drugs.

(9) Handling of narcotics, barbiturates and tax free alcohol.

(a) Careful records shall be kept of receipt of narcotics and a perpetual inventory of narcotics shall be maintained.

(b) Adequate records of all narcotics issued shall be maintained in the pharmacy and shall contain for each issue of narcotics:

(i) The date.

(ii) The name of the drug.

(iii) The amount of the drug issued.

(iv) The name of the person who issued the drug.

(v) Name of the department to which the drug was issued.

(vi) The name of the person who received the drug.

(c) Adequate records of narcotic usage shall be maintained and shall contain for each drug used:

(i) The date.

(ii) The time of administration.

(iii) The dosage of the drug which was used.

(iv) The name of the person to whom the drug was administered.

(v) The name of the physician who ordered the drug.

(vi) The signature of the person who administered the drug. These records shall be submitted to the pharmacist for safe keeping.

(d) Periodic check of narcotic usage records should be made by the nursing supervisor and/or the pharmacist to determine whether the drugs recorded on usage records have also been recorded on patients' charts.

(e) Use of multiple dose vials of narcotics is not recommended as they make accounting for narcotics difficult and make substitution and dilution of narcotics possible.

(f) All narcotics in any hospital department except the pharmacy shall be checked by actual count by two persons at the change of each shift.

Adequate day-to-day accountability records shall be maintained and shall contain the time each check of a narcotic supply was made and the signature of the persons who made each check.

(g) All narcotic records shall be kept for three years.

(h) Adequate accountability records for barbiturates shall be maintained and include records of purchase, receipt, usage and inventory of barbiturates. Such records shall be kept for three years in compliance with federal food and drug law on legend drugs.

(10) Access to pharmacy.

(a) Only a pharmacist may have access to the pharmacy stock of barbiturates and narcotics.

(b) Only a pharmacist may have access to the pharmacy stock of drugs except that in a pharmacist's absence from a hospital a registered nurse, designated by the hospital, may obtain from a hospital pharmacy stock of drugs such drugs as are needed in an emergency, not available in floor supplies (excepting narcotics and barbiturates), and the nurse, not the pharmacist, becomes accountable for her actions. Only one registered, professional nurse in any given eight hour shift may have access to the pharmacy stock of drugs. A registered nurse is not permitted to compound or dispense drugs.

A nurse may remove from the pharmacy stock of drugs:

(i) A drug in its original container or a drug pre-packaged by a hospital pharmacist for nursing service use in the hospital.

(ii) A single dose of a drug from the original container for a specific patient.

(c) A nurse shall leave in the pharmacy on a suitable form a record of any drugs removed showing:

(i) The name of the drug.

(ii) The name of the manufacturer.

(iii) The dosage size.

(iv) The amount taken.

(v) The date.

(vi) The time.

(vii) The signature of the nurse.

Further, she shall leave with the record the container from which the single dose was taken for drug administration purposes in order that it may be properly checked by a pharmacist. Such records shall be kept three years.

(11) Responsibilities of pharmacist.

(a) The pharmacist shall be responsible for:

(i) Preparing and sterilizing of injectable medication when manufactured in the hospital.

(ii) Issuing drugs, chemicals and pharmaceuticals.

(iii) Filling and labeling drug containers issued to other hospital departments.

(iv) Inspecting all drugs and pharmaceuticals in all hospital departments.

(v) Maintaining the approved stock of drugs.

(vi) Issuing all narcotic drugs and alcohol and maintaining a perpetual inventory of them.

(vii) Maintaining records which are required legally.

(viii) Supervising the maintenance of the facilities of the pharmacy.

(ix) Maintaining current information on state and federal laws pertaining to drugs and drug handling and keeping the hospital administration properly informed.

(b) It is recommended the pharmacist also be responsible for:

(i) Specifying quality and sources for purchasing of all drugs, chemicals, antibiotics and pharmaceuticals for use in treatment of patients.

(ii) Furnishing information concerning medications to physicians, residents and nurses.

(iii) Participating in formulating pharmacy policies and carrying them out in accordance with the established policies of the hospital.

