Wash. Admin. Code Ch. 246-856 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-856**. Board of Pharmacy-general
➡➡ **Ch. 246-856 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-856-030. Delegation of authority to initiate investigations. (Statutory Authority: RCW 18.64.005, 18.130.050 and 18.130.080. WSR 08-06-030, S 246-856-030, filed 2/25/08, effective 3/27/08.) Repealed by WSR 11-10-046, filed 4/28/11, effective 5/29/11. Statutory Authority: RCW 18.130.050(1), 18.64.005(7).

WAC Ch. 246-856 Disp Table, WA ADC Ch. 246-856 Disp Table

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

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Wash. Admin. Code 246-856-001

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-856**. Board of Pharmacy-general (Refs & Annos)
➡➡ **246-856-001. Purpose.**

The purpose of this chapter is to combine the common rules adopted by the board of pharmacy for all holders of licenses, registrations and certifications, as well as any other authorizations, issued by the board of pharmacy.

Statutory Authority: RCW 18.64.005. WSR 94-17-144, S 246-856-001, filed 8/23/94, effective 9/23/94.

WAC 246-856-001, WA ADC 246-856-001

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Wash. Admin. Code 246-856-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-856**. Board of Pharmacy-general (Refs & Annos)
➡➡ **246-856-020. Adjudicative proceedings-Procedural rules for the board of pharmacy.**

The board adopts the model procedural rules for adjudicative proceedings as adopted by the department of health and contained in chapter 246-11 WAC, including subsequent amendments.

Statutory Authority: RCW 18.64.005. WSR 94-17-144, S 246-856-020, filed 8/23/94, effective 9/23/94.

WAC 246-856-020, WA ADC 246-856-020

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Wash. Admin. Code Ch. 246-857 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-857**. Pharmacists-Practice and Procedure
➡➡ **Ch. 246-857 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-857-020. Practice and procedure-Adoption by reference. (Statutory Authority: RCW 18.64.005 and 34.05.220. WSR 92-12-035 (Order 277B), S 246-857-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-06-026 (Order 210), S 360-08-005, filed 2/25/88.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-030. Appearance and practice before board-Who may appear. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-030, filed 8/30/91, effective 9/30/91; Regulation .08.010, filed 1/10/63; Regulation .08.010, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-040. Appearance and practice before board-Standards of ethical conduct. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-040, filed 8/30/91, effective 9/30/91; Regulation .08.030, filed 1/10/63; Regulation .08.040, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-050. Appearance and practice before board-Appearance by former employee of board or former member of attorney general's staff. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-050, filed 8/30/91, effective 9/30/91; Regulation .08.040, filed 1/10/63; Regulation .08.050, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-060. Appearance and practice before board-Former employee as expert witness. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-060, filed 8/30/91, effective 9/30/91; Regulation .08.050, filed 1/10/63; Regulation .08.060, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-070. Depositions and interrogatories in contested cases-Right to take. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-070, filed 8/30/91, effective 9/30/91; Regulation .08.230, filed 1/10/63; Regulation .08.230, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-080. Depositions and interrogatories in contested cases-Scope. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-080, filed 8/30/91, effective 9/30/91; Regulation .08.240, filed 1/10/63; Regulation .08.240, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-090. Depositions and interrogatories in contested cases-Officer before whom taken. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-090, filed 8/30/91, effective 9/30/91; Regulation .08.250, filed 1/10/63; Regulation .08.250, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-100. Depositions and interrogatories in contested cases-Authorization. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-100, filed 8/30/91, effective 9/30/91; Regulation .08.260, filed 1/10/63; Regulation .08.260, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-110. Depositions and interrogatories in contested cases-Protection of parties and deponents. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-110, filed 8/30/91, effective 9/30/91; Regulation .08.270, filed 1/10/63; Regulation .08.270, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-120. Depositions and interrogatories in contested cases-Oral examination and cross-examination. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-120, filed 8/30/91, effective 9/30/91; Regulation .08.280, filed 1/10/63; Regulation .08.280, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-130. Depositions and interrogatories in contested cases-Recordation. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-130, filed 8/30/91, effective 9/30/91; Regulation .08.290, filed 1/10/63; Regulation .08.290, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-140. Depositions and interrogatories in contested cases-Signing attestation and return. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-140, filed 8/30/91, effective 9/30/91; Regulation .08.300, filed 1/10/63; Regulation .08.300, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-150. Depositions and interrogatories in contested cases-Use and effect. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-150, filed 8/30/91,

effective 9/30/91; Regulation .08.310, filed 1/10/63; Regulation .08.310, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-160. Depositions and interrogatories in contested cases-Fees of officers and deponents. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-160, filed 8/30/91, effective 9/30/91; Regulation .08.320, filed 1/10/63; Regulation .08.320, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-170. Depositions upon interrogatories-Submission of interrogatories. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-170, filed 8/30/91, effective 9/30/91; Regulation .08.330, filed 1/10/63; Regulation .08.330, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-180. Depositions upon interrogatories-Interrogation. (Statutory Authority: RCW 18.64.005 and 34.05.220. WSR 92-12-035 (Order 277B), S 246-857-180, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-180, filed 8/30/91, effective 9/30/91; Regulation .08.340, filed 1/10/63; Regulation .08.340, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-190. Depositions upon interrogatories-Attestation and return. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-190, filed 8/30/91, effective 9/30/91; Regulation .08.350, filed 1/10/63; Regulation .08.350, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-200. Depositions upon interrogatories-Provisions of deposition rule. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-200, filed 8/30/91, effective 9/30/91; Regulation .08.360, filed 1/10/63; Regulation .08.360, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-210. Official notice-Matters of law. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-210, filed 8/30/91, effective 9/30/91; Regulation .08.370, filed 1/10/63; Regulation .08.370, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-220. Official notice-Material facts. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-220, filed 8/30/91, effective 9/30/91; Regulation .08.380, filed 1/10/63; Regulation .08.380, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-230. Presumptions. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057

(Order 191B), recodified as S 246-857-230, filed 8/30/91, effective 9/30/91; Regulation .08.390, filed 1/10/63; Regulation .08.390, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-240. Stipulations and admissions of record. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-240, filed 8/30/91, effective 9/30/91; Regulation .08.400, filed 1/10/63; Regulation .08.400, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-250. Definition of issues before hearing. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-250, filed 8/30/91, effective 9/30/91; Regulation .08.420, filed 1/10/63; Regulation .08.420, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-260. Rules of evidence-Admissibility criteria. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-260, filed 8/30/91, effective 9/30/91; Regulation .08.520, filed 1/10/63; Regulation .08.520, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-270. Rules of evidence-Tentative admission-Exclusion-Discontinuance-Objections. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-270, filed 8/30/91, effective 9/30/91; Regulation .08.530, filed 1/10/63; Regulation .08.530, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-280. Petitions for rule making, amendment or repeal-Who may petition. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-280, filed 8/30/91, effective 9/30/91; Regulation .08.540, filed 1/10/63; Regulation .08.540, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-290. Petitions for rule making, amendment or repeal-Requisites. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-290, filed 8/30/91, effective 9/30/91; Regulation .08.550, filed 1/10/63; Regulation .08.550, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-300. Petitions for rule making, amendment or repeal-Agency must consider. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-300, filed 8/30/91, effective 9/30/91; Regulation .08.560, filed 1/10/63; Regulation .08.560, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-310. Petitions for rule making, amendment or repeal-Notice of disposition.(Statutory Authority: RCW

18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-310, filed 8/30/91, effective 9/30/91; Regulation .08.570, filed 1/10/63; Regulation .08.570, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-320. Declaratory rulings. (Statutory Authority: RCW 18.64.005 and 34.05.220. WSR 92-12-035 (Order 277B), S 246-857-320, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-320, filed 8/30/91, effective 9/30/91; Regulation .08.580, filed 1/10/63; Regulation .08.580, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-330. Forms. (Statutory Authority: RCW 18.64.005 and 34.05.220. WSR 92-12-035 (Order 277B), S 246-857-330, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-330, filed 8/30/91, effective 9/30/91; Regulation .08.590, filed 1/10/63; Regulation .08.590, filed 3/23/60.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

246-857-340. SEPA exemption. (Statutory Authority: Chapter 43.21C RCW. WSR 92-12-035 (Order 277B), S 246-857-340, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-857-340, filed 8/30/91, effective 9/30/91; Order 128, S 360-45-010, filed 5/19/76.) Repealed by WSR 93-04-017 (Order 330B), filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005.

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Wash. Admin. Code 246-858-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-858**. Pharmacists-Internship Requirements
➡➡ **246-858-020. General requirements.**

(1) RCW 18.64.080(3) states: 'Any person enrolled as a student of pharmacy in an accredited college may file with the department an application for registration as a pharmacy intern---.' 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(3) the board of pharmacy hereby establishes fifteen hundred hours for the internship requirement.

(a) For graduates prior to January 1, 1999, 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) Eight hundred hours or more for experience obtained after completing the first quarter/semester of pharmacy education.

(b) For graduates after January 1, 1999, credit may be allowed:

(i) Up to twelve 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) Three hundred or more hours for experience obtained after completing the first quarter/semester of pharmacy education.

(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. The hours must be completed and a pharmacist license issued within eighteen months of the date of graduation.

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(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 246-858-060 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. WSR 96-02-006, S 246-858-020, filed 12/20/95, effective 1/20/96; WSR 92-12-035 (Order 277B), S 246-858-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-858-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 88-06-060 (Order 211), S 360-10-010, filed 3/2/88; Order 139, S 360-10-010, filed 12/9/77; Order 106, S 360-10-010, filed 6/3/71; Regulation 48, S I, filed 6/17/66.

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Wash. Admin. Code 246-858-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-858**. Pharmacists-Internship Requirements
➡➡ **246-858-030. Registration of interns.**

To register as a pharmacy intern, an applicant shall file with the department 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 246-907-030. 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. WSR 92-12-035 (Order 277B), S 246-858-030, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-858-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 88-01-025 (Order 208), S 360-10-020, filed 12/9/87. Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 83-18-021 (Order 175), S 360-10-020, filed 8/30/83; Order 106, S 360-10-020, filed 6/3/71; Regulation 48, S II, filed 6/17/66.

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Wash. Admin. Code 246-858-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-858**. Pharmacists-Internship Requirements
**246-858-040. Rules for the pharmacy intern.**

(1) The intern shall send notification to the board of pharmacy on or before the intern's first day of 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 the intern is under the direct and personal supervision of a certified preceptor or a licensed pharmacist designated by the preceptor to supervise that intern during the preceptor's absence from the site. Provided, that hours of experience gained while the certified preceptor is absent from the site shall not be counted toward fulfilling any internship requirement.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-858-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-858-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 91-11-041 (Order 170B), S 360-10-030, filed 5/10/91, effective 6/10/91. Statutory Authority: RCW 18.64.005(11). WSR 88-01-025 (Order 208), S 360-10-030, filed 12/9/87; Regulation 48, S III, filed 6/17/66.

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Wash. Admin. Code 246-858-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-858**. Pharmacists-Internship Requirements
➡➡ **246-858-050. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-858-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 88-01-025 (Order 208), S 360-10-040, filed 12/9/87; Order 106, S 360-10-040, filed 6/3/71; Order 102, S 360-10-040, filed 12/5/69; Regulation 48, S IV, filed 6/17/66.

WAC 246-858-050, WA ADC 246-858-050

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Wash. Admin. Code 246-858-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-858**. Pharmacists-Internship Requirements
➡➡ **246-858-060. 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 June 30, 1991.

(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 246-858-080, the board may approve alternative qualification requirements for the preceptors of such programs.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-858-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-858-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 91-11-041 (Order 170B), S 360-10-050, filed 5/10/91, effective 6/10/91; WSR 90-11-079 (Order 055), S 360-10-050, filed 5/16/90, effective 6/16/90. Statutory Authority: RCW 18.64.005(11). WSR 88-06-060 (Order 211), S 360-10-050, filed 3/2/88; Order 106, S 360-10-050, filed 6/3/71; Regulation 48, S V, filed 6/17/66.

WAC 246-858-060, WA ADC 246-858-060

Wash. Admin. Code 246-858-060

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Wash. Admin. Code 246-858-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-858**. Pharmacists-Internship Requirements
**246-858-070. Rules for preceptors.**

(1) The pharmacist preceptor, or his or her designee in accordance with WAC 246-858-040(2), 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 approved 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. WSR 92-12-035 (Order 277B), S 246-858-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-858-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 91-11-041 (Order 170B), S 360-10-060, filed 5/10/91, effective 6/10/91. Statutory Authority: RCW 18.64.005(11). WSR 88-06-060 (Order 211), S 360-10-060, filed 3/2/88; Order 102, S 360-10-060, filed 12/5/69; Regulation 48, S VI, filed 6/17/66.

WAC 246-858-070, WA ADC 246-858-070

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Wash. Admin. Code 246-858-070

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Wash. Admin. Code 246-858-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-858**. Pharmacists-Internship Requirements
➡➡ **246-858-080. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-858-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 88-01-025 (Order 208), S 360-10-080, filed 12/9/87; Order 114, S 360-10-080, filed 6/28/73.

WAC 246-858-080, WA ADC 246-858-080

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Wash. Admin. Code Ch. 246-863 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing
➡➡ **Ch. 246-863 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-863-050. Licensed pharmacists change of address. (Statutory Authority: RCW 18.64.005. WSR 93-10-007 (Order 357B), S 246-863-050, filed 4/22/93, effective 5/23/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-23-078, S 360-12-110, filed 11/17/89, effective 12/18/89. Statutory Authority: RCW 18.64.005(11). WSR 79-10-007 (Order 151, Resolution No. 9/79), S 360-12-110, filed 9/6/79; Regulation 5, filed 3/23/60.) Repealed by WSR 98-05-060, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.280.

WAC Ch. 246-863 Disp Table, WA ADC Ch. 246-863 Disp Table

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Wash. Admin. Code 246-863-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-020. 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 examination shall be 75. In addition, the score achieved in the jurisprudence section of the exam shall be no lower than 75.

(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 a pharmacy law course provided by a college of pharmacy or board directed study or tutorial program approved by the board.

(5) A person taking the licensing examination in another state for the purpose of score transfer to Washington shall be required to meet the same licensure requirements as a person taking the licensing examination in Washington. All of the documentation, fees, intern hours and reports shall be submitted. In order for the score transfer application to be valid, the licensing process must be completed within one year of the date the score transfer notification is received in the board office.

Statutory Authority: RCW 18.64.005. WSR 94-08-099, S 246-863-020, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-22-045, S 360-12-015, filed 10/30/89, effective 11/30/89; WSR 87-18-066 (Order 207), S 360-12-015, filed 9/2/87. Statutory Authority: RCW 18.64.005(1) and 18.64.080. WSR 84-04-029 (Order 183), S 360-12-015, filed 1/25/84. Statutory Authority: RCW 69.50.201. WSR 79-04-048 (Order 147, Resolution No. 3-79), S 360-12-015, filed 3/27/79.

WAC 246-863-020, WA ADC 246-863-020

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Wash. Admin. Code 246-863-020

END OF DOCUMENT

Wash. Admin. Code 246-863-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-030. 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. If the licensing process has not been completed within two years of the date of application, the application shall be considered abandoned.

(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 43.70.280. WSR 98-05-060, S 246-863-030, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 94-08-099, S 246-863-030, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-18-066 (Order 207), S 360-12-050, filed 9/2/87. Statutory Authority: RCW 69.50.201. WSR 79-04-048 (Order 147, Resolution No. 3-79), S 360-12-050, filed 3/27/79; Order 121, S 360-12-050, filed 8/8/74; Regulation 4, filed 3/23/60.

WAC 246-863-030, WA ADC 246-863-030

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Wash. Admin. Code 246-863-035

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-035. Temporary permits.**

(1) A temporary practice permit to practice pharmacy may be issued to an applicant who meets all of the requirements and qualifications for the license, except the results of the fingerprint-based national background check, if required.

(2) A temporary practice permit to practice pharmacy may be issued to an applicant who:

(a) Holds an unrestricted, active license by examination in another state which participates in the license transfer or reciprocity process;

(b) Has completed a Washington application for pharmacist license by transfer or reciprocity;

(c) Has submitted pharmacist license application fees;

(d) Has passed the Washington state jurisprudence exam;

(e) Is not subject to denial of a license or issuance of a conditional or restricted license; and

(f) Does not have a criminal record in Washington state.

(3) A temporary practice permit grants the individual the full scope of practice of pharmacy, except the ability to qualify as a responsible pharmacist manager.

(4) A temporary practice permit expires when any one of the following occurs:

(a) The license is granted;

(b) A notice of decision on the application is mailed to the applicant, unless the notice of decision specifically extends the duration of the temporary practice permit; or

(c) One hundred eighty days after the temporary practice permit is issued.

(5) To receive a temporary practice permit, the applicant must submit the fingerprint card, a written request for a temporary practice permit, and applicable fees.

Statutory Authority: RCW 18.130.075, 18.130.064, 18.64.005 and 18.64.080. WSR 10-23-080, S 246-863-035, filed 11/15/10, effective 12/16/10. Statutory Authority: RCW 18.64.005. WSR 92-23-058 (Order 317B), S 246-863-035, filed 11/17/92, effective 12/18/92.

WAC 246-863-035, WA ADC 246-863-035

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Wash. Admin. Code 246-863-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-040. Foreign-trained applicants.**

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-015 (Order 180), S 360-12-065, filed 1/9/84. Statutory Authority: RCW 69.50.201. WSR 79-04-048 (Order 147, Resolution No. 3-79), S 360-12-065, filed 3/27/79; Order 122, S 360-12-065, filed 9/30/74.

WAC 246-863-040, WA ADC 246-863-040

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Wash. Admin. Code 246-863-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-060. Licensed pharmacists-Employed as responsible managers-Duty to notify board.**

Licensed pharmacists employed as responsible managers for a pharmacy shall at once notify the state board of pharmacy of such employment and shall comply with such instructions as may be received. A pharmacist shall also at once notify the state board of pharmacy of termination of employment as a responsible manager. Please refer to WAC 246-869-070 for additional information.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-863-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 79-10-007 (Order 151, Resolution No. 9/79), S 360-12-120, filed 9/6/79; Regulation 8, filed 3/23/60.

WAC 246-863-060, WA ADC 246-863-060

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Wash. Admin. Code 246-863-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-070. Inactive credential.**

(1) A pharmacist may obtain an inactive credential. Refer to the requirements of chapter 246-12 WAC, Part 4.

(2) Practitioners with an inactive credential for three years or less who wish to return to active status must meet the requirements of chapter 246-12 WAC, Part 4.

(3) Practitioners with an inactive credential for more than three years, who have been in active practice in another United States jurisdiction, and wish to return to active status must:

(a) Submit verification of active practice from any other United States jurisdiction;

(b) Take and pass the jurisprudence examination given by the department;

(c) Meet the requirements of chapter 246-12 WAC, Part 4.

(4) Practitioners with an inactive credential for between three and five years, who have not been in active practice in another United States jurisdiction, and wish to return to active status must:

(a) Take and pass the jurisprudence examination given by the department;

(b) Either serve an internship of 300 hours or take and pass such further written practical examinations as specified by the board in each individual case;

(c) Meet the requirements of chapter 246-12 WAC, Part 4.

(5) Practitioners with an inactive credential for over five years, who have not been in active practice in another United States jurisdiction, and wish to return to active status must:

(a) Take and pass the full board examination;

Wash. Admin. Code 246-863-070

(b) Serve an internship of 300 hours;

(c) Meet the requirements of chapter 246-12 WAC, Part 4.

Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-863-070, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-863-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.140. WSR 85-06-010 (Order 193), S 360-12-125, filed 2/22/85.

WAC 246-863-070, WA ADC 246-863-070

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Wash. Admin. Code 246-863-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-080. Retired pharmacist license.**

(1) Any pharmacist who has been licensed in the state for twenty-five consecutive years, who wishes to retire from the practice of pharmacy, may apply for a retired pharmacist license by submitting to the board:

(a) An application on a form provided by the department; and

(b) A fee as specified in WAC 246-907-030.

(2) The holder of a retired pharmacist license shall not be authorized to practice pharmacy and need not comply with the continuing education requirements of chapter 246-861 WAC.

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

(4) In order to reactivate a retired pharmacist license, the holder must comply with the provision of WAC 246-863-090 and chapter 246-12 WAC, Part 2.

(5) The annual renewal fee for a retired pharmacist license is set by the secretary in WAC 246-907-030.

Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-863-080, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-863-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 43.70.040. WSR 91-19-028 (Order 194), recodified as S 246-863-080, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 43.70.250. WSR 91-13-002 (Order 173), S 360-12-128, filed 6/6/91, effective 7/7/91. Statutory Authority: RCW 18.64.005(11). WSR 86-24-057 (Order 203), S 360-12-128, filed 12/2/86.

WAC 246-863-080, WA ADC 246-863-080

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Wash. Admin. Code 246-863-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-090. Expired license.**

(1) If the license has expired for three years or less, the practitioner must meet the requirements of chapter 246-12 WAC, Part 2.

(2) If the license has expired for more than three years, and the practitioner has been in active practice in another United States jurisdiction, the practitioner must:

(a) Submit verification of active practice from any other United States jurisdiction;

(b) Take and pass the jurisprudence examination given by the department;

(c) Meet the requirements of chapter 246-12 WAC, Part 2.

(3) If the license has expired for between three and five years, and the practitioner has not been in active practice in another United States jurisdiction, the practitioner must:

(a) Take and pass the jurisprudence examination given by the department;

(b) Either serve an internship of 300 hours or take and pass such further written practical examinations as specified by the board in each individual case;

(c) Meet the requirements of chapter 246-12 WAC, Part 2.

(4) If the license has expired for over five years, and the practitioner has not been in active practice in another United States jurisdiction, the practitioner must:

(a) Take and pass the full board examination;

(b) Serve an internship of 300 hours;

(c) Meet the requirements of chapter 246-12 WAC, Part 2.

Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-863-090, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-863-090, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.140. WSR 85-06-010 (Order 193), S 360-12-130, filed 2/22/85. Statutory Authority: RCW 69.50.201. WSR 79-04-048 (Order 147, Resolution No. 3-79), S 360-12-130, filed 3/27/79; Regulation 2, filed 3/23/60.

WAC 246-863-090, WA ADC 246-863-090

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Wash. Admin. Code 246-863-095

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
**246-863-095. Pharmacist's professional responsibilities.**

(1) A pharmacist's primary responsibility is to ensure patients receive safe and appropriate medication therapy.

(2) A pharmacist shall not delegate the following professional responsibilities:

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

(b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not prohibit pharmacy ancillary personnel from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.

(c) Consultation with the prescriber regarding the patient and the patient's prescription.

(d) Extemporaneous compounding of the prescription, however, bulk compounding from a formula and IV admixture products prepared in accordance with chapter 246-871 WAC may be performed by a pharmacy technician when supervised by a pharmacist.

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

(f) Ultimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.

(g) Dispense prescriptions to patient with proper patient information as required by WAC 246-869-220.

(h) Signing of the poison register and the Schedule V controlled substance registry book at the time of sale in accordance with RCW 69.38.030 and WAC 246-887-030 and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.

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

(j) Decision to not dispense lawfully prescribed drugs or devices or to not distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies.

(3) Utilizing personnel to assist the pharmacist.

(a) The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel. The responsible pharmacist manager shall determine the extent to which personnel may be utilized to assist the pharmacist and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities.

(b) This does not preclude delegation to an intern or extern.

(4) It is considered unprofessional conduct for any person authorized to practice or assist in the practice of pharmacy to engage in any of the following:

(a) Destroy unfilled lawful prescription;

(b) Refuse to return unfilled lawful prescriptions;

(c) Violate a patient's privacy;

(d) Discriminate against patients or their agent in a manner prohibited by state or federal laws; and

(e) Intimidate or harass a patient.

Statutory Authority: RCW 18.64.005, 18.130.050, 18.64.165, 18.130.180. WSR 07-14-025, S 246-863-095, filed 6/25/07, effective 7/26/07. Statutory Authority: RCW 18.64.005. WSR 96-02-005, S 246-863-095, filed 12/20/95, effective 1/20/96.

WAC 246-863-095, WA ADC 246-863-095

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Wash. Admin. Code 246-863-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)

**➡➡ 246-863-100. Pharmacist prescriptive authority-Prior board notification of written guideline or protocol required.**

(1) A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW 18.64.011(11)) by initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy.

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

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

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

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

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

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

(d) A statement of the activities pharmacist(s) is (are) to follow in the course of exercising prescriptive authority, including documentation of decisions made, and a plan for communication or feedback to the

authorizing practitioner concerning specific decisions made. Documentation may occur on the prescription record, patient drug profile, patient medical chart, or in a separate log book.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-19-086 (Order 163, Resolution No. 8/81), S 360-12-140, filed 9/17/81. Statutory Authority: RCW 18.64.005 (4) and (11). WSR 80-08-035 (Order 155, Resolution No. 6/80), S 360-12-140, filed 6/26/80, effective 9/30/80.

WAC 246-863-100, WA ADC 246-863-100

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Wash. Admin. Code 246-863-110

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-110. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-18-066 (Order 207), S 360-12-150, filed 9/2/87. Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 83-20-053 (Order 176), S 360-12-150, filed 9/29/83. Statutory Authority: RCW 18.64.005 and 69.41.240. WSR 83-10-013 (Order 174), S 360-12-150, filed 4/26/83.

WAC 246-863-110, WA ADC 246-863-110

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Wash. Admin. Code 246-863-120

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-863**. Pharmacists-licensing (Refs & Annos)
➡➡ **246-863-120. AIDS prevention and information education requirements.**

Applicants must complete seven clock hours of AIDS education as required in chapter 246-12 WAC, Part 8.

Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-863-120, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-863-120, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-23-058 (Order 221), S 360-12-160, filed 11/15/88.

WAC 246-863-120, WA ADC 246-863-120

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Wash. Admin. Code 246-865-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-865**. Pharmaceutical Services-Extended Care Facility
➡➡ **246-865-010. 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 administer 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-865-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-18-066 (Order 207), S 360-13-045, filed 9/2/87. Statutory Authority: RCW 18.64.005(11). WSR 81-06-077 (Order 158), S 360-13-045, filed 3/4/81; Order 121, S 360-13-045, filed 8/8/74.

WAC 246-865-010, WA ADC 246-865-010

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Wash. Admin. Code 246-865-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-865**. Pharmaceutical Services-Extended Care Facility
➡➡ **246-865-020. Promulgation.**

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-865-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-10-027 (Order 159), S 360-13-010, filed 4/28/81; Order 104, S 360-13-010, filed 12/5/69; Order 50 (part), filed 3/28/67.

WAC 246-865-020, WA ADC 246-865-020

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Wash. Admin. Code 246-865-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-865**. Pharmaceutical Services-Extended Care Facility
➡➡ **246-865-030. Emergency kit.**

(1) The contents and quantity of drugs and supplies in the emergency kit shall be determined by the pharmaceutical services committee as defined in WAC 246-865-010(9) which shall consider the number of residents to be served and their potential need for emergency medications.

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

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

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

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

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

(b) Emergency kit drugs shall be accessible only to licensed nurses as defined in WAC 246-865-010(6).

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

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-865-030, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-865-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-06-077 (Order 158), S 360-13-020, filed 3/4/81; Order 104, S 360-13-020, filed 12/5/69; Order 50, subsection 1-12, filed 3/28/67.

WAC 246-865-030, WA ADC 246-865-030

Wash. Admin. Code 246-865-030

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Wash. Admin. Code 246-865-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-865**. Pharmaceutical Services-Extended Care Facility
➡➡ **246-865-040. Supplemental dose kits.**

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-865-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-06-077 (Order 158), S 360-13-030, filed 3/4/81; Order 114, S 360-13-030, filed 6/28/73.

WAC 246-865-040, WA ADC 246-865-040

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Wash. Admin. Code 246-865-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-865**. Pharmaceutical Services-Extended Care Facility
➡➡ **246-865-050. Drug facilities.**

(1) There shall be facilities for drug preparation and storage near the nurses' station on each unit.

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

(3) The drug storage units shall provide:

(a) Locked storage for all drugs,

(b) Separately keyed storage for Schedule II and III controlled substances,

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-865-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-06-077 (Order 158), S 360-13-055, filed 3/4/81; Order 121, S 360-13-055, filed 8/8/74.

WAC 246-865-050, WA ADC 246-865-050

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Wash. Admin. Code 246-865-060

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Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-865**. Pharmaceutical Services-Extended Care Facility
➡➡ **246-865-060. 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 246-865-040.

(g) If an emergency kit is provided, it shall comply with Washington state board of pharmacy regulations WAC 246-865-020 and 246-865-030.

(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. Nonlegend 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 two of the following individuals: A licensed pharmacist, the director of nursing or a registered nurse designee, and a registered nurse employee of the nursing home 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. WSR 94-02-077, S 246-865-060, filed 1/5/94, effective 2/5/94; WSR 92-12-035 (Order 277B), S 246-865-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-865-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-11-007 (Order 214), S 360-13-066, filed 5/9/88. Statutory Authority: RCW 18.64.005(11). WSR 81-14-055 (Order 161), S 360-13-066, filed 6/30/81.

