

Chapter 358-20 WAC

APPEALS--FILINGS--DECLARATORY RULINGS

WAC

358-20-040 Filing appeals.

WAC 358-20-040 Filing appeals. (1) An appeal must be received in writing at the principal office of the personnel appeals board within 30 days after: (a) The effective date of the disciplinary or dismissal for abandonment action (WAC 358-20-010); (b) notification of disability separation (WAC 358-20-010); (c) notification of the allocation determination of the director of personnel or director's designee made pursuant to WAC 356-10-060(5) (WAC 358-20-030); or (d) the employee could reasonably be expected to have knowledge of the action giving rise to a law or rule violation claim under WAC 358-20-020 or the stated effective date of the action, whichever is later.

(2) The appeal shall include the name and address of the appellant, the name of the employing agency, and a telephone number at which the appellant can be reached. Appellants who are represented shall include the name, address and telephone number of their representative.

(3) An appeal of a violation of the state civil service law or the merit system rules must cite the law(s) or rule(s) which the appellant claims has been violated, the particular circumstances of the alleged violation, how the employee is adversely affected by the alleged violation, and the remedy requested.

(4) Forms which may be used in filing appeals shall be available from the executive secretary of the board. The forms shall contain appropriate spaces for the information required by subsections (2) and (3) of this rule. Appellants may prepare and use their own appeal documents. However, such documents must contain all of the information required by subsections (2) and (3) of this rule.

(5) Upon receipt of an appeal, the executive secretary may review the document(s) filed to determine whether the information required by subsections (2) and (3) of this rule has been provided. If any of the required information is not contained on the appeal documents, the executive secretary shall direct the appellant, with notification to all affected parties, to provide such information. The appellant must provide the missing information to the executive secretary within fifteen calendar days of the date the executive secretary mails the notification. Upon receipt of the requested information, the executive secretary of the personnel appeals board shall send a copy to the other affected parties.

(6) If an appellant fails to provide required information within the time limits set forth in subsection (5) of this rule, the executive secretary shall note the matter for a dismissal hearing before the board. At the dismissal hearing, the appellant shall have the burden of demonstrating compliance with subsections (2) and (3) of this rule. The respondent(s) may appear and present argument at the dismissal hearing.

(7) Failure of an appellant to comply with the requirements of this rule may result in dismissal for failure to state grounds for an appeal.

[Statutory Authority: Chapter 41.64 RCW. 87-20-035 (Order 87-1), § 358-20-040, filed 9/30/87. Statutory Authority: RCW 41.64.060 and chapter 41.64 RCW. 82-14-007 and 82-16-027 (Orders 82-1 and 82-1A), § 358-20-040, filed 6/25/82 and 7/28/82. Statutory Authority: Chapter 41.64 RCW. 82-01-053 (Order 81-4), § 358-20-040, filed 12/16/81.]

Chapter 358-30 WAC
HEARINGS--PROCEDURES

WAC

358-30-015 Motion for more definite statement.

WAC 358-30-015 Motion for more definite statement. (1) When an appeal is filed pursuant to WAC 358-20-020, the respondent may move for an order requiring the appellant to provide any information required by subsections (2) and (3) of WAC 358-20-040 which does not appear in the appeal documents and/or to make the allegations sufficiently clear to enable the respondent to prepare its defense. Any such motion must be made within fifteen calendar days of the mailing of the acknowledgment required in WAC 358-30-010, or, if the executive secretary requires more information pursuant to WAC 358-20-040(5), within fifteen calendar days after the appellant's response is filed. The board will examine the motion and the appeal, and, if it finds merit in the motion, shall issue such order as it deems necessary to obtain compliance with WAC 358-20-040.

(2) If the motion is granted, the appellant shall provide the information required within fifteen calendar days of the date of the order. Failure to provide the required information in a timely manner may result in dismissal of the appeal for failure to state grounds for an appeal.

(3) If a respondent does not move for an order to correct deficiencies within the prescribed time, any objection on its part to the sufficiency of the appeal shall be deemed waived.

[Statutory Authority: Chapter 41.64 RCW. 87-20-035 (Order 87-1), § 358-30-015, filed 9/30/87.]

Title 360 WAC
PHARMACY, BOARD OF

Chapters

360-08	Practice and procedure.
360-10	Internship requirements.
360-12	Pharmacists.
360-13	Extended care facility.
360-16	Pharmacies.
360-18	Licensing periods and fees.
360-36	Regulations implementing the Uniform Controlled Substances Act.
360-38	Precursor substance control.

- 360-40 Prophylactics.
- 360-46 Good manufacturing practice for finished pharmaceuticals.
- 360-49 Drug product substitution.
- 360-52 Pharmacy assistant.
- 360-60 Home dialysis program.

**Chapter 360-08 WAC
PRACTICE AND PROCEDURE**

WAC

- 360-08-005 Practice and procedure cross reference.
- 360-08-030 Repealed.
- 360-08-070 Repealed.
- 360-08-080 Repealed.
- 360-08-090 Repealed.
- 360-08-100 Repealed.
- 360-08-110 Repealed.
- 360-08-120 Repealed.
- 360-08-130 Repealed.
- 360-08-140 Repealed.
- 360-08-410 Repealed.
- 360-08-430 Repealed.
- 360-08-440 Repealed.
- 360-08-450 Repealed.
- 360-08-460 Repealed.
- 360-08-470 Repealed.
- 360-08-480 Repealed.
- 360-08-490 Repealed.
- 360-08-500 Repealed.
- 360-08-510 Repealed.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

- 360-08-030 Appearance and practice before board—Solicitation of business unethical. [Regulation .08.020, filed 1/10/63; Regulation .08.030, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-070 Computation of time. [Regulation .08.060, filed 1/10/63; Regulation .08.070, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-080 Notice and opportunity for hearing in contested cases. [Regulation .08.070, filed 1/10/63; Regulation .08.080, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-090 Service of process—By whom served. [Regulation .08.080, filed 1/10/63; Regulation .08.090, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-100 Service of process—Upon whom served. [Regulation .08.090, filed 1/10/63; Regulation .08.100, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-110 Service of process—Service upon parties. [Regulation .08.100, filed 1/10/63; Regulation .08.110, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-120 Service of process—Method of service. [Regulation .08.110, filed 1/10/63; Regulation .08.120, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-130 Service of process—When service complete. [Regulation .08.120, filed 1/10/63; Regulation .08.130, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-140 Service of process—Filing with the board. [Regulation .08.130, filed 1/10/63; Regulation .08.140, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.