(iv) Cooperating in teaching courses in the school of nursing and in other educational programs.

(v) Implementing the decision of the pharmacy and therapeutics Committee.

(vi) Preparing periodic pharmacy reports for submission to the administrator of the hospital.

(vii) Maintaining, in cooperation with the accounting department, a satisfactory system of records and book-keeping in accordance with the policies of the hospital for: (A) Charging patients for drugs and pharmaceutical supplies, and (B) maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceuticals.

(12) **Effective date.** This regulation being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this regulation shall take effect upon October 2, 1959. [Regulation 35, effective 10/2/59, filed 3/23/60, subsection (4)(b), as corrected, filed 12/8/60.]

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 prohibited. 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. [Regulation 28, filed 3/23/60.]

WAC 360-16-170 Drug vending machine[s] for over-the-counter drugs. Over-the-counter drugs may be sold by the use of a mechanical device or vending machine. Any mechanical device or vending machine so used shall be licensed as a shopkeeper outlet pursuant to chapter 18.64 RCW. All over-the-counter drugs so sold shall be in the original manufacturer's package with complete labeling as required by federal law and 21 CFR which requirements are specifically incorporated herein by this reference. [Statutory Authority: RCW 18.64.005(11), 79-10-007 (Order 151, Resolution 9/79), § 360-16-170, filed 9/6/79; Regulation 17, filed 3/23/60.]

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 360-16-180 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 place of business must maintain at all times a representative assortment of FDA-approved preparations, commonly used chemicals, oils, drugs, patent medicines and drug sundries, in such assortments and quantities as will enable the said place of business regularly to supply from stock from day to day the usual immediate medical requirements of physicians and persons in the neighborhood and community in which said business is located, all stock to be clean and of proper quality.

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(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 protected from excessive heat (40 degrees centigrade, 104 degrees Fahrenheit). If such heat exceeded all drugs must be destroyed. (USP standards shall be met.)

(7) All drugs shall be protected from freezing except those so marked on the label. (USP standards shall be met.) [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 following equipment in good repair and proper quantities:

(a) Graduates (assortment, capable of accurately measuring volumes from 1 cc to 500 cc's).

(b) Mortars and pestles (two required – one wedge-wood and one glass).

(c) Spatulas (at least two, one of which must be stainless steel, rubber, bone, or other nonmetallic substance).

(d) Funnels (at least one glass funnel).

(e) Filter paper of a size to fit funnel.

(f) Stirring rod.

(g) Pill tile, ointment slab or parchment paper.

(h) Class A balance sensitive to current requirements as found in USP.

(i) Weights (accurately weighing 1 gram to 50 grams).

(j) Powder or weighing paper.

(k) Adequate assortment of prescription containers.

(l) Towels, clean and available.

(m) Prescription files (two or three as preferred).

(n) Poison register (if sold at retail).

(o) Controlled substances act schedule V register (if sold at retail).

(p) Prescription labels.

(q) Cautionary labels.

(r) Typewriter.

(s) Label moistener if self adhesive labels not in use.

(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, narcotics and medicines maintained in a loose leaf binder.

(b) Five standard, acceptable reference books relating to the practice of pharmacy, three of which must be current; one file or book or other reference on drug hazards or drug interactions which must also be current.

(3) All pharmacies shall have in their possession distilled or de-ionized water (at least one quart). [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) Forms and instructions for a self inspection program shall be mailed to all pharmacies. Up to five points may be granted on the inspection conducted by the investigator for pharmacy compliance with this program[.]

(7) 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 score as found in (2) above. Refer to (3) above for specific information on "C" grades[.] [Statutory Authority: RCW 18.64.005(9) and 69.50.201. 79-02-060 (Order 146, Resolution 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.]

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 360-16-245 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 360-16-260 Patient medication record system. (1) After January 1, 1976, a patient medication record system shall be maintained in all pharmacies. The record shall be devised so as to contain the information which the pharmacist feels necessary to give the patient the best professional advice and required drug information. The pharmacist shall *attempt* to determine through examination of the record and other information the patient may contribute, prior to the dispensing of a prescription, the possibility of a harmful drug interaction or other problems caused or influenced by the prescription presented for dispensing.