WAC 246-865-060, WA ADC 246-865-060

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Wash. Admin. Code 246-865-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-865**. Pharmaceutical Services-Extended Care Facility
➡➡ **246-865-070. Provision for continuity of drug therapy for residents.**

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

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

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

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

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

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

(b) The drug and quantity provided;

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

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

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

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

Refer to WAC 246-839-810 for related regulations on this practice.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-865-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-865-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.41.240. WSR 83-10-013 (Order 174), S 360-13-100, filed 4/26/83.

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Wash. Admin. Code 246-867-001

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-867**. Impaired Pharmacist Rehabilitation
➡➡ **246-867-001. Purpose and scope.**

These rules are designed to assist the board of pharmacy regarding a registrant/licensee whose competency may be impaired due to the abuse of alcohol and/or drugs. The board intends that such registrants/licensees be treated and their treatment monitored so that they can return or continue to practice pharmacy with judgment, skill, competence, and safety to the public. To accomplish this, the board shall approve voluntary substance abuse monitoring programs and shall refer registrants/licensees impaired by substance abuse to approved programs.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-867-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-054 (Order 025), S 360-15-010, filed 1/17/90, effective 2/17/90.

WAC 246-867-001, WA ADC 246-867-001

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Wash. Admin. Code 246-867-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-867**. Impaired Pharmacist Rehabilitation
➡➡ **246-867-010. Definitions.**

For the purpose of this chapter:

(1) ‘Chemical dependence - Substance abuse‘ means a chronic progressive illness which involves the use of alcohol and/or other drugs to a degree that it interferes in the functional life of the registrant/licensee, as manifested by health, family, job (professional services), legal, financial, or emotional problems.

(2) ‘Board‘ means the Washington state board of pharmacy.

(3) ‘Diversion‘ means illicit dispensing, distribution, or administration of a scheduled controlled substance or other legend drug not in the normal course of professional practice.

(4) ‘Drug‘ means a chemical substance alone or in combination, including alcohol.

(5) ‘Impaired pharmacist‘ means a pharmacist who is unable to practice pharmacy with judgment, skill, competence, or safety to the public due to chemical dependence, mental illness, the aging process, loss of motor skills, or any other mental or physical condition.

(6) ‘Approved substance abuse monitoring program‘ means a pharmacy recovery assistance program or program which the board has determined meets the requirement of the law and the criteria established by the board in WAC 246-867-040 which enters into a contract with pharmacists who have substance abuse problems regarding the required components of the pharmacists recovery activity and oversees the pharmacist's compliance with these requirements. Substance abuse monitoring programs do not provide evaluation or treatment to participating pharmacists.

(7) ‘Contract‘ means a comprehensive, structured agreement between the recovering pharmacist and the approved monitoring program stipulating the pharmacist's consent to comply with the monitoring program and its required components of the pharmacist's recovery program.

(8) ‘Approved treatment program‘ means a facility approved by the bureau of alcohol and substance abuse, department of social and health services according to RCW 70.96A.020(3) to provide concentrated alcoholism or drug addiction treatment if located within Washington state. Drug and alcohol addiction treatment programs

located out-of-state must be equivalent to the standards required for approval under RCW 70.96A.020(3).

(9) ‘Aftercare‘ means that period of time after intensive treatment that provides the pharmacist and the pharmacist's family with group, or individualized counseling sessions, discussions with other families, ongoing contact and participation in self-help groups, and ongoing continued support of treatment program staff.

(10) ‘Twelve-step groups‘ means groups such as Alcoholics Anonymous, Narcotics Anonymous, Cocaine Anonymous, and related organizations based on a philosophy of anonymity, peer group associations, self-help belief in a power outside of oneself which offer support to the recovering individual to maintain a chemically free lifestyle.

(11) ‘Random drug screens‘ are laboratory tests to detect the presence of drugs of abuse in body fluids which are performed at irregular intervals not known in advance by the person to be tested. The collection of the body fluid must be observed by a treatment or health care professional or other board or monitoring program-approved observer.

(12) ‘Recovering‘ means that a chemically dependent pharmacist is in compliance with a treatment plan of rehabilitation in accordance with criteria established by an approved treatment facility and an approved substance abuse monitoring program.

(13) ‘Rehabilitation‘ means the process of restoring a chemically dependent pharmacist to a level of professional performance consistent with public health and safety.

(14) ‘Reinstatement‘ means the process whereby a recovering pharmacist is permitted to resume the practice of pharmacy.

(15) ‘Pharmacist support group‘ means a group of pharmacists meeting regularly to support the recovery of its members. The group provides a confidential setting with a trained and experienced pharmacist facilitator in which pharmacists may safely discuss drug diversion, licensure issues, return to work, and other issues related to recovery.

Statutory Authority: RCW 18.64.005 and 18.130.050. WSR 92-12-035 (Order 277B), S 246-867-010, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-867-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-054 (Order 025), S 360-15-020, filed 1/17/90, effective 2/17/90.

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Wash. Admin. Code 246-867-010

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Wash. Admin. Code 246-867-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-867**. Impaired Pharmacist Rehabilitation
➡➡ **246-867-020. Applicability.**

This chapter is applicable to all registered/licensed externs, interns, pharmacists, and any pharmacy assistants. For the purpose of this chapter, the word ‘pharmacist‘ shall include externs, interns and pharmacy assistants, as defined under chapter 18.64A RCW.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-867-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-054 (Order 025), S 360-15-030, filed 1/17/90, effective 2/17/90.

WAC 246-867-020, WA ADC 246-867-020

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Wash. Admin. Code 246-867-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-867**. Impaired Pharmacist Rehabilitation
➡➡ **246-867-030. Reporting and freedom from liability.**

(1) Reporting.

(a) If any pharmacist or pharmacy owner knows or suspects that a pharmacist is impaired by chemical dependence, mental illness, physical incapacity, or other factors, that person shall report any relevant information to a pharmacy recovery assistance program or to the board.

(b) If a person is required by law to report an alleged impaired pharmacist to the board, the requirement is satisfied when the person reports the pharmacist to a board-approved and contracted pharmacist recovery assistance program.

(2) Any person who in good faith reports information concerning a suspected impaired pharmacist to a pharmacy recovery assistance program or to the board shall be immune from civil liability.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-867-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-054 (Order 025), S 360-15-040, filed 1/17/90, effective 2/17/90.

WAC 246-867-030, WA ADC 246-867-030

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Wash. Admin. Code 246-867-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-867**. Impaired Pharmacist Rehabilitation
➡➡ **246-867-040. Approval of substance abuse monitoring programs.**

The board will approve pharmacist recovery, assistance, and monitoring programs which will participate in the board's substance abuse monitoring program. The board may contract for these services.

(1) The approved monitoring program will not provide evaluation or treatment to participating pharmacists.

(2) The approved monitoring program/recovery assistance staff must have the qualifications and knowledge of both substance abuse and the practice of pharmacy as defined in this chapter to be able to evaluate:

(a) Clinical laboratories.

(b) Laboratory results.

(c) Providers of substance abuse treatment, both individuals and facilities.

(d) Pharmacist support groups.

(e) The pharmacist's work environment.

(f) The ability of the pharmacist to practice with reasonable skill and safety.

(3) The approved monitoring program will enter into a contract with the pharmacist and the board to oversee the pharmacists' compliance with the requirements of the program.

(4) The approved monitoring program may make exceptions to individual components of the contract on an individual basis.

(5) The approved monitoring program staff will determine, on an individual basis, whether a pharmacist will be prohibited from engaging in the practice of pharmacy for a period of time and restrictions, if any, on the pharmacist's access to controlled substances in the work place.

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(6) The approved monitoring program shall maintain records on participants.

(7) The approved monitoring program will be responsible for providing feedback to the pharmacist as to whether treatment progress is acceptable.

(8) The approved monitoring program shall report to the board any pharmacist who fails to comply with the requirements of the monitoring program.

(9) The approved monitoring program shall provide the board with a statistical report on the program, including progress of participants, at least annually.

(10) The approved monitoring program shall receive from the board guidelines on treatment, monitoring, and limitations on the practice of pharmacy for those participating in the program.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-867-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-054 (Order 025), S 360-15-050, filed 1/17/90, effective 2/17/90.

WAC 246-867-040, WA ADC 246-867-040

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Wash. Admin. Code 246-867-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-867**. Impaired Pharmacist Rehabilitation
➡➡ **246-867-050. Participation in approved substance abuse monitoring program.**

(1) The pharmacist who has been investigated by the board may accept board referral into the approved substance abuse monitoring program. This may be part of disciplinary action.

(a) The pharmacist shall undergo a complete physical and psychosocial evaluation before entering the approved monitoring program. This evaluation will be performed by health care professionals with expertise in chemical dependency. The person(s) performing the evaluation shall not also be the provider of the recommended treatment.

(b) The pharmacist shall enter into a contract with the board and the approved substance abuse monitoring program to comply with the requirements of the program which shall include, but not be limited to:

(i) The pharmacist will undergo intensive substance abuse treatment in an approved treatment facility.

(ii) The pharmacist will agree to abstain from the use of all mind-altering substances, including alcohol, except for medications prescribed by an authorized prescriber, as defined in RCW 69.41.030 and 69.50.101. Said prescriber shall notify the monitoring program of all drugs prescribed within fourteen days of the date care was provided.

(iii) The pharmacist must complete the prescribed aftercare program of the intensive treatment facility. This may include individual and/or group psychotherapy.

(iv) The pharmacist must cause the treatment counselor(s) and authorized prescriber(s) to provide reports to the appropriate monitoring program at specified intervals. Reports shall include treatment prognosis, goals, drugs prescribed, etc.

(v) The pharmacist shall submit to random drug screening, with observed specimen collection, as specified by the approved monitoring program.

(vi) The pharmacist will attend pharmacist support groups facilitated by a pharmacist and/or twelve-step group meetings as specified by the contract.

(vii) The pharmacist will comply with specified employment conditions and restrictions as defined by the contract.

(viii) The pharmacist shall sign a waiver allowing the approved monitoring program to release information to the board if the pharmacist does not comply with the requirements of this contract.

(c) The pharmacist is responsible for paying the costs of the physical and psychosocial evaluation, substance abuse treatment, random urine screens, and other personal expenses incurred in compliance with this contract.

(d) The pharmacist may be subject to disciplinary action under RCW 18.64.160 if the pharmacist does not consent to be referred to the approved monitoring program, does not comply with specified employment restrictions, or does not successfully complete the program.

(2) A pharmacist who is not being investigated by the board or subject to current disciplinary action or currently being monitored by the board for substance abuse may voluntarily participate in the approved substance abuse monitoring program without being referred by the board. Such voluntary participants shall not be subject to disciplinary action under RCW 18.64.160 for their substance abuse and shall not have their participation known to the board if they meet the requirements of the approved monitoring program:

(a) The pharmacist shall undergo a complete physical and psychosocial evaluation before entering the approved monitoring program. This evaluation will be performed by a health care professional with expertise in chemical dependency. The person(s) performing the evaluation shall not also be the provider of the recommended treatment.

(b) The pharmacist shall enter into a contract with the approved substance abuse monitoring program to comply with the requirements of the program which shall include, but not be limited to:

(i) The pharmacist will undergo intensive substance abuse treatment in an approved treatment facility.

(ii) The pharmacist will agree to abstain from the use of all mind-altering substances, including alcohol, except for medications prescribed by an authorized prescriber, as defined in RCW 69.41.030 and 69.50.101. Said prescriber shall notify the monitoring program of all drugs prescribed within fourteen days of the date care was provided.

(iii) The pharmacist must cause the treatment counselor(s) and authorized prescriber(s) to provide reports to the approved monitoring program at specified intervals. Reports shall include treatment prognosis, goals, drugs prescribed, etc.

(v) The pharmacist shall submit to random drug screening, with observed specimen collection, as specified by

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the approved monitoring program.

(vi) The pharmacist will attend pharmacist support groups facilitated by a pharmacist and/or twelve-step group meetings as specified by the contract.

(vii) The pharmacist will comply with specified employment conditions and restrictions as defined by the contract.

(viii) The pharmacist shall sign a waiver allowing the approved monitoring program to release information to the board if the pharmacist does not comply with the requirements of this contract.

(c) The pharmacist is responsible for paying the costs of the physical and psychosocial evaluation, substance abuse treatment, random urine screens, and other personal expenses incurred in compliance with this contract.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-867-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-054 (Order 025), S 360-15-060, filed 1/17/90, effective 2/17/90.

WAC 246-867-050, WA ADC 246-867-050

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Wash. Admin. Code 246-867-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-867**. Impaired Pharmacist Rehabilitation
➡➡ **246-867-060. Confidentiality.**

(1) The treatment and pretreatment records of license holders referred to or voluntarily participating in approved monitoring programs shall be confidential, shall be exempt from RCW 42.17.250 through 42.17.450 and shall not be subject to discovery by subpoena or admissible as evidence except for monitoring records reported to the disciplinary authority for cause as defined in WAC 246-867-050 (1) and (2). Records held by the board under this section shall be exempt from RCW 42.17.250 through 42.17.450 and shall not be subject to discovery by subpoena except by the license holder.

(2) Notwithstanding subsection (1) of this section, board orders shall be subject to RCW 42.17.250 through 42.17.450.

Statutory Authority: RCW 18.64.005 and 18.130.050. WSR 92-12-035 (Order 277B), S 246-867-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-867-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-054 (Order 025), S 360-15-070, filed 1/17/90, effective 2/17/90.

WAC 246-867-060, WA ADC 246-867-060

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Wash. Admin. Code Ch. 246-869 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing
➡➡ **Ch. 246-869 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-869-050. Pharmacy license renewal. (Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-869-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-14-041 (Order 215), S 360-16-025, filed 6/30/88. Statutory Authority: RCW 18.64.043. WSR 84-12-019 (Order 186), S 360-16-025, filed 5/25/84.) Repealed by WSR 98-05-060, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.280.

246-869-095. Facsimile transmission of prescription orders. (Statutory Authority: RCW 18.64.005. WSR 92-14-032 (Order 283B), S 246-869-095, filed 6/23/92, effective 7/24/92.) Repealed by WSR 05-07-108, filed 3/18/05, effective 4/18/05. Statutory Authority: RCW 18.64.005.

246-869-240. Pharmacist's professional responsibilities. (Statutory Authority: RCW 18.64.005. WSR 92-08-058 (Order 260B), S 246-869-240, filed 3/26/92, effective 4/26/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-240, filed 8/30/91, effective 9/30/91; Order 129, S 360-16-290, filed 7/13/76; Order 127, S 360-16-290, filed 12/1/75.) Repealed by WSR 96-03-016, filed 1/5/96, effective 2/5/96. Statutory Authority: RCW 18.64.005.

246-869-260. Pharmacist supervised sales-General. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-260, filed 8/30/91, effective 9/30/91; Regulation 15, filed 3/23/60.) Repealed by WSR 97-20-165, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

WAC Ch. 246-869 Disp Table, WA ADC Ch. 246-869 Disp Table

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Wash. Admin. Code 246-869-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-010. Pharmacies' responsibilities.**

(1) Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device in a timely manner consistent with reasonable expectations for filling the prescription, except for the following or substantially similar circumstances:

(a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-875-040.

(b) National or state emergencies or guidelines affecting availability, usage or supplies of drugs or devices;

(c) Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine;

(d) Potentially fraudulent prescriptions; or

(e) Unavailability of drug or device despite good faith compliance with WAC 246-869-150.

(2) Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge.

(3) If despite good faith compliance with WAC 246-869-150, the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (1)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include but are not limited to:

(a) Contact the prescriber to address concerns such as those identified in subsection (1)(a) of this section or to obtain authorization to provide a therapeutically equivalent product;

(b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent; or

(c) If requested by the patient or their agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner.

(4) Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:

(a) Destroy unfilled lawful prescription.

(b) Refuse to return unfilled lawful prescriptions.

(c) Violate a patient's privacy.

(d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.

(e) Intimidate or harass a patient.

Statutory Authority: RCW 18.64.005, 18.130.050, 18.64.165, 18.130.180. WSR 07-14-025, S 246-869-010, filed 6/25/07, effective 7/26/07.

WAC 246-869-010, WA ADC 246-869-010

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Wash. Admin. Code 246-869-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-020. Pharmacies and differential hours.**

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

(2) All equipment and records referred to in WAC 246-869-180 and all drugs, devices, poisons and other items or products which are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area.

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

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

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

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

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

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

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

(10) Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy must notify the board of pharmacy at least thirty days prior to commencing such differential hours. In order to constitute notification the applicant must complete the file forms provided by the board providing the required information. Board inspection and approval must be completed prior to the commencing of such differential hours. Such inspection and approval or disapproval shall be within 10 days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and pharmacy standards under chapter 246-869 WAC.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-869-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-020, filed 8/30/91, effective 9/30/91; Order 106, S 360-16-005, filed 9/11/70.

WAC 246-869-020, WA ADC 246-869-020

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Wash. Admin. Code 246-869-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-030. Pharmacy license notice requirements.**

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-030, filed 8/30/91, effective 9/30/91; Order 114, S 360-16-011, filed 6/28/73.

WAC 246-869-030, WA ADC 246-869-030

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Wash. Admin. Code 246-869-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-040. New pharmacy registration.**

The state board of pharmacy shall issue no new pharmacy registrations after December 1, 1976 unless:

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-040, filed 8/30/91, effective 9/30/91; Order 130, S 360-16-020, filed 11/10/76; Regulation 10, filed 3/23/60.

WAC 246-869-040, WA ADC 246-869-040

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Wash. Admin. Code 246-869-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-060. Employers to require evidence of pharmacist's qualifications.**

It shall be the duty of every employer to require suitable evidence of qualifications to practice pharmacy before they permit anyone to be in charge, compound or dispense drugs on their premises.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-060, filed 8/30/91, effective 9/30/91; Regulation 19 (part), filed 3/23/60.

WAC 246-869-060, WA ADC 246-869-060

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Wash. Admin. Code 246-869-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-070. Responsible manager-Appointment.**

Every nonlicensed proprietor of one or more pharmacies shall place in charge of each pharmacy a licensed pharmacist who shall be known as the ‘responsible manager.‘ The nonlicensed proprietor shall immediately report to the state board of pharmacy the name of the ‘responsible manager,‘ who shall ensure that the pharmacy complies with all the laws, rules and regulations pertaining to the practice of pharmacy. Every portion of the establishment coming under the jurisdiction of the pharmacy laws shall be under the full and complete control of such responsible manager. A now-licensed proprietor shall at once notify the board of pharmacy of the termination of employment of a responsible manager. Please refer to WAC 246-863-060 for additional information.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-869-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 79-10-007 (Order 151, Resolution No. 9/79), S 360-16-050, filed 9/6/79; Regulation 6, filed 3/23/60.

WAC 246-869-070, WA ADC 246-869-070

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Wash. Admin. Code 246-869-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-080. Clinic dispensaries.**

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-080, filed 8/30/91, effective 9/30/91; Regulation 9, filed 3/23/60.

WAC 246-869-080, WA ADC 246-869-080

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Wash. Admin. Code 246-869-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-090. Prescription transfers.**

The transfer of original prescription information for a noncontrolled 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; prescriber'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 C.F.R. 1306.25.

(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 data base 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 and 69.41.050. WSR 09-19-068, S 246-869-090, filed 9/14/09, effective 10/15/09. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-23-058 (Order 221), S 360-16-094, filed 11/15/88.

WAC 246-869-090, WA ADC 246-869-090

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Wash. Admin. Code 246-869-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-100. 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 two years and shall be made available for inspection to representatives of the board of pharmacy.

(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 246-869-090 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. WSR 92-12-035 (Order 277B), S 246-869-100, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-22-046, S 360-16-096, filed 10/30/89, effective 11/30/89; WSR 88-23-058 (Order 221), S 360-16-096, filed 11/15/88; Order 131, S 360-16-096, filed 2/4/77; Order 126, S 360-16-096, filed 5/21/75; Order 117, S 360-16-096, filed 11/9/73; Regulation 49, filed 12/1/65.

WAC 246-869-100, WA ADC 246-869-100

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Wash. Admin. Code 246-869-110

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-110. Refusal to permit inspection.**

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-110, filed 8/30/91, effective 9/30/91; Order 109, S 360-16-098, filed 5/23/72; Order 103, S 360-16-098, filed 12/5/69.

WAC 246-869-110, WA ADC 246-869-110

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Wash. Admin. Code 246-869-120

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-120. Mechanical devices in hospitals.**

Mechanical devices for storage of floor stock, shall be limited to hospitals and shall comply with all the following provisions:

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

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

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

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

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

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

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

permits the device to operate.

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

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

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

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

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

(a) Name and address of the hospital

(b) Name of the registered pharmacist who is to be responsible for stocking the device

(c) Location of the device in the hospital

(d) Manufacturer's name of the device and the serial number of the device.

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

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

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-869-120, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-120, filed 8/30/91, effective 9/30/91; Regulation 47, filed 12/1/65.

WAC 246-869-120, WA ADC 246-869-120

Wash. Admin. Code 246-869-120

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Wash. Admin. Code 246-869-130

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-130. Return or exchange of drugs.**

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

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

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

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

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

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

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-12-020 (Order 187), S 360-16-150, filed 5/25/84; Regulation 28, filed 3/23/60.

WAC 246-869-130, WA ADC 246-869-130

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Wash. Admin. Code 246-869-140

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-140. Prescription department-Conversing with pharmacist prohibited.**

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-140, filed 8/30/91, effective 9/30/91; Regulation 37, filed 11/23/60.

WAC 246-869-140, WA ADC 246-869-140

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Wash. Admin. Code 246-869-150

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-150. Physical standards for pharmacies-Adequate stock.**

(1) The pharmacy must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients.

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-150, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 85-11-066 (Order 194), S 360-16-200, filed 5/21/85; Order 131, S 360-16-200, filed 2/4/77; Order 51 (part), filed 8/15/67.

WAC 246-869-150, WA ADC 246-869-150

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Wash. Admin. Code 246-869-160

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-160. Physical standards for pharmacies-Adequate facilities.**

(1) The prescription department shall be well lighted (adequately to allow any person with normal vision to read a label without strain, 30-50 foot candles).

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

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

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

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

(6) There shall be refrigeration facilities with a thermometer in the prescription compounding area for the storage of pharmaceutical items requiring refrigeration. USP standards of refrigeration require that the temperature be maintained between two degrees and eight degrees Centigrade (36 degrees and 46 degrees Fahrenheit). A locked refrigerator in the immediate vicinity of the prescription department will meet the requirements of this paragraph.

(7) The prescription department shall be situated so that the public shall not have free access to the area where legend drugs, controlled substances, poisons, or other restricted items are stored, compounded or dispensed.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-160, filed 8/30/91, effective 9/30/91; Order 131, S 360-16-210, filed 2/4/77; Order 51 (part), filed 8/15/67.

WAC 246-869-160, WA ADC 246-869-160

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Wash. Admin. Code 246-869-160

END OF DOCUMENT

Wash. Admin. Code 246-869-170

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-170. Physical standards for pharmacies-Sanitary conditions.**

(1) The walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order.

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-170, filed 8/30/91, effective 9/30/91; Order 131, S 360-16-220, filed 2/4/77; Order 51 (part), filed 8/15/67.

WAC 246-869-170, WA ADC 246-869-170

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Wash. Admin. Code 246-869-180

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-180. Physical standards for pharmacies-Adequate equipment.**

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

(2) All pharmacies will have in their possession one up-to-date copy of the state of Washington statutes and rules governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines. Electronic or online versions are acceptable.

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

Statutory Authority: RCW 18.64.005. WSR 09-08-085, S 246-869-180, filed 3/30/09, effective 4/30/09. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-180, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 85-11-066 (Order 194), S 360-16-230, filed 5/21/85; WSR 84-03-015 (Order 180), S 360-16-230, filed 1/9/84; Order 131, S 360-16-230, filed 2/4/77; Order 118, S 360-16-230, filed 1/2/74; Order 51 (part), filed 8/15/67.

WAC 246-869-180, WA ADC 246-869-180

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Wash. Admin. Code 246-869-190

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-190. 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 246-901 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. WSR 92-12-035 (Order 277B), S 246-869-190, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-190, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-08-031 (Order 205), S 360-16-235, filed 3/27/87.

WAC 246-869-190, WA ADC 246-869-190

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Wash. Admin. Code 246-869-200

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-200. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-200, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-08-031 (Order 205), S 360-16-245, filed 3/27/87; Order 120, S 360-16-245, filed 3/11/74.

WAC 246-869-200, WA ADC 246-869-200

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Wash. Admin. Code 246-869-210

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-210. Prescription labeling.**

To every prescription container, there shall be fixed a label or labels bearing the following information:

(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account:

(a) The nature of the drug;

(b) The container in which it was packaged by the manufacturer and the expiration date thereon;

(c) The characteristics of the patient's container, if the drug is repackaged for dispensing;

(d) The expected conditions to which the article may be exposed;

(e) The expected length of time of the course of therapy; and

(f) Any other relevant factors.

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

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

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

(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220.

Wash. Admin. Code 246-869-210

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-869-210, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-210, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.246. WSR 85-06-010 (Order 193), S 360-16-255, filed 2/22/85. Statutory Authority: RCW 18.64.005. WSR 84-22-027 (Order 191), S 360-16-255, filed 11/1/84.

WAC 246-869-210, WA ADC 246-869-210

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Wash. Admin. Code 246-869-220

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-220. Patient counseling required.**

The purpose of this counseling requirement is to educate the public in the use of drugs and devices dispensed upon a prescription.

(1) The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices.

(2) For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist.

(3) For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription.

(4) This rule applies to all prescriptions except where a medication is to be administered by a licensed health professional authorized to administer medications.

Statutory Authority: RCW 18.64.005(7). WSR 01-04-055, S 246-869-220, filed 2/5/01, effective 3/8/01. Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-869-220, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-220, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-04-016 (Order 223), S 360-16-265, filed 1/23/89.

WAC 246-869-220, WA ADC 246-869-220

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Wash. Admin. Code 246-869-230

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-230. Child-resistant containers.**

(1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including C.F.R. Part 1700 of Title 16, unless:

(a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.

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

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-230, filed 8/30/91, effective 9/30/91; Order 126, S 360-16-270, filed 5/21/75.

WAC 246-869-230, WA ADC 246-869-230

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Wash. Admin. Code 246-869-230

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Wash. Admin. Code 246-869-235

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-235. Prescription drug repackaging-Definitions.**

(1) ‘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.

(2) ‘Unit-of-use‘ means a sufficient quantity of a drug for one normal course of therapy.

(3) ‘Lot number,‘ ‘control number‘ means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which a complete history of the manufacturer, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

(4) ‘Med-pack‘ means any package prepared under the immediate supervision of a pharmacist for a specific patient comprising a series of containers and containing one or more prescribed solid oral dosage forms including multifill blister packs.

Statutory Authority: RCW 18.64.005. WSR 93-01-051 (Order 320B), S 246-869-235, filed 12/10/92, effective 1/10/93.

WAC 246-869-235, WA ADC 246-869-235

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Wash. Admin. Code 246-869-250

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-250. Closing a pharmacy.**

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

(a) The date the pharmacy will close;

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

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

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

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

(b) A written statement containing the following information;

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-869-250, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.41.240. WSR 83-10-013 (Order 174), S 360-16-300, filed 4/26/83.

WAC 246-869-250, WA ADC 246-869-250

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Wash. Admin. Code 246-869-255

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-869**. Pharmacy Licensing (Refs & Annos)
➡➡ **246-869-255. Customized patient medication packages.**

The board approves the use of med-pack containers in the dispensing of prescription drugs within the same pharmacy, provided that:

(1) The pharmacy must maintain custody of the original prescription container at the pharmacy;

(2) No more than a thirty-one day supply of drugs is packaged;

(3) The signature of the patient or the patient's agent is obtained for dispensing in a nonchild resistant container;

(4) The container's label bear the following information:

(a) Pharmacy name and address;

(b) Patient's name;

(c) Drug name, strength, quantity;

(d) Directions;

(e) Serial prescription numbers; date

(f) Prescriber's name, and pharmacist's initials.

Statutory Authority: RCW 18.64.005. WSR 93-01-051 (Order 320B), S 246-869-255, filed 12/10/92, effective 1/10/93.

WAC 246-869-255, WA ADC 246-869-255

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Wash. Admin. Code 246-869-255

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Wash. Admin. Code 246-870-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
➡➡ **246-870-010. Purpose.**

The purpose of this chapter is to ensure compliance with the law on electronic transfer of prescription information and to provide guidance on how compliance can be achieved.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-010, filed 12/1/03, effective 1/1/04.

WAC 246-870-010, WA ADC 246-870-010

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Wash. Admin. Code 246-870-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
➡➡ **246-870-020. What definitions do I need to know to understand these rules?**

(1) ‘Electronic transmission of prescription information‘ means the communication from an authorized prescriber to a pharmacy or from one pharmacy to another pharmacy, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with state and federal law.

(2) ‘Confidential patient information‘ means information maintained in the patient's health care records or individually identifiable health care records. Confidential information must be maintained and protected from release in accordance with chapter 70.02 RCW and applicable federal law.

(3) ‘Digital signature‘ means an electronic identifier that provides for message integrity, nonrepudiation, user authentication, and encryption and is intended to have the force and effect of a manual signature.

(4) ‘Electronic signature‘ means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription.