- 360-08-410 Form and content of decisions in contested cases. [Regulation .08.410, filed 1/10/63; Regulation .08.410, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-430 Prehearing conference rule—Authorized. [Regulation .08.430, filed 1/10/63; Regulation .08.430, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-440 Prehearing conference rule—Record of conference action. [Regulation .08.440, filed 1/10/63; Regulation .08.440, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-450 Submission of documentary evidence in advance. [Regulation .08.450, filed 1/10/63; Regulation .08.450, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-460 Excerpts from documentary evidence. [Regulation .08.460, filed 1/10/63; Regulation .08.460, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-470 Expert or opinion testimony and testimony based on economic and statistical data—Number and qualifications of witnesses. [Regulation .08.470, filed 1/10/63; Regulation .08.470, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-480 Expert or opinion testimony and testimony based on economic and statistical data—Written sworn statements. [Regulation .08.480, filed 1/10/63; Regulation .08.480, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-490 Expert or opinion testimony and testimony based on economic and statistical data—Supporting data. [Regulation .08.490, filed 1/10/63; Regulation .08.490, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 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. [Regulation .08.500, filed 1/10/63; Regulation .08.500, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.
- 360-08-510 Continuances. [Regulation .08.510, filed 1/10/63; Regulation .08.510, filed 3/23/60.] Repealed by 88-06-026 (Order 210), filed 2/25/88. Statutory Authority: RCW 18.64.005.

WAC 360-08-005 Practice and procedure cross reference. In order to conform the board's practice and procedure rules to the uniform procedural rules for the conduct of contested cases, the board has repealed certain practice and procedure rules. The following cross reference will assist in locating the superseding uniform procedural rule.

Repealed Board Rule	Uniform Procedural Rule
WAC 360-08-070 -	WAC 10-08-080
WAC 360-08-080 -	WAC 10-08-040
WAC 360-08-090 -	WAC 10-08-110
WAC 360-08-100 -	WAC 10-08-110

<u>Repealed Board Rule</u>	<u>Uniform Procedural Rule</u>
WAC 360-08-110 -	WAC 10-08-110
WAC 360-08-120 -	WAC 10-08-110
WAC 360-08-130 -	WAC 10-08-110
WAC 360-08-140 -	WAC 10-08-110
WAC 360-08-410 -	WAC 10-08-210
WAC 360-08-430 -	WAC 10-08-130
WAC 360-08-440 -	WAC 10-08-130
WAC 360-08-450 -	WAC 10-08-140
WAC 360-08-460 -	WAC 10-08-140
WAC 360-08-510 -	WAC 10-08-090

[Statutory Authority: RCW 18.64.005, 88-06-026 (Order 210), § 360-08-005, filed 2/25/88.]

WAC 360-08-030 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-070 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-080 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-090 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-100 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-110 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-120 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-130 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-140 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-410 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-430 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-440 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-450 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-460 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-470 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-480 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-490 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-500 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-08-510 Repealed. See Disposition Table at beginning of this chapter.

**Chapter 360-10 WAC
INTERNSHIP REQUIREMENTS**

WAC	
360-10-010	General requirements.
360-10-020	Registration of interns.
360-10-030	Rules for the pharmacy intern.
360-10-040	Intern training reports.
360-10-050	Requirements for preceptor certification.
360-10-060	Rules for preceptors.
360-10-070	Repealed.
360-10-080	Special internship approval.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-10-070	Repeal of prior regulations. [Regulation 48, § VII, filed 6/17/66.] Repealed by 88-01-025 (Order 208), filed 12/9/87. Statutory Authority: RCW 18.64.005(11).
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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 or school of pharmacy accredited by the board of pharmacy or any graduate of any accredited college or school of pharmacy.

(2) As provided for in RCW 18.64.080(4) the board of pharmacy hereby establishes fifteen hundred hours for the internship requirement.

(a) For graduates prior to July 1, 1991, credit may be allowed:

(i) Up to seven hundred hours for experiential classes as part of the curriculum of an accredited college or school of pharmacy commonly referred to as externship/ clerkship;

(ii) Up to five hundred hours of credit for the internship shall be granted to graduates of board approved schools or colleges of pharmacy;

(iii) Seven hundred hours or more for experience obtained after completing the first quarter/semester of pharmacy education, and including any breaks or vacations.

(b) For graduates after July 1, 1991, credit may be allowed:

(i) Up to seven hundred hours of experiential classes as part of the curriculum of an accredited college or school of pharmacy commonly referred to as externship/clerkship;

(ii) Eight hundred or more hours for experience obtained after completing the first quarter/semester of pharmacy education, and including any breaks or vacations of which at least two hundred hours must be gained within the last twelve months prior to licensure.

(c) The board will document hours in excess of these requirements for students qualifying for out-of-state licensure.

(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) To retain a certificate as a pharmacy intern, the intern must make continuing satisfactory progress in completing the pharmacy course.

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

(6) 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.

[Statutory Authority: RCW 18.64.005(11), 88-06-060 (Order 211), § 360-10-010, filed 3/2/88; 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. In order to be registered as a pharmacy intern, the applicant must file with the board of pharmacy an application for registration as a pharmacy intern as provided for in RCW 18.64.080. The application shall be accompanied by a fee as specified in WAC 360-18-020. Prior to engaging in the practice of pharmacy as an intern or extern, under the supervision of a preceptor, the applicant must be registered by the board as a pharmacy intern.

[Statutory Authority: RCW 18.64.005(11), 88-01-025 (Order 208), § 360-10-020, filed 12/9/87. Statutory Authority: RCW 18.64.005 and 18.64A.020, 83-18-021 (Order 175), § 360-10-020, filed 8/30/83; Order 106, § 360-10-020, filed 6/3/71; Regulation 48, § II, filed 6/17/66.]

WAC 360-10-030 Rules for the pharmacy intern.
(1) The intern shall send notification to the board of

pharmacy on or before the first day of beginning of his/her 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/her 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 practice of pharmacy, and the selling of items restricted to sale under the supervision of a licensed pharmacist, only while he/she is under the direct and personal supervision of a certified preceptor.

[Statutory Authority: RCW 18.64.005(11), 88-01-025 (Order 208), § 360-10-030, filed 12/9/87; Regulation 48, § III, filed 6/17/66.]

WAC 360-10-040 Intern training reports. (1) The intern shall file with the board on forms provided by the board an internship evaluation report at the completion of internship training experience at each site.

(2) The board of pharmacy shall provide the necessary affidavit forms to the intern for the purpose of certification of the 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 after the completion of any site internship experience. Completion of any site experience is intended to mean those situations when neither the intern nor the preceptor anticipate further intern experience at some later date at that site.

(3) 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 the practice of pharmacy adequately.

(4) Certification of at least seven hundred hours must be submitted to the board office thirty days prior to licensing examination.