(2) The information in the patient medication record shall be deemed confidential and may be released to other than patient or prescriber only on written release of the patient. If in the judgment of the pharmacist, 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 pharmacist may communicate this information to the prescribers. [Order 125, § 360-16-260, filed 1/28/75, effective 7/1/75.]

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 (non-child-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.]

Chapter 360-18 WAC

LICENSING PERIODS AND FEES

WAC

360-18-010	Licensing periods.
360-18-020	License fees.
360-18-030	Intern registration fee.

WAC 360-18-010 Licensing periods. (1) Effective October 1, 1980, the following are established by the Board of Pharmacy as the licensing periods for each license specified:

(a) Pharmacist licenses will be renewable beginning on February 1 of each year, and will be subject to a penalty fee for renewal after April 1 of each year.

(b) Pharmacy location, CSA (retail), prophylactic (retail pharmacy), pharmacy assistant utilization, shopkeeper and shopkeeper differential hours licenses will be renewable beginning on June 1 of each year and will be subject to a penalty fee for renewal after August 1 of each year.

(c) CSA (sodium pentobarbital), Level A assistant, physician's assistant, wholesaler (full line), wholesaler (OTC only), intern, manufacturer, CSA wholesaler, CSA manufacturer, prophylactic (vending machine), and prophylactic wholesaler licenses will be renewable beginning on October 1 of each year and will be subject to a penalty fee for renewal after December 1 of each year.

(2) Effective until October 1, 1980, the board establishes licensing periods as specified in the various provisions of the Pharmacy Practice Act as they appeared prior to the effective date of chapter 90, Laws of 1979 which prior provisions are incorporated herein by this reference. [Statutory Authority: RCW 18.64.005(4) and (11). 80-05-074 (Order 154, Resolution 4/80), § 360-18-010, filed 4/28/80.]

WAC 360-18-020 License fees. (1) Pursuant to chapter 90, Laws of 1979, the board hereby determines, sets and establishes, effective October 1, 1980, the following fees for licenses issued by the board:

(a) PHARMACY LOCATION, CSA & PROPHYLACTIC

Original pharmacy fee	\$100.00
Original CSA fee	30.00
Original prophylactic fee	10.00
Original pharmacy assistant utilization fee	25.00
Renewal pharmacy fee	50.00
Renewal CSA fee	25.00
Renewal prophylactic fee	10.00
Renewal pharmacy assistant utilization fee	25.00
Penalty pharmacy fee	100.00

(b) VENDOR

Original fee	20.00
Renewal fee	20.00
Penalty fee	20.00

(c) PHARMACIST

Exam fee	75.00
Original license fee	50.00
Renewal fee	25.00
Penalty fee	25.00
Reciprocity fee	150.00

(d) SHOPKEEPER

Original fee	20.00
Renewal fee	20.00
Penalty fee	20.00

(i) SHOPKEEPER - 6 or fewer drugs

Original fee	5.00
Renewal fee	5.00
Penalty fee	5.00

(ii) SHOPKEEPER - with differential hours

Original fee	20.00
Renewal fee	20.00
Penalty fee	20.00

(e) DRUG MANUFACTURER

Original fee	125.00
Renewal fee	125.00
Penalty fee	125.00

(f) DRUG WHOLESALER - full line

Original fee	125.00
Renewal fee	125.00
Penalty fee	125.00

(g) DRUG WHOLESALER - OTC only

Original fee	100.00
Renewal fee	100.00
Penalty fee	100.00

(h) PHARMACY ASSISTANT - Level "A"

Original fee	10.00
Renewal fee	10.00

(2) Effective until October 1, 1980, the board establishes as licensing fees those amounts specified in the various provisions of the Pharmacy Practice Act as they appeared prior to the effective date of chapter 90, Laws of 1979, which prior provisions are incorporated herein by this reference. [Statutory Authority: RCW 18.64.005(4) and (11). 80-08-035 (Order 155, Resolution 6/80), § 360-18-020, filed 6/26/80, effective 9/30/80; 80-05-074 (Order 154, Resolution 4/80), § 360-18-020, filed 4/28/80.]