(5) ‘Security‘ means a system to maintain the confidentiality and integrity of patient records including:

(a) Documented formal procedures for selecting and executing security measures;

(b) Physical safeguards to protect computer systems and other pertinent equipment from intrusion;

(c) Processes to protect, control and audit access to confidential patient information; and

(d) Processes to prevent unauthorized access to the data when transmitted over communication networks or when data physically moves from one location to another using media such as magnetic tape, removable drives or CD media.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-020, filed 12/1/03, effective 1/1/04.

Wash. Admin. Code 246-870-020

WAC 246-870-020, WA ADC 246-870-020

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Wash. Admin. Code 246-870-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
**➡➡ 246-870-030. What is included in the electronic transmission and transfer of prescription information?**

The electronic transfer of prescription information includes the communication of prescription information by computer, fax, or other electronic means. It includes the transfer of original and refill prescriptions and the transfer of prescription information from one pharmacy to another pharmacy.

Transmission of original prescriptions must include:

(1) Prescriber's name and the physical address of the prescriber;

(2) Prescriber's Drug Enforcement Administration Registration number where required for controlled substance prescriptions;

(3) Date of issuance;

(4) Patient's name and address;

(5) Drug name, dose, route, form, directions for use, quantity;

(6) Electronic, digital, or manual signature of the prescriber;

(7) Refills or renewals authorized, if any;

(8) A place to note allergies and a notation of purpose for the drug;

(9) Indication of preference for a generic equivalent drug substitution;

(10) Any other requirements consistent with laws and rules pertaining to prescription content and form, RCW 69.41.120 and 21 Code of Federal Regulations Part 1300; and

Wash. Admin. Code 246-870-030

(11) Identification of the electronic systemreadily retrievable for board of pharmacy inspection.

Transfer of prescription information from pharmacy to pharmacy by facsimile, or verbally, must include:

(a) All elements of the original prescription;

(b) Date of transfer maintained in records at each site;

(c) Number of refills remaining and the date of last refill;

(d) State and federal required information for controlled substances;

(e) No further refills may be issued by the transferring pharmacy unless the pharmacies use a common electronic data base for prescription filling which provides an audit trail to document each refill and limits refills to the number authorized.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-030, filed 12/1/03, effective 1/1/04.

WAC 246-870-030, WA ADC 246-870-030

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Wash. Admin. Code 246-870-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
➡➡ **246-870-040. Can all prescriptions be transmitted electronically?**

Consistent with state and federal laws and rules over-the-counter, legend drug and controlled substance prescriptions may be transmitted electronically.

Federal and state law do not allow the electronic transfer of Schedule II prescriptions except exact visual images as described in WAC 246-870-050(3). The pertinent requirements for Schedule II prescriptions are found in RCW 69.50.308 and 21 C.F.R. Part 1306.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-040, filed 12/1/03, effective 1/1/04.

WAC 246-870-040, WA ADC 246-870-040

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Wash. Admin. Code 246-870-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
➡➡ **246-870-050. What are the requirements for fax machines?**

Prescription orders may be transmitted to pharmacists directly from the prescriber using facsimile transmission devices subject to the following requirements:

(1) The order contains the date, time, and telephone number and location of the transmitting device.

(2) Prescriptions for Schedule III, IV, and V drugs may be transmitted at any time.

(3) Prescriptions for Schedule II drugs may be transmitted only under the following conditions:

(a) The order is for an injectable Schedule II narcotic substance that is to be compounded by the pharmacist for patient use; or

(b) The prescription is written for patients in a long-term care facility or a hospice program as defined in RCW 69.50.308;

(c) The prescription must be signed by the prescriber;

(d) In a nonemergent situation, an order for Schedule II controlled substances may be prepared for delivery to a patient pursuant to a facsimile transmission but may not be dispensed to the patient except upon presentation of a written order;

(e) In an emergent situation, an order for Schedule II controlled substances may be dispensed to the patient upon the oral prescription of a prescriber subject to the requirements of RCW 69.50.308(c). The pharmacy has seven days to obtain a written prescription that covers an emergency Schedule II oral prescription;

(f) To a hospital as defined in WAC 246-873-010 for a patient admitted to or being discharged from the hospital.

(4) The transmitted order shall be filed in the same manner as any other prescription. However, the pharmacist is responsible for assuring that the quality of the order is sufficient to be legible for at least two years pursuant to

the records retention requirements of WAC 246-869-100.

(5) Refill authorizations for prescriptions may be electronically transmitted.

(6) The pharmacist is responsible for assuring that each electronically transmitted prescription is valid and shall verify authenticity with the prescriber whenever there is a question.

(7) No agreement between a prescriber and a pharmacist or pharmacy shall require that prescription orders be electronically transmitted from the prescriber to only that pharmacy.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-050, filed 12/1/03, effective 1/1/04.

WAC 246-870-050, WA ADC 246-870-050

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Wash. Admin. Code 246-870-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
**➡➡ 246-870-060. What are the board requirements for electronic prescription transmission systems?**

(1) Systems for the electronic transmission of prescription information must be approved by the board. Board approval of systems will be for a period of three years. The board will maintain a list of approved systems.

(2) Systems in which prescriptions are transmitted from the prescriber's facsimile machine to the pharmacy facsimile machine do not require board approval.

(3) Each system shall have policies and procedures on the electronic transmission of prescription information available that address the following:

(a) Patient access. The system may not restrict the patient's access to the pharmacy of their choice.

(b) Security. The system shall have security and system safeguard designed to prevent and detect unauthorized access, modification, or manipulation of prescription information. Accordingly, the system should include:

(i) Documented formal procedures for selecting and executing security measures;

(ii) Physical safeguards to protect computer systems and other pertinent equipment from intrusion;

(iii) Processes to protect, control and audit access to confidential patient information; and

(iv) Processes to prevent unauthorized access to the data when transmitted over communication networks or when data physically moves from one location to another using media such as magnetic tape, removable drives or CD media.

(c) Systems that utilize intermediaries in the electronic communication or processing of prescriptions such as third party payers shall be responsible to insure that their contracts with these intermediaries require security measures that are equal to or better than those provided by this rule and prohibit the modification of any prescription record after it has been transmitted by the practitioner to the pharmacist.

(d) Confidentiality of patient records. The system shall maintain the confidentiality of patient information in accordance with the requirements of chapters 18.64, 69.50, and 70.02 RCW Health Care Information Act and any applicable federal law.

(e) Authentication. To be valid prescriptions transmitted by an authorized prescriber from computer to fax machine or from computer to computer must use an electronic signature or digital signature.

(4) The system shall provide for the transmission and retention of the information by the sender and the receiver of the prescription asrequired in WAC 246-870-030.

(5) The system must authenticate the sender's authority and credentials to transmit a prescription.

(a) The system shall provide an audit trail of all prescriptionselectronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including authorized delegation of transmission;

(b) The right of the Washington state board of pharmacy to access electronically submitted prescriptions for purposes of investigations in disciplinary proceedings.

(6) If a hard copy of an electronic prescription is given directly to the patient, the prescription must be printed on approved tamper-resistant paper and must be manually signed by the prescriber as required in RCW 18.64.500.

Statutory Authority: RCW 18.64.500 and 18.64.005. WSR 11-12-036, S 246-870-060, filed 5/25/11, effective 6/25/11. Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-060, filed 12/1/03, effective 1/1/04.

WAC 246-870-060, WA ADC 246-870-060

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Wash. Admin. Code 246-870-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
**➡➡ 246-870-070. What are the board requirements for pharmacies using electronic prescription transmission systems?**

Each pharmacy must have policies and procedures that ensure the integrity and confidentiality of patient information transmitted electronically as required by chapter 70.02 RCW and applicable federal law. All pharmacy employees and agents of the pharmacy are required to read, sign and comply with the policy and procedures.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-070, filed 12/1/03, effective 1/1/04.

WAC 246-870-070, WA ADC 246-870-070

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Wash. Admin. Code 246-870-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
➡➡ **246-870-080. Can prescription records be stored electronically?**

Prescription records for legend drugs can be stored electronically if they are in compliance withchapter 246-875 WAC patient medication record systems and are readily retrievable by the board, or its agent for inspection. Controlled substance prescriptions must be maintained in accordance with state and federal regulations.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-080, filed 12/1/03, effective 1/1/04.

WAC 246-870-080, WA ADC 246-870-080

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Wash. Admin. Code 246-870-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-870**. Electronic Transmission of Prescription Information
➡➡ **246-870-090. Can electronic mail systems be used to transmit patient information?**

Electronic mail systems can be used to transmit patient information concerning an original prescription or information concerning a prescription refill if all direct communications between a pharmacist and a practitioner are kept secure and confidential. The system used to communicate patient information shall meet the requirements for security and confidentiality in WAC 246-870-020.

Statutory Authority: Chapters 69.41, 69.50 RCW, RCW 18.64.005. WSR 03-24-070, S 246-870-090, filed 12/1/03, effective 1/1/04.

WAC 246-870-090, WA ADC 246-870-090

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Wash. Admin. Code 246-871-001

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
**246-871-001. Scope and purpose.**

The purpose of this chapter is to provide standards for the preparation, labeling, and distribution of parenteral products by licensed pharmacies, pursuant to an order or prescription. These standards are intended to apply to all parenteral products not administered in a hospital.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-010, filed 1/17/90, effective 2/17/90.

WAC 246-871-001, WA ADC 246-871-001

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Wash. Admin. Code 246-871-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
**246-871-010. Definitions.**

(1) Biological safety cabinet - A containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment according to National Sanitation Foundation (NSF) Standard 49.

(2) Class 100 environment - An atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209B.

(3) Antineoplastic - A pharmaceutical that has the capability of killing malignant cells.

(4) Parenteral - Sterile preparations of drugs for injection through one or more layers of skin.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-020, filed 1/17/90, effective 2/17/90.

WAC 246-871-010, WA ADC 246-871-010

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Wash. Admin. Code 246-871-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
➡➡ **246-871-020. Policy and procedure manual.**

(1) A policy and procedure manual as it relates to parenteral products shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis by the on-site pharmacist-in-charge.

(2) The manual shall include policies and procedures for:

(a) Clinical services;

(b) Parenteral product handling, preparation, dating, storage, and disposal;

(c) Major and minor spills of antineoplastic agents, if applicable;

(d) Disposal of unused supplies and medications;

(e) Drug destruction and returns;

(f) Drug dispensing;

(g) Drug labeling-relabeling;

(h) Duties and qualifications for professional and nonprofessional staff;

(i) Equipment;

(j) Handling of infectious waste pertaining to drug administration;

(k) Infusion devices and drug delivery systems;

(l) Dispensing of investigational medications;

(m) Training and orientation of professional and nonprofessional staff commensurate with the services provided;

(n) Quality assurance;

(o) Recall procedures;

(p) Infection control:

(i) Suspected contamination of parenteral products;

(ii) Orientation of employees to sterile technique;

(q) Sanitation;

(r) Security;

(s) Transportation; and

(t) Absence of a pharmacist.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-030, filed 1/17/90, effective 2/17/90.

WAC 246-871-020, WA ADC 246-871-020

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Wash. Admin. Code 246-871-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
**➡➡ 246-871-030. Physical requirements.**

(1) Space. The pharmacy shall have a designated area with entry restricted to designated personnel for preparing compounded parenteral products. This area shall be designed to minimize traffic and airflow disturbances. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(2) Equipment. The pharmacy preparing parenteral products shall have:

(a) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environment conditions during normal activity;

(b) Clean room and laminar flow hood certification shall be conducted annually by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports shall be maintained for at least two years;

(c) Prefilters. Prefilters for the clean air source shall be replaced on a regular basis and the replacement date documented;

(d) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

(e) Appropriate disposal containers for used needles, syringes, etc., and if applicable, antineoplastic agents;

(f) Refrigerator/freezer with thermometer;

(g) Temperature controlled delivery container, if appropriate;

(h) Infusion devices, if appropriate.

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(3) Reference library. The pharmacy shall have current reference materials related to parenteral products. These reference materials will contain information on stability, incompatibilities, mixing guidelines, and the handling of antineoplastic products.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-040, filed 1/17/90, effective 2/17/90.

WAC 246-871-030, WA ADC 246-871-030

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Wash. Admin. Code 246-871-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
**246-871-040. Personnel.**

(1) Pharmacist-in-charge. Each pharmacy shall be managed on site by a pharmacist who is licensed to practice pharmacy in this state and who has been trained in the specialized functions of preparing and dispensing compounded parenteral products, including the principles of aseptic technique and quality assurance. This training may be obtained through residency training programs, continuing education programs, or experience in an IV admixture facility. The pharmacist-in-charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all parenteral products. He/she shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs. The pharmacist-in-charge may be assisted by additional pharmacists trained in this area of practice.

(2) Supportive personnel. The pharmacist-in-charge may be assisted by a level A pharmacy assistant. The level A pharmacy assistant shall have specialized training in this field and shall work under the immediate supervision of a pharmacist. The training provided to these personnel shall be described in writing in a training manual pursuant to chapter 246-901 WAC and chapter 18.64A RCW. The duties and responsibilities of the level A pharmacy assistant must be consistent with his/her training and experience.

(3) Staffing. A pharmacist shall be accessible twenty-four hours per day for each pharmacy to respond to patient's and other health professionals' questions and needs.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-871-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-060, filed 1/17/90, effective 2/17/90.

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Wash. Admin. Code 246-871-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
➡➡ **246-871-050. Drug distribution and control.**

(1) Prescription. The pharmacist, or pharmacy intern acting under the immediate supervision of a pharmacist, must receive a written or verbal prescription from an authorized prescriber before dispensing any parenteral product. Prescriptions may be filed within the pharmacy by patient-assigned consecutive numbers. A new prescription is required every twelve months or upon any prescription change. These prescriptions shall, at a minimum, contain the following:

(a) Patient name;

(b) Patient address;

(c) Drug name, strength, and dispensing quantity;

(d) Patient directions for use;

(e) Date written;

(f) Authorizing prescriber's name;

(g) Physician's address and Drug Enforcement Administration identification code, if applicable;

(h) Refill instructions, if applicable; and

(i) Provision for generic substitution.

(2) Profile or medication record system. A pharmacy-generated profile or medication record system must be separated from the oral prescription file. The patient profile or medication record system shall be maintained under the control of the pharmacist-in-charge for a period of two years after the last dispensing activity. The patient profile or medication record system shall contain, at a minimum:

(a) Patient's full name;

(b) Date of birth or age;

(c) Weight, if applicable;

(d) Sex, if applicable;

(e) Parenteral products dispensed;

(f) Date dispensed;

(g) Drug content and quantity;

(h) Patient directions;

(i) Prescription identifying number;

(j) Identification of dispensing pharmacist and preparing level A pharmacy assistant, if applicable;

(k) Other drugs patient is receiving;

(l) Known drug sensitivities and allergies to drugs and foods;

(m) Primary diagnosis, chronic conditions; and

(n) Name of manufacturer and lot numbers of components or a policy for return of recalled product if lot numbers are not recorded.

(3) Labeling. Parenteral products dispensed to patients shall be labeled with the following information with a permanent label:

(a) Name, address, and telephone number of the pharmacy;

(b) Date and prescription identifying number;

(c) Patient's full name;

(d) Name of each component, strength, and amount;

(e) Directions for use including infusion rate;

(f) Prescriber's name;

(g) Required transfer warnings;

(h) Date of compounding;

(i) Expiration date and expiration time, if applicable;

(j) Identity of pharmacist compounding and dispensing or other authorized individual;

(k) Storage requirements;

(l) Auxiliary labels, where applicable;

(m) Antineoplastic drug auxiliary labels, where applicable; and

(n) On all parenteral products, a twenty-four hour phone number where a pharmacist can be contacted.

(4) Records and reports. The pharmacist-in-charge shall maintain access to and submit, as appropriate, such records and reports as are required to ensure patient's health, safety, and welfare. Such records shall be readily available, maintained for two years, and subject to inspections by the board of pharmacy. These shall include, as a minimum, the following:

(a) Patient profile/medication record system;

(b) Policy and procedure manual;

(c) Training manuals; and

(d) Such other records and reports as may be required by law and rules of the board of pharmacy.

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Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with federal and/or state laws or rules.

(5) Delivery service. There will be a provision for the timely delivery of parenteral products from a pharmacy so a practitioner's order for drug therapy can be implemented without undue delay. The pharmacist-in-charge shall assure the environmental control of all parenteral products shipped. Therefore, any parenteral products must be shipped or delivered to a patient in appropriate temperature controlled delivery containers (as defined by USP Standards) and stored appropriately in the patient's home. Chain of possession for the delivery of controlled substances via contracted courier must be documented, and a receipt required. The pharmacy, on request, will provide instruction for the destruction of unused parenteral products and supplies in the event a parenteral product is being discontinued or a patient dies.

(6) Disposal of infectious wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of infectious waste pertaining to drug administration in a manner so as not to endanger the public health.

(7) Emergency kit. When parenteral products are provided to home care patients, the dispensing pharmacy may supply the registered nurse with emergency drugs if the physician has authorized the use of these drugs by a protocol for use in an emergency situation, e.g., anaphylactic shock. A protocol for the emergency kit must be submitted to and approved by the board of pharmacy.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-070, filed 1/17/90, effective 2/17/90.

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Wash. Admin. Code 246-871-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
➡➡ **246-871-060. Antineoplastic medications.**

The following additional requirements are necessary for those pharmacies that prepare antineoplatic medications to assure the protection of the personnel involved.

(1) All antineoplastic medications shall be compounded within a certified Class II type A or Class II type B vertical laminar airflow hood.

Policy and procedures shall be developed for the cleaning of the laminar airflow hood between compounding antineoplastic medications and other parenteral products, if applicable.

(2) Protective apparel shall be worn by personnel compounding antineoplastic medications. This shall include disposable gloves, gowns with tight cuffs, masks, and protective eye shields if the safety cabinet is not equipped with splash guards.

(3) Appropriate safety containment techniques for compounding antineoplastic medications shall be used in conjunction with the aseptic techniques required for preparing parenteral products.

(4) Disposal of antineoplastic waste shall comply with all applicable local, state, and federal requirements, i.e., Occupational Safety and Health Administration (OSHA) and Washington Industrial Safety and Health Administration (WISHA).

(5) Written procedures for handling both major and minor spills of antineoplastic medications must be developed and must be included in the policy and procedure manual. These procedures will include providing spill kits along with directions for use to those persons receiving therapy.

(6) Prepared doses of antineoplastic medications must be dispensed and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(7) Documentation that personnel have been trained in compounding, handling, and destruction of antineoplastic medications.

Wash. Admin. Code 246-871-060

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-080, filed 1/17/90, effective 2/17/90.

WAC 246-871-060, WA ADC 246-871-060

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Wash. Admin. Code 246-871-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
**246-871-070. Clinical services.**

(1) Primary provider. There shall be an authorizing practitioner primarily responsible for the patient's medical care. There shall be a clear understanding between the authorizing practitioner, the patient, the home health care agency, and the pharmacy of the responsibilities of each in the areas of the delivery of care and the monitoring of the patient. This shall be documented in the patient's medication record system.

(2) A systematic process of medication use review must be designed, followed, and documented on an ongoing basis.

(3) Pharmacist-patient relationship. The pharmacist is responsible for seeing that the patient's compliance and adherence to a medication regimen is followed.

(4) Patient monitoring. The pharmacist will have access to clinical and laboratory data concerning each patient. Any abnormal values will be reported to the authorizing practitioner in a timely manner.

(5) Documentation. There must be documentation of ongoing drug therapy monitoring and assessment shall include but not be limited to:

(a) Therapeutic duplication in the patient's drug regimen;

(b) The appropriateness of the dose, frequency, and route of administration;

(c) Clinical laboratory or clinical monitoring methods to detect side effects, toxicity, or adverse effects and whether the findings have been reported to the authorizing practitioner.

(6) Patient training. The patient, the patient's agent, the authorizing practitioner, the home health care agency, or the pharmacy must demonstrate or document the patient's training and competency in managing this type of therapy in the home environment. A pharmacist is responsible for the patient training process in any area that relates to medication compounding, labeling, storage, stability, or incompatibility. The pharmacist must be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

(7) A pharmacist will verify that any parenteral product a patient has not received before will be administered under the supervision of a person authorized to manage anaphylaxis.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-090, filed 1/17/90, effective 2/17/90.

WAC 246-871-070, WA ADC 246-871-070

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Wash. Admin. Code 246-871-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-871**. Pharmaceutical-Parenteral Products for Nonhospitalized Patients
➡➡ **246-871-080. Quality assurance.**

There shall be a documented, ongoing quality assurance program that is reviewed at least annually.

(1) The quality assurance program shall include but not be limited to methods to document:

(a) Medication errors;

(b) Adverse drug reactions;

(c) Patient satisfaction;

(d) Product sterility.

There shall be written documentation that the end product has been tested on a sampling basis for microbial contamination by the employee responsible for compounding parenteral products. Documentation shall be on a quarterly basis at a minimum.

(2) Nonsterile compounding. If bulk compounding of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing, as referenced in *Remington*, must be documented prior to the release of the product from quarantine. This process must include appropriate testing for particulate matter and testing for pyrogens.

(3) Expiration dates. There shall be written justification of the chosen expiration dates for compounded parenteral products.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-871-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 90-03-055 (Order 026), S 360-16A-100, filed 1/17/90, effective 2/17/90.

WAC 246-871-080, WA ADC 246-871-080

Wash. Admin. Code 246-871-080

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Wash. Admin. Code 246-872-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-872**. Automated Drug Distribution Devices
➡➡ **246-872-010. Purpose.**

The purpose of this chapter is to define the requirements for automated drug distribution devices in licensed pharmacies and health care facilities as defined in RCW 70.38.025(6) and medical facilities as defined in RCW 70.40.020(7) that choose to use them. The requirements for automated drug distribution devices provide drug security to protect public health and safety and provides access to medications for quality care. The chapter defines appropriate medication security, accountability, device performance, and patient confidentiality. Facilities with automated drug distribution devices must obtain board of pharmacy approval for the use of the devices.

Statutory Authority: RCW 18.64.005. WSR 06-23-078, S 246-872-010, filed 11/13/06, effective 12/14/06.

WAC 246-872-010, WA ADC 246-872-010

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Wash. Admin. Code 246-872-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-872**. Automated Drug Distribution Devices
➡➡ **246-872-020. What definitions do I need to know to understand these rules?**

(1) ‘Automated drug distribution devices‘ means automated equipment used for remote storage and distribution of medication for use in patient care. The system is supported by an electronic data base.

(2) ‘Information access‘ means entry into a recordkeeping component of the automated drug distribution device, by electronic or other means, to add, update, or retrieve any patient record, medication record, or other data.

(3) ‘Medication access‘ means the physical entry into any component of the automated drug distribution devices to stock, inventory, remove medications, or repair the device.

Statutory Authority: RCW 18.64.005. WSR 06-23-078, S 246-872-020, filed 11/13/06, effective 12/14/06.

WAC 246-872-020, WA ADC 246-872-020

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Wash. Admin. Code 246-872-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-872**. Automated Drug Distribution Devices
➡➡ **246-872-030. What are the pharmacy's responsibilities?**

Each facility using drug distribution devices must designate a registered pharmacist responsible for the oversight of the use of these devices. The responsibilities of this pharmacist are to ensure:

(1) Policies and procedures are in place for the safe use of patient medications that are removed from the devices, prior to pharmacist review of the prescriber's order.

(2) Conduct of quarterly audits of compliance with policies and procedures.

(3) Approval of the medication inventory to be stocked in the automated drug distribution devices.

(4) The checking and stocking of medications in the automated drug distribution devices is reserved to a pharmacist, pharmacy intern, or a pharmacy technician.

(a) A pharmacy technician checking the accuracy of medications to be refilled into automated drug distribution devices must have met the criteria for specialized functions in WAC 246-901-035 and have documentation of the training on file in the pharmacy.

(b) The board may approve electronic bar code checking, or other approved technology, in place of manual double-checking of the medications stocked in the automated drug distribution devices.

(5) Ensure the security of medications in automated drug distribution devices by:

(a) Limiting access to licensed health personnel consistent with the patient care services identified within their scope of practice;

(b) Using safeguards to prevent unauthorized access to the devices, including termination of access at the end of employment;

(c) Monitoring controlled substance usage and taking appropriate action as warranted; and

(d) Working in cooperation with nursing administration to maintain an ongoing medication discrepancy resolution and monitoring process.

(6) A process is in place for all staff using the automated drug distribution devices to receive adequate training.

(7) Pharmacist participation in the facility automated drug distribution devices system quality assurance and performance improvement program.

Statutory Authority: RCW 18.64.005. WSR 06-23-078, S 246-872-030, filed 11/13/06, effective 12/14/06.

WAC 246-872-030, WA ADC 246-872-030

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Wash. Admin. Code 246-872-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-872**. Automated Drug Distribution Devices
**➡➡ 246-872-040. What are the responsibilities of the facility in the use of automated drug distribution devices?**

The licensed health care facility must maintain readily available policies and procedures for the use of automated drug distribution devices that address:

(1) Type of equipment, components, and locations.

(2) Medication and information access.

(a) The automated drug distribution devices must have a system in place to record all medication removal, waste, and returns including date and time, identity of user, patient name, complete description of medication, quantity, and witness signature or verification, if required;

(b) The record of medications filled, inventoried, or stocked including identification of the person accessing the automated drug distribution devices shall be readily retrievable and maintained by authorized personnel;

(c) Verification that a patient's information in the automated drug distribution device matches the information in facility records; and

(d) The records for patients discharged from the facility must be removed from the automated drug distribution devices data base within twelve hours.

(3) Medication management.

(a) All medications in the automated drug distribution devices must be packaged and labeled in compliance with state and federal laws;

(b) All controlled substances activities must comply with requirements of state and federal laws. The responsible pharmacist must have a system in place to verify the accuracy of controlled substance counts. Once in place, the counting system no longer requires compliance with WAC 246-873-080 (7)(h). The process for securing and accounting for returned or wasted medication is defined.

Wash. Admin. Code 246-872-040

Statutory Authority: RCW 18.64.005. WSR 06-23-078, S 246-872-040, filed 11/13/06, effective 12/14/06.

WAC 246-872-040, WA ADC 246-872-040

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Wash. Admin. Code 246-872-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-872**. Automated Drug Distribution Devices
➡➡ **246-872-050. What are quality assurance and performance improvement requirements for the use of automated drug distribution devices?**

Each facility shall establish and maintain a quality assurance and performance program that includes but is not limited to:

(1) Accuracy of medication filling and removal;

(2) Regular review of controlled substances discrepancies;

(3) Use of the data collected to take action to insure quality of care and make improvements to the automated drug distribution device system;

(4) Documentation of the outcomes of the quality assurance activities.

Statutory Authority: RCW 18.64.005. WSR 06-23-078, S 246-872-050, filed 11/13/06, effective 12/14/06.

WAC 246-872-050, WA ADC 246-872-050

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Wash. Admin. Code 246-873-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-010. Definitions.**

For the purpose of these rules and regulations, the following definitions apply:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), S 360-17-010, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S

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360-17-010, filed 7/29/81.

WAC 246-873-010, WA ADC 246-873-010

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Wash. Admin. Code 246-873-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-020. Applicability.**

The following rules and regulations are applicable to all facilities licensed pursuant to chapters 70.41 and 71.12 RCW or designated pursuant to RCW 72.23.020.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), S 360-17-020, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-020, filed 7/29/81.

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Wash. Admin. Code 246-873-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-030. Licensure.**

Hospital pharmacists shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-030, filed 7/29/81.

WAC 246-873-030, WA ADC 246-873-030

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Wash. Admin. Code 246-873-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-040. Personnel.**

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-040, filed 7/29/81.

WAC 246-873-040, WA ADC 246-873-040

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Wash. Admin. Code 246-873-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-050. Absence of a pharmacist.**

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

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-050, filed 7/29/81.

WAC 246-873-050, WA ADC 246-873-050

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Wash. Admin. Code 246-873-050

END OF DOCUMENT

Wash. Admin. Code 246-873-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-060. Emergency outpatient medications.**

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

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

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

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

(b) The name of the drug (as required by chapter 246-899 WAC), strength and number of units.

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

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

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

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

(a) Name of patient;

(b) Directions for use by the patient;

(c) Date;

(d) Identifying number;

(e) Name of prescribing practitioner;

(f) Initials of the registered nurse;

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

(a) Name and address of patient;

(b) Date of issuance;

(c) Units issued;

(d) Initials of designated registered nurse.

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

(7) The procedures outlined in this rule may not be used for controlled substances except at the following rural hospitals which met all three of the rural access project criteria on May 17, 1989:

| Hospital | City | |
|---|---|---|
| 1. | Lake Chelan Community Hospital | Chelan |
| 2. | St. Joseph's Hospital | Chewelah |
| 3. | Whitman Community Hospital | Colfax |
| 4. | Lincoln Hospital | Davenport |
| 5. | Dayton General Hospital | Dayton |
| 6. | Ocean Beach Hospital | Ilwaco |
| 7. | Newport Community Hospital | Newport |
| 8. | Jefferson General Hospital | Port Townsend |
| 9. | Ritzville Memorial Hospital | Ritzville |
| 10. | Willapa Harbor Hospital | South Bend |

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-873-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-12-011 (Order 225), S 360-17-055, filed 5/26/89; WSR 83-23-109 (Order 179), S 360-17-055, filed 11/23/83.