[Statutory Authority: RCW 18.64.005(11), 88-01-025 (Order 208), § 360-10-040, filed 12/9/87; 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 licensed 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 completed a board approved training program within the last five years, and who has been certified by the board of pharmacy shall be known as "pharmacist preceptor." The requirement for completion of an approved training program becomes effective January 1, 1990.

(2) The pharmacist preceptor must have completed twelve months as a licensed pharmacist engaged in the practice of pharmacy as defined in RCW 18.64.011(11).

(3) Any preceptor or preceptor applicant who has been found guilty of a drug or narcotic violation or

whose pharmacist license has been revoked, suspended, or placed on probation by the state board of pharmacy shall not be eligible for certification as a preceptor, until completion of the probationary period, and a showing of good cause for certification as a pharmacist preceptor.

(4) The preceptor shall be responsible for the quality of the internship training under his/her supervision and he/she shall assure 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 or maintain the requirements as stated in this section.

(6) In considering the approval of special internship programs pursuant to WAC 360-10-080, the board may approve alternative qualification requirements for the preceptors of such programs.

[Statutory Authority: RCW 18.64.005(11), 88-06-060 (Order 211), § 360-10-050, filed 3/2/88; 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 pharmacist preceptor shall supervise the pharmacy intern and shall be responsible for the sale of restricted items, and the compounding and dispensing of pharmaceuticals dispensed by an intern.

(2) The pharmacist preceptor must use the board approval plan of instruction for interns.

(3) Upon completion of the intern's experience at each site, the 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 evaluation of the intern's ability to practice pharmacy at that stage of internship.

(4) The board of pharmacy shall provide the necessary affidavit forms to certify hours of experience under the personal supervision of a preceptor. Affidavits must be certified and recorded in the office of the board not later than thirty days after the completion of any site intern experience; provided that any experience necessary for eligibility to take the licensing examination must be in the board office no later than thirty days prior to the examination.

(5) The pharmacist preceptor may supervise more than one intern during a given time period; however, two interns may not dispense concurrently under the direct supervision of the same preceptor.

[Statutory Authority: RCW 18.64.005(11), 88-06-060 (Order 211), § 360-10-060, filed 3/2/88; Order 102, § 360-10-060, filed 12/5/69; Regulation 48, § VI, filed 6/17/66.]

WAC 360-10-070 Repealed. See Disposition Table at beginning of this chapter.

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 thirty days prior to the next board

meeting which will afford the board an opportunity to review the program.

[Statutory Authority: RCW 18.64.005(11), 88-01-025 (Order 208), § 360-10-080, filed 12/9/87; Order 114, § 360-10-080, filed 6/28/73.]

Chapter 360-12 WAC PHARMACISTS

WAC

360-12-015	Examinations.
360-12-020	Repealed.
360-12-050	Applicants—Reciprocity applicants.
360-12-150	Monitoring of drug therapy by pharmacists.
360-12-160	AIDS prevention and information education requirements.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-12-020	Applicants—Application forms—Fees. [Order 109, § 360-12-020, filed 5/23/72; Regulation 19 (part), filed 3/23/60.] Repealed by 87-18-066 (Order 207), filed 9/2/87. Statutory Authority: RCW 18.64.005.
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WAC 360-12-015 Examinations. (1) The examination for licensure as a pharmacist shall be known as the full board examination in such form as may be determined by the board.

(2) The score required to pass the overall examination shall be 75. In addition, the score achieved in the jurisprudence section of the exam shall be no lower than 75 percent.

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

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

[Statutory Authority: RCW 18.64.005, 87-18-066 (Order 207), § 360-12-015, filed 9/2/87. Statutory Authority: RCW 18.64.005(1) and 18.64.080, 84-04-029 (Order 183), § 360-12-015, filed 1/25/84. Statutory Authority: RCW 69.50.201, 79-04-048 (Order 147, Resolution No. 3-79), § 360-12-015, filed 3/27/79.]

WAC 360-12-020 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-12-050 Applicants—Reciprocity applicants. (1) Applicants for license by reciprocity whose applications have been approved 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.

(2) An applicant for license by reciprocity 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.

(3) An applicant for license by reciprocity 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 18.64.005. 87-18-066 (Order 207), § 360-12-050, filed 9/2/87. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-12-050, filed 3/27/79; Order 121, § 360-12-050, filed 8/8/74; Regulation 4, filed 3/23/60.]

WAC 360-12-150 Monitoring of drug therapy by pharmacists. The term "monitoring drug therapy" used in RCW 18.64.011(11) shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. Monitoring of drug therapy shall include, but not be limited to:

(1) Collecting and reviewing patient drug use histories;

(2) Measuring and reviewing routine patient vital signs including, but not limited to, pulse, temperature, blood pressure and respiration; and

(3) Ordering and evaluating the results of laboratory tests relating to drug therapy including, but not limited to, blood chemistries and cell counts, drug levels in blood, urine, tissue or other body fluids, and culture and sensitivity tests when performed in accordance with policies and procedures or protocols applicable to the practice setting, which have been developed by the pharmacist and prescribing practitioners and which include appropriate mechanisms for reporting to the prescriber monitoring activities and results.

[Statutory Authority: RCW 18.64.005. 87-18-066 (Order 207), § 360-12-150, filed 9/2/87. Statutory Authority: RCW 18.64.005 and 69.41.075. 83-20-053 (Order 176), § 360-12-150, filed 9/29/83. Statutory Authority: RCW 18.64.005 and 69.41.240. 83-10-013 (Order 174), § 360-12-150, filed 4/26/83.]

WAC 360-12-160 AIDS prevention and information education requirements. (1) Definitions.

(a) "Acquired immunodeficiency syndrome" or "AIDS" means the clinical syndrome of human immunodeficiency virus-related illness as defined by the board of health by rule.

(b) "Office on AIDS" means that section within the department of social and health services or any successor department with jurisdiction over public health matters as defined in chapter 70.24 RCW.

(2) Application for licensure. Effective January 1, 1989, persons applying for licensure shall submit, in addition to the other requirements, evidence to show compliance with the AIDS education requirements of subsection (4) of this section, or shall certify that they will comply with the AIDS education requirement no later than December 31, 1989.

(3) 1989 renewal of licenses. Effective with the renewal period beginning February 1, 1989, all persons making application for licensure renewal in 1989 shall submit, in addition to the other requirements, evidence to show compliance with the education requirements of

subsection (4) of this section. Pharmacists may submit compliance documentation with their renewal or at any time prior to December 31, 1989. Approved AIDS education may be counted towards a pharmacist's continuing education requirement.

(4) AIDS education and training.