WAC 360-18-030 Intern registration fee. Pursuant to RCW 18.64.080(3) as amended by chapter 90, Laws of 1979, the board hereby determines that the fee for registration as an intern shall be \$5.00 per year and that the examination fee for licensure as a pharmacist shall be \$75.00. [Statutory Authority: RCW 18.64.005(4) and (11). 80-05-074 (Order 154, Resolution 4/80), § 360-18-030, filed 4/28/80.]

Chapter 360-20 WAC SALES PROHIBITED

WAC

360-20-100 Drug sample prohibited

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.

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.]

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.
- 360-23-040 Advertising or mail order solicitation of sale or distribution of prescription drugs prohibited.
- 360-23-050 Drug price disclosure—Required.

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 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 360-23-040 Advertising or mail order solicitation of sale or distribution of prescription drugs prohibited. Whereas, the purpose of regulating the practice of pharmacy and the sale of drugs is the protection of the public health; and

Whereas, the sale and distribution of drugs by prescription is safeguarded by a direct, constant, and professional contact between the physician, patient, and pharmacist; and

Whereas, RCW 18.64.250 prohibits any person from advertising in Washington in any manner drugs or names of like import, without having pharmacists licensed by Washington employed; and

Whereas, mail solicitation of drugs by prescription impairs this professional personal contact, tends to lead to falsification, forgery, and fraudulent prescription, and in many instances violates RCW 18.64.250;

Now, therefore, we adopt the following regulation:

(1) Hereafter no person shall solicit by advertising of any kind the sale or distribution of drugs by prescription by any mail order plan of any form. The mail order sale of drugs by prescription is prohibited whenever such sale has been solicited by advertising of any kind by any person or persons.

(2) The term "person" is defined as individual, partnership, corporation, association, or agency. [Order 124, § 360-23-040, 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.

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 360-30 WAC HYPODERMIC SYRINGES, NEEDLES AND DEVICES

WAC

- 360-30-010 Hypodermic devices sale registrations.
360-30-020 Hypodermic devices destruction.
360-30-030 Enforcement.

WAC 360-30-010 Hypodermic devices sale registrations. (1) Every pharmacy, person or firm selling or furnishing syringes, needles or devices without a prescription must keep a register book. Syringes, needles or devices sold or furnished without a prescription shall be recorded in the register book and the following information must be recorded therein:

- (a) Date sold or furnished;
- (b) Printed name of purchaser;
- (c) Signature of purchaser;
- (d) Address of purchaser;
- (e) Name of the syringes, needles or devices sold or furnished;
- (f) Quantity sold or furnished;
- (g) Initials of name of person who sold or furnished the syringe, needle or device;
- (h) Proof of identification (driver's license number, or any other identification code unique to that particular individual).

(2) All register books used to record the sale or furnishing of syringes, needles or devices shall conform to the following standards:

(a) The book shall be 8-1/2 inches wide, 11 inches long;

(b) The book shall be securely bound, not loose leaf or spiral bound;

(d) The book shall have its pages consecutively numbered with a unique number assigned to each book and identified on each page.

(3) Register books shall be retained for five years from the last entry date. [Order 134, § 360-30-010, filed 9/7/77.]

WAC 360-30-020 Hypodermic devices destruction.

(1) After final use, any used hypodermic syringe, needle or similar device shall be immediately destroyed in such a manner as to render such device unfit for reuse in any manner. Such destruction may include, but is not limited to, breaking the needle and separation of the syringe plunger and barrel. Used devices should be treated as infectious waste and disposed of properly.

(2) Immediate destruction shall mean destruction as soon as possible after final use without interfering with patient safety or the clinical situation.

(3) All pharmacies and other retail outlets shall notify all purchasers of hypodermic devices that state law requires immediate destruction after final use. [Order 137, § 360-30-020, filed 11/8/77.]

WAC 360-30-030 Enforcement. (1) Citations. All employees of the board of pharmacy designated as peace officers are authorized to issue citations for violation of chapter 249, Laws of 1977 ex. sess. or the regulations adopted pursuant to that chapter upon probable cause to believe that a violation has been committed.