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Wash. Admin. Code 246-873-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-070. Physical requirements.**

(1) Area. The pharmacy facilities shall include:

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

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

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

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

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

(c) Other equipment necessary.

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 85-11-066 (Order 194), S 360-17-060, filed 5/21/85. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-060, filed 7/29/81.

WAC 246-873-070, WA ADC 246-873-070

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Wash. Admin. Code 246-873-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-080. Drug procurement, distribution and control.**

(1) General. Pharmaceutical service shall include:

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

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

(c) Monitoring the drug therapy.

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

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

(2) Additional pharmaceutical services should include:

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

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

(c) Distribution and control of all radiopharmaceuticals.

(d) Administration of drugs.

(e) Prescribing.

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

practice of pharmacy.

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

(5) Labeling:

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

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

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

(6) Medication orders. Drugs are to be dispensed and administered only upon orders of authorized practitioners. A pharmacist shall review the original order or direct copy thereof, prior to dispensing any drug, except for emergency use or as authorized in WAC 246-873-050.

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

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

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

(i) Date

(ii) Name of the drug

(iii) Amount of drug issued

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

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

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

(i) Date

(ii) Time of administration

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

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

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

(vi) Name of the practitioner who authorized the drug

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

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

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

(i) All destructions shall render the drugs unrecoverable.

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

(iii) Records of all destructions shall be maintained by the pharmacy. Quarterly summary reports shall

be mailed to the DEA with copies to the state board of pharmacy.

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

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

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

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

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

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

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

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

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

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

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

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-873-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-070, filed 7/29/81.

Wash. Admin. Code 246-873-080

WAC 246-873-080, WA ADC 246-873-080

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Wash. Admin. Code 246-873-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-090. Administration of drugs.**

(1) General. Drugs shall be administered only upon the order of a practitioner who has been granted clinical privileges to write such orders. Verbal orders for drugs shall only be issued in emergency or unusual circumstances and shall be accepted only by a licensed nurse, pharmacist, or physician, and shall be immediately recorded and signed by the person receiving the order. Such orders shall be authenticated by the prescribing practitioner within 48 hours.

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

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

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

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

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order

162), S 360-17-080, filed 7/29/81.

WAC 246-873-090, WA ADC 246-873-090

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Wash. Admin. Code 246-873-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-100. Investigational drugs.**

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

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-090, filed 7/29/81.

WAC 246-873-100, WA ADC 246-873-100

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Wash. Admin. Code 246-873-110

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-873**. Pharmacy-Hospital Standards
**246-873-110. Additional responsibilities of pharmacy service.**

(1) General. The pharmacy service shall participate in other activities and committees within the hospital affecting pharmaceutical services, drugs and drug use.

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-873-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), S 360-17-100, filed 7/29/81.

WAC 246-873-110, WA ADC 246-873-110

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Wash. Admin. Code Ch. 246-875 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems
➡➡ **Ch. 246-875 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-875-090. Effective date. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-100, filed 1/9/84.) Repealed by WSR 92-12-035 (Order 277B), filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005.

WAC Ch. 246-875 Disp Table, WA ADC Ch. 246-875 Disp Table

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Wash. Admin. Code 246-875-001

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-001. Purpose.**

The purpose of this chapter shall be to insure that a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place, in order to insure the health and welfare of the patients served. This system will consist of certain patient and prescription information, and shall provide the pharmacist within the pharmacy means to retrieve all new prescription and refill prescription information relevant to patients of the pharmacy. It shall be designed to provide adequate safeguards against the improper manipulation or alteration of records, and to provide an audit trail. It may be either a manual system or an automated data processing system for the storage and retrieval of prescription and patient information. If an automated data processing system is utilized, an auxiliary recordkeeping procedure shall be available for documentation of new and refill prescriptions in case the automated system is inoperative for any reason. Establishment of a patient medication record system is intended to insure that the information it contains will be reviewed by the pharmacist in a manner consistent with sound professional practice when each prescription is filled.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-010, filed 1/9/84.

WAC 246-875-001, WA ADC 246-875-001

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Wash. Admin. Code 246-875-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-010. Definitions.**

Terms used in this chapter shall have the meaning set forth in this section unless the context clearly indicates otherwise:

(1) ‘Address‘ means the place of residence of the patient.

(2) ‘Audit trail‘ means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription order, and authorization of subsequent modifications of that order.

(3) ‘Auxiliary recordkeeping procedure‘ means a back-up procedure used to record medication record system data in case of scheduled or unscheduled down-time of an automated data processing system.

(4) ‘Hard copy of the original prescription‘ shall include the prescription as defined in RCW 18.64.011(8) and/or the medical records or chart.

(5) ‘Therapeutic duplication‘ means two or more drugs in the same pharmacological or therapeutic category which when used together may have an additive or synergistic effect.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-020, filed 1/9/84.

WAC 246-875-010, WA ADC 246-875-010

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Wash. Admin. Code 246-875-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)

## ➡➡ 246-875-020. Minimum required information in an automated patient medication record system.

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

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

(a) Patient's full name and address.

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

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

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

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

(f) Any refill instructions by the prescriber.

(g) The prescriber's name, address, and DEA number where required.

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

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

(j) Authorization for other than child-resistant containers pursuant to WAC 246-869-230, if applicable.

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

(a) Patient's full name.

(b) Unique patient identifier.

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

(d) Patient location.

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

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

(g) Minimum prescription data elements:

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

(ii) Start date and time when appropriate.

(iii) Stop date and time when appropriate.

(iv) Amount dispensed when appropriate.

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

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

Wash. Admin. Code 246-875-020

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-875-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-030, filed 1/9/84.

WAC 246-875-020, WA ADC 246-875-020

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Wash. Admin. Code 246-875-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-030. Minimum required information in a manual patient medication record system.**

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

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

(a) Patient's full name and address.

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

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

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

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

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

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

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

(a) Patient's full name.

(b) Unique patient identifier.

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

(d) Patient location.

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

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

(g) Minimum prescription data elements:

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

(ii) Start date and time when appropriate.

(iii) Stop date and time when appropriate.

(iv) Amount dispensed when appropriate.

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

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-040, filed 1/9/84.

WAC 246-875-030, WA ADC 246-875-030

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Wash. Admin. Code 246-875-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-040. Minimum procedures for utilization of a patient medication record system.**

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-050, filed 1/9/84.

WAC 246-875-040, WA ADC 246-875-040

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Wash. Admin. Code 246-875-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-050. Auxiliary recordkeeping procedure.**

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

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-060, filed 1/9/84.

WAC 246-875-050, WA ADC 246-875-050

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Wash. Admin. Code 246-875-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-060. Retrieval of information from an automated system.**

All automated patient medication record systems must provide within 72 hours, via CRT or hard copy printout, the information required by WAC 246-875-020 and by 21 C.F.R. S 1306.22(b) as amended July 1, 1980. Any data purged from an automated patient medication record system must be available within 72 hours.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-875-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-070, filed 1/9/84.

WAC 246-875-060, WA ADC 246-875-060

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Wash. Admin. Code 246-875-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-070. Confidentiality and security of data.**

(1) Information contained in patient medication record systems shall be considered to be a part of prescription records maintained in accordance with RCW 18.64.245 and shall be maintained for a period of at least two years in the same manner as provided for all prescription records (see WAC 246-869-100).

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

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

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-875-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-080, filed 1/9/84.

WAC 246-875-070, WA ADC 246-875-070

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Wash. Admin. Code 246-875-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-875**. Pharmacy-Patient Medication Record Systems (Refs & Annos)
➡➡ **246-875-080. Extension of time for compliance.**

The rules regarding patient medication record systems contained in chapter 246-875 WAC shall apply to all pharmacists practicing pharmacy in the state of Washington upon the effective date of the chapter unless an extension is granted by the board pursuant to this rule. In order to seek an extension that will allow compliance with this chapter to be delayed, good cause for granting such extension must be shown. The board shall consider requests for extensions and if, in the board's judgment good cause is shown, the board may grant an extension for a period of time, specifying those portions of the rules with respect to which an extension is being granted.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-875-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-875-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-03-016 (Order 181), S 360-19-090, filed 1/9/84.

WAC 246-875-080, WA ADC 246-875-080

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Wash. Admin. Code Ch. 246-877 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-877**. Pharmaceutical-Sales Prohibited
➡➡ **Ch. 246-877 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-877-030. Unsealed hard gelatin capsule restrictions. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-877-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 86-21-033 (Order 202), S 360-20-210, filed 10/9/86.) Repealed by WSR 97-20-166, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

WAC Ch. 246-877 Disp Table, WA ADC Ch. 246-877 Disp Table

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Wash. Admin. Code 246-877-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-877**. Pharmaceutical-Sales Prohibited (Refs & Annos)
➡➡ **246-877-020. Drug sample prohibitions.**

(1) The possession, distribution or dispensing of legend drug samples by a pharmacy is hereby prohibited.

(2) This shall not apply to any pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request of an authorized practitioner pursuant to RCW 69.45.050.

(3) A health care entity means any organization or business entity that provides diagnostic, medical, surgical, or dental treatment and/or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-877-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-22-047, S 360-20-100, filed 10/30/89, effective 11/30/89; Order 114, S 360-20-100, filed 6/28/73.

WAC 246-877-020, WA ADC 246-877-020

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Wash. Admin. Code 246-878-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-010. Definitions.**

(1) ‘Compounding‘ shall be the act of combining two or more ingredients in the preparation of a prescription.

(2) ‘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.

(3) ‘Component‘ means any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-010, filed 4/6/94, effective 5/7/94.

WAC 246-878-010, WA ADC 246-878-010

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Wash. Admin. Code 246-878-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-020. Compounded drug products-Pharmacist.**

(1) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace. When a compounded product is to be substituted for a commercially available product, both the patient and also the prescriber must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription or in the computerized patient medication record. The prescriber's authorization shall be in addition to signing on the ‘substitution permitted‘ side of a written prescription or advising that substitution is permitted when a verbal prescription is issued.

(2) Pharmacists shall receive, store, or use drug substances for compounding prescriptions that meet official compendia requirements. If these requirements can not be met, and pharmacists document such, pharmacists shall use their professional judgment in the procurement of acceptable alternatives.

(3) Pharmacists may compound drugs in very limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy. The compounding of inordinate amounts of drugs, relative to the practice site, in anticipation of receiving prescriptions without any historical basis is considered manufacturing.

(4) Pharmacists shall not offer compounded drug products to other state-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a practitioner to administer to an individual patient. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug products.

(5) The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-020, filed 4/6/94, effective 5/7/94.

WAC 246-878-020, WA ADC 246-878-020

Wash. Admin. Code 246-878-020

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

END OF DOCUMENT

Wash. Admin. Code 246-878-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-030. Organization and personnel.**

(1) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

(2) Pharmacists who engage in drug compounding, and level A pharmacy assistants, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Every pharmacist who engages in drug compounding and any level A pharmacy assistant who assists in compounding, must be aware of and familiar with all details of these good compounding practices.

(3) Pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

(4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded 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 the products being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-030, filed 4/6/94, effective 5/7/94.

WAC 246-878-030, WA ADC 246-878-030

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

Wash. Admin. Code 246-878-030

END OF DOCUMENT

Wash. Admin. Code 246-878-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-040. Facilities.**

(1) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding of nonsterile drug products. The area(s) used for compounding of drugs shall be maintained in a good state of repair.

(2) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(3) Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air driers or single-use towels.

(4) The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-040, filed 4/6/94, effective 5/7/94.

WAC 246-878-040, WA ADC 246-878-040

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END OF DOCUMENT

Wash. Admin. Code 246-878-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-050. Sterile pharmaceutical.**

If sterile products are being compounded, the conditions of chapter 246-871 WAC (Pharmaceutical-Parenteral products for nonhospitalized patients) shall be met.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-050, filed 4/6/94, effective 5/7/94.

WAC 246-878-050, WA ADC 246-878-050

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Wash. Admin. Code 246-878-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-060. Radiopharmaceuticals.**

If radiopharmaceuticals are being compounded, the conditions of chapter 246-903 WAC shall be met.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-060, filed 4/6/94, effective 5/7/94.

WAC 246-878-060, WA ADC 246-878-060

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

END OF DOCUMENT

Wash. Admin. Code 246-878-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-070. Special precaution products.**

If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for preparation of other drugs, must be utilized in order to prevent cross-contamination.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-070, filed 4/6/94, effective 5/7/94.

WAC 246-878-070, WA ADC 246-878-070

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END OF DOCUMENT

Wash. Admin. Code 246-878-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-080. Equipment.**

(1) Equipment used in the compounding of drug products shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

(2) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in WAC 246-871-080.

(3) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

(4) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-080, filed 4/6/94, effective 5/7/94.

WAC 246-878-080, WA ADC 246-878-080

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

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Wash. Admin. Code 246-878-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-090. Control of components and drug product containers and closures.**

(1) Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area (e.g., floors) and inspection.

(2) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

(3) Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists, or under the pharmacist's supervision.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-090, filed 4/6/94, effective 5/7/94.

WAC 246-878-090, WA ADC 246-878-090

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

END OF DOCUMENT

Wash. Admin. Code 246-878-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**➡➡ 246-878-100. Drug compounding controls.**

(1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure.

(2) Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container), the new container shall be identified with the:

(a) Component name; and

(b) Weight or measure.

(3) To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(a) Capsule weight variation;

(b) Adequacy of mixing to assure uniformity and homogeneity;

(c) Clarity, completeness, or pH of solutions.

Wash. Admin. Code 246-878-100

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

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-100, filed 4/6/94, effective 5/7/94.

WAC 246-878-100, WA ADC 246-878-100

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END OF DOCUMENT

Wash. Admin. Code 246-878-110

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-110. Labeling control of excess products.**

(1) In the case where a quantity of compounded drug product in excess of that to be initially dispensed in accordance with WAC 246-878-020 is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on shelf or in the refrigerator) to ensure its strength, quality, and purity.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-110, filed 4/6/94, effective 5/7/94.

WAC 246-878-110, WA ADC 246-878-110

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Wash. Admin. Code 246-878-120

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-878**. Good Compounding Practices
**246-878-120. Records and reports.**

(1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in WAC 246-869-100 for the retention of prescription files.

(2) All records required to be retained under this chapter, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Statutory Authority: RCW 18.64.005. WSR 94-08-101, S 246-878-120, filed 4/6/94, effective 5/7/94.

WAC 246-878-120, WA ADC 246-878-120

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END OF DOCUMENT

Wash. Admin. Code 246-879-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-010. Definitions.**

(1) ‘Full line wholesaler‘ means any wholesaler authorized by the board to possess and sell legend drugs, controlled substances (additional registration required see WAC 246-879-080) and nonprescription drugs (over-the-counter - OTC see WAC 246-879-070) to a licensed pharmacy or other legally licensed or authorized person.

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

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

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

(5) ‘Blood‘ means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(6) ‘Blood component‘ means that part of the blood separated by physical or mechanical means.

(7) ‘Drug sample‘ means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(8) ‘Manufacturer‘ means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, provided that a pharmacist compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients shall not be considered a manufacturer.

(9) ‘Prescription drug‘ means any drug required by state or federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

Wash. Admin. Code 246-879-010

(10) ‘Wholesale distribution‘ means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription:

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(c) The sale, purchase, or trade of blood and blood components intended for transfusion.

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner.

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, ‘emergency medical reasons‘ includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

(11) ‘Wholesale distributor‘ means anyone engaged in wholesale distribution of drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses; including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-010, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-010, filed 3/2/82.

WAC 246-879-010, WA ADC 246-879-010

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Wash. Admin. Code 246-879-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-020. Minimum standards for wholesalers.**

The following shall constitute minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with the requirements in the 22nd edition of the United States Pharmacopeia/National Formulary (USP/NF). United States Pharmacopeia/National Formulary (USP/NF) is available for public inspection at the Office of the State Board of Pharmacy, 1300 Quince St SE, PO Box 47863, Olympia WA 98504-7863.

(a) If no storage requirements are established for a prescription drug, the drug may be held at ‘controlled‘ room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) Examination of materials.

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(4) Returned, damaged, and outdated prescription drugs.

(a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(b) Any drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.

(c) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(5) Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies:

(a) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other governmental agency, including the board of pharmacy;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(d) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

(6) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-020, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-020, filed 3/2/82.

WAC 246-879-020, WA ADC 246-879-020

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Wash. Admin. Code 246-879-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-030. Inspections.**

(1) Inspections shall be performed by representatives of the board of pharmacy to ensure compliance with chapter 246-879 WAC. The following items shall be included in these inspections:

(a) Housekeeping, sanitation, recordkeeping, accountability, security, types of outlets sold to and sources of drugs purchased.

(b) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(2) Wholesale drug distributors shall permit the board's authorized personnel and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-030, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-030, filed 3/2/82.

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Wash. Admin. Code 246-879-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-040. Records.**

(1) Recordkeeping. Wholesale drug distributors shall establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(b) The identity and quantity of the drugs received and distributed or disposed of; and

(c) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by an authorized official of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of these rules.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-040, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-040, filed 3/2/82.

WAC 246-879-040, WA ADC 246-879-040

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Wash. Admin. Code 246-879-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-050. Security.**

(1) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(2) Access from outside the premises shall be kept to a minimum and be well-controlled.

(3) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(4) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(5) Drug storage areas shall be constructed in such a manner as to prevent illegal entry.

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

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

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-050, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-050, filed 3/2/82.

WAC 246-879-050, WA ADC 246-879-050

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Wash. Admin. Code 246-879-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-060. Unauthorized sales.**

No wholesaler distributor shall sell or distribute any prescription drugs or devices except to an individual, corporation, or entity who is authorized by law or regulation to possess such drugs or devices. No wholesaler shall sell any prescription drugs or devices to an ultimate consumer.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-060, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-060, filed 3/2/82.

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Wash. Admin. Code 246-879-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
**➡➡ 246-879-070. Application for full line wholesaler license and over-the-counter only wholesaler license.**

(1) All applications for licensure of a new or relocated wholesaler shall be accompanied by the required fee as set forth in chapter 246-907 WAC.

(2) All license renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (6) of this section.

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

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

(5) The license fee cannot be prorated.

(6) Every wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging in wholesale distribution of prescription drugs.

(a) Minimum required information for licensure. The board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license.

(i) The name, full business address, and telephone number of the licensee;

(ii) All trade or business names used by the licensee;

(iii) Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(iv) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(v) The name(s) of the owner and/or operator of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(vi) When operations are conducted at more than one location by a single wholesale distributor, each such location shall be licensed by the board.

(vii) Change in any information required by this section shall be submitted to the board within thirty days after such change.

(b) Minimum qualifications. The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the state:

(i) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale, or retail drug distribution, or distribution of controlled substances;

(ii) Any felony convictions of the applicant under federal, state, or local laws;

(iii) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(iv) Any false or fraudulent material furnished by the applicant in any application made in connection with drug manufacturing or distribution;

(v) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(vi) Compliance with licensing requirements under previously granted licenses, if any;

(vii) Compliance with requirements to maintain and/or make available to the board, federal, state, or

local enforcement officials those records required to be maintained by wholesale drug distributors; and

(viii) Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

(c) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based on factors and qualifications that are directly related to the protection of the public health and safety.

(d) Personnel. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-879-070, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-070, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-070, filed 3/2/82.

WAC 246-879-070, WA ADC 246-879-070

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END OF DOCUMENT

Wash. Admin. Code 246-879-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-080. Application for controlled substance wholesaler license.**

Wholesale drug distributors that deal in controlled substances shall register with the board and with the Drug Enforcement Administration (DEA), and shall comply with applicable state, local, and DEA regulations.

(1) He/she must be licensed as a full line wholesaler.

(2) He/she must meet all security requirements as set forth in WAC 246-879-050.

(3) He/she must meet additional requirements for registration and fees as set forth in chapter 246-907 WAC.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-080, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-080, filed 3/2/82.

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Wash. Admin. Code 246-879-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-090. Export wholesaler.**

(1) Upon application the board may issue a wholesaler license for the primary business of exporting drugs to foreign countries.

(2) Such license authorizes the holder to export non-controlled drugs to persons in a foreign jurisdiction that have legitimate reasons to possess such drugs.

(3) Letters from consulate of the country to which drugs are exported should verify consignee receiving such drugs is legally entitled in that country to receive them, if applicable. These letters shall be made available to the board upon its request.

(4) Records to be kept by export wholesaler:

(a) Complete description of drug, including, name, quantity, strength, and dosage unit.

(b) Name and address of purchaser.

(c) Name and address of consignee in the country of destination.

(d) Name and address of forwarding agent.

(e) Proposed export date.

(f) Shippers involved and methods of shipment.

(5) The issuance of an export wholesaler license does not authorize delivery of drugs in the United States.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-879-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-21-090, filed 3/2/82.

Wash. Admin. Code 246-879-090

WAC 246-879-090, WA ADC 246-879-090

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Wash. Admin. Code 246-879-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-100. Salvaging and reprocessing companies.**

Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to prescription drug product salvaging or reprocessing, including this chapter.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-100, filed 7/14/92, effective 8/14/92.

WAC 246-879-100, WA ADC 246-879-100

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Wash. Admin. Code 246-879-110

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-110. Violations and penalties.**

The board shall have the authority to suspend or revoke any licenses granted under this chapter upon conviction of violations of the federal, state, or local drug laws or rules. Before any license may be suspended or revoked, a wholesale distributor shall have a right to prior notice and a hearing pursuant to the Administrative Procedure Act, chapter 34.05 RCW.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-110, filed 7/14/92, effective 8/14/92.

WAC 246-879-110, WA ADC 246-879-110

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END OF DOCUMENT

Wash. Admin. Code 246-879-120

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-879**. Pharmaceutical Wholesalers
➡➡ **246-879-120. Reciprocity.**

A wholesale distributor licensed in another state may be licensed in this state upon submission of the fee required in chapter 246-907 WAC and submission of information compiled by the National Association of Boards of Pharmacy (NABP) Clearinghouse demonstrating that the license is not, and has not been, the subject of adverse license action.

Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), S 246-879-120, filed 7/14/92, effective 8/14/92.

WAC 246-879-120, WA ADC 246-879-120

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END OF DOCUMENT

Wash. Admin. Code 246-881-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-881**. Pharmacy-Prescription Drug Price Advertising
➡➡ **246-881-010. Drug price advertising defined.**

Drug price advertising is the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-881-010, filed 8/30/91, effective 9/30/91; Order 124, S 360-23-010, filed 10/31/74; Order 120, S 360-23-010, filed 3/11/74.

WAC 246-881-010, WA ADC 246-881-010

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Wash. Admin. Code 246-881-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-881**. Pharmacy-Prescription Drug Price Advertising
➡➡ **246-881-020. Drug price advertising conditions.**

A pharmacy may advertise legend or prescription drug prices provided:

(1) The advertising complies with all state and federal laws, including regulations of the United States Food and Drug Administration and the Washington State Consumer Protection Act, chapter 19.86 RCW.

(2) The advertising is solely directed towards providing consumers with drug price information and does not promote the use of a prescription drug or drugs to the public.

(3) The drug price advertising shall contain all the following information for all drug products or brand names used in the advertisement:

(a) The proprietary name of the drug product advertised, if any,

(b) The generic name of the drug product advertised, if any,

(c) The strength of the drug product advertised. If the drug product advertised contains more than one active ingredient and a relevant strength can be associated with it without indicating each active ingredient, the generic name and quantity of each active ingredient is not required.

(d) The dosage form of the drug product advertised, and

(e) The price charged for a specified quantity of the drug product.

(4) Advertising of any generic drug that in any way compares a generic drug to a brand name drug may not in any manner imply that the brand name drug is the product offered for sale.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-881-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 79-10-007 (Order 151, Resolution No. 9/79), S 360-23-020, filed 9/6/79; Order 124, S 360-23-020, filed 10/31/74; Order 120, S 360-23-020, filed 3/11/74.

Wash. Admin. Code 246-881-020

WAC 246-881-020, WA ADC 246-881-020

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Wash. Admin. Code 246-881-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-881**. Pharmacy-Prescription Drug Price Advertising
➡➡ **246-881-030. Prohibition on advertising controlled substances.**

No person, partnership, corporation, association or agency shall advertise controlled substances for sale to the general public in any manner that promotes or tends to promote the use or abuse of those drugs. Controlled substances shall not be physically displayed to the public.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-881-030, filed 8/30/91, effective 9/30/91; Order 124, S 360-23-030, filed 10/31/74.

WAC 246-881-030, WA ADC 246-881-030

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END OF DOCUMENT

Wash. Admin. Code 246-881-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-881**. Pharmacy-Prescription Drug Price Advertising
➡➡ **246-881-040. Drug price disclosure-Required.**

No pharmacy shall refuse to disclose the retail price of a prescription drug upon request by a consumer.

Statutory Authority: RCW 18.64.005. WSR 96-02-008, S 246-881-040, filed 12/20/95, effective 1/20/96. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-881-040, filed 8/30/91, effective 9/30/91; Order 124, S 360-23-050, filed 10/31/74.

WAC 246-881-040, WA ADC 246-881-040

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END OF DOCUMENT

Wash. Admin. Code 246-883-020

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Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-883**. Pharmaceutical-Sales Requiring Prescriptions
➡➡ **246-883-020. Identification of legend drugs for purposes of chapter 69.41 RCW.**

(1) In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

(2) For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2009 edition of the *Drug Topics Red Book*. Copies of the list of legend drugs as contained in the *Drug Topics Red Book* are available for public inspection at the headquarters office of the State Board of Pharmacy, 310 Israel Road S.E., P.O. BOX 47863, Olympia, Washington 98504-7863. To obtain copies of this list from the department, interested persons must submit a written request, indicating which format they wish to receive, and payment of the actual cost of the text or CD, including shipping and handling charges from the publisher. Requestors may also contact the publisher directly to obtain copies. The department takes no responsibility for periodic updates or online access. Arrangements for periodic updates or online access must be made directly with the publisher.

(3) There may be changes in the marketing status of drugs after the publication of the above reference. Upon application of a manufacturer or distributor, the board may grant authority for the over the counter distribution of certain drugs which had been designated as legend drugs in this reference. These determinations will be made after public hearing and will be published as an amendment to this chapter.

Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 10-02-081, S 246-883-020, filed 1/5/10, effective 2/5/10. Statutory Authority: RCW 69.41.075 and 18.64.005(7). WSR 02-14-049, S 246-883-020, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 69.41.075, 18.64.005. WSR 00-06-078, S 246-883-020, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 69.41.075. WSR 96-21-041, S 246-883-020, filed 10/11/96, effective 11/11/96. Statutory Authority: RCW 18.64.005. WSR 92-09-070 (Order 264B), S 246-883-020, filed 4/14/92, effective 5/15/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-883-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 (69.41.075). WSR 85-18-091 (Order 196), S 360-32-050, filed 9/4/85. Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 83-20-053 (Order 176), S 360-32-050, filed 9/29/83. Statutory Authority: RCW 69.41.075. WSR 81-10-025 (Order 160), S 360-32-050, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. WSR 79-09-138 (Order 149, Resolution No. 9/79), S 360-32-050, filed 9/5/79.

Wash. Admin. Code 246-883-020

WAC 246-883-020, WA ADC 246-883-020

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Wash. Admin. Code 246-883-025

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-883**. Pharmaceutical-Sales Requiring Prescriptions
➡➡ **246-883-025. Introductory trade or stock packages.**

Introductory trade or stock packages may be distributed by registered drug manufacturers to licensed pharmacies under the following conditions:

(1) The package shall be invoiced by the drug manufacturer as a no charge sale.

(2) The product shall be distributed by the manufacturer to the pharmacy by mail or common carrier.

(3) The drug's package shall not be marked as a sample or with any other labeling that is inconsistent with the claim that the manufacturer intended the package for sale.

(4) The manufacturer shall be limited to distributing one introductory package of each dosage strength of a product on a one-time basis to a pharmacy in order to familiarize and assure that a company's new product will be available in pharmacies. The quantity shall not be larger than one hundred solid dosage units or sixteen liquid ounces.

Statutory Authority: RCW 18.64.005. WSR 92-09-072 (Order 266B), S 246-883-025, filed 4/14/92, effective 5/15/92.

WAC 246-883-025, WA ADC 246-883-025

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Wash. Admin. Code 246-883-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-883**. Pharmaceutical-Sales Requiring Prescriptions
**246-883-030. Ephedrine prescription restrictions.**

(1) The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.