(a) Acceptable education and training. The board will accept education and training that covers the required subjects and otherwise qualifies for continuing education credit. Such education and training shall be a minimum of seven clock hours (.7 CE units) and shall include, but is not limited to, the following: Etiology and epidemiology; testing and counseling; infection control guidelines; clinical manifestations and treatment; legal economic and ethical issues to include confidentiality; and psychosocial issues to include special population considerations.

(b) Implementation. Effective February 1, 1989, the requirement for licensure, renewal, or reinstatement of any license on lapsed, inactive, or disciplinary status shall include the one-time requirement of completion of AIDS education and training. All persons affected by this section shall show evidence of completion of an education and training program, which meets the requirements of (a) of this subsection.

(c) Documentation. The licensee shall:

(i) Certify, on forms provided, that the minimum education and training has been completed after January 1, 1987;

(ii) Keep records for two years documenting attendance and description of the learning;

(iii) Be prepared to validate, through submission of these records, that attendance has taken place.

[Statutory Authority: RCW 18.64.005. 88-23-058 (Order 221), § 360-12-160, filed 11/15/88.]

Chapter 360-13 WAC EXTENDED CARE FACILITY

WAC

360-13-045 Definitions.

360-13-066 Pharmaceutical services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[Statutory Authority: RCW 18.64.005, 87-18-066 (Order 207), § 360-13-045, filed 9/2/87. Statutory Authority: RCW 18.64.005(11), 81-06-077 (Order 158), § 360-13-045, filed 3/4/81; Order 121, § 360-13-045, filed 8/8/74.]

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

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

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

consultant pharmacist supervises the entire spectrum of pharmaceutical services in the nursing home.

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

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

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

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

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

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

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

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

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

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

(3) Security and storage of drugs.

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

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

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

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

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

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

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

(4) Labeling of drugs.

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

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

(c) Nonlegend drugs shall be clearly labeled with at least the patient's name, date of receipt by the facility, as well as display a manufacturer's original label or a pharmacy label if repackaged by the pharmacist. Non-legend drugs supplied by the extended care facility pursuant to WAC 388-88-050 need not be labeled with the patient's name.

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

(5) Control and accountability.

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

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

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

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

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

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

(6) Special requirements for controlled substances.

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

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

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

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

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

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

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

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

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

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

disposition of all Schedule II and III controlled substances.

(7) Drug administration.

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

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

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

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

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

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

(i) Verification of administration

(ii) Reasons for ordered doses not taken

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

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

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

(i) Assessment of the resident's capabilities

(ii) Instructions for administration

(iii) Monitoring of progress and compliance with orders

(iv) Safe storage of drugs.

[Statutory Authority: RCW 18.64.005. 88-11-007 (Order 214), § 360-13-066, filed 5/9/88. Statutory Authority: RCW 18.64.005(11). 81-14-055 (Order 161), § 360-13-066, filed 6/30/81.]

Chapter 360-16 WAC PHARMACIES

WAC

360-16-025	Pharmacy license renewal.
360-16-094	Prescription transfers.
360-16-096	Prescription record requirements.
360-16-235	Pharmacy inspections.
360-16-240	Repealed.
360-16-245	Poison control.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-16-240	General. [Statutory Authority: RCW 18.64.043. 84-12-019 (Order 186), § 360-16-240, filed 5/25/84. Statutory Authority: RCW 18.64.005(9) and 69.50-.201. 79-02-060 (Order 146, Resolution No. 2-79), § 360-16-240, filed 2/1/79; Order 131, § 360-16-240, filed 2/4/77; Order 51 (part), filed 8/15/67.] Repealed by 87-08-031 (Order 205), filed 3/27/87. Statutory Authority: RCW 18.64.005.
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WAC 360-16-025 Pharmacy license renewal. The state board of pharmacy will not renew any pharmacy license unless the following are submitted:

(1) A complete renewal application form; and

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

[Statutory Authority: RCW 18.64.005. 88-14-041 (Order 215), § 360-16-025, filed 6/30/88. Statutory Authority: RCW 18.64.043. 84-12-019 (Order 186), § 360-16-025, filed 5/25/84.]

WAC 360-16-094 Prescription transfers. The transfer of original prescription information for a non-controlled substance legend drug for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(a) Record in the patient medication record system that a copy has been issued.

(b) Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(2) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(a) Write the word "TRANSFER" on the face of the transferred prescription.

(b) Provide all information required to be on the prescription - patient's name and address; doctor's name and address, and also include:

(i) Date of issuance of original prescription.

(ii) Number of valid refills remaining and date of last refill.

(iii) The pharmacy's name, address, and original prescription number from which the prescription information was transferred.

(iv) Name of transferor pharmacist.

(c) Both the original and transferred prescription must be maintained as if they were original prescriptions.

(d) A transferred prescription may not be refilled after one year from the date the original was issued.

(e) The above subsections apply to the transfer of prescription information for noncontrolled substances. The transfer of controlled substance prescription information must conform to the requirements of 21 CFR 1306.26.

(3) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.

(4) If two or more pharmacies utilize a common electronic database for prescription recordkeeping, prescriptions may be refilled at any of these pharmacies as long as there is provided an audit trail which documents the location of each filling and provisions are made to assure that the number of authorized refills are not exceeded.

[Statutory Authority: RCW 18.64.005. 88-23-058 (Order 221), § 360-16-094, filed 11/15/88.]

WAC 360-16-096 Prescription record requirements.

(1) 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.

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

(a) 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.

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

(c) 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.

(d) 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.

(e) 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. The transfer of original prescription information is permitted if the provisions of WAC 360-16-094 are met.

(f) 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.

[Statutory Authority: RCW 18.64.005, 88-23-058 (Order 221), § 360-16-096, filed 11/15/88; 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 360-16-235 Pharmacy inspections. (1) All pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.

(2) Each inspected pharmacy shall receive a classification rating which will depend upon the extent of that pharmacy's compliance with the inspection standards.

(3) There shall be three rating classifications:

(a) "Class A" – for inspection scores of 90 to 100;

(b) "Conditional" – for inspection scores of 80 to 89; and,

(c) "Unsatisfactory" – for inspection scores below 80.

(4) Any pharmacy receiving a conditional rating shall have sixty days to raise its inspection score rating to 90 or better. If upon reinspection after sixty days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

(5) Any pharmacy receiving an unsatisfactory rating shall have fourteen days to raise its inspection score rating to 90 or better. If upon reinspection after fourteen days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

(6) The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced.

(7) Noncompliance with the provisions of chapter 18.64A RCW (Pharmacy assistants) and, chapter 360-52 WAC (Pharmacy assistants) resulting in a deduction of at least five points shall result in an automatic unsatisfactory rating regardless of the total point score.