(2) Hearing. Any person who disputes the grounds for issuance of a citation may apply to the board for a hearing which will be conducted pursuant to the provisions of chapter 34.04 RCW.

(3) Forfeiture. In lieu of a hearing, a person who receives a citation may forfeit a fine according to the following schedule:

- (a) First violation - \$25.00;
- (b) Second violation - \$100.00;
- (c) Third violation - \$500.00.

(4) Warning notice. If in the opinion of the pharmacy board employee any person's first violation of the laws or regulations governing the sale, transfer or destruction of hypodermic syringes was not a deliberate unlawful act, the board employee may issue that person a warning notice in lieu of a citation. [Order 137, § 360-30-030, filed 11/8/77.]

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 9/79), filed 9/5/79. Statutory Authority: RCW 18.64.005(11).
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 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 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 1979 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 \$10 per copy. [Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution 9/79), § 360-32-050, filed 9/5/79.]

WAC 360-32-055 Ephedrine prescription restrictions. (1) No person shall prepare, compound, dispense, sell, give away, barter, or otherwise distribute ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity, except as stated in subsections (2) and (3) of this regulation or as provided in RCW 69.41.030.

(2) Preparation or distribution of the drugs in subsection (1) shall be:

(a) Upon a written prescription of a licensed medical practitioner;

(b) Upon an oral prescription of a licensed medical practitioner which is reduced promptly to writing and filed by the pharmacist; or

(c) By refilling the written or oral prescription if such refilling is authorized by the licensed medical practitioner either in the original prescription or by oral order which is reduced promptly to writing and shall include the date of the refill authorization, the initials of the pharmacist receiving the authorization and the filing by the pharmacist.

(3) The following products containing ephedrine or its stereoisomers are exempted from the provisions of this regulation:

1. AMORDRINE tablet (Searle)	25mg (as racemic hydrochloride)
2. BRONITIN tablet (Whitehall)	24mg ephedrine
3. BRONKAID tablet (Breon)	24mg (as sulfate)
4. BRONKOTABS tablet (Breon)	24mg (as sulfate)
5. CALCIDRINE SYRUP (Abbott)	4.2mg/5cc Hcl
6. CHLOR-TRIMENTON DECONGESTANT (Schering)	60mg ephedrine
7. CODIMAL tablet - capsule (Central Pharmacal)	pseudoephedrine hydrochloride, 30mg
8. CO-TYLENOL COLD FORMULA for CHILDREN (McNeil)	pseudoephedrine hydrochloride, 7.5mg/5 ml
9. D-FEDA (Dooner)	pseudoephedrine hydrochloride, 30mg/5 ml
10. DIMOCOL LIQUID and CAPSULES (Robins)	pseudoephedrine hydrochloride, 30mg/5 ml or capsules
11. FEDAHIST tablet - syrup (Dooner)	pseudoephedrine hydrochloride, 60mg/tablet 30mg/5 ml
12. FEDAHIST EXPECTORANT (Dooner)	pseudoephedrine hydrochloride, 30mg/5 ml
13. FEDRAZIL tablet (Burroughs Wellcome)	pseudoephedrine hydrochloride, 30mg
14. HISTADYL EC (Lilly)	ephedrine hydrochloride, 30mg/30 ml
15. HISTIVITE-D (Vitarine)	ephedrine sulfate, 30mg/30 ml
16. NALDEGESIC tablet (Bristol)	pseudoephedrine, 15mg
17. NOVAFED syrup (Dow)	pseudoephedrine hydrochloride, 30mg/5 ml
18. NOVAFED A (Dow)	pseudoephedrine hydrochloride, 30mg/5 ml
19. NOVAHISTINE DMX (Dow)	pseudoephedrine hydrochloride, 30mg/5 ml
20. NYQUIL (Vicks)	ephedrine sulfate, 8mg/30 ml
21. PRIMATINE M tablet (Whitehall)	24mg (as hydrochloride)
22. QUELIDRINE (Abbott)	ephedrine hydrochloride, 5mg/5 ml
23. QUIET-NITE (Rexall)	ephedrine sulfate, 10mg/30 ml
24. ROBITUSSION-PE (Robins)	pseudoephedrine hydrochloride, 30mg/5 ml