(2) The following products containing ephedrine or its salts in the amount of 25 mg. or less per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts are exempt from subsection (1) of this section:

| TRADE NAME | EPHEDRINE CONTENT | |
|---|---|---|
| 1. | AMESAC capsule (Russ) | 25 mg. ephedrine HCL |
| 2. | AZMA AID tablet (Various, eg Purepac) | 24 mg. ephedrine HCL |
| 3. | BRONC-EASE PLUS (Natur-Pharma) | 25 mg. ephedrine HCL |
| 4. | BRONCHODILATOR AND EXPECTORANT (PDK Labs) | 25 mg. ephedrine HCL |
| 5. | BRONITIN tablet (Whitehall) | 24 mg. ephedrine HCL |
| 6. | BRONKAID tablet (Breon) | 24 mg. ephedrine sulfate |
| 7. | BRONKOLIXER (Sterling Winthrop) | 12 mg. ephedrine |
| 8. | BRONKOTABS tablet (Breon) | 24 mg. ephedrine sulfate |
| 9. | EFEDRON nasal jelly (Hyrex) | 0.6% ephedrine HCL in 20 g. |
| 10. | MINI THINS asthma relief (BDI Pharmaceuticals) | 25 mg. ephedrine |
| 11. | PAZO HEMORRHOID suppositor (Bristol-Meyers) | 3.86 mg. ephedrine sulfate |
| 12. | PAZO HEMORRHOID ointment (Bristol-Meyers) | 0.2% ephedrine sulfate |
| 13. | PRIMATENE tablet (Whitehall) | 24 mg. ephedrine HCL |
| 14. | PRIMATENE M tablet (Whitehall) | 24 mg. ephedrine HCL |
| 15. | PRIMATENE P tablet (Whitehall) | 24 mg. ephedrine HCL |
| 16. | QUELIDRINE (Abbott) | 5 mg. ephedrine HCL |

| | | |
|---|---|---|
| 17. | TEDRAL tablet (Parke-Davis) | 24 mg. ephedrine HCL |
| 18. | THEODRINE tablet (Rugby) | 25 mg. ephedrine HCL |
| 19. | VATRONOL nose drops (Vicks Health Care) | 0.5% ephedrine sulfate |

(3) Ma Huang or other botanical products of genus ephedra used in their natural state and containing 25 mg. or less of ephedrine per recommended dosage as a preparation for human consumption are not legend drugs for the purposes of this section.

(4) Any reformulation of listed products which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms shall negate the exemption. The manufacturers of listed products shall notify the board of any reformulation which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms prior to distributing that product in the state of Washington.

(5) Manufacturers of products containing 25 mg. or less of ephedrine per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts may gain exemption from subsection (1) of this section if, prior to the distributing of any such product in the state of Washington, the manufacturer:

(a) Provides the board with the formulation of any such product;

(b) Provides the board samples of all dosage forms in which the product is to be marketed in the packaging in which the product is to be marketed; and

(c) Receives the board's approval to market such product.

Statutory Authority: RCW 18.64.005. WSR 94-08-100, S 246-883-030, filed 4/6/94, effective 5/7/94; WSR 93-05-046 (Order 333B), S 246-883-030, filed 2/17/93, effective 3/20/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-883-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), S 360-32-055, filed 3/2/82. Statutory Authority: RCW 69.41.075. WSR 81-10-025 (Order 160), S 360-32-055, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. WSR 79-09-138 (Order 149, Resolution No. 9/79), S 360-32-055, filed 9/5/79.

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Wash. Admin. Code 246-883-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-883**. Pharmaceutical-Sales Requiring Prescriptions
➡➡ **246-883-040. Regulated steroids.**

The board finds that the following drugs shall be classified as steroids for the purposes of RCW 69.41.310. The drugs designated shall include the following and any synthetic derivatives or any isomer, ester, salt, or derivative of the following that act in the same manner on the human body from the attached list:

(1) Anabolicum

(2) Anadrol

(3) Anatrofin

(4) Anavar

(5) Androxon

(6) Andriol

(7) Android

(8) bolandiol

(9) bolasterone

(10) boldenone

(11) boldenone undecylenate

(12) bolenol

(13) Bolfortan

(14) bolmantalate

(15) Cheque

(16) chlorotestosterone

(17) clostebol

(18) Deca Durabolin

(19) dehydrochlormethyl-testosterone

(20) Delatestyl

(21) Dianabol

(22) Dihydrolone

(23) dihydrotestosterone

(24) dimethazine

(25) Drive

(26) Drolban

(27) drostanolone

(28) Durabolin

(29) Durateston

(30) Equipoise

(31) Esiclene

(32) ethylestrenol

(33) Exoboline

(34) Finaject

(35) Fluoxymesterone

(36) formebolone

(37) Halotestin

(38) Halostein

(39) Hombreol

(40) Iontanyl

(41) Laurabolin

(42) Lipodex

(43) Maxibolin

(44) mesterolone

(45) metanabol

(46) methenolone acetate

(47) methenolone enanthate

(48) methandienone

(49) methandranone

(50) methandriol

(51) methandrostenolone

(52) methyltestosterone

(53) mibolerone

(54) Myagen

(55) Nandrolin

(56) nandrolone

(57) nandrolone decanoate

(58) nandrolone cyclotate

(59) nandrolone phenpropionate

(60) Nelavar

(61) Nerobol

(62) Nilevar

(63) nisterime acetate

(64) Norbolethone

(65) Nor-Diethylin

(66) norethandrolone

(67) Normethazine

(68) Omnifin

(69) oxandrolone

(70) oxymesterone

(71) oxymetholone

(72) Parabolan

(73) Permastril

(74) pizotyline

(75) Primobolone/Primobolan depot

(76) Primotestin/Primotestin depot

(77) Proviron

(78) Quinalone

(79) Quinbolone

(80) Restandol

(81) silandrone

(82) Sostanon

(83) Spectriol

(84) stanolone

(85) stanozolol

(86) stenbolone acetate

(87) Stromba

(88) Sustanon

(89) Tes-10

(90) Tes-20

(91) Tes-30

(92) Teslac

(93) testolactone

(94) testosterone

(95) testosterone cypionate

(96) testosterone enanthate

(97) testosterone ketolaurate

(98) testosterone phenylacetate

(99) testosterone propionate

(100) testosterone undecanoate

(101) Thiomucase

(102) tibolone

(103) trenbolone

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(104) trenbolone acetate

(105) trestolone acetate

(106) Trophobolene

(107) Winstrol

Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 92-12-035 (Order 277B), S 246-883-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-883-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-22-048, S 360-32-060, filed 10/30/89, effective 11/30/89.

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Wash. Admin. Code 246-883-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-883**. Pharmaceutical-Sales Requiring Prescriptions
**246-883-050. Theophylline prescription restrictions.**

The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies theophylline, or any of its salts in a solid or liquid form normally intended for oral administration in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030. Provided, products containing 130 mg or less of theophylline per solid dosage unit or 130 mg or less per 5 ml of liquid forms, shall not be considered a legend drug and where the product contains other recognized therapeutic ingredients, may be sold or distributed without a prescription. Products with theophylline as the only active ingredient are identified as legend drugs.

Statutory Authority: RCW 18.64.005. WSR 92-09-070 (Order 264B), S 246-883-050, filed 4/14/92, effective 5/15/92.

WAC 246-883-050, WA ADC 246-883-050

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Wash. Admin. Code 246-885-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-885**. Pharmacy-Identification, Imprints, Markings, and Labeling of Legend Drugs
➡➡ **246-885-020. Drug imprint information provided by manufacturers and distributors.**

Each manufacturer and distributor who manufacturers or commercially distributes any legend drug in the state of Washington shall provide written information to the board identifying all current imprints used. This information shall be submitted on a form provided by the board and shall be updated annually, or as changes in imprints occur.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-885-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.41.240. WSR 83-10-013 (Order 174), S 360-33-050, filed 4/26/83.

WAC 246-885-020, WA ADC 246-885-020

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END OF DOCUMENT

Wash. Admin. Code 246-885-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-885**. Pharmacy-Identification, Imprints, Markings, and Labeling of Legend Drugs
➡➡ **246-885-030. Over-the-counter (OTC) drug imprint regulation.**

(1) Pursuant to the provisions of RCW 69.60.090, chapter 69.60 RCW will cease to exist in its entirety upon implementation by the federal Food and Drug Administration (FDA) of provisions regulating solid dosage imprinting of OTC medications and upon a finding by the Washington state board of pharmacy that the FDA regulations are substantially equivalent to those in chapter 69.60 RCW.

(2) The FDA adopted a final rule regarding OTC solid dosage imprinting, codified in 21 C.F.R. 206.01-10. This rule became effective September 13, 1995. The applicability of the federal rule is limited to those products introduced into interstate commerce on or after the effective date of the regulation. The rule is inapplicable to those noncompliant products introduced into interstate commerce prior to the effective date and to those products pending FDA review and approval of applications submitted by the manufacturer.

(3) The board finds that the inapplicability of the FDA rule to noncompliant products introduced into interstate commerce before the effective date and to those products currently on the market would permit the sale of these products in the state of Washington and thus fails to adequately protect the citizens of the state of Washington.

(4) Therefore, notwithstanding the provisions of 21 C.F.R. 206.1 et seq. no nonimprinted solid dosage form drug that is intended for OTC sale may be distributed into or sold in the state of Washington unless it has been found by the board to be exempt from the provisions of this chapter or has received an exemption from the FDA pursuant to 21 C.F.R. 206.7. Copies of official documents that support such exemptions shall be filed with the board prior to any distribution of the nonimprinted product(s).

Statutory Authority: RCW 18.64.005. WSR 96-07-012, S 246-885-030, filed 3/11/96, effective 4/11/96.

WAC 246-885-030, WA ADC 246-885-030

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Wash. Admin. Code Ch. 246-887 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act
➡➡ **Ch. 246-887 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-887-050. Sodium pentobarbital for animal euthanasia. (Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-887-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-210, filed 8/8/89, effective 9/8/89; Order 138, S 360-36-210, filed 11/8/77.) Repealed by WSR 12-21-118, filed 10/23/12, effective 11/23/12. Statutory Authority: RCW 69.41.080, 69.50.310, and 18.64.005. Later promulgation, see chapter 246-886 WAC.

246-887-060. Sodium pentobarbital administration. (Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-887-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-250, filed 8/8/89, effective 9/8/89; Order 138, S 360-36-250, filed 11/8/77.) Repealed by WSR 12-21-118, filed 10/23/12, effective 11/23/12. Statutory Authority: RCW 69.41.080, 69.50.310, and 18.64.005. Later promulgation, see chapter 246-886 WAC.

246-887-070. Sodium pentobarbital records and reports. (Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-887-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-260, filed 8/8/89, effective 9/8/89; Order 138, S 360-36-260, filed 11/8/77.) Repealed by WSR 12-21-118, filed 10/23/12, effective 11/23/12. Statutory Authority: RCW 69.41.080, 69.50.310, and 18.64.005. Later promulgation, see chapter 246-886 WAC.

WAC Ch. 246-887 Disp Table, WA ADC Ch. 246-887 Disp Table

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Wash. Admin. Code 246-887-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-020. Uniform Controlled Substances Act.

(1) Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), 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, 1991, 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) 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.

(3) 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 two 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).

(4) 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.

(5) 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.

(6) 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 43.70.280. WSR 98-05-060, S 246-887-020, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 92-04-029 (Order 239B), S 246-887-020, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-010, filed 8/8/89, effective 9/8/89. Statutory Authority: RCW 69.50.301. WSR 87-10-029 (Order 206), S 360-36-010, filed 5/1/87. Statutory Authority: RCW 18.64.005(4). WSR 85-06-010 (Order 193), S 360-36-010, filed 2/22/85. Statutory Authority: RCW 69.50.301. WSR 80-05-074 (Order 154, Resolution No. 4/80), S 360-36-010, filed 4/28/80; WSR 79-10-007 (Order 151, Resolution No. 9/79), S 360-36-010, filed 9/6/79. Statutory Authority: RCW 69.50.301 and chapter 69.50 RCW. WSR 78-02-070 (Order 140), S 360-36-010, filed 1/25/78; Order 132, S 360-36-010, filed 5/4/77; Order 108, S 360-36-010, filed 10/26/71.

WAC 246-887-020, WA ADC 246-887-020

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END OF DOCUMENT

Wash. Admin. Code 246-887-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-030. Dispensing Schedule V controlled substances.

(1) Those drugs classified in Schedule V of the Uniform Controlled Substances Act (RCW 69.50.212) which can be dispensed without a prescription can be so distributed only for the medical purpose(s) indicated on the manufacturer's label (e.g., cough syrups may only be dispensed for the treatment of coughs) and shall be dispensed in accordance with the following rules.

(2) Only a licensed pharmacist or a pharmacy intern may dispense a Schedule V drug. The pharmacist or pharmacy intern making the sale is responsible for the recording of the required information in the Schedule V register book. The pharmacist or pharmacy intern shall not sell a Schedule V drug to a person below the age of 21 and shall require the purchaser to supply identification so that the purchaser's true name, address and age can be verified. The pharmacist must keep the Schedule V drugs in a safe place not accessible to members of the public. The name and address of the pharmacy must be placed on the bottle or vial of each Schedule V drug sold and the pharmacist or pharmacy intern dispensing the product must place the date of sale and his/her initials on the label at the time of sale. The pharmacist or pharmacy intern is required to show every purchaser of a Schedule V product a copy of subsections (3) and (4) of this rule (sections relating to purchaser(s) of Schedule V drugs).

(3) No person shall obtain a Schedule V drug without a practitioner's prescription unless he/she complies with the following:

(a) The product must be purchased as a medicine for its indicated medical use only;

(b) The purchaser must sign the Schedule V register book with his/her true name and address and supply proof of identification.

(c) The purchaser cannot purchase more than 120 mls (four fluid ounces) of Schedule V cough preparations, nor more than 240 mls (eight fluid ounces) of Schedule V anti-diarrheal preparations.

(4) In the absence of a practitioner's prescription, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain, within a ninety-six hour period, more than the maximum quantity set forth in subsection (3)(c) of this rule. Further, no pharmacist or pharmacy shall sell to any person, nor shall any person obtain more than twice the maximum quantity set forth in (3)(c) above in any sixty-day period.

(5)(a) Every pharmacy handling Schedule V drugs must keep a Schedule V register book in which the following statement must appear at the top of each page: ‘I have not obtained any Schedule V preparations within the last ninety-six hours, nor obtained Schedule V preparations more than twice within the last sixty days. This is my true name and address.‘ All sales of Schedule V preparations without a practitioner's prescription shall be recorded in the Schedule V register book and the following information must be recorded therein:

(i) Printed name of purchaser

(ii) Signature of purchaser

(iii) Address of purchaser

(iv) Name of the Schedule V preparation sold

(v) Quantity of Schedule V preparation sold

(vi) Date of sale

(vii) Initials or name of pharmacist or pharmacy intern who sold the Schedule V drug

(viii) Proof of identification: A unique identification number from a driver's license or from other state or federally issued photo identification card.

(b) All register books used to record the sale of Schedule V preparations shall conform to the following standards:

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

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

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

(iv) Each page shall consist of an original and duplicate. If any sales are recorded, the duplicate sheet must be mailed to the board of pharmacy when completed or on the last day of each month, whichever is earlier.

(3) All pharmacy records relating to Schedule V drugs shall be open to examination by state board of pharmacy

investigators during normal business hours. The refusal to permit such examination shall constitute grounds for the suspension or revocation of the pharmacist's license.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. WSR 83-01-083 (Order 171), S 360-36-020, filed 12/17/82. Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 82-19-022 (Order 169), S 360-36-020, filed 9/8/82; Order 108, S 360-36-020, filed 10/26/71.

WAC 246-887-030, WA ADC 246-887-030

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Wash. Admin. Code 246-887-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-040. Designation of nonnarcotic stimulant drugs for purposes of RCW 69.50.402 (a)(3).

The board of pharmacy hereby designates, the following Schedule II controlled substances as nonnarcotic stimulants for purposes of RCW 69.50.402 (a)(3):

(1) Amphetamine sulfate in any of its generic forms.

(2) Dextroamphetamine sulfate in any of its generic forms and under the following brand names:

(a) Dexedrine (SKF);

(b) Dexedrine spansules (SKF).

(3) Dextroamphetamine HCL in any of its generic forms.

(4) Dextroamphetamine tannate in any of its generic forms.

(5) Methamphetamine HCL (Desoxyephedrine HCL) in any of its generic forms and under the following brand name:

Desoxyn (Abbott).

(6) Amphetamine complex in any of its generic forms and under the following brand names:

(a) Biphetamine 12 1/2 (Pennwalt);

(b) Biphetamine 20 (Pennwalt).

(7) Combined amphetamines sold under the following brand names:

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Obetrol-10 and 20 (Obetrol).

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

(a) Preludin (Boehringer-Ingelheim).

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

(a) Ritalin (Ciba).

Statutory Authority: RCW 18.64.005. WSR 92-04-029 (Order 239B), S 246-887-040, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 79-08-069 (Order 148, Resolution No. 7-79), S 360-36-115, filed 7/24/79.

WAC 246-887-040, WA ADC 246-887-040

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Wash. Admin. Code 246-887-045

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-045. Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants.

The Schedule II stimulants listed in WAC 246-887-040 may be prescribed, dispensed, or administered to patients for the following disease states or conditions:

(1) Disease states or conditions listed in RCW 69.50.402 (3)(ii);

(2) Multiple sclerosis.

Statutory Authority: RCW 69.50.402 and 18.64.005(7). WSR 03-04-045, S 246-887-045, filed 1/28/03, effective 2/28/03.

WAC 246-887-045, WA ADC 246-887-045

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Wash. Admin. Code 246-887-080

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-080. Sodium pentobarbital registration disciplinary action.**

In addition to any criminal or civil liabilities that may occur, the board may deny, suspend, or revoke registration upon determination that (1) the registration was procured through fraud or misrepresentation, (2) the registrant or any agent or employee of the registrant has violated any of the federal or state laws related to drugs, or has violated any of the rules or regulations of the board of pharmacy.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-270, filed 8/8/89, effective 9/8/89; Order 138, S 360-36-270, filed 11/8/77.

WAC 246-887-080, WA ADC 246-887-080

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Wash. Admin. Code 246-887-090

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-090. Authority to control.**

Pursuant to the authority granted to the board of pharmacy in RCW 69.50.201, the board has considered the following factors with regards to each of the substances listed in this chapter and in chapter 69.50 RCW:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the substance;

(4) The history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) The risk to the public health;

(7) The potential of the substance to produce psychic or psychological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under the Uniform Controlled Substances Act (chapter 69.50 RCW).

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. WSR 84-22-062 (Order 190), S 360-36-400, filed 11/7/84.

WAC 246-887-090, WA ADC 246-887-090

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Wash. Admin. Code 246-887-090

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Wash. Admin. Code 246-887-100

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-100. Schedule I.**

The board finds that the following substances have high potential for abuse and have no accepted medical use in treatment in the United States or that they lack accepted safety for use in treatment under medical supervision. The board, therefore, places each of the following substances in Schedule I.

(a) The controlled substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name, are included in Schedule I.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenethyl)-4-piperidinyl)-N-phenylacetamide);

(2) Acetylmethadol;

(3) Allylprodine;

(4) Alphacetylmethadol; (except for levo-alphacetylmethadol - Also known as levo-alpha-acetylmethadol, levomethadyl acetate or LAAM);

(5) Alphameprodine;

(6) Alphamethadol;

(7) Alpha-methylfentanyl (N-(1-alpha-methyl-beta-phenyl) ethyl-4-piperidyl) propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(8) Benzethidine;

(9) Betacetylmethadol;

(10) Betameprodine;

(11) Betamethadol;

(12) Betaprodine;

(13) Clonitazene;

(14) Dextromoramide;

(15) Diampromide;

(16) Diethylthiambutene;

(17) Difenoxin;

(18) Dimenoxadol;

(19) Dimepheptanol;

(20) Dimethylthiambutene;

(21) Dioxaphetyl butyrate;

(22) Dipipanone;

(23) Ethylmethylthiambutene;

(24) Etonitazene;

(25) Etoxeridine;

(26) Furethidine;

(27) Gamma-hydroxybutyric Acid (other names include: GHB);

(28) Hydroxypethidine;

(29) Ketobemidone;

(30) Levomoramide;

(31) Levophenacylmorphan;

(32) 3-Methylfentanyl (N-(3-Methyl-1-(2-phenylethyl)-4-piperidyl))-N-phenylpropanamide);

(33) Morpheridine;

(34) MPPP (1-Methyl-4-phenyl-4-propionoxypiperidine);

(35) Noracymethadol;

(36) Norlevorphanol;

(37) Normethadone;

(38) Norpipanone;

(39) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

(40) Phenadoxone;

(41) Phenampromide;

(42) Phenomorphan;

(43) Phenoperidine;

(44) Piritramide;

(45) Proheptazine;

(46) Properidine;

(47) Propiram;

(48) Racemoramide;

(49) Tilidine;

(50) Trimeperidine.

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;

(2) Acetyldihydrocodeine;

(3) Benzylmorphine;

(4) Codeine methylbromide;

(5) Codeine-N-Oxide;

(6) Cyprenorphine;

(7) Desomorphine;

(8) Dihydromorphine;

(9) Drotebanol;

(10) Etorphine (except hydrochloride salt);

(11) Heroin;

(12) Hydromorphinol;

(13) Methyldesorphine;

(14) Methyldihydromorphine;

(15) Morphine methylbromide;

(16) Morphine methylsulfonate;

(17) Morphine-N-Oxide;

(18) Myrophine;

(19) Nicocodeine;

(20) Nicomorphine;

(21) Normorphine;

(22) Pholcodine;

(23) Thebacon.

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of paragraph (d) of this section, only, the term ‘isomer‘ includes the optical, position, and geometric isomers):

(1) 4-bromo-2,5-dimethoxy-amphetamine: Some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA;

(2) 2,5-dimethoxyamphetamine: Some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA;

(3) 2,5-dimethoxy-4-ethylamphetamine (DOET)

(4) 4-methoxyamphetamine: Some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine, PMA;

(5) 5-methoxy-3,4-methylenedioxy-amphetamine;

(6) 4-methyl-2,5-dimethoxy-amphetamine: Some trade and other names: 4-methyl-2,5-dimethoxy-a-methylphenethylamine; ‘DOM‘; and ‘STP‘;

(7) 3,4-methylenedioxy amphetamine;

(8) 3,4-methylenedioxymethamphetamine (MDMA);

(9) 3,4,5-trimethoxy amphetamine;

(10) Bufotenine: Some trade or other names: 3-(beta-Dimethylaminoethyl)-5-hydroxindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;

(11) Diethyltryptamine: Some trade or other names: N,N-Diethyltryptamine; DET;

(12) Dimethyltryptamine: Some trade or other names: DMT;

(13) Ibogaine: Some trade or other names: 7-Ethyl-6,6 beta,7,8,9,10,12,13,-octahydro-2-methoxy-6,9methano-5H-pyndo (1',2':1,2) azepino (5,4-b) indole; Tabernanthe iboga;

(14) Lysergic acid diethylamide;

(15) Marihuana;

(16) Mescaline;

(17) Parahexyl-7374; some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo(b,d)pyran; synhexyl;

(18) Peyote, meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds, or extracts; (interprets 21 U.S.C. S 812 (c), Schedule I (c)(12))

(19) N-ethyl-3-piperidyl benzilate;

(20) N-methyl-3-piperidyl benzilate;

(21) Psilocybin;

(22) Psilocyn;

(23) Any of the following synthetic cannabimimetics, their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(i) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl) indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent including, but not limited to, JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, and AM-2201;

(ii) Naphthylmethylindoles: Any compound containing a1H-indol-3-yl-(1-naphthyl) methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent including, but not limited to, JWH-175, JWH-184, and JWH-199;

(iii) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent including, but not limited to, JWH-307;

(iv) Naphthylmethylindenes: Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to

any extent including, but not limited to, JWH-176;

(v) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent including, but not limited to, JWH-203, JWH-250, JWH-251, and RCS-8;

(vi) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl) phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not substituted in the cyclohexyl ring to any extent including, but not limited to, Cannabicyclohexanol, and CP 47,497;

(vii) Benzoylindoles: Any compound containing a 3-(benzoyl) indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent including, but not limited to, AM-694, Pravadoline (WIN 48,098), RCS-4, and AM-1241;

(viii) 2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl) pyrrolo
(1,2,3-de)-(1,4-benzoxazin-6-yl)-1-napthalenylmethanone: Some trade or other names: WIN 55,212-2.

(24) Tetrahydrocannabinols, synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp., and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

(i) Delta 1 - cis - or transtetrahydrocannabinol, and their optical isomers, excluding tetrahydrocannabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration;

(ii) Delta 6 - cis - or transtetrahydrocannabinol, and their optical isomers;

(iii) Delta 3,4 - cis - or transtetrahydrocannabinol, and its optical isomers;

(iv) (6aR,10aR)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10, 10a-tetrahydrobenzo(c)chromen-1-ol: Some trade or other names: HU-210.

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(25) Ethylamine analog of phencyclidine: Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE;

(26) Pyrrolidine analog of phencyclidine: Some trade or other names: 1-(1-phencyclohexyl)pyrrolidine; PCPy; PHP;

(27) Thiophene analog of phencyclidine: Some trade or other names: 1-(1-(2-thenyl)-cyclohexly)-pipendine; 2-thienylanalog of phencyclidine; TPCP; TCP;

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(i) Mecloqualone;

(ii) Methaqualone.

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Cathinone (also known as 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone and norephedrone);

(2) 4-Fluoromethcathinone (Flephedrone);

(3) Beta-keto-N-Methylbenzodioxolylpropylamine (bk-MBDB, Butylone);

(4) 3,4-Methylenedioxymethcathinone (Methylone);

(5) 3,4-Methylenedioxypyrovalerone (MDPV);

(6) 4-Methylmethcathinone (Mephedrone);

(7) Fenethylline;

(8) N-ethylamphetamine;

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(9) 4-methylaminorex;

(10) N,N-dimethylamphetamine.

Statutory Authority: RCW 18.64.005, 69.50.201, and 69.50.203. WSR 11-22-086, S 246-887-100, filed 11/1/11, effective 12/2/11. WSR 01-03-108, S 246-887-100, filed 1/22/01, effective 1/22/01. Statutory Authority: RCW 18.64.005. WSR 94-08-098, S 246-887-100, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.65.005 and 18.64.005. WSR 94-07-105, S 246-887-100, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 18.64.005. WSR 92-04-029 (Order 239B), S 246-887-100, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-410, filed 8/8/89, effective 9/8/89; WSR 86-16-057 (Order 200), S 360-36-410, filed 8/1/86. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. WSR 84-22-062 (Order 190), S 360-36-410, filed 11/7/84.

**Reviser's note:** The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-887-100, WA ADC 246-887-100

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

END OF DOCUMENT

Wash. Admin. Code 246-887-110

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-110. Adding MPPP to Schedule I.**

The Washington state board of pharmacy finds that 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 (69.41.075). WSR 85-18-091 (Order 196), S 360-36-411, filed 9/4/85.

WAC 246-887-110, WA ADC 246-887-110

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Wash. Admin. Code 246-887-120

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-120. Adding PEPAP to Schedule I.**

The Washington state board of pharmacy finds that 1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-120, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 (69.41.075). WSR 85-18-091 (Order 196), S 360-36-412, filed 9/4/85.

WAC 246-887-120, WA ADC 246-887-120

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END OF DOCUMENT

Wash. Admin. Code 246-887-130

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-130. Adding MDMA to Schedule I.**

The Washington state board of pharmacy finds that 3,4-methylenedioxymethamphetamine (MDMA) has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision, and hereby places that substance in Schedule I.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 (69.41.075). WSR 85-18-091 (Order 196), S 360-36-413, filed 9/4/85.

WAC 246-887-130, WA ADC 246-887-130

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END OF DOCUMENT

Wash. Admin. Code 246-887-131

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-131. Adding Methcathinone to Schedule I.**

The Washington state board of pharmacy finds that Methcathinone (also called 2-methylamino-1-phenylpropan-1-one, ephedrone, Monomethylpropion, UR 1431) its salts, optical isomers and salts of optical isomers has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision and hereby places that substance in Schedule I.

Statutory Authority: RCW 18.64.005. WSR 92-23-059 (Order 318B), S 246-887-131, filed 11/17/92, effective 12/18/92.

WAC 246-887-131, WA ADC 246-887-131

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END OF DOCUMENT

Wash. Admin. Code 246-887-132

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-132. Adding Aminorex to Schedule I.

The Washington state board of pharmacy finds that Aminorex (also called aminoxaphen, 2-amino-5-phenyl-2-oxazoline or 4.5-dihydro-5-phenyl-2-oxazolamine) its salts, optical isomers and salts of optical isomers has high potential for abuse and has no medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision and hereby places that substance in Schedule I.

Statutory Authority: RCW 18.64.005. WSR 93-14-037 (Order 375B), S 246-887-132, filed 6/29/93, effective 7/30/93.

WAC 246-887-132, WA ADC 246-887-132

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END OF DOCUMENT

Wash. Admin. Code 246-887-133

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-133. Adding Alpha-ethyltryptamine to Schedule I.**

The Washington state board of pharmacy finds that Alpha-ethyltryptamine has been classified as both a central nervous system stimulant and as a tryptamine hallucinogen. The DEA used its emergency scheduling authority to place this under Schedule I after finding that immediate CSA control was necessary to avoid an imminent hazard to public safety. The substance has been found by DEA in clandestine laboratories and on the illicit drug market. Therefore the Washington state board of pharmacy places Alpha-ethyltryptamine under control of Schedule I of the Controlled Substances Act.

Statutory Authority: RCW 18.64.005. WSR 94-08-098, S 246-887-133, filed 4/6/94, effective 5/7/94.

WAC 246-887-133, WA ADC 246-887-133

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END OF DOCUMENT

Wash. Admin. Code 246-887-140

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-140. Schedule II.

The board finds that the following substances have a high potential for abuse and have currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions and that the abuse of the following substances may lead to severe psychic or psychological dependence. The board, therefore, places each of the following substances in Schedule II.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule II.