(8) Pharmacies receiving an unsatisfactory rating which represent a clear and present danger to the public health, safety and welfare will be subject to summary suspension of the pharmacy license.

[Statutory Authority: RCW 18.64.005, 87-08-031 (Order 205), § 360-16-235, filed 3/27/87.]

WAC 360-16-240 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-16-245 Poison control. (1) The telephone number of the nearest poison control center shall be readily available.

(2) Each pharmacy shall maintain at least one ounce bottle of Ipecac syrup in stock at all times.

[Statutory Authority: RCW 18.64.005, 87-08-031 (Order 205), § 360-16-245, filed 3/27/87; Order 120, § 360-16-245, filed 3/11/74.]

Chapter 360-18 WAC

LICENSING PERIODS AND FEES

WAC

360-18-010	Licensing periods.
360-18-020	Fees.
360-18-025	Fee payment.

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

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

(b) Pharmacy location, controlled substance registration (pharmacy), pharmacy assistant utilization, and shopkeeper differential hours licenses will expire on June 1 of each year.

(c) All other licenses, permits, or registrations will expire on October 1 of each year.

(2) Any license, permit, or registration that is not renewed on or before the expiration date established

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

[Statutory Authority: RCW 18.64.005. 88-14-042 (Order 216), § 360-18-010, filed 6/30/88. Statutory Authority: RCW 18.64.005, 18-81.080 and 42.17.290. 83-01-083 (Order 171), § 360-18-010, filed 12/17/82. Statutory Authority: RCW 18.64.005 (4) and (11). 80-05-074 (Order 154, Resolution No. 4/80), § 360-18-010, filed 4/28/80.]

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

(a) PHARMACY LOCATION	
Original pharmacy fee	\$165.00
Original pharmacy assistant utilization fee	35.00
Renewal pharmacy fee	85.00
Renewal pharmacy assistant utilization fee	35.00
Penalty pharmacy fee	165.00
(b) VENDOR	
Original fee	40.00
Renewal fee	40.00
Penalty fee	40.00
(c) PHARMACIST	
Exam fee (full exam)	175.00
Reexamination fee (jurisprudence portion)	25.00
Original license fee	75.00
Renewal fee, active and inactive license	60.00
Penalty fee	60.00
Reciprocity fee	250.00
Certification of license status to other states	10.00
(d) SHOPKEEPER	
(i) SHOPKEEPER - sixteen or more drugs	
Original fee	10.00
Renewal fee	10.00
Penalty fee	5.00
(ii) SHOPKEEPER - with differential hours	
Original fee	10.00
Renewal fee	10.00
Penalty fee	5.00
(e) DRUG MANUFACTURER	
Original fee	250.00
Renewal fee	250.00
Penalty fee	250.00
(f) DRUG WHOLESALER - full line	
Original fee	250.00
Renewal fee	250.00
Penalty fee	250.00
(g) DRUG WHOLESALER - OTC only	
Original fee	150.00
Renewal fee	150.00
Penalty fee	150.00

(h) DRUG WHOLESALER - export	
Original fee	250.00
Renewal fee	250.00
Penalty	250.00
(i) PHARMACY ASSISTANT - Level "A"	
Original fee	30.00
Renewal fee	20.00
(j) PHARMACY INTERN	
Original registration fee	15.00
Renewal registration fee	15.00
(k) CONTROLLED SUBSTANCES ACT (CSA) REGISTRATIONS	
Dispensing registration fee (i.e. pharmacies)	35.00
Dispensing renewal fee (i.e. pharmacies)	30.00
Distributors registration fee (i.e. wholesalers)	50.00
Distributors renewal fee (i.e. wholesalers)	50.00
Manufacturers registration fee	50.00
Manufacturers renewal fee	50.00
Physician assistant registration fee	15.00
Physician assistant renewal fee	10.00
ARNP with prescriptive authorization registration fee	15.00
ARNP with prescriptive authorization renewal fee	10.00
Sodium pentobarbital for animal euthanization registration fee	20.00
Sodium pentobarbital for animal euthanization renewal fee	15.00
(l) LEGEND DRUG SAMPLE - distributor registration fees	
Original fee	125.00
Renewal fee	85.00
(m) POISON MANUFACTURER/SELLER - license fees	
Original fee	20.00
Renewal fee	20.00
(n) Facility inspection fee	100.00
(o) PRECURSOR CONTROL PERMIT	
Original fee	40.00
Renewal fee	40.00

[Statutory Authority: RCW 18.64.005. 88-14-042 (Order 216), § 360-18-020, filed 6/30/88; 88-07-011 (Order 209), § 360-18-020, filed 3/3/88; 87-18-066 (Order 207), § 360-18-020, filed 9/2/87. Statutory Authority: RCW 18.64.005(4). 85-22-033 (Order 196), § 360-18-020, filed 10/31/85; 85-06-010 (Order 193), § 360-18-020, filed 2/22/85. Statutory Authority: RCW 18.64.005. 84-17-142 (Order 189), § 360-18-020, filed 8/22/84; 84-04-030 (Order 184), § 360-18-020, filed 1/25/84; 83-22-034 (Order 177), § 360-18-020, filed 10/26/83. Statutory Authority: RCW 18.64.005 and 18.64A.020. 83-18-021 (Order 175), § 360-18-020, filed 8/30/83. Statutory Authority: RCW 18.64.005(12). 82-12-041 (Order 168), § 360-18-020, filed 5/28/82. Statutory Authority: RCW 18.64.005 (4) and (11). 80-08-035 (Order 155, Resolution No. 6/80), § 360-18-020, filed 6/26/80, effective 9/30/80; 80-05-074 (Order 154, Resolution No. 4/80), § 360-18-020, filed 4/28/80.]

WAC 360-18-025 Fee payment. (1) A licensed pharmacist, wholesaler, or manufacturer shall pay a facility inspection fee in lieu of the original license fee when there is only a change of facility location within the premises identified by the license address. Any change of location to a different address shall require a new application and payment of the original license fee.

(2) An original license fee shall be paid whenever there is any change in ownership, including change in business structure or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than fifty percent ownership in a corporation.

(3) All fees are charged on an annual basis and will not be prorated.

[Statutory Authority: RCW 18.64.005, 88-07-011 (Order 209), § 360-18-025, filed 3/3/88.]

Chapter 360-36 WAC

REGULATIONS IMPLEMENTING THE UNIFORM CONTROLLED SUBSTANCES ACT

WAC

360-36-010 Uniform Controlled Substances Act.
360-36-425 Schedule II immediate precursors.

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, 1987, 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.