25. SINACET tablet
(Meyer) pseudophedrine hydrochloride, 15mg
26. SUDAFED tablet - syrup
(Burroughs Wellcome) psuedoephedrine hydrochloride, 30mg and 60mg tablets or 5 ml (30mg/ml)
27. VERAQUAD tablet - suspension (Knoll) 24mg tablet, 12mg/5 ml (as hydrochloride)

[Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution 9/79), § 360-32-055, filed 9/5/79.]

- 360-36-160 Placement of phencyclidine in Schedule II. [Statutory Authority: RCW 69.50.201. 78-05-048 (Order 144, Resolution 12-78), § 360-36-160, filed 4/24/78.] Repealed by 79-02-060 (Order 146, Resolution 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 12-78), § 360-36-170, filed 4/24/78.] Repealed by 79-02-060 (Order 146, Resolution 2-79), filed 2/1/79. Statutory Authority: RCW 18.64.005(9) and 69.50.201.

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.
- 360-36-230 Registration.
- 360-36-240 Storage.
- 360-36-250 Drug administration.
- 360-36-260 Records and reports.
- 360-36-270 Penalties.

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 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 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 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 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 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 9/80) 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 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 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 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 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 2-79), filed 2/1/79. Statutory Authority: RCW 18.64.005(9) and 69.50.201.

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, 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. The registration fee shall be as follows:

- (a) \$30.00 for a dispensing registration (i.e., pharmacies);
- (b) \$25.00 for the annual renewal for dispensing (i.e., pharmacies);
- (c) \$50.00 for registration for distributors (i.e., wholesalers);
- (d) \$50.00 for the annual renewal for distributors (i.e., wholesalers);
- (e) \$50.00 for a registration for manufacturers;
- (f) \$50.00 for the annual renewal for manufacturers;
- (g) \$15.00 for application for physician's assistant;
- (h) \$10.00 for the annual renewal for physician's assistant;
- (i) \$15.00 for application for limited registration to obtain sodium pentobarbital for animal euthanasia;
- (j) \$10.00 for annual renewal of limited sodium pentobarbital registration.

(3) A separate registration is required for each principle 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 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 69.50.301. 80-05-074 (Order 154, Resolution 4/80), § 360-36-010, filed 4/28/80; 79-10-007 (Order 151, Resolution 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.]

WAC 360-36-020 Dispensing schedule V controlled substances. 1. Those drugs classified on schedule V under the uniform controlled substances act which can be dispensed without a prescription can be so distributed only if it is for a medical purpose and is dispensed in accordance with the following rules.

2. Only a registered pharmacist or a pharmacy intern may dispense a schedule V drug and he can only do so if it is sold in good faith as a medicine. 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 a pharmacy intern shall not sell a schedule V drug to a person below the age of 21 and he shall require the purchaser to identify himself so that he will know the purchaser's true name, address, and that he is at least 21 years of age. 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 initials on the label at the time of sale. The pharmacist or pharmacy intern is further required to show every purchaser of a schedule V product a copy of Rule 3 (rule relating to purchasers of schedule V drugs).

3. No person shall purchase a schedule V drug without a doctor's prescription unless he complies with the following:

(1) The product must be purchased in good faith as a medicine;

(2) The purchaser must sign the schedule V register book with his true name and address and supply adequate proof of identification.

(3) The purchaser cannot purchase without a prescription more than four fluid ounces (120cc's) of liquid schedule V drugs, nor more than four grains of nonliquid schedule V drugs.

4. In the absence of a doctor's prescription, no pharmacist or pharmacy shall sell to any person, nor shall any person purchase, within a forty-eight hour period, more than the maximum quantity set forth in Rule 3(3).