(b) Substances. (Vegetable origin or chemical synthesis.) Unless specifically excepted, any of the following substances, except those listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, naloxone, and naltrexone, and their respective salts, but including the following:

(i) Raw opium;

(ii) Opium extracts;

(iii) Opium fluid;

(iv) Powdered opium;

(v) Granulated opium;

(vi) Tincture of opium;

(vii) Codeine;

(viii) Ethylmorphine;

(ix) Etorphine hydrochloride;

(x) Hydrocodone;

(xi) Hydromorphone;

(xii) Metopon;

(xiii) Morphine;

(xiv) Oxycodone;

(xv) Oxymorphone; and

(xvi) Thebaine.

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b)(1) of this section, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Methylbenzoylecgonine (cocaine-its salts, optical isomers, and salts of optical isomers).

(6) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy).

(c) Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers,

esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil;

(2) Alphaprodine;

(3) Anileridine;

(4) Bezitramide;

(5) Bulk dextropropoxyphene (nondosage forms);

(6) Carfentanil;

(7) Dihydrocodeine;

(8) Diphenoxylate;

(9) Fentanyl;

(10) Isomethadone;

(11) Levo-alphacetylmethadol - also known as levo-alpha-acetylmethadol, levomethadyl acetate or LAAM;

(12) Levomethorphan;

(13) Levorphanol;

(14) Metazocine;

(15) Methadone;

(16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane;

(17) Moramide-Intermediate, 2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid;

(18) Pethidine (meperidine);

(19) Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine;

(20) Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate;

(21) Pethidine-Intermediate-C,1-methyl-4-phenylpiperidine-4-carboxylic acid;

(22) Phenazocine;

(23) Piminodine;

(24) Racemethorphan;

(25) Remifentanil;

(26) Racemorphan;

(27) Sufentanil.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) Methamphetamine, its salts, optical isomers, and salts of optical isomers;

(3) Phenmetrazine and its salts;

(4) Methylphenidate.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital;

(2) Glutethimide;

(3) Pentobarbital;

(4) Phencyclidine;

(5) Secobarbital.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(2) Phenylacetone: Some trade or other names phenyl-2-propanone, P2P, benzyl methyl ketone, methyl benzyl ketone.

(3) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine;

(ii) 1-piperidinocyclohexanecarbonitrile (PCC).

(g) Hallucinogenic substances.

(1) Nabilone. (Another name for nabilone: (B )-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo(b,d)pyran-9-one.)

WSR 00-01-075, S 246-887-140, filed 12/13/99. WSR 97-21-054, S 246-887-140, filed 10/13/97, effective 11/13/97. Statutory Authority: RCW 18.65.005 and 18.64.005. WSR 94-07-105, S 246-887-140, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 18.64.005. WSR 92-04-029 (Order 239B), S 246-887-140, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-140, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-420, filed 8/8/89, effective 9/8/89; WSR 86-16-057 (Order 200), S 360-36-420, filed 8/1/86. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. WSR 84-22-062 (Order 190), S 360-36-420, filed 11/7/84.

Wash. Admin. Code 246-887-140

**Reviser's note:** The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

**Reviser's note:** Under RCW 69.50.201 (2)(e), the above section was **not** adopted under the Administrative Procedure Act, chapter 34.05 RCW, but was published in the Washington State Register and codified into the Washington Administrative Code exactly as shown by the agency filing with history notes added by the code reviser's office.

WAC 246-887-140, WA ADC 246-887-140

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END OF DOCUMENT

Wash. Admin. Code 246-887-150

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-150. 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) Hydriodic acid.

(d) Methylamine.

(e) Phenylacetic acid.

(f) Pseudoephedrine.

(g) Methephedrine.

(h) Lead acetate.

(i) Methyl formamide.

Provided: That any drug or compound containing Ephedrine, or any of its salts or isomers, or Pseudoephedrine,

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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 18.65.005 and 18.64.005. WSR 94-07-105, S 246-887-150, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-150, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-11-007 (Order 214), S 360-36-425, filed 5/9/88. Statutory Authority: RCW 18.64.005(11). WSR 88-06-060 (Order 211), S 360-36-425, filed 3/2/88.

WAC 246-887-150, WA ADC 246-887-150

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

END OF DOCUMENT

Wash. Admin. Code 246-887-160

C

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-160. Schedule III.**

The board finds that the following substances have a potential for abuse less than the substances listed in Schedules I and II, and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to moderate or low physical dependency or high psychological dependency. The board, therefore, places each of the following substances in Schedule III.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations are referred to as excepted compounds in Schedule III as published in 21 C.F.R. 1308.13 (b)(1) as of April 1, 1984, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances;

(2) Benzphetamine;

(3) Chlorphentermine;

(4) Clortermine;

(5) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing:

(i) Amobarbital;

(ii) Secobarbital;

(iii) Pentobarbital;

or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;

(2) Any suppository dosage form containing:

(i) Amobarbital;

(ii) Secobarbital;

(iii) Pentobarbital;

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid;

(4) Chlorhexadol;

(5) Ketamine, its salts, isomers, and salts of isomers-some other names for ketamine: (<plus-minus>)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone;

(6) Lysergic acid;

(7) Lysergic acid amide;

(8) Methyprylon;

(9) Sulfondiethylmethane;

(10) Sulfonethylmethane;

(11) Sulfonmethane;

(12) Tiletamine and zolazepam or any salt thereof-some trade or other names for a tiletamine-zolazepam combination product: Telazol some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl) cyclohexanone-some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-(3,4-e) (1,4) diazepin 7 (1H)-one flupyrazapon.

(d) Nalorphine.

(e) Anabolic steroids. The term ‘anabolic steroid‘ means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

(1) Boldenone;

(2) Chlorotestosterone;

(3) Clostebol;

(4) Dehydrochlormethyltestosterone;

(5) Dihydrotestosterone;

(6) Drostanolone;

(7) Ethylestrenol;

(8) Fluoxymesterone;

(9) Formebulone (Formebolone);

(10) Mesterolone;

(11) Methandienone;

(12) Methandranone;

(13) Methandriol;

(14) Methandrostenolone;

(15) Methenolone;

(16) Methyltestosterone;

(17) Mibolerone;

(18) Nandrolone;

(19) Norethandrolone;

(20) Oxandrolone;

(21) Oxymesterone;

(22) Oxymetholone;

(23) Stanolone;

(24) Stanozolol;

(25) Testolactone;

(26) Testosterone;

(27) Trenbolone; and

(28) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the secretary of health and human services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid

within the meaning of this paragraph.

The following are implants or pellets which are exempt:

| Ingredients | Trade Name | Company |
|---|---|---|
| Testosterone Propionate, Oestradiol Benzoate | F-TO | Animal Health Div. Upjohn International Kalamazoo, MI |
| Trenbolone Acetate | Finaplix-H | Hoechst-Roussel Agri-Vet Co., Somerville, NJ |
| Trenbolone Acetate | Finaplix-S | Hoechst-Roussel Agri-Vet Co., Somerville, NJ |
| Testosterone Propionate, Estradiol Benzoate | Heifer-oid | Anchor Division Boehringer Ingelheim St. Joseph, MO |
| Testosterone Propionate, Estradiol Benzoate | Heifer-oid | Bio-Ceutic Division Boehringer Ingelheim St. Joseph, MO |
| Testosterone Propionate, Estradiol Benzoate | Heifer-oid | Ivy Laboratories, Inc. Overland Park, KS |
| Testosterone Propionate, Estradiol Benzoate | Implus | The Upjohn Co. Kalamazoo, MI |
| Trenbolone Acetate, Estradiol | Revalor-s | Hoechst-Roussel Agri-Vet Co., Somerville, NJ |
| Testosterone Propionate, Estradiol Benzoate | Synovex H | Syntex Laboratories Palo Alto, CA |

(f) The following anabolic steroid products containing compounds, mixtures, or preparations are exempt from the recordkeeping, refill restrictions, and other Controlled Substances Act requirements:

| Ingredients | Trade Name | Company |
|---|---|---|
| Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml | Androgyn L.A. | Forest Pharmaceuticals St. Louis, MO |
| Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml | Andro-Estro 90-4 | Rugby Laboratories Rockville Centre, NY |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | depANDROGYN | Forest Pharmaceuticals St. Louis, MO |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | DEPO-T.E. | Quality Research Laboratories Carmel, IN |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | depTESTROGEN | Martica Pharmaceuticals Phoenix, AZ |
| Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml | Duomone | Wintec Pharmaceutical Pacific, MO |
| Testosterone cypionate 50 mg/ml | DURATESTRIN | W.E. Hauck Alpharetta, GA |

| | | |
|---|---|---|
| Estradiol cypionate 2 mg/ml | | |
| Testosterone cypionate 50 mg/ml Esterified cypionate 2 mg/ml | DUO-SPAN II | Primedics Laboratories Gardena, CA |
| Esterified estrogens 1.25 mg. Methyltestosterone 2.5 mg. | Estratest | Solvay Pharmaceuticals Marietta, GA |
| Esterified estrogens 0.525 mg. Methyltestosterone 1.25 mg. | Estratest HS | Solvay Pharmaceuticals Marietta, GA |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | PAN ESTRA TEST | Pan American Labs Covington, LA |
| Conjugated estrogens 1.25 mg. Methyltestosterone 10 mg. | Premarin with Methyltestosterone | Ayerst Labs, Inc. New York, NY |
| Conjugated estrogens 0.625 mg. Methyltestosterone 5 mg. | Premarin with Methyltestosterone | Ayerst Labs, Inc. New York, NY |
| Testosterone propionate 25 mg Estradiol benzoate 2.5 mg | Synovex H Pellets in process | Syntex Animal Health Palo Alto, CA |
| Testosterone propionate 10 parts Estradiol benzoate 1 part | Synovex H Pellets in process, granulation | Syntex Animal Health Palo Alto, CA |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | Testagen | Clint Pharmaceutical Nashville, TN |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | TEST-ESTRO Cypionates | Rugby Laboratories Rockville Centre, NY |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | Testosterone Cyp 50 Estradiol Cyp 2 | I.D.E.-Interstate Amityville, NY |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | Testosterone Cypionate-Estradiol Cypionate Injection | Best Generics No. Miami Beach, FL |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | Testosterone Cypionate-Estradiol Cypionate Injection | Goldline Labs Ft. Lauderdale FL |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | Testosterone Cypionate-Estradiol Cypionate Injection | Schein Pharmaceuticals Port Washington, NY |
| Testosterone cypionate 50 mg/ml Estradiol cypionate 2 mg/ml | Testosterone Cypionate-Estradiol Cypionate Injection | Steris Labs, Inc. Phoenix, AZ |
| Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml | Testosterone Enanth-ate-Estradiol Valer-ate Injection | Goldline Labs Ft. Lauderdale FL |
| Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml | Testosterone Enanthate-Estradiol Valerate Injection | Schein Pharmaceuticals Port Washington, NY |
| Testosterone enanthate 90 mg/ml Estradiol valerate 4 mg/ml | Testosterone Enanthate-Estradiol Valerate Injection | Steris Labs, Inc. Phoenix, AZ |

(g) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof calculated as the free

anhydrous base or alkaloid, in limited quantities as set forth in paragraph (e) of this section:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(h) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below;

(1) Buprenorphine.

(i) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product. (Some other names for dronabinol (6aR-trans)-6a,7,8, 10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo(b,d) pyran-i-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.)

Statutory Authority: RCW 18.64.005 and 69.50.201. WSR 04-13-162, S 246-887-160, filed 6/23/04, effective 7/24/04.

Wash. Admin. Code 246-887-160

Statutory Authority: RCW 69.50.201 and 18.64.005(7). WSR 03-02-021, S 246-887-160, filed 12/23/02, effective 1/23/03. WSR 00-10-113, S 246-887-160, filed 5/3/00. WSR 00-01-075, S 246-887-160, filed 12/13/99. Statutory Authority: RCW 18.64.005. WSR 96-01-032, S 246-887-160, filed 12/12/95, effective 1/12/96; WSR 94-08-098, S 246-887-160, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64.005. WSR 93-14-038 (Order 376B), S 246-887-160, filed 6/29/93, effective 7/30/93; WSR 93-06-093 (Order 343B), S 246-887-160, filed 3/3/93, effective 4/3/93; WSR 92-04-029 (Order 239B), S 246-887-160, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-160, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-430, filed 8/8/89, effective 9/8/89. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. WSR 84-22-062 (Order 190), S 360-36-430, filed 11/7/84.

**Reviser's note:** The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-887-160, WA ADC 246-887-160

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

END OF DOCUMENT

Wash. Admin. Code 246-887-165

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-165. Adding Xyrem to Schedule III.

The Washington state board of pharmacy finds that Xyrem, sodium oxybate, Gamma-hydroxybutyric (GHB), is approved for medical use by the Food and Drug Administration and hereby places that substance in Schedule III.

Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. WSR 03-09-064, S 246-887-165, filed 4/15/03, effective 5/16/03.

WAC 246-887-165, WA ADC 246-887-165

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END OF DOCUMENT

Wash. Admin. Code 246-887-170

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-170. Schedule IV.**

The board finds that the following substances have a low potential for abuse relative to substances in Schedule III and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III. The board, therefore, places each of the following substances in Schedule IV.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule IV.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha-(+)-e-dimethylamino-1,2-diphenyl-3-methyl-2 propionoxybutane).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam;

(2) Barbital;

(3) Bromazepam;

(4) Camazepam;

(5) Carisoprodol;

(6) Chloral betaine;

(7) Chloral hydrate;

(8) Chlordiazepoxide;

(9) Clobazam;

(10) Clonazepam;

(11) Clorazepate;

(12) Clotiazepam;

(13) Cloxazolam;

(14) Delorazepam;

(15) Diazepam;

(16) Estazolam;

(17) Ethchlorvynol;

(18) Ethinamate;

(19) Ethyl loflazepate;

(20) Fludiazepam;

(21) Flunitrazepam;

(22) Flurazepam;

(23) Halazepam;

(24) Haloxazolam;

(25) Ketazolam;

(26) Loprazolam;

(27) Lorazepam;

(28) Lormetazepam;

(29) Mebutamate;

(30) Medazepam;

(31) Meprobamate;

(32) Methohexital;

(33) Methylphenobarbital (mephobarbital);

(34) Midazolam;

(35) Nimetazepam;

(36) Nitrazepam;

(37) Nordiazepam;

(38) Oxazepam;

(39) Oxazolam;

(40) Paraldehyde;

(41) Petrichloral;

(42) Phenobarbital;

(43) Pinazepam;

(44) Prazepam;

(45) Quazepam;

(46) Temazepam;

(47) Tetrazepam;

(48) Triazolam;

(49) Zolpidem.

(d) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position or geometric), and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible.

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Cathine ((+) - norpseudoephedrine);

(2) Diethylpropion;

(3) Fencamfamin;

(4) Fenproporex;

(5) Mazindol;

(6) Mefenorex;

(7) Pemoline (including organometallic complexes and chelates thereof);

(8) Phentermine;

(9) Pipradrol;

(10) SPA ((-)-1-dimethylamino-1, 2-dephenylethane.

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine;

(2) Butorphanol.

Statutory Authority: RCW 69.50.201 and 18.64.005. WSR 10-02-080, S 246-887-170, filed 1/5/10, effective 2/5/10. WSR 98-02-084 S 246-887-170, filed 1/7/98, effective 1/7/98. Statutory Authority: RCW 18.64.005. WSR 94-08-098, S 246-887-170, filed 4/6/94, effective 5/7/94; WSR 92-04-029 (Order 239B), S 246-887-170, filed 1/28/92, effective 2/29/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-170, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-440, filed 8/8/89, effective 9/8/89. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. WSR 84-22-062 (Order 190), S 360-36-440, filed 11/7/84.

WAC 246-887-170, WA ADC 246-887-170

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END OF DOCUMENT

Wash. Admin. Code 246-887-180

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-180. Schedule V.**

The board finds that the following substances have low potential for abuse relative to substances in Schedule IV and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. The board, therefore, places each of the following substances in Schedule V.

(a) The drugs and other substances listed in this section, by whatever official name, common or usual name, chemical name, or brand name designated, are included in Schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth in this section, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S

Wash. Admin. Code 246-887-180

246-887-180, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201, 69.50.203, 69.50.205, 69.50.207, 69.50.209 and 69.50.211. WSR 84-22-062 (Order 190), S 360-36-450, filed 11/7/84.

WAC 246-887-180, WA ADC 246-887-180

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END OF DOCUMENT

Wash. Admin. Code 246-887-190

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Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-190. Adding buprenorphine to Schedule V.**

The Washington state board of pharmacy finds that buprenorphine has a low potential for abuse relative to substances in Schedule IV; has currently accepted medical use in treatment in the United States; and the substance has limited physical dependence or psychological dependence liability relative to the substances in Schedule IV, and hereby places that substance in Schedule V.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-190, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 (69.41.075). WSR 85-18-091 (Order 196), S 360-36-451, filed 9/4/85.

WAC 246-887-190, WA ADC 246-887-190

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Wash. Admin. Code 246-887-200

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-200. Other controlled substance registrants-Requirements.

(1) All persons and firms, except persons exempt from registration, shall register with the board in order legally to possess or use controlled substances.

(2) Persons or firms which are not classified as pharmacies, wholesalers, manufacturers, or researchers shall be classified as other controlled substance registrants. Examples of persons or firms in this classification include analytical laboratories, dog handlers/trainers who use dogs for drug detection purposes, school laboratories and other agencies which have a legitimate need to use precursor chemicals as defined in WAC 246-887-150.

(3) The applicant for a controlled substance registration shall complete and return an application form supplied by the board. Either on the form or on an addendum, the applicant shall list the controlled substances to be used, the purpose for such use, and the names of the persons authorized to access the controlled substances.

(4) All controlled substances shall be stored in a substantially constructed locked cabinet. The registrant shall maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances. An inventory of all controlled substances in the possession of the registrant shall be completed every two years on the anniversary of the issuances of the registration and shall be maintained for two years. Unwanted, outdated, or unusable controlled substances shall be returned to the source from which obtained or surrendered to the Federal Drug Enforcement Administration.

Statutory Authority: Chapter 69.50 RCW and RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-887-200, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-887-200, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.50.201. WSR 89-17-023 (Order 226), S 360-36-500, filed 8/8/89, effective 9/8/89.

WAC 246-887-200, WA ADC 246-887-200

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END OF DOCUMENT

Wash. Admin. Code 246-887-210

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-210. Standards for transmission of controlled substances sample distribution reports.

These standards describe the format for transmission of data regarding distribution of controlled substance samples by manufacturers or distributors to licensed practitioners in the state of Washington.

(1) Each report shall contain the following information regarding the firm distributing controlled substance samples:

(a) Name of firm.

(b) DEA number of firm.

(c) Complete address of firm including zip code.

(d) Name and phone number of contact person.

(2) Each report shall contain the following information regarding the licensed practitioner to whom samples are distributed:

(a) First and last name of practitioner.

(b) DEA number of practitioner.

(c) Professional designation of practitioner. (E.g., MD, DO, DDS.)

(d) Complete address of practitioner including zip code.

(3) Each report shall contain the following information regarding the controlled substance(s) distributed:

(a) Name of controlled substance(s) distributed.

(b) Dosage units of controlled substance(s) distributed.

(c) Quantity distributed.

(d) Date distributed.

(4) Each report shall be submitted in alphabetical order by practitioner's last name.

(5) Each report shall be submitted quarterly.

Statutory Authority: RCW 18.64.005. WSR 92-09-071 (Order 265B), S 246-887-210, filed 4/14/92, effective 5/15/92.

WAC 246-887-210, WA ADC 246-887-210

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Wash. Admin. Code 246-887-220

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-220. Chemical capture programs.

**Purpose.** Wildlife management programs often require the use of controlled substances for chemical capture programs. The purpose of these rules is to set requirements for the use of controlled substances in department of fish and wildlife chemical capture programs. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or other legitimate purpose.

Statutory Authority: RCW 69.50.320, 18.64.005. WSR 05-20-106, S 246-887-220, filed 10/5/05, effective 11/8/05.

WAC 246-887-220, WA ADC 246-887-220

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END OF DOCUMENT

Wash. Admin. Code 246-887-230

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-230. Registration requirements.

(1) The department of fish and wildlife may apply to the board for a limited registration under chapter 69.50 RCW (Controlled Substance Act) to purchase, possess, and administer controlled substances for use in chemical capture programs.

(2) Each department of fish and wildlife field office that stores controlled substances must register with the board. The department of fish and wildlife shall notify the board in writing of the names of individuals who are authorized to possess and administer controlled substances.

(3) In addition, the department of fish and wildlife shall designate one individual at each field office who shall be responsible for the ordering, possession, safe storage, and utilization of controlled substances. The department of fish and wildlife shall notify the board in writing of the name of the designated individual.

(4) Controlled substances obtained under this limited registration shall be for veterinary use only.

Statutory Authority: RCW 69.50.320, 18.64.005. WSR 05-20-106, S 246-887-230, filed 10/5/05, effective 11/8/05.

WAC 246-887-230, WA ADC 246-887-230

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Wash. Admin. Code 246-887-240

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-240. Authorized individuals.

To be eligible to possess and/or administer controlled substances, individuals must successfully complete an approved training program. The following individuals are authorized to possess and administer controlled substances:

(1) Department of fish and wildlife officers;

(2) Department of fish and wildlife biologists; and

(3) Department of fish and wildlife veterinarians.

Statutory Authority: RCW 69.50.320, 18.64.005. WSR 05-20-106, S 246-887-240, filed 10/5/05, effective 11/8/05.

WAC 246-887-240, WA ADC 246-887-240

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END OF DOCUMENT

Wash. Admin. Code 246-887-250

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-250. Controlled substances training.

The department of fish and wildlife shall establish written policies and procedures to ensure that officers and biologists who administer controlled substances have received sufficient training. The training shall include, at a minimum, the safe handling and administration of controlled substances and the potential hazards. Officers and biologists must be able to demonstrate adequate knowledge of the potential hazards and proper techniques to be used in administering controlled substances.

The written policies and procedures shall be approved by the board. Any amendments or deletions to the policies and procedures must be approved by the board prior to implementation.

Statutory Authority: RCW 69.50.320, 18.64.005. WSR 05-20-106, S 246-887-250, filed 10/5/05, effective 11/8/05.

WAC 246-887-250, WA ADC 246-887-250

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END OF DOCUMENT

Wash. Admin. Code 246-887-260

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-260. Storage requirements.

Each registered location shall store the controlled substances in a securely locked, substantially constructed cabinet. Keys to the storage area shall be restricted to those persons authorized by the department of fish and wildlife to possess and administer the drugs.

Schedule II controlled substances shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

In addition to field offices, the department of fish and wildlife may allow officers, biologists, and veterinarians to possess a supply of controlled substances for use in the field. The field supply shall be stored in a locked metal box securely attached to a vehicle. The designated officer, biologist, or veterinarian shall be responsible to ensure that the controlled substances are accounted for at all times. All receipts and use of controlled substances from the field supply shall be recorded in a bound logbook with sequentially numbered pages.

Statutory Authority: RCW 69.50.320, 18.64.005. WSR 05-20-106, S 246-887-260, filed 10/5/05, effective 11/8/05.

WAC 246-887-260, WA ADC 246-887-260

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Wash. Admin. Code 246-887-270

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-270. Controlled substances records and reports.

(1) The department of fish and wildlife shall be responsible for maintaining all records and submitting all reports required by federal or state law or regulation.

(2) A bound logbook with sequentially numbered pages shall be kept documenting the receipt and disposition of all controlled substances. In addition, all receipts and invoices shall be maintained for a period of two years.

(3) All records shall be available for inspection by the board or any officer who is authorized to enforce this chapter.

(4) A physical inventory of approved controlled substances shall be performed, reconciled, and documented every twelve months. The inventory shall be signed and dated by the designated individual.

(5) Any discrepancy in the actual inventory of approved controlled substances shall be documented and reported immediately to the responsible supervisor who shall investigate the discrepancy. Any discrepancy that has not been corrected within seven days shall be reported in writing to the board of pharmacy and the Drug Enforcement Administration (DEA).

(6) Unwanted or unused controlled substances shall be returned to the manufacturer or destroyed in accordance with the rules and requirements of the board, the Drug Enforcement Administration, and the department of ecology.

Statutory Authority: RCW 69.50.320, 18.64.005. WSR 05-20-106, S 246-887-270, filed 10/5/05, effective 11/8/05.

WAC 246-887-270, WA ADC 246-887-270

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END OF DOCUMENT

Wash. Admin. Code 246-887-280

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)

## ➡➡ 246-887-280. Approved controlled substances.

The following controlled substances are approved for use by officers and biologists of the department of fish and wildlife for chemical capture programs:

(1) Butorphanol;

(2) Diazepam (Valium);

(3) Diprenorphine;

(4) Carfentanil (Wildnil);

(5) Fentanyl;

(6) Ketamine;

(7) Midazolam; and

(8) Tiletamine and zolazepam (Telazol).

Statutory Authority: RCW 69.50.320 and 18.64.005. WSR 11-05-034, S 246-887-280, filed 2/8/11, effective 3/11/11; WSR 05-20-106, S 246-887-280, filed 10/5/05, effective 11/8/05.

WAC 246-887-280, WA ADC 246-887-280

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END OF DOCUMENT

Wash. Admin. Code 246-887-290

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Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-887**. Pharmacy-Regulations Implementing The Uniform Controlled Substances Act (Refs & Annos)
➡➡ **246-887-290. Controlled substances registration disciplinary actions.**

In addition to any criminal or civil liabilities that may occur, the board may suspend or revoke a registration upon determination that the person administering controlled substances has not demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering controlled substances.

Statutory Authority: RCW 69.50.320, 18.64.005. WSR 05-20-106, S 246-887-290, filed 10/5/05, effective 11/8/05.

WAC 246-887-290, WA ADC 246-887-290

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Wash. Admin. Code Ch. 246-889 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control
➡➡ **Ch. 246-889 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-889-075. Definitions. (Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-075, filed 12/22/05, effective 1/1/06.) Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.

246-889-080. Records of sale. (Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-080, filed 12/22/05, effective 1/1/06.) Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.

246-889-100. Methods for collecting, recording, and storing records of sales data. (Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-100, filed 12/22/05, effective 1/1/06.) Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.

246-889-105. Record retention and destruction. (Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-105, filed 12/22/05, effective 1/1/06.) Repealed by WSR 11-19-018, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.165 and 18.64.005.

WAC Ch. 246-889 Disp Table, WA ADC Ch. 246-889 Disp Table

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END OF DOCUMENT

Wash. Admin. Code 246-889-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-010. Definitions.**

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) ‘Board‘ means the Washington state board of pharmacy.

(2) ‘Electronic reporting‘ means detailed reporting obligations of a pharmacy, shopkeeper, or itinerant vendor to submit to the real-time methamphetamine precursor tracking system the retail purchase or attempted purchase of any nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts or isomers, or salts of isomers.

(3) ‘Law enforcement‘ means any general or limited authority Washington peace officer or federal law enforcement officer.

(4) ‘Methamphetamine precursor tracking system‘ means the real-time electronic sales tracking system established by RCW 69.43.110 used to capture the retail purchase or attempted purchase of any nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts or isomers, or salts of isomers.

(5) ‘Purchaser‘ means an individual who purchases or attempts to purchase a restricted product.

(6) ‘Restricted product‘ means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

(7) ‘Retailer‘ means a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW that sells, dispenses, or otherwise provides restricted products to purchasers.

(8) ‘Sale‘ means the transfer, selling, or otherwise furnishing of any restricted product to any person.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-010, filed 9/8/11, effective 10/15/11.

Wash. Admin. Code 246-889-010

WAC 246-889-010, WA ADC 246-889-010

Current with amendments adopted through the 13-24 Washington State Register dated, December 18, 2013.

END OF DOCUMENT

Wash. Admin. Code 246-889-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-020. 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) Chlorephedrine;

(d) Diethyl malonate;

(e) D-lysergic acid;

(f) Ephedrine;

(g) Ergotamine tartrate;

(h) Ethylamine;

(i) Ethyl malonate;

(j) Ethylephedrine;

(k) Gamma-butyrolactone (GBL);

(l) Hydriodic acid;

(m) Lead acetate;

(n) Malonic acid;

(o) Methylamine;

(p) Methylformamide;

(q) Methylephedrine;

(r) Methylpseudoephedrine;

(s) N-acetylanthranilic acid;

(t) Norpseudoephedrine;

(u) Phenylacetic acid;

(v) Phenylpropanolamine;

(w) Piperidine;

(x) Pseudoephedrine; and

(y) 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 methylformanide in RCW 69.43.010, was intended to refer to methylformamide and corrects that reference by deleting ‘methylformanide‘ and adding ‘methylformamide.‘ This change is based upon the finding that this revision conforms to the tests set forth in RCW 69.43.010(2).

(3) Registrants should be aware that precursor substances in subsection (1)(a), (f), (k), (l), (n), (o), (p), (t), and (w) of this section are also regulated as schedule II immediate precursors pursuant to WAC 246-887-150 and all applicable rules and laws governing the distribution of schedule II controlled substances must also be complied with.