(3) A separate registration is required for each place of business (as defined in section 1301.23) where controlled substances are manufactured, distributed or dispensed. Application for registration must be made on forms supplied by the pharmacy board, and all information called for thereon must be supplied unless the information is not applicable, in which case it must be indicated. An applicant for registration must hold the appropriate wholesaler, manufacturer or pharmacy license provided for in chapter 18.64 RCW.

(4) Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by 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, 87-10-029 (Order 206), § 360-36-010, filed 5/1/87. Statutory Authority: RCW 18.64.005(4), 85-06-010 (Order 193), § 360-36-010, filed 2/22/85. Statutory Authority: RCW 69.50.301, 80-05-074 (Order 154, Resolution No. 4/80), § 360-36-010, filed 4/28/80; 79-10-007 (Order 151, Resolution No. 9/79), § 360-36-010, filed 9/6/79. Statutory Authority: RCW 69.50.301 and chapter 69.50 RCW, 78-02-070 (Order 140), §

360-36-010, filed 1/25/78; Order 132, § 360-36-010, filed 5/4/77; Order 108, § 360-36-010, filed 10/26/71.]

WAC 360-36-425 Schedule II immediate precursors. (1) The board finds and designates the following substances as being the principal compound used or produced primarily for use and which are an immediate chemical intermediary used or likely to be used, in the manufacture of a Schedule II controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

(2) Unless specifically excepted or listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances or their salts or isomers having potential for abuse associated with the preparation of controlled substances shall be a Schedule II controlled substance.

- (a) Anthranilic acid.
- (b) Ephedrine.
- (c) Methylamine.
- (d) Phenylacetic acid.
- (e) Pseudoephedrine.
- (f) Methamphetamine.
- (g) Lead acetate.
- (h) Methyl formamide.

Provided: That any drug or compound containing Ephedrine, or any of its salts or isomers, or Pseudoephedrine, or any of its salts or isomers that are prepared for dispensing or over-the-counter distribution and are in compliance with the Federal Food, Drug and Cosmetic Act and applicable regulations are not controlled substances for the purpose of this section: *And Provided Further,* That any cosmetic containing lead acetate that is distributed in compliance with the Federal Food, Drug and Cosmetic Act and applicable regulations are not controlled substances.

[Statutory Authority: RCW 18.64.005. 88-11-007 (Order 214), § 360-36-425, filed 5/9/88. Statutory Authority: RCW 18.64.005(11). 88-06-060 (Order 211), § 360-36-425, filed 3/2/88.]

Chapter 360-38 WAC PRECURSOR SUBSTANCE CONTROL

WAC

360-38-010	Precursor substance defined.
360-38-020	Reports of precursor receipt.
360-38-030	Monthly reporting option.

WAC 360-38-010 Precursor substance defined. (1) For the purpose of this chapter a precursor substance is any of the following substances or their salts or isomers:

- (a) Anthranilic acid;
- (b) Barbituric acid;
- (c) Chlorophedrine;
- (d) Diethyl malonate;
- (e) D-lysergic acid;
- (f) Ephedrine;
- (g) Ergotamine tartrate;
- (h) Ethylamine;
- (i) Ethyl malonate;

- (j) Ethylephedrine;
- (k) Lead acetate;
- (l) Malonic acid;
- (m) Methylamine;
- (n) Methylformamide;
- (o) Methylephedrine;
- (p) Methylpseudoephedrine;
- (q) N-acetylanthranilic acid;
- (r) Norpseudoephedrine;
- (s) Phenylacetic acid;
- (t) Phenylpropanolamine;
- (u) Piperidine;
- (v) Pseudoephedrine; and
- (w) Pyrrolidine.

Provided; that this definition shall not include any drug that contains ephedrine, phenylpropanolamine, or pseudoephedrine or any cosmetic if that drug or cosmetic can be lawfully sold, transferred, or furnished over-the-counter without a prescription or by a prescription under chapter 69.04 or 69.41 RCW.

(2) The board finds that the reference to methylformamide in section 1, chapter 147, Laws of 1988, was intended to refer to methylformamide and corrects that reference by deleting "methylformamide" and adding "methylformamide." This change is based upon the finding that this revision conforms to the tests set forth in section 1(2), chapter 147, Laws of 1988.

(3) Registrants should be aware that precursor substances in subsection (1)(a), (f), (k), (m), (n), (s), and (v) of this section are also regulated as schedule II immediate precursors pursuant to WAC 360-36-425 and all applicable rules and laws governing the distribution of schedule II controlled substances must also be complied with.

[Statutory Authority: 1988 c 147 § 5. 88-14-096 (Order 218), § 360-38-010, filed 7/6/88.]

WAC 360-38-020 Reports of precursor receipt. (1) Any manufacturer, wholesaler, retailer, or any other person who receives from any source outside the state of Washington any precursor substance listed in WAC 360-38-010 shall submit a report of such transaction within fourteen days of the receipt of that substance.

- (2) The report shall contain the following information:
- (a) Name of substance;
 - (b) Quantity received;
 - (c) Date received;
 - (d) Name and address of firm or person receiving substance; and
 - (e) Name and address of the source selling, transferring, or furnishing the substance.

(3) The report shall be on a form approved by the board: *Provided,* That in lieu of an approved form the board will accept a copy of an invoice, packing list, or other shipping document which contains the information set forth in subsection (2) of this section. Under this option purchase price information appearing on the document can be deleted.

[Statutory Authority: 1988 c 147 § 5. 88-14-096 (Order 218), § 360-38-020, filed 7/6/88.]

WAC 360-38-030 Monthly reporting option. (1) Permit holders who regularly transfer the same precursor substance to the same recipient can apply to the board for authorization to submit the report of said transactions on a monthly basis. Requests for monthly reporting authorization must be received at the board office at least thirty days prior to the board meeting at which the request will be considered. The board will review each request to determine if the requirements of section 1(5), chapter 147, Laws of 1988, are met and will notify the permit holder of its decision and the reporting format that will be authorized.

(2) Permit holders may also petition the board to accept the monthly report on a computer-generated basis. The report can be furnished in hard copy, on board-approved data storage methods or by computer interface with a board-operated computer. The permit holder will be responsible for the accuracy of the report and the prompt correction of any data entry or transmission errors.

(3) The authorization to use monthly reports or computer-generated monthly reports can be rescinded at the board's discretion and with thirty days notice.

[Statutory Authority: 1988 c 147 § 5. 88-14-096 (Order 218), § 360-38-030, filed 7/6/88.]

Chapter 360-40 WAC PROPHYLACTICS

WAC

360-40-040 Conditions for the sale of condoms.