5. (1) Every pharmacy handling schedule V drugs (RCW 69.50.212) must keep a schedule V register book. When entries are being made on a specific page the following statement must appear at the top of the page: "I have not purchased any schedule V preparations within the last forty-eight hours and this is my true signature and address". All sales of schedule V drugs without a doctor's prescription shall be recorded in the schedule V register book and the following information must be recorded therein:

(a) Printed name of purchaser

(b) Signature of purchaser

(c) Address of purchaser

(d) Name of the schedule V preparation sold

(e) Quantity of schedule V preparation sold

(f) Date of sale
(g) Initials or name of pharmacist who sold the schedule V drug

(h) Proof of identification (driver's license number, social security number or any other identification code unique to that particular individual).

(2) All register books used to record the sale of schedule V drugs shall conform to the following standards:

(a) The book shall be 8 1/2 inches wide, 11 inches long.

(b) The book shall be securely bound, not loose leaf or spiral bound.

(c) The book shall have its pages consecutively numbered with a unique number assigned to each book and identified on each page.

(d) Each page shall contain a carbon and second sheet. When each page of the book is filled, it shall be promptly mailed to the board of pharmacy office.

(3) All pharmacy records relating to the purchase and/or sales of schedule V drugs and inventory of schedule V drugs shall be open to examination by state board of pharmacy inspectors during normal business hours. The refusal to permit such examination constitutes grounds for the suspension or revocation of the pharmacists license. [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 (beechem 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-ingenelheim).

(9) Methylphenidate HCL in any of its generic forms and under the following brand name:

(a) Ritalin (ciba). [Statutory Authority: RCW 69.50-201. 79-08-069 (Order 148, Resolution 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 9/79), § 360-36-220, filed 9/6/79; Order 138, § 360-36-220, filed 11/8/77.]

WAC 360-36-230 Registration. (1) Registrations under chapter 69.50 RCW shall be for an annual period with the registration period ending on December 1st of each year. The registration fee shall be as follows:

(a) \$15.00 for application for limited registration.

(b) \$10.00 for annual renewal of limited registration.

(2) A separate registration is required for each separate location.

(3) Registration with the drug enforcement administration shall be limited to schedule II nonnarcotic controlled substances and shall be used only for the acquisition of sodium pentobarbital for animal euthanasia. [Statutory Authority: RCW 69.50.301. 80-05-074 (Order 154, Resolution 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 9/79), § 360-36-230, filed 9/6/79; Order 138, § 360-36-230, 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.]

Chapter 360-40 WAC PROPHYLACTICS

WAC
360-40-010 Definitions.

[Title 360 WAC—p 36]

WAC 360-40-010 Definitions. (1) The definitions set forth in RCW 18.81.010 and 18.64.011 shall be applicable to these rules. In addition, the following terms are defined:

(a) A "condom" is 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.

(2) Application for license. Any person seeking a wholesale or retail license under chapter 18.81 RCW shall file with the board of pharmacy the appropriate license fee and an application on a form prepared by the board. Retail pharmacies shall not be required to submit a separate application form for a prophylactic license. All other applicants must submit the required form setting forth at least the following information:

(a) Name of the applicant; if a corporation, the officers thereof;

(b) Location for which the license is sought;

(c) Whether condoms are to be sold personally or through means of a vending machine.

(d) The applicant must be either (i) a pharmacy, (ii) a hospital pharmacy, (iii) a public or private program approved by state or county health department engaged in venereal disease prevention or treatment or family planning or the care and treatment for rehabilitation of any person; (iv) vending machine operation; if the applicant is not the lessee or owner of the premises then consent by the same is required; (v) a person or program that a local health officer has determined in the interest of public health prophylactics should be made available (if (v) is appropriate, a written statement by the local health officer must accompany the application;)

(e) If a vending machine outlet, then the times at which the purchasers will have access to the machine.

(3) The holder of any retail or wholesale license for the sale of prophylactics must display that license so that it is readily available for examination by an inspector for the board. Any vending machine which is licensed must have a current decal supplied by the board permanently attached to the machine. Each machine requires a separate retail license.

(4) No condoms shall be sold in this state unless the following conditions are met:

(a) The product is on a list of condom products which have been tested by the board and are on an approved list or have been specifically tested and approved by the board on the basis of three dozen samples submitted to the board for testing prior to sale in this state.