Wash. Admin. Code 246-889-020

Statutory Authority: RCW 69.43.050, 18.64.005. WSR 02-18-024, S 246-889-020, filed 8/23/02, effective 9/23/02. Statutory Authority: RCW 18.65.005 and 18.64.005. WSR 94-07-105, S 246-889-020, filed 3/18/94, effective 3/18/94. Statutory Authority: RCW 69.43.050. WSR 92-12-035 (Order 277B), S 246-889-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-889-020, filed 8/30/91, effective 9/30/91. Statutory Authority: 1988 c 147 S 5. WSR 88-14-096 (Order 218), S 360-38-010, filed 7/6/88.

WAC 246-889-020, WA ADC 246-889-020

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END OF DOCUMENT

Wash. Admin. Code 246-889-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-030. 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 246-889-020 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: RCW 69.43.050. WSR 92-12-035 (Order 277B), S 246-889-030, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-889-030, filed 8/30/91, effective 9/30/91. Statutory Authority: 1988 c 147 S 5. WSR 88-14-096 (Order 218), S 360-38-020, filed 7/6/88.

WAC 246-889-030, WA ADC 246-889-030

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Wash. Admin. Code 246-889-030

END OF DOCUMENT

Wash. Admin. Code 246-889-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-040. 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 RCW 69.43.010(5), 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: RCW 69.43.050. WSR 92-12-035 (Order 277B), S 246-889-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-889-040, filed 8/30/91, effective 9/30/91. Statutory Authority: 1988 c 147 S 5. WSR 88-14-096 (Order 218), S 360-38-030, filed 7/6/88.

WAC 246-889-040, WA ADC 246-889-040

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Wash. Admin. Code 246-889-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-050. Suspicious transactions and reporting requirements.**

(1) A manufacturer or wholesaler who sells, transfers, or furnishes a regulated product to any licensee shall report any suspicious transaction in writing to the state board of pharmacy.

(2) For the purpose of this rule, a regulated product is defined as a product specified in RCW 69.43.010(1) or WAC 246-889-020.

(3) For the purposes of this rule, a ‘suspicious transaction‘ is defined as any sale or transfer that meets any of the following criteria:

(a) Any sale or transfer that would lead a reasonable person to believe that the substance is likely to be used for the purpose of unlawfully manufacturing a controlled substance under chapter 69.50 RCW, based on such factors as:

(i) The amount of the substance involved;

(ii) The method of payment;

(iii) The method of delivery; or

(iv) Any past dealings with any participant in the transaction.

(b) Any sale or transfer involving payment for a regulated product in cash or money orders in a total amount of more than two hundred dollars.

(c) Any sale or transfer of a regulated product that meets the criteria identifying suspicious orders in the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Program Report of the Suspicious Orders Task Force. Copies of the publication are available upon request from the board of pharmacy.

(d) Any individual sale or transfer of a regulated product that exceeds ten percent of the nonprescription

drugs contained in the order. (Example: If a wholesaler sells three thousand dollars worth of products to a shopkeeper and that order contains one thousand dollars worth of nonprescription drugs, the wholesaler must submit a suspicious transaction report if the order contains over one hundred dollars worth of regulated products.)

(e) Any order which contains regulated products and has no additional nonprescription drugs is considered a suspicious transaction.

(4) For the purposes of this rule, nonprescription drugs are defined as those drugs which may be sold at retail without a prescription for the diagnosis, treatment, cure or prevention of any disease that has been approved by the FDA and bears an appropriate label. An over-the-counter (OTC) drug is the same as a nonprescription drug.

The following are examples of products sold at retail which are not defined as OTC drugs:

(a) Cosmetics;

(b) Food, dietary, and vitamin supplements;

(c) Herbs;

(d) Products that carry the statements ‘this product is not intended to diagnose, treat, cure or prevent any disease‘ or ‘not evaluated by FDA.‘

(5) The written report of a suspicious transaction shall contain, at a minimum, the following information:

(a) Name, address and phone number of the manufacturer and/or wholesaler making the report;

(b) Washington state license number of the wholesaler;

(c) Washington state Unified Business Identifier (UBI) number of the recipient of the suspicious transaction;

(d) Trade/brand name of regulated product;

(e) Generic name of regulated product's active ingredients;

(f) Name, address and phone number of the recipient of the suspicious transaction;

(g) Quantity of substance purchased, transferred, or furnished, by number of units and doses per unit;

(h) Date of purchase or transfer;

(i) Method of payment of the substance;

(j) Lot number if available; and

(k) National Drug Code Number if available.

Statutory Authority: RCW 18.64.005 and 69.43.035. WSR 07-23-018, S 246-889-050, filed 11/9/07, effective 12/10/07. Statutory Authority: RCW 69.43.035 and 18.64.005(7). WSR 03-13-027, S 246-889-050, filed 6/10/03, effective 7/11/03.

WAC 246-889-050, WA ADC 246-889-050

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Wash. Admin. Code 246-889-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-070. Retail sales of nonprescription ephedrine, pseudoephedrine, and phenylpropanolamine products.**

Purpose.

The legislature has recognized that restricting access to ephedrine, pseudoephedrine, and phenylpropanolamine products, or their salts or isomers, or salts of isomers, is a valid method to reduce the availability of these products for the manufacture of methamphetamine. To reduce the use of these products in the manufacture of methamphetamine, while continuing access for legitimate purposes, the legislature directed the board to adopt rules to implement a statewide methamphetamine precursor tracking system for the nonprescription sales of products containing ephedrine, pseudoephedrine or phenylpropanolamine or their salts or isomers, or salts of isomers. This chapter describes the requirements for the retail sales of restricted products.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-070, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-070, filed 12/22/05, effective 1/1/06.

WAC 246-889-070, WA ADC 246-889-070

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Wash. Admin. Code 246-889-085

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-085. Requirements for the sale of restricted product.**

Unless exempted in RCW 69.43.110, a retailer must:

(1) Verify the purchaser's identity by means of acceptable identification as defined in this chapter.

(2) Ensure that the purchaser is at least eighteen years of age.

(3) Record all of the information required in WAC 246-889-095 in the record of transaction before completing the sale.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-085, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-085, filed 12/22/05, effective 1/1/06.

WAC 246-889-085, WA ADC 246-889-085

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Wash. Admin. Code 246-889-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-090. Acceptable forms of photo identification.**

Acceptable forms of identification are defined as current foreign, federal, state, or tribal government-issued identification which include the person's photograph, name, date of birth, signature, and physical description. Acceptable forms of identification include, but are not limited to:

(1) A valid driver's license or instruction permit issued by any U.S. state or foreign government. If the purchaser's driver's license has expired, he or she must also show a valid temporary driver's license with the expired card.

(2) A United States armed forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.

(3) A merchant marine identification card issued by the United States Coast Guard.

(4) An identification card issued by any foreign, federal, or state government.

(5) An official U.S. passport or an unexpired foreign passport that contains a temporary I-551 stamp.

(6) An enrollment card issued by the governing authority of a federally recognized Indian tribe located in Washington state, if the enrollment card incorporates security features comparable to those implemented by the department of licensing for Washington state drivers' licenses.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-090, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-090, filed 12/22/05, effective 1/1/06.

WAC 246-889-090, WA ADC 246-889-090

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Wash. Admin. Code 246-889-095

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-095. Record of sales-Electronic methamphetamine precursor tracking.**

(1) Unless granted an exemption under RCW 69.43.110 upon the sale or attempted sale of a restricted product, each retailer must enter and electronically transmit the following information to the methamphetamine precursor tracking system prior to completion of the transaction:

(a) Sale transaction information including:

(i) Date and time of the intended purchase;

(ii) Product description;

(iii) Quantity of product to be sold including:

(A) Total grams of restricted product per box;

(B) Number of boxes per transaction; and

(b) Purchaser's information including:

(i) Full name as it appears on the acceptable identification;

(ii) Date of birth;

(iii) The address as it appears on the photo identification or the current address if the form of photo identification used does not contain the purchaser's address. The address information must include the house number, street, city, state, and zip code;

(iv) Form of photo identification presented by the purchaser, including the issuing agency of the acceptable identification, and the identification number appearing on the identification; and

(v) Purchaser's signature. If the retailer is not able to secure an electronic signature, the retailer shall maintain a hard copy of a signature logbook consisting of each purchaser's signature and the transaction number provided by the methamphetamine precursor tracking system.

(c) The full name or initials of the individual conducting the transaction.

(d) Other information as required by the methamphetamine precursor tracking system data base.

(2) If a transaction occurs during a time when the methamphetamine precursor tracking system is temporarily unavailable due to power outage or other technical difficulties, the retailer shall record the information required in this section in a written logbook for entry into the methamphetamine precursor tracking system within seventy-two hours of the system becoming operational.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-095, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-095, filed 12/22/05, effective 1/1/06.

WAC 246-889-095, WA ADC 246-889-095

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Wash. Admin. Code 246-889-110

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-110. Maintenance of and access to retail sales records of restricted products.**

(1) The retail sales records required under WAC 246-889-095 are confidential and accessible by the board of pharmacy and law enforcement agencies. Law enforcement may access the retail sales records for criminal investigations when, at a minimum, there is an articulated individualized suspicion of criminal activity.

(2) Each law enforcement agency's administrator, chief, sheriff, or other chief executive officer shall ensure:

(a) Only authorized employees have access to the data bases;

(b) Each employee use his or her unique password or access code to access the data bases;

(c) Each employee adheres to all state and federal laws regarding confidentiality; and

(d) As employees change, new passwords or access codes are assigned to new employees and passwords of ex-employees or transferred employees are removed.

(3) Retail sales records of restricted products, electronic or written, must be kept for a minimum of two years.

(4) Retail sales records must be destroyed in a manner that leaves the record unidentifiable and nonretrievable.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-110, filed 9/8/11, effective 10/15/11. Statutory Authority: RCW 69.43.170, 18.64.005. WSR 06-02-010, S 246-889-110, filed 12/22/05, effective 1/1/06.

WAC 246-889-110, WA ADC 246-889-110

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Wash. Admin. Code 246-889-115

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-115. Exemptions from electronic reporting.**

(1) Pharmacies are exempt from entering purchase information into the methamphetamine precursor tracking system when the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine or their salts or isomers, or salts of isomers is sold pursuant to a prescription written by an authorized practitioner.

(2) A retailer must demonstrate ‘good cause‘ to qualify for an exemption from electronic reporting requirements. ‘Good cause‘ includes, but is not limited to, situations where the installation of the necessary equipment to access the methamphetamine precursor tracking system is unavailable or cost prohibitive to the retailer.

(a) A retailer must submit a written request on a form provided by the board, which shall include the following information:

(i) The reason for the exemption; and

(ii) The anticipated duration needed for the exemption.

(b) An exemption from electronic reporting may not exceed one hundred eighty days.

(c) A retailer may request additional exemptions by submitting a form defined in this subsection at least thirty days before the current exemption expires. The retailer must show that compliance will cause the business significant hardship.

(d) For all sales transactions involving the sale or attempted sale of a restricted product occurring during the period of an exemption, the retailer shall record into a written logbook, at the time of the sale or attempted sale, the information required under WAC 246-889-095(1).

(e) The written logbook of each sale or attempted sale shall be available for inspection by any law enforcement officer or board inspector during normal business hours.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-115, filed 9/8/11, effective 10/15/11.

Wash. Admin. Code 246-889-115

WAC 246-889-115, WA ADC 246-889-115

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Wash. Admin. Code 246-889-120

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-889**. Pharmaceutical-Precursor Substance Control (Refs & Annos)
➡➡ **246-889-120. Denial of sale-Override.**

(1) The retailer must deny the sale of restricted product to purchasers who are not able to produce acceptable identification or if the sale would violate RCW 69.43.110 or federal law.

(2) In the event that the retailer perceives that refusal of the purchase may place him or her in imminent physical harm, the retailer may use the data base safety override function to proceed with the sale, provided that when the threat is no longer perceived, the retailer must immediately contact local law enforcement to report the incident.

Statutory Authority: RCW 69.43.165 and 18.64.005. WSR 11-19-018, S 246-889-120, filed 9/8/11, effective 10/15/11.

WAC 246-889-120, WA ADC 246-889-120

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Wash. Admin. Code 246-891-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-891**. Pharmacy-prophylactics
➡➡ **246-891-010. Definitions.**

(1) The following definitions shall be applicable to these rules.

(1) ‘Board‘ shall mean the Washington state board of pharmacy;

(2) ‘Condom‘ shall mean a prophylactic consisting of a very thin sheath designed to be placed over the penis to prevent conception or venereal disease during coitus, and is commonly made of rubber, parchment skins, plastic or similar materials;

(3) ‘Prophylactic‘ shall mean any device or medical preparation or compound which is or may be used, designed, intended or which has or may have special utility, for the prevention and/or treatment of venereal diseases;

(4) ‘Sell‘ and ‘sale‘ shall, in addition to their usual and ordinary meanings, include possession in violation of the intent of this chapter, exchange, give away or gift, or any disposal.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-891-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.040.730 (69.04.730). WSR 85-06-010 (Order 193), S 360-40-010, filed 2/22/85. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. WSR 83-01-083 (Order 171), S 360-40-010, filed 12/17/82; Order 108, S 360-40-010, filed 10/26/71.

WAC 246-891-010, WA ADC 246-891-010

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Wash. Admin. Code 246-891-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-891**. Pharmacy-prophylactics
➡➡ **246-891-020. 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 five years after the date of manufacture. Condoms may not be sold in this state five years after the date of manufacture. Condoms bearing an expiration date may not be sold in this state after their expiration date. Condoms not bearing an expiration date may not be sold in this state more than five years after the date of manufacture.

(3) All consumer packages containing one or more individually wrapped condoms shall contain easily understood directions for use.

Statutory Authority: RCW 18.64.005. WSR 95-08-020, S 246-891-020, filed 3/27/95, effective 4/27/95. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-891-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-20-038 (Order 219), S 360-40-040, filed 9/30/88. Statutory Authority: RCW 18.64.005 and 69.040.730 (69.04.730). WSR 85-06-010 (Order 193), S 360-40-040, filed 2/22/85. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. WSR 83-01-083 (Order 171), S 360-40-040, filed 12/17/82.

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Wash. Admin. Code 246-891-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-891**. Pharmacy-prophylactics
➡➡ **246-891-030. Condom standards.**

All condoms shall meet the following standards:

(1) Latex rubber condoms shall comply with applicable United States Food and Drug Administration requirements current at the time of manufacture.

(2) Condoms made from materials other than rubber shall conform to applicable United States Food and Drug Administration requirements current at the time of manufacture.

Statutory Authority: RCW 18.64.005. WSR 95-08-020, S 246-891-030, filed 3/27/95, effective 4/27/95. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-891-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.040.730 (69.04.730). WSR 85-06-010 (Order 193), S 360-40-070, filed 2/22/85. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. WSR 83-01-083 (Order 171), S 360-40-070, filed 12/17/82.

WAC 246-891-030, WA ADC 246-891-030

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Wash. Admin. Code Ch. 246-893 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-893**. Pharmacy-Public Records Access Pursuant to Initiative 276
➡➡ **Ch. 246-893 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-893-001. Purpose. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-010, filed 4/12/89; Order 113, S 360-44-010, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-010. Definitions. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. WSR 83-01-083 (Order 171), S 360-44-020, filed 12/17/82; Order 113, S 360-44-020, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-020. Description of central and field organization of the board. (Statutory Authority: RCW 42.17.250. WSR 92-12-035 (Order 277B), S 246-893-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-020, filed 8/30/91, effective 9/30/91; Order 113, S 360-44-030, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-030. Operations and procedures. (Statutory Authority: RCW 42.17.250. WSR 92-12-035 (Order 277B), S 246-893-030, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-040, filed 4/12/89. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. WSR 83-01-083 (Order 171), S 360-44-040, filed 12/17/82; Order 113, S 360-44-040, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-040. Public records available. (Statutory Authority: RCW 42.17.250. WSR 92-12-035 (Order 277B), S 246-893-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-050, filed 4/12/89; Order 113, S 360-44-050, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-050. Public records officer. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR

91-18-057 (Order 191B), recodified as S 246-893-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-060, filed 4/12/89; Order 113, S 360-44-060, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-060. Office hours. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-060, filed 8/30/91, effective 9/30/91; Order 113, S 360-44-070, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-070. Requests for public records. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-080, filed 4/12/89; Order 113, S 360-44-080, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-080. Copying. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-090, filed 4/12/89; Order 113, S 360-44-090, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-090. Exemptions. (Statutory Authority: RCW 42.17.250. WSR 92-12-035 (Order 277B), S 246-893-090, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-100, filed 4/12/89; Order 113, S 360-44-100, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-100. Review of denials of public records requests. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-100, filed 8/30/91, effective 9/30/91; Order 113, S 360-44-110, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-110. Protection of public records. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-110, filed 8/30/91, effective 9/30/91; Order 113, S 360-44-120, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-120. Index of public records available. (Statutory Authority: RCW 42.17.250. WSR 92-12-035 (Order 277B), S 246-893-120, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-120, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-130, filed 4/12/89; Order 113, S 360-44-130, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority:

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RCW 18.64.005.

246-893-130. Address where requests to be directed. (Statutory Authority: RCW 42.17.250. WSR 92-12-035 (Order 277B), S 246-893-130, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-140, filed 4/12/89; Order 113, S 360-44-140, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-140. Adoption of form. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-140, filed 8/30/91, effective 9/30/91; Order 113, S 360-44-150, filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-893-998. Appendix A-Form. (Statutory Authority: RCW 42.17.250. WSR 92-12-035 (Order 277B), S 246-893-998, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-893-998, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 42.17.250. WSR 89-09-020 (Order 224), S 360-44-990, filed 4/12/89; Order 113, Appendix A (codified as WAC 360-44-990), filed 4/27/73.) Repealed by WSR 97-20-167, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

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Wash. Admin. Code 246-895-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-010. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-010, filed 10/10/88; Order 133, S 360-46-010, filed 8/4/77.

WAC 246-895-010, WA ADC 246-895-010

Wash. Admin. Code 246-895-010

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Wash. Admin. Code 246-895-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-020. Finished pharmaceuticals-Manufacturing practice.**

(1) The criteria in WAC 246-895-040 through 246-895-160, 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. WSR 92-12-035 (Order 277B), S 246-895-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-020, filed 10/10/88; Order 133, S 360-46-020, filed 8/4/77.

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Wash. Admin. Code 246-895-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-030. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-030, filed 10/10/88; Order 133, S 360-46-030, filed 8/4/77.

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Wash. Admin. Code 246-895-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-040. 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:

Wash. Admin. Code 246-895-040

(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 246-895-110.

(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. WSR 92-12-035 (Order 277B), S 246-895-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-040, filed 10/10/88; Order 133, S 360-46-040, filed 8/4/77.

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Wash. Admin. Code 246-895-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-050. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-050, filed 10/10/88; Order 133, S 360-46-050, filed 8/4/77.

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Wash. Admin. Code 246-895-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-060. 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 repacking. If the product is neither destroyed nor returned to stock, it may be reprocessed provided the final product meets all its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date, and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-060, filed 10/10/88; Order 133, S 360-46-060, filed 8/4/77.

WAC 246-895-060, WA ADC 246-895-060

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Wash. Admin. Code 246-895-060

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Wash. Admin. Code 246-895-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-070. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-070, filed 10/10/88; Order 133, S 360-46-070, filed 8/4/77.

WAC 246-895-070, WA ADC 246-895-070

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Wash. Admin. Code 246-895-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-080. 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 246-895-090, drug product containers and closures shall not be reused for component or drug product packaging.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-895-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 88-01-025 (Order 208), S 360-46-081, filed 12/9/87.

WAC 246-895-080, WA ADC 246-895-080

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Wash. Admin. Code 246-895-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-090. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 88-01-025 (Order 208), S 360-46-082, filed 12/9/87.

WAC 246-895-090, WA ADC 246-895-090

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Wash. Admin. Code 246-895-090

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Wash. Admin. Code 246-895-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-100. 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 246-895-070.

(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. WSR 92-12-035 (Order 277B), S 246-895-100, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-090, filed 10/10/88; Order 133, S 360-46-090, filed 8/4/77.

WAC 246-895-100, WA ADC 246-895-100

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Wash. Admin. Code 246-895-110

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-110. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-100, filed 10/10/88; Order 133, S 360-46-100, filed 8/4/77.

WAC 246-895-110, WA ADC 246-895-110

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Wash. Admin. Code 246-895-120

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-120. Expiration dating.**

To assure that drug products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use, the label of all such drugs shall have suitable expiration dates which relate to stability tests performed on the product.

(1) Expiration dates appearing on the drug labeling shall be justified by readily available data from stability studies such as described in WAC 246-895-110.

(2) Expiration dates shall be related to appropriate storage conditions stated on the labeling wherever the expiration date appears.

(3) When the drug is marketed in the dry state for use in preparing a liquid product, the labeling shall bear expiration information for the reconstituted product as well as an expiration date for the dry product.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-895-120, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-120, filed 8/30/91, effective 9/30/91; Order 133, S 360-46-110, filed 8/4/77.

WAC 246-895-120, WA ADC 246-895-120

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Wash. Admin. Code 246-895-130

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-130. 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 246-895-060(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 C.F.R. Part 1700).

(7) Provide for compliance with WAC 246-895-080(2).

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-895-130, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-120, filed 10/10/88; Order 133, S 360-46-120, filed 8/4/77.

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Wash. Admin. Code 246-895-140

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-140. 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 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 246-895-060(9).

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-895-140, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-140, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-130, filed 10/10/88; Order 133, S 360-46-130, filed 8/4/77.

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Wash. Admin. Code 246-895-150

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-150. Distribution records.**

(1) Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the drug. Records shall be retained for at least two years after the distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.

(2) To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest approved stock is distributed whenever possible.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-150, filed 8/30/91, effective 9/30/91; Order 133, S 360-46-140, filed 8/4/77.

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Wash. Admin. Code 246-895-160

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-160. Complaint files.**

Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with WAC 246-895-060(8). The record of each investigation shall be maintained for at least two years after distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.

Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), S 246-895-160, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-160, filed 8/30/91, effective 9/30/91; Order 133, S 360-46-150, filed 8/4/77.

WAC 246-895-160, WA ADC 246-895-160

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Wash. Admin. Code 246-895-170

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-895**. Pharmacy-Good Manufacturing Practice for Finished Pharmaceuticals
➡➡ **246-895-170. Variance and procedure.**

Licensees may request that the board issue a variance from specific requirements of WAC 246-895-040 through 246-895-160. 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. WSR 92-12-035 (Order 277B), S 246-895-170, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-895-170, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), S 360-46-160, filed 10/10/88.

WAC 246-895-170, WA ADC 246-895-170

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Wash. Admin. Code Ch. 246-897 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-897**. Pharmacy-Drug Availability
➡➡ **Ch. 246-897 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-897-030. License. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-030, filed 8/30/91, effective 9/30/91; Order 135, S 360-47-020, filed 10/5/77.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-040. License application. (Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 92-12-035 (Order 277B), S 246-897-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-040, filed 8/30/91, effective 9/30/91; Order 135, S 360-47-030, filed 10/5/77.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-050. Good manufacturing practices. (Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 92-12-035 (Order 277B), S 246-897-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-050, filed 8/30/91, effective 9/30/91; Order 135, S 360-47-040, filed 10/5/77.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-120. Availability. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-120, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-010, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-130. License. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-020, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-140. License application. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-140, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-030, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-150. Good manufacturing practices. (Statutory Authority: RCW 18.64.005 and 69.41.075. WSR

92-12-035 (Order 277B), S 246-897-150, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-150, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-040, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-160. Purity. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-160, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-050, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-170. Contents. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-170, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-060, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-180. Labeling. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-180, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-070, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

246-897-190. Other forms of DMSO. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-190, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.075 and 1981 c 50 S 1. WSR 81-22-048 (Order 164), S 360-48-080, filed 11/2/81.) Repealed by WSR 97-20-168, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

WAC Ch. 246-897 Disp Table, WA ADC Ch. 246-897 Disp Table

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Wash. Admin. Code 246-897-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-897**. Pharmacy-Drug Availability
Amygdalin (Laetrile) (Refs & Annos)
**246-897-020. Availability.**

Amygdalin (laetrile) shall be available in intrastate commerce to the citizens of the state of Washington in accordance with all applicable state laws and regulations. Amygdalin (laetrile) imported into the state of Washington shall be so imported in conformity with federal regulations and/or court decisions.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-020, filed 8/30/91, effective 9/30/91; Order 135, S 360-47-010, filed 10/5/77.

WAC 246-897-020, WA ADC 246-897-020

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Wash. Admin. Code 246-897-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-897**. Pharmacy-Drug Availability
Amygdalin (Laetrile) (Refs & Annos)
**246-897-060. Identity.**

Certification of batches of amygdalin (laetrile) shall be made under the direction of the state board of pharmacy, with the costs for required testing, including purity and potency, to be borne by the manufacturer and/or wholesale distributor. The manufacturer and/or wholesale distributor shall be held totally responsible for the quality of the drug product, in accordance with RCW 18.64.270.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-897-060, filed 8/30/91, effective 9/30/91; Order 135, S 360-47-050, filed 10/5/77.

WAC 246-897-060, WA ADC 246-897-060

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Wash. Admin. Code 246-899-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-899**. Pharmaceutical-Drug Product Substitution
➡➡ **246-899-020. Dispensing responsibilities.**

When the pharmacist dispenses, with the practitioner's authorization, a therapeutically equivalent drug product, the following information shall be noted:

(a) On oral prescriptions, the pharmacist shall indicate on the permanent prescription record, if substitution is permitted.

(b) The manufacturer or distributor of the drug product actually dispensed or its national drug code number or short name code or trade name shall be noted on the permanent record, or on the patient medication record if this document is utilized for providing and recording refills. This requirement shall also apply to refill prescriptions when a different distributor or manufacturer's product is used.

(c) The generic or trade name of the drug actually dispensed shall be noted on the prescription label or package label. For combination drug products, the generic names of the drugs combined or the trade name of the manufacturer or distributor shall be noted on the prescription label. For prescriptions compounded with multiple ingredients, the label designation will be left to the discretion of the pharmacist.

(d) For institutionalized and closed system patients, the pharmacist may identify the manufacturer or distributor of the product actually dispensed through pharmacy purchasing records or packaging records, and a published formulary designation may be used on the label.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-899-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.180. WSR 79-12-063 (Order 152), S 360-49-010, filed 11/29/79; Order 143, S 360-49-010, filed 12/9/77.

WAC 246-899-020, WA ADC 246-899-020

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Wash. Admin. Code 246-899-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-899**. Pharmaceutical-Drug Product Substitution
➡➡ **246-899-030. Product selection responsibilities.**

(1) The determination of the drug product to be dispensed on a prescription is a professional responsibility of the pharmacist, and the pharmacist shall not dispense any product that in his/her professional opinion does not meet adequate standards.

(2) Pharmacists may utilize as the basis for their decisions on therapeutically equivalent drug products:

(a) Available drug product information from federal and state agencies, official compendia, and drug manufacturers, or

(b) Other scientific or professional resources, or

(c) The federal food and drug administration ‘approved drug products‘ as a board approved reference for a positive formulary of therapeutically equivalent products within the limitations stipulated in that publication.

(3) Those pharmacies that fill prescriptions based on prior authorization for therapeutically equivalent drug substitution must have available for inspection and review such authorization documentation in the institutional records or in the pharmacy.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-899-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 69.41.180. WSR 79-12-063 (Order 152), S 360-49-020, filed 11/29/79; Order 143, S 360-49-020, filed 12/9/77.

WAC 246-899-030, WA ADC 246-899-030

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Wash. Admin. Code 246-899-040

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Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-899**. Pharmaceutical-Drug Product Substitution

**➡➡ 246-899-040. Manufacturers, wholesalers, distributors, pharmacy location, requirement that drug products offered for sale comply with 21 U.S.C. 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 RCW 69.41.110 through 69.41.180 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 U.S.C. 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 he (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 deem necessary to proceed to the premises of the manufacturer, wholesaler, distributor or pharmacy location and to then inform the owner, or person in charge, of the contraband status of the drugs in question.

(5) The pharmacy board investigative personnel shall offer the owner, or person in charge, of the premises at which the drug products are being kept the opportunity to immediately voluntarily surrender to the board all stocks of the drug products whether kept at the premises of the manufacturer, wholesaler, distributor, or

pharmacy location, or at any separate storage facility under the control of the manufacturer, wholesaler, distributor or retailer, which are contraband under subsection (2) 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 69.41.180. WSR 92-12-035 (Order 277B), S 246-899-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-899-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-18-066 (Order 207), S 360-49-040, filed 9/2/87. Statutory Authority: RCW 69.41.180. WSR 80-14-012 (Order 157, Resolution No. 9/80), S 360-49-040, filed 9/22/80; WSR 80-02-113 (Order 153, Resolution No. 1/80), S 360-49-040, filed 1/28/80.

WAC 246-899-040, WA ADC 246-899-040

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Wash. Admin. Code 246-899-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-899**. Pharmaceutical-Drug Product Substitution
➡➡ **246-899-050. Out-of-state prescriptions.**

(1) When dispensing a prescription issued by a practitioner licensed in a state other than Washington, and recognized in RCW 69.41.030, the pharmacist must honor the instructions of the practitioner regarding substitution. These instructions may be on a prescription blank different than that required for Washington practitioners by RCW 69.41.120 and may include the use of the words ‘dispense as written,‘ words of similar meaning, a checkoff box, or some other indication of intent.