WAC 360-40-040 Conditions for the sale of condoms. Condoms sold in this state must meet the following conditions:

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

(2) The container in which the condom is sold to the purchaser shall bear the date of manufacture or shall bear an expiration date not more than three years after the date of manufacture. Condoms may not be sold in this state three years after the date of manufacture.

[Statutory Authority: RCW 18.64.005. 88-20-038 (Order 219), § 360-40-040, filed 9/30/88. Statutory Authority: RCW 18.64.005 and 69.040.730 [69.04.730]. 85-06-010 (Order 193), § 360-40-040, filed 2/22/85. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17-.290. 83-01-083 (Order 171), § 360-40-040, filed 12/17/82.]

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 Repealed.
360-46-081 Component and drug product containers and closures.
360-46-082 Reuse of teat dip containers and closures.
360-46-090 Laboratory controls.
360-46-100 Stability.
360-46-120 Packaging and labeling.
360-46-130 Master production and control records—Batch production and control records.
360-46-160 Variance and procedure.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

360-46-080 Product containers and their packaging material. [Order 133, § 360-46-080, filed 8/4/77.] Repealed by 88-01-025 (Order 208), filed 12/9/87. Statutory Authority: RCW 18.64.005(11).

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 a drug product, including those that may not appear in the finished product.

(b) The term "drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(c) The term "active ingredient" means any component that 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 humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(d) The term "inactive ingredient" means any component other than an "active ingredient" present in a drug product.

(e) The term "batch" means a specific quantity of a drug or other material that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(f) The term "lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(g) The terms "lot number," "control number," or "batch number" mean any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a

batch or lot of drug product or other material can be determined.

(h) The term "quality control unit" means any person or organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

(i) The term "strength" means:

(i) The concentration of the drug product (for example, w/w, w/v, or unit dose/volume basis); and/or

(ii) The potency, that is, the therapeutic activity of the drug product 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).

(j) The term "fiber" means any particulate contaminant with a length at least three times greater than its width.

(k) The term "nonfiber-releasing filter" means any filter, which after any appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. All filters composed of asbestos are deemed to be fiber-releasing filters.

(l) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages or labels such substance or device.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-010, filed 10/10/88; 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 chapter permit the use of precision automatic, mechanical, or electronic equipment in the production and control of drugs when written inspection and checking policies and procedures are used to assure proper performance.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-020, filed 10/10/88; 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 components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All employees shall be instructed to report to supervisory personnel any conditions that may have such an adverse effect on drug products.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-030, filed 10/10/88; 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, repacking, 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, drug products, 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 quality control 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.

(7) Be maintained in a clean, orderly, and sanitary condition. There shall be written procedures assigning responsibility for sanitation and describing the cleaning schedule and methods.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-040, filed 10/10/88; 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 component, in-process material, or drug product shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product 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.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-050, filed 10/10/88; 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, including batch number, 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 written procedures, designed to prevent objectionable microorganisms in drug products not requiring to be sterile, shall be established and followed.

(5) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of any sterilization process.

(6) Appropriate procedures shall be established to minimize the hazard of cross-contamination of any drugs while being manufactured or stored.

(7) 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.

(8) Representative samples of all dosage form drugs shall be tested to determine their conformance with the specifications for the product before distribution.

(9) 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.

(10) 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 product, 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 repackaging. 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 subsection (9) of this section.

(11) 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.

(12) Appropriate procedures shall be established to destroy beyond recognition and retrievability any and all components or drug products that are to be discarded or destroyed for any reason.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-060, filed 10/10/88; 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 quality control 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) Sample containers shall be identified so that the following information can be determined: Name of the material sampled, the lot number, the container from which the sample was taken, and the name of the person who collected the sample.

(4) Containers from which samples have been taken shall be marked to show that samples have been removed from them.

(5) Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.

(6) 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.

(7) Representative samples of components liable to microbiological 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.

(8) 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.

(9) 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.

(10) 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.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-070, filed 10/10/88; Order 133, § 360-46-070, filed 8/4/77.]

WAC 360-46-080 Repealed. See Disposition Table at beginning of this chapter.

WAC 360-46-081 Component and drug product containers and closures. (1) Component and drug product containers and closures shall:

(a) Not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quantity, or purity of the product or its components beyond the official or established requirements;

(b) Provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product; and

(c) Be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Containers and their components for parenterals shall be cleansed with water which has been filtered through a nonfiber-releasing filter.

(2) Standards or specifications, methods of testing, and, where indicated, processing to remove pyrogenic properties shall be written and followed for component and drug product containers and closures.

(3) Except as provided for in WAC 360-46-082, drug product containers and closures shall not be reused for component or drug product packaging.

[Statutory Authority: RCW 18.64.005(11), 88-01-025 (Order 208), § 360-46-081, filed 12/9/87.]

WAC 360-46-082 Reuse of teat dip containers and closures. The reuse of teat dip containers and closures shall be allowed under the following circumstances:

(1) Teat dip containers for reuse must have attached a labelling panel bearing product name, brand name and distributor address if marketed by other than the manufacturer, manufacturer name and address, product strength, quantity, expiration date, directions for use, and appropriate cautionary statements for the product contained within.

(2) All reusable teat dip containers will be hot stamped for permanent identification as teat dip containers. The hot stamp shall imprint on the plastic container, in an immutable manner, the words "teat dip only" and the manufacturer's name. Teat dip manufacturers may only refill containers bearing their company name.

(3) With cooperation from dairy producers, dairy sanitarians will take random samples of teat dip in reusable containers while on regular farm inspections. The samples, along with appropriate label information, will be forwarded to the board of pharmacy for analysis to insure that the product meets label specifications and is free of contamination.

(4) Reusable teat dip containers shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quantity, or purity of the product.

(5) Upon return to the manufacturer, reusable teat dip containers shall be cleaned and sanitized. To insure adequate cleaning occurs, the board of pharmacy may require a manufacturer to submit and have approved a cleaning procedure. Containers showing structural damage, or any signs of being used for substances or materials other than teat dip shall not be reused as teat dip containers.

[Statutory Authority: RCW 18.64.005(11), 88-01-025 (Order 208), § 360-46-082, filed 12/9/87.]

WAC 360-46-090 Laboratory controls. Laboratory controls shall include the establishment of scientifically sound and appropriate written 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 microorganisms 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 humans 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.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-090, filed 10/10/88; Order 133, § 360-46-090, filed 8/4/77.]

WAC 360-46-100 Stability. There shall be written procedures for 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.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-100, filed 10/10/88; Order 133, § 360-46-100, 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 (9).

(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.

(6) Provide for compliance with the Poison Prevention Packaging Act, (16 CFR Part 1700).

(7) Provide for compliance with WAC 360-46-080(2).

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-120, filed 10/10/88; 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 (9).