(b) All condoms shall be individually sealed in plastic, foil or a comparable type seal to protect the product from deterioration from exposure to air.

(c) Individual condoms or individual condom containers shall bear the date of manufacture.

(5) The board shall annually prepare a list of condom products which have successfully met the testing requirements set forth in Rule 6. Said list shall be prepared no later than May 1st of each year. In order to be included in that annual testing, three dozen samples of the product must be submitted to the board prior to

April 1st. Condoms can be submitted for testing at other times, but in order to be approved prior to the annual May 1st listing date the individual submitting three dozen samples for testing must pay a special testing fee of \$50.00, and the board shall have at least forty-five days in which to complete such special tests.

(6) Condom testing. The tests shall be performed under the supervision of an employee of the Washington State Board of Pharmacy. Three dozen samples of each brand of condoms are to be tested.

(a) Rubber condoms (this is any elastic material):

(i) Rubber condoms shall be air tested, capable of standing inflation with one cubic foot of air, and free from holes, imperfect rings and/or blisters.

(ii) Procedure for air testing. The rubber condoms are mechanically inflated with one cubic foot of air at prevailing atmospheric pressure in room temperature of approximately 70° Fahrenheit. The apparatus used is an air compressor equipped with a gauge indicating the amount of air injected into the device being tested. The rate of air injection to inflate the article is approximately 1 minute per cubic foot of air.

(iii) Water testing. Condoms shall have no holes as may be demonstrated by the following procedure: 300 cc's of water shall be poured into the condom to be tested, and the open end of the condom then firmly closed with the fingers. The condom shall then be placed on its side on a blotter or clean towel and gently rolled from side to side to remove any water that may have spilled. If any droplets of water appear on subsequent examination each droplet will indicate the presence of a hole. Any holes within one inch of the open end of the condom will be disregarded.

(b) Nonrubber condoms (nonelastic material): Such condoms shall be of suitable length, not patched, free from grease or any foreign substances that may be used as a filler for hiding imperfections or discolorations.

(i) Water testing. Such condoms to be inflated with water, suspended and observed for a twelve-hour period and accepted if the water is retained. No product being so tested shall be approved if the failure rate exceeds one percent. A product which has failed the test may be re-submitted for testing. However, for such retesting six dozen samples must be supplied and if the retesting is at any time other than the annual testing period, there is a one hundred dollar fee for retesting.

(7) Any license issued pursuant to these regulations is subject to suspension or revocation if the board determines that the licensee has retailed nonapproved condoms or distributed condoms to a nonlicensed outlet.

(8) The list of approved condoms by the Oregon state board of pharmacy is hereby adopted as the approved list under these regulations until the first annual list is prepared by the board no later than May 1, 1972.

(9) No condoms may be sold in this state if they are three years or older from the date of manufacture. [Order 108, § 360-40-010, filed 10/26/71.]

Chapter 360-44 WAC

PUBLIC RECORDS ACCESS PURSUANT TO INITIATIVE 276

WAC

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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 governmental 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. [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 three 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, 18.81, 69.04, 69.40, and 69.50 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 licenses suspension or revocation, unlawful practices, prescription labels and records.

(b) Chapter 18.81 RCW – prophylactic law – regulation and licensing of prophylactics and distributors.

(c) 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.

(d) Chapter 69.40 RCW – poison act – labeling of drugs incorrectly and selling poisons without labeling and recording sales.

(e) Chapter 69.50 RCW – controlled substances act – places all narcotics, barbiturates, amphetamines, hallucinogenics and marihuana 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.

(5) Information concerning all licenses or registrations issued by the board may be obtained by writing or calling the administrative office of the board. [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. [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.

(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.

(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" 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 purporting 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 360-49 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.]

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) 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 9/80), § 360-49-040, filed 9/22/80; 80-02-113 (Order 153, Resolution 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 1/80), § 360-52-060, filed 1/28/80. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution 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.
360-54-020	Definitions.
360-54-030	Nuclear pharmacies.
360-54-040	Nuclear pharmacists.
360-54-050	Minimum equipment requirements.

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 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 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 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 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 1-79), § 360-54-050, filed 2/1/79.]