(2) If the practitioner has not clearly provided instructions regarding substitution, a pharmacist may substitute a therapeutically equivalent generic drug only if the pharmacist has determined substitution is permitted by one of the following means:

(a) The pharmacist has personal knowledge and is familiar with the laws and rules regarding substitution in the state of origin; or

(b) The pharmacist obtains oral or written authorization from the practitioner; or

(c) The pharmacist obtains current information regarding the manner in which an out-of-state practitioner provides instruction from:

(i) The Washington state board of pharmacy; or

(ii) The board of pharmacy in the state, other than Washington, in which the practitioner practices; or

(iii) Some other professional source.

(3) Drug product selection shall be based on Washington law and rule as set forth in WAC 246-899-030.

Statutory Authority: RCW 69.41.180. WSR 92-12-035 (Order 277B), S 246-899-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-899-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 91-13-004 (Order 174B), S 360-49-050, filed 6/7/91, effective 7/8/91.

Wash. Admin. Code 246-899-050

WAC 246-899-050, WA ADC 246-899-050

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Wash. Admin. Code Ch. 246-901 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel
➡➡ **Ch. 246-901 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-901-110. Level A experience equivalency. (Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-901-110, filed 8/30/91, effective 9/30/91; Order 141, S 360-52-100, filed 12/9/77.) Repealed by WSR 00-15-081, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.005, chapter 18.64A RCW.

WAC Ch. 246-901 Disp Table, WA ADC Ch. 246-901 Disp Table

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Wash. Admin. Code 246-901-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-010. Definitions.**

(1) ‘Consultation‘ means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-869-220.

(2) ‘Dispense‘ as defined in RCW 18.64.011(16).

(3) ‘Intravenous admixture preparation‘ means the preparation of a drug product that combines two or more ingredients using aseptic technique and is intended for administration into a vein.

(4) ‘Parenteral‘ as defined in WAC 246-871-010.

(5) ‘Pharmacy technician specialized function‘ means certain tasks normally reserved to a pharmacist according to WAC 246-863-095 that may be performed by a pharmacy technician who has met board requirements.

(6) ‘Prescription‘ as defined in RCW 18.64.011(8).

(7) ‘Responsible manager‘ as defined in WAC 246-869-070.

(8) ‘Unit-dose‘ and ‘unit-dose drug distribution system‘ as defined in WAC 246-865-010.

(9) ‘Unit-dose medication cassettes‘ means containers for a patient's medications into which each individually packaged and labeled drug is placed.

(10) ‘Verification‘ means the pharmacist has reviewed a patient drug order initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the drug order after taking into account pertinent drug

and disease information to insure the correctness of the drug order for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a drug order is responsible for all reports generated by the approval of that order. The unit-dose medication fill and check reports are an example.

(11) 'Immediate supervision' means visual and/or physical proximity to a licensed pharmacist to ensure patient safety.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-010, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.050. WSR 94-08-097, S 246-901-010, filed 4/6/94, effective 5/7/94.

WAC 246-901-010, WA ADC 246-901-010

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Wash. Admin. Code 246-901-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-020. Pharmacy ancillary personnel utilization.**

(1) Pharmacy technicians may perform certain nondiscretionary and specialized functions consistent with their training in pharmacy practice while under the immediate supervision of a licensed pharmacist.

(2) The discretionary tasks reserved to a pharmacist are listed in WAC 246-863-095.

(3) Unless authorized as a specialized function according to WAC 246-901-035, the pharmacy technician shall assist a pharmacist in the performance of all tasks except those reserved to a pharmacist in subsection (2) of this section.

(4) Entry of a new medication order into the pharmacy computer system and retrieval of the drug product to fill a prescription are tasks reserved to the pharmacist and pharmacy technician.

(5) The pharmacy assistant may assist a pharmacist in performance of all tasks except those reserved to the pharmacist and pharmacy technician.

(6) Pharmacy ancillary personnel may record or provide medication data when no interpretation is required.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-020, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.050. WSR 94-08-097, S 246-901-020, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64A.020 and 18.64A.030. WSR 92-12-035 (Order 277B), S 246-901-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-901-020, filed 8/30/91, effective 9/30/91; Order 141, S 360-52-010, filed 12/9/77.

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Wash. Admin. Code 246-901-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-030. Technician education and training.**

(1) Applicants must obtain education and training from one of the following:

(a) Formal academic pharmacy technician training program approved by the board.

(b) On-the-job pharmacy technician training program approved by the board.

(2) The minimum educational prerequisite for entering a training program shall be high school graduation or G.E.D.

(3) Applicants must pass a board-approved national standardized pharmacy technician certification examination.

(4) An out-of-state pharmacy technician applicant must meet the same requirements as a pharmacy technician trained in this state. The board must approve training programs approved in other states.

(5) Applicants whose academic training has been obtained in foreign countries shall meet certification requirements as listed below:

(a) Foreign pharmacy school graduates. Board approval of program completed for the degree.

(b) Foreign medical school graduates. Board approval of program completed for the degree.

(c) All foreign graduates for whom English is not the primary language shall provide proof of receiving a score of at least 173 on the Test of English as a Foreign Language (TOEFL) and a score of 50 on the Test of Spoken English (TSE) prior to certification.

(d) Foreign trained applicants must earn 520 hours of supervised experience in an approved pharmacy technician training program.

(6) Prior to performing specialized functions, pharmacy technicians shall complete specialized training and meet

proficiency criteria set forth by the board.

(a) Unit-dose medication checking. The training proficiency criteria requires demonstration of 99% accuracy in medication checking.

(b) Intravenous admixture preparation. The training proficiency criteria requires demonstration of 100% accuracy in intravenous admixture preparation of a representative sample of preparations provided by the facility using aseptic technique.

Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 08-22-005, S 246-901-030, filed 10/24/08, effective 1/1/09. Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-030, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.050. WSR 94-08-097, S 246-901-030, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-901-030, filed 8/30/91, effective 9/30/91; Order 141, S 360-52-020, filed 12/9/77.

WAC 246-901-030, WA ADC 246-901-030

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Wash. Admin. Code 246-901-035

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-035. Pharmacy technician specialized functions.**

A pharmacy technician who meets established criteria for employment, experience, training and demonstrated proficiency may perform specialized functions. The criteria shall be specified in the utilization plan of the pharmacy for pharmacy technicians performing specialized functions required in WAC 246-901-100 (2)(b). Records of pharmacy technician training and of demonstration of proficiency shall be retrievable within seventy-two hours upon request of the board. Specialized functions include the following:

(1) Unit-dose medication checking. Following verification of the drug order by a licensed pharmacist, a pharmacy technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20 or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.

(2) Intravenous admixture and other parenteral preparations. A pharmacy technician may prepare intravenous admixtures and other parenteral drugs. A licensed pharmacist must check each parenteral drug prepared by a pharmacy technician.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-035, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.050. WSR 94-08-097, S 246-901-035, filed 4/6/94, effective 5/7/94.

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Wash. Admin. Code 246-901-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-040. Limitations, trainees.**

An individual enrolled in a training program for pharmacy technicians will perform technician functions only under the immediate supervision of a pharmacist preceptor or a delegated alternate pharmacist.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-040, filed 7/19/00, effective 8/19/00; WSR 91-18-057 (Order 191B), recodified as S 246-901-040, filed 8/30/91, effective 9/30/91; Order 141, S 360-52-030, filed 12/9/77.

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Wash. Admin. Code 246-901-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-050. Technician program approval.**

(1) Program standards. The board will establish standards for judging pharmacy technician training programs.

(2) Approval. In order for a program for training pharmacy technicians to be considered for approval by the board, the director of the program, who shall be a pharmacist, shall submit to the board a description of the course of training offered, including subjects taught, method of teaching, and practical experience provided. The director of the program shall also advise the board concerning the skills and knowledge which are obtained in the course, and the method by which the proficiency of the pharmacy technician in those skills and knowledge is tested or ascertained. The board may require such additional information from program sponsors.

(3) Program change. The director shall request board approval before implementing any significant program change.

(4) Reapproval. The director shall submit each approved program to the board for reapproval every five years.

(5) Registry. The board will maintain a registry of approved programs. Interested persons may request a copy of the registry by contacting the board.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-050, filed 7/19/00, effective 8/19/00; WSR 91-18-057 (Order 191B), recodified as S 246-901-050, filed 8/30/91, effective 9/30/91; Order 141, S 360-52-040, filed 12/9/77.

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Wash. Admin. Code 246-901-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-060. Technician certification.**

To become certified as a pharmacy technician, an individual must apply to the board for certification. The application must include:

(1) A statement signed by the program director verifying the applicant has successfully completed the board-approved pharmacy technician training program.

(2) Proof of passing a board-approved national standardized pharmacy technician certification examination.

It is the responsibility of the pharmacy technician to maintain a current mailing address with the board as required by chapter 246-12 WAC. Pharmacy technicians shall notify the board of any change of mailing address within thirty days of the change.

Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 08-22-005, S 246-901-060, filed 10/24/08, effective 1/1/09. Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-060, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.005. WSR 93-17-097 (Order 387B), S 246-901-060, filed 8/17/93, effective 9/17/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-901-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64A.030. WSR 88-14-043 (Order 217), S 360-52-050, filed 6/30/88; Order 141, S 360-52-050, filed 12/9/77.

WAC 246-901-060, WA ADC 246-901-060

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Wash. Admin. Code 246-901-061

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-061. Pharmacy technician-Continuing education requirements.**

(1) A pharmacy technician certified under this chapter shall complete a minimum of ten continuing education hours or 1.0 continuing education unit (CEU) every renewal cycle following their first certification renewal. One contact hour equals 0.1 CEU.

(2) For each renewal cycle, continuing education must include:

(a) A minimum of one hour of course work in pharmacy law; and

(b) Nine hours in any course work that relates to pharmacy practice.

(3) Approved continuing education credits must be earned through a board approved continuing education program or course. Board approved continuing education includes:

(a) Courses and programs that are accredited or approved by the Accreditation Council of Pharmaceutical Education (ACPE).

(b) Courses and programs as established in WAC 246-861-050, that have been submitted by a pharmacist and approved by the board of pharmacy for purposes of pharmacist education. The course or program must be submitted on a form provided by the board and the course work must be directly related to the scope of practice of a pharmacy technician.

(4) A pharmacy technician must obtain a certificate of participation from a board-approved continuing education program for each course completed. The certificate must be kept for a minimum of four years from the date of course completion. The certificate must contain:

(a) The participant's name;

(b) Course title;

(c) Course date; and

(d) The number of continuing education hours or CEUs.

(5) In lieu of a certificate of participation, approved courses can be verified through the ACPE central repository of continuing pharmacy education monitoring system.

(6) Continuing education hours or CEUs may not be carried over from one reporting cycle to another.

(7) A pharmacy technician may request to be excused from meeting the continuing education requirements if the inability to satisfy the requirements was due to extenuating circumstances. The board determines if the requirement can be waived.

Statutory Authority: RCW 18.64A.020. WSR 12-16-071, S 246-901-061, filed 7/31/12, effective 8/31/12.

WAC 246-901-061, WA ADC 246-901-061

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Wash. Admin. Code 246-901-065

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-065. Expired technician license.**

(1) If the technician license has expired for five years or less, the practitioner must meet the requirements of chapter 246-12 WAC, Part 2.

(2) If the license has expired for over five years, the practitioner must:

(a) Complete certification requirements within one year of application to the board for certification;

(b) Meet the requirements of chapter 246-12 WAC, Part 2.

(3) If the practitioner has been in an active practice in another United States jurisdiction with duties that are substantially equivalent to a pharmacy technician in Washington state, the practitioner must:

(a) Submit verification of active practice from any other United States jurisdiction;

(b) Meet the requirements of chapter 246-12 WAC, Part 2.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-065, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-901-065, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 93-17-097 (Order 387B), S 246-901-065, filed 8/17/93, effective 9/17/93.

WAC 246-901-065, WA ADC 246-901-065

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Wash. Admin. Code 246-901-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-070. Pharmacy assistant utilization.**

Pharmacy assistants may perform, under the general supervision of a licensed pharmacist, all duties except those reserved to the pharmacist and the pharmacy technician.

Pharmacy assistants may:

(1) Prepackage and label drugs for subsequent use in prescription dispensing operations.

(2) Count, pour, and label for individual prescriptions.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-070, filed 7/19/00, effective 8/19/00; WSR 91-18-057 (Order 191B), recodified as S 246-901-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64A.030. WSR 88-14-043 (Order 217), S 360-52-060, filed 6/30/88. Statutory Authority: RCW 18.64.005(11) and 18.64A.030. WSR 80-02-113 (Order 153, Resolution No. 1/80), S 360-52-060, filed 1/28/80. Statutory Authority: RCW 69.50.201. WSR 79-04-048 (Order 147, Resolution No. 3-79), S 360-52-060, filed 3/27/79; Order 141, S 360-52-060, filed 12/9/77.

WAC 246-901-070, WA ADC 246-901-070

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Wash. Admin. Code 246-901-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-080. Pharmacy assistant registration.**

(1) Training. No formal training or educational program will be required by the board, and there will be no age or educational restrictions. The supervising pharmacist shall thoroughly instruct the pharmacy assistant in the limitations of the functions he or she may perform.

(2) Registration of pharmacy assistants. Any person desiring registration as a pharmacy assistant shall apply to the board for registration on forms to be supplied by the board. The fee for registration will be included in the fee for authorization to utilize the services of pharmacy ancillary personnel.

(3) It is the responsibility of the pharmacy assistant to maintain a current mailing address with the board as required by chapter 246-12 WAC. Pharmacy assistants shall notify the board of any change of mailing address within thirty days of the change.

(4) A pharmacy assistant registration must be renewed every two years on the assistant's birthdate. The fee for renewal is included in the fee the pharmacy pays to utilize pharmacy ancillary personnel.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-080, filed 7/19/00, effective 8/19/00; WSR 91-18-057 (Order 191B), recodified as S 246-901-080, filed 8/30/91, effective 9/30/91; Order 141, S 360-52-070, filed 12/9/77.

WAC 246-901-080, WA ADC 246-901-080

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Wash. Admin. Code 246-901-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-090. Identification.**

All pharmacy ancillary personnel working within the pharmacy and having contact with patients or the general public shall wear badges or tags clearly identifying them as pharmacy assistants or technicians.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-090, filed 7/19/00, effective 8/19/00; WSR 91-18-057 (Order 191B), recodified as S 246-901-090, filed 8/30/91, effective 9/30/91; Order 141, S 360-52-080, filed 12/9/77.

WAC 246-901-090, WA ADC 246-901-090

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Wash. Admin. Code 246-901-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)

**➡➡ 246-901-100. Board approval of pharmacies utilizing pharmacy ancillary personnel and specialized functions.**

(1) Application. All licensed pharmacies may apply on a form supplied by the board for permission to utilize the services of pharmacy ancillary personnel.

(2) Utilization plan for pharmacy technicians.

(a) General. The application for approval must describe the manner in which the pharmacy technicians 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.

(b) Specialized function. The utilization plan for pharmacy technicians performing specialized functions. The utilization plan must include:

(i) The criteria for selection of pharmacy technicians to perform specialized functions;

(ii) A description of the methods of training and of initial demonstration of proficiency;

(iii) A copy of the part of the section of the pharmacy's quality assurance plan related to pharmacy technician specialized functions;

(iv) Other information that may be required by the board.

(c) To gain approval for specialized functions, a pharmacy must follow board-approved guidelines regarding pharmacy technician training, implementation and evaluation.

(3) Utilization plan for 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 ancillary personnel.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-100, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.050. WSR 94-08-097, S 246-901-100, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-901-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64A.030. WSR 88-14-043 (Order 217), S 360-52-090, filed 6/30/88; Order 141, S 360-52-090, filed 12/9/77.

WAC 246-901-100, WA ADC 246-901-100

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Wash. Admin. Code 246-901-120

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-120. AIDS prevention and information education requirements.**

Pharmacy technician and assistant applicants must complete four clock hours of AIDS education as required in chapter 246-12 WAC, Part 8.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-120, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-901-120, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-901-120, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-04-015 (Order 222), S 360-52-110, filed 1/23/89.

WAC 246-901-120, WA ADC 246-901-120

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Wash. Admin. Code 246-901-130

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-130. Pharmacist to pharmacy technician ratio.**

(1) A standard ratio of one pharmacist to a maximum of three technicians is established for each licensed pharmacy.

(2) The pharmacist must be actively practicing pharmacy.

(3) In determining which pharmacists may be included in the calculation of the ratio, the board will consider approval of pharmacy technician utilization plans which include all pharmacists within the pharmacy who are engaged in the actual practice of pharmacy. When the pharmacy provides service to inpatients of a hospital or extended care facility, pharmacists who are practicing pharmacy outside of the confines of the licensed pharmacy (for example, performing nursing unit inspections, reviewing charts, consulting with health professional staff) may be included in the ratio, if:

(a) There are sufficient numbers of pharmacists within the pharmacy to properly supervise the work of the pharmacy technicians;

(b) The pharmacy is not open to the public;

(c) The medications are being checked by another health professional before being given to the patient;

(d) Drug orders are not dispensed from the pharmacy without being checked by a licensed pharmacist or pharmacy intern except for board-approved pharmacy technician specialized functions provided a pharmacy technician may check unit-dose medication cassettes.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-130, filed 7/19/00, effective 8/19/00. Statutory Authority: RCW 18.64.050. WSR 94-08-097, S 246-901-130, filed 4/6/94, effective 5/7/94. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-901-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 91-11-040 (Order 169B), S 360-52-120, filed 5/10/91, effective 6/10/91.

WAC 246-901-130, WA ADC 246-901-130

Wash. Admin. Code 246-901-130

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Wash. Admin. Code 246-901-140

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-901**. Pharmacy Ancillary Personnel (Refs & Annos)
➡➡ **246-901-140. Pharmacy services plan.**

A pharmacy may use more pharmacy technicians than prescribed by the standard ratio if the board approves the pharmacy's pharmacy services plan.

(1) The pharmacy services plan shall include, at a minimum, the following information: Pharmacy design and equipment, information systems, workflow, and quality assurance procedures. In addition, the pharmacy services plan shall demonstrate how it facilitates the provision of pharmaceutical care by the pharmacy.

(2) The board may require additional information to ensure appropriate oversight of pharmacy technicians before approving a pharmacy services plan.

(3) The board may give conditional approval for pilot or demonstration projects.

Statutory Authority: RCW 18.64.005, chapter 18.64A RCW. WSR 00-15-081, S 246-901-140, filed 7/19/00, effective 8/19/00.

WAC 246-901-140, WA ADC 246-901-140

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Wash. Admin. Code 246-903-001

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-903**. Nuclear Pharmacies and Pharmacists
**246-903-001. Purpose and scope.**

(1) No person may lawfully provide radiopharmaceutical services unless he or she is a nuclear pharmacist, or is performing radiopharmaceutical services under the supervision of a nuclear pharmacist, and is acting in accordance with the state board of pharmacy and state radiation control agency regulations.

(2) These regulations shall not apply to anyone who is an ‘authorized practitioner‘ as that term is defined in section 2 of these regulations.

(3) The requirements imposed by these nuclear pharmacy regulations shall apply in addition to, and not in place of, any other requirements contained in regulations of the state board of pharmacy, the state radiation control agency, or any other state or federal agency.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-903-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), S 360-54-010, filed 2/1/79.

WAC 246-903-001, WA ADC 246-903-001

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Wash. Admin. Code 246-903-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-903**. Nuclear Pharmacies and Pharmacists
➡➡ **246-903-010. Definitions.**

(1) A ‘nuclear pharmacy‘ is a class A pharmacy providing radiopharmaceutical services.

(2) ‘Nuclear pharmacist‘ means a licensed pharmacist who has submitted evidence to the board of pharmacy that he or she meets the requirements of WAC 246-903-030 of these regulations regarding training, education, and experience, and who has received notification by letter from the board of pharmacy that, based on the evidence submitted, he or she is recognized by the board of pharmacy as qualified to provide radiopharmaceutical services.

(3) ‘Radiopharmaceutical service‘ shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(4) A ‘radiopharmaceutical‘ is any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) ‘Radiopharmaceutical quality assurance‘ means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(6) ‘Internal test assessment‘ means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

(7) ‘Authentication of product history‘ means, but is not limited to, identifying the purchasing source, the

ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

(8) ‘Authorized practitioner‘ means a practitioner duly authorized by law to possess, use, and administer radiopharmaceuticals.

(9) ‘Accepted professional standards‘ are those set forth in the *Nuclear Pharmacy Practice Standards* published by the American Pharmaceutical Association, Board of Pharmaceutical Specialties, adopted on March 18, 1986.

Statutory Authority: RCW 18.64.005. WSR 93-04-016 (Order 329B), S 246-903-010, filed 1/25/93, effective 2/25/93; WSR 92-12-035 (Order 277B), S 246-903-010, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-903-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), S 360-54-020, filed 2/1/79.

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Wash. Admin. Code 246-903-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-903**. Nuclear Pharmacies and Pharmacists
➡➡ **246-903-020. Nuclear pharmacies.**

(1) A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

(2) Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel. A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy and the state radiation control agency before approval of the license.

(3) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted professional standards.

(4) The board recognizes that the preparation of nuclear pharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(5) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the state board of pharmacy, the state radiation control agency and other state and federal agencies.

(6) For nuclear pharmacies handling radiopharmaceuticals exclusively, the state board of pharmacy may waive regulations pertaining to the pharmacy permits for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(7) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(8) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(9) In addition to any labeling requirements of the state board of pharmacy for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: (a) Standard radiation symbol; (b) the words ‘caution-radioactive material‘; (c) the name of the radiopharmaceutical; (d) the amount of radioactive material contained, in millicuries or microcuries; (e) if a liquid, the volume in milliliters; (f) the requested calibration time for the amount of radioactivity contained; (g) expiration data, if applicable; and (h) specific concentration of radioactivity.

(10) The immediate container shall be labeled with: (a) The standard radiation symbol; (b) the words ‘caution-radioactive material‘; (c) the name of the nuclear pharmacy; (d) the prescription number; (e) the name of the radiopharmaceutical; (f) the date; and (g) the amount of radioactive material contained in millicuries or microcuries.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) Nuclear pharmacies may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have the current revisions of state laws and regulations of the state board of pharmacy and state radiation control agency.

(14) The nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided. A detailed library listing shall be submitted to the state board of pharmacy and state radiation control agency before approval of the license.

Statutory Authority: RCW 18.64.005. WSR 93-04-016 (Order 329B), S 246-903-020, filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-903-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), S 360-54-030, filed 2/1/79.

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Wash. Admin. Code 246-903-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-903**. Nuclear Pharmacies and Pharmacists
➡➡ **246-903-030. Nuclear pharmacists.**

In order for a pharmacist to qualify under these regulations as a nuclear pharmacist, he or she must:

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the state radiation control agency; and,

(2) Be a pharmacist licensed to practice in Washington; and,

(3) Submit to the board of pharmacy either:

(a) Certification that he or she has completed a minimum of 6 months on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services, or

(b) Certification that he or she has completed a nuclear pharmacy training program in an accredited college of pharmacy or

(c) That upon application to the board in affidavit form, and upon the furnishing of such other information as the board may require, the board may grant partial or equivalent credit for education and experience gained in programs not sponsored by an accredited college of pharmacy, if, in the opinion of the board, the education and experience gained by participants in these programs would provide the same level of competence as participation in a program at an accredited college of pharmacy; and

(4) Receive a letter of notification from the board of pharmacy that the evidence submitted that the pharmacist meets the requirements of subsections 1, 2, and 3 above has been accepted by the board and that, based thereon, the pharmacist is recognized by the board as a nuclear pharmacist.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-903-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), S 360-54-040, filed 2/1/79.

Wash. Admin. Code 246-903-030

WAC 246-903-030, WA ADC 246-903-030

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Wash. Admin. Code 246-903-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-903**. Nuclear Pharmacies and Pharmacists
**246-903-040. Minimum equipment requirements.**

(1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the state board of pharmacy and radiation control agency before approval of the license.

(2) The state board of pharmacy may, for good cause shown, waive regulations pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-903-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), S 360-54-050, filed 2/1/79.

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Wash. Admin. Code 246-904-010

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-010. Definition.**

Health care entity - an organization that provides health care services in a setting that is not otherwise licensed by the state. Health care entity includes any of the following which are not part of another licensed facility, including: Outpatient surgery centers, cardiac care centers, or kidney dialysis centers. It does not include an individual practitioner's office or a multipractitioner clinic.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-010, filed 12/20/96, effective 1/20/97.

WAC 246-904-010, WA ADC 246-904-010

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Wash. Admin. Code 246-904-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-020. New health care entity licensing.**

No health care entity shall be issued a license until the facility has submitted an application along with the applicable fees set forth in WAC 246-907-020 through 246-907-030 and has passed an inspection by a Washington state board of pharmacy investigator. The investigator shall determine if the purchase, ordering, storing, compounding, delivering, dispensing and administration of controlled substances and/or legend drugs complies with all applicable state and federal statutes and regulations. Physical requirements for the areas of a health care entity where drugs are stored, compounded, delivered or dispensed shall comply with WAC 246-873-070.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-020, filed 12/20/96, effective 1/20/97.

WAC 246-904-020, WA ADC 246-904-020

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Wash. Admin. Code 246-904-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-030. Pharmacist in charge.**

Every health care entity licensed under this chapter shall designate a pharmacist in charge. The pharmacist in charge may be employed in a full-time capacity or as a pharmacist consultant. The pharmacist in charge must be licensed to practice pharmacy in the state of Washington. The pharmacist in charge designated by a health care entity shall have the authority and responsibility to assure that the area(s) within the health care entity where drugs are stored, compounded, delivered or dispensed are operated in compliance with all applicable state and federal statutes and regulations.

It shall be the responsibility of the pharmacist in charge:

(1) To create and implement policy and procedures relating to:

(a) Purchasing, ordering, storing, compounding, delivering, dispensing or administering of controlled substances or legend drugs.

(b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal regulations.

(c) Adequate security of legend drugs and controlled substances.

(d) Controlling access to controlled substances and legend drugs.

(2) To assure that the Washington state board of pharmacy is in possession of all current policies and procedures identified in subsection (1) of this section.

(3) To execute all forms for the purchase and order of legend drugs and controlled substances.

(4) To verify receipt of all legend drugs and controlled substances purchased and ordered by the health care facility.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-030, filed 12/20/96, effective 1/20/97.

Wash. Admin. Code 246-904-030

WAC 246-904-030, WA ADC 246-904-030

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END OF DOCUMENT

Wash. Admin. Code 246-904-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-040. Drug procurement, distribution and control.**

The procurement, distribution and control of drugs shall be in accordance with WAC 246-873-080.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-040, filed 12/20/96, effective 1/20/97.

WAC 246-904-040, WA ADC 246-904-040

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Wash. Admin. Code 246-904-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-050. Dispensing of prescription medications from health care entities.**

Drugs dispensed to patients of a health care entity must be dispensed in a manner consistent with the requirements of RCW 18.64.246 through 18.64.247, chapters 69.41 and 69.50 RCW, and WAC 246-869-220 through 246-869-240.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-050, filed 12/20/96, effective 1/20/97.

WAC 246-904-050, WA ADC 246-904-050

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Wash. Admin. Code 246-904-060

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-060. Labeling.**

Drugs dispensed to patients of a health care entity must comply with the labeling requirements of WAC 246-869-210.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-060, filed 12/20/96, effective 1/20/97.

WAC 246-904-060, WA ADC 246-904-060

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Wash. Admin. Code 246-904-070

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-070. Records.**

To the extent applicable, all prescription records shall be maintained in accordance with WAC 246-869-100 and chapter 246-875 WAC et seq.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-070, filed 12/20/96, effective 1/20/97.

WAC 246-904-070, WA ADC 246-904-070

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Wash. Admin. Code 246-904-080

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-080. Absence of a pharmacist.**

Pharmaceutical services shall be available at all times patients are present in the facility. At times when no pharmacist is in the facility, the entity must comply with the requirements of WAC 246-873-050 and 246-873-060.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-080, filed 12/20/96, effective 1/20/97.

WAC 246-904-080, WA ADC 246-904-080

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Wash. Admin. Code 246-904-090

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-090. Administration.**

Administration of drugs to patients of a health care entity shall be in accordance with WAC 246-873-090.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-090, filed 12/20/96, effective 1/20/97.

WAC 246-904-090, WA ADC 246-904-090

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Wash. Admin. Code 246-904-100

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-904**. Health Care Entities
➡➡ **246-904-100. Closing.**

When a health care entity ceases to do business or to provide pharmaceutical services to patients, the entity shall follow the provisions of WAC 246-869-250.

Statutory Authority: RCW 18.64.450. WSR 97-02-015, S 246-904-100, filed 12/20/96, effective 1/20/97.

WAC 246-904-100, WA ADC 246-904-100

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Wash. Admin. Code 246-905-020

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-905**. Pharmacy-Home Dialysis Program
**246-905-020. 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:

(a) Sterile heparin, 1000u/ml, in vials;

(b) Sterile potassium chloride, 2mEq/ml, for injection;

(c) Commercially available dialysate; and,

(d) Sterile sodium chloride, 0.9%, for injection in containers of not less than 150ml.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-905-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-06-026 (Order 210), S 360-60-010, filed 2/25/88.

WAC 246-905-020, WA ADC 246-905-020

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Wash. Admin