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-130, filed 10/10/88; Order 133, § 360-46-130, filed 8/4/77.]

WAC 360-46-160 Variance and procedure. Licensees may request that the board issue a variance from specific requirements of WAC 360-46-040 through 360-46-150. The request must be in writing and must explain why the criteria should not apply and how the public's safety would be protected. Issuance of a variance shall be based on the information supplied by the manufacturer requesting the variance, as well as any other information available as a result of any investigation by the board and/or any other relevant information available. After due consideration of all the information, the board may issue or deny the requested variance. Any variance granted shall be limited to the particular case described in the request and shall be posted at the manufacturing location during the time it is in effect. Variances will be reviewed at least every three years. Variances shall be subject to withdrawal or modification at any time if the board finds the variance has resulted in actual or potential harm to the public.

[Statutory Authority: RCW 18.64.005. 88-21-025 (Order 220), § 360-46-160, filed 10/10/88.]

Chapter 360-49 WAC DRUG PRODUCT SUBSTITUTION

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.

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) 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 subsection (1) of this section, 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 subsection (2) of this section 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 subsection (2) of this section, 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 deems 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) of this section. 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) of this section 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 thirty 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) of this section 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) of this section after notification of their status.

[Statutory Authority: RCW 18.64.005. 87-18-066 (Order 207), § 360-49-040, filed 9/2/87. Statutory Authority: RCW 69.41.180. 80-14-012 (Order 157, Resolution No. 9/80), § 360-49-040, filed 9/22/80; 80-02-113 (Order 153, Resolution No. 1/80), § 360-49-040, filed 1/28/80.]

Chapter 360-52 WAC PHARMACY ASSISTANT

WAC

360-52-050	Level A certification.
360-52-060	Level B pharmacy assistants utilization.
360-52-090	Board approval of pharmacies utilizing pharmacy assistants.

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.

[Statutory Authority: RCW 18.64A.030. 88-14-043 (Order 217), § 360-52-050, filed 6/30/88; 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 typing of prescription labels, filing, re-filing, bookkeeping, pricing or determination of cost or charge, stocking, delivery, nonprofessional phone inquiries, and documentation of third party reimbursements.

Level B pharmacy assistants may prepackage and label drugs for subsequent use in prescription dispensing operations. However, they cannot count, pour, or label for individual prescriptions.

[Statutory Authority: RCW 18.64A.030. 88-14-043 (Order 217), § 360-52-060, filed 6/30/88. Statutory Authority: RCW 18.64.005(11) and 18.64A.030. 80-02-113 (Order 153, Resolution No. 1/80), § 360-52-060, filed 1/28/80. Statutory Authority: RCW 69.50.201. 79-04-048 (Order 147, Resolution No. 3-79), § 360-52-060, filed 3/27/79; Order 141, § 360-52-060, filed 12/9/77.]

WAC 360-52-090 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.

(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.

[Statutory Authority: RCW 18.64A.030. 88-14-043 (Order 217), § 360-52-090, filed 6/30/88; Order 141, § 360-52-090, filed 12/9/77.]

Chapter 360-60 WAC HOME DIALYSIS PROGRAM

WAC

360-60-010	Home dialysis program—Legend drugs.
360-60-020	Pharmacist consultant.
360-60-030	Records.
360-60-040	Quality assurance.

WAC 360-60-010 Home dialysis program—Legend drugs. Pursuant to RCW 18.64.257 and 69.41.032, a Medicare-approved dialysis center or facility operating a Medicare-approved home dialysis program may sell, deliver, possess and/or dispense directly to its home dialysis patients in cases or full shelf package lots, if prescribed by a physician, the following legend drugs:

- Sterile heparin, 1000u/ml, in vials;
- Sterile potassium chloride, 2mEq/ml, for injection;
- Commercially available dialysate; and,
- Sterile sodium chloride, 0.9%, for injection in containers of not less than 150ml.

[Statutory Authority: RCW 18.64.005. 88-06-026 (Order 210), § 360-60-010, filed 2/25/88.]

WAC 360-60-020 Pharmacist consultant. Home dialysis programs involved in the distribution of legend drugs as permitted by RCW 18.64.257 and 69.41.032, shall have an agreement with a pharmacist which provides for consultation as necessary. This shall include advice on the drug distribution process to home dialysis patients and on the location used for storage and distribution of the authorized drugs, which shall be reasonably separated from other activities and shall be secure.

[Statutory Authority: RCW 18.64.005. 88-06-026 (Order 210), § 360-60-020, filed 2/25/88.]

WAC 360-60-030 Records. (1) A record of shipment shall be attached to the prescriber's order and shall include: The name of the patient, strengths, and quantities of drugs; the manufacturers' names; date of shipment; names of persons who selected, assembled and packaged for shipment; and, the name of the pharmacist or designated individual responsible for the distribution.

(2) Prescription and drug distribution records shall be maintained in accordance with board of pharmacy record retention requirements.

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[Statutory Authority: RCW 18.64.005. 88-06-026 (Order 210), § 360-60-030, filed 2/25/88.]

WAC 360-60-040 Quality assurance. Home dialysis programs involved in the distribution of legend drugs as permitted by RCW 18.64.257 and 69.41.032, shall develop a quality assurance program for drug distribution and shall maintain records of drug distribution errors and other problems, including loss due to damage or theft.

[Statutory Authority: RCW 18.64.005. 88-06-026 (Order 210), § 360-60-040, filed 2/25/88.]

Title 365 WAC COMMUNITY DEVELOPMENT, DEPARTMENT OF

(Formerly: Planning and Community Affairs Agency)

Chapters

365-40	State funding of local Head Start programs.
365-100	Winter utility moratorium program.
365-110	State Building Code—Building permit surcharges and fees.
365-120	State funding of local emergency shelter programs.
365-135	Bond cap allocation.
365-140	State funding of local emergency food programs.
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Chapter 365-40 WAC

STATE FUNDING OF LOCAL HEAD START PROGRAMS

WAC

365-40-020	Definitions.
365-40-051	Eligibility criteria.
365-40-071	Method of payment and reporting requirements.

WAC 365-40-020 Definitions. (1) "Applicant" means a unit(s) of local government, a qualified private organization, or a combination thereof, which applies for state Head Start funds.

(2) "Contractor" means an applicant which has been allocated state Head Start funds and which has entered into a contract to carry out a Head Start program.

(3) "Director" means the director of the department of community development (hereafter, the agency).

(4) "Head Start program" means an operation undertaken in accordance with the program performance standards set forth in the OCD-HS HEAD START POLICY MANUAL (OCD Notice N-30-364-4) "Head Start program performance standards," published by the United States Department of Health, Education, and Welfare July, 1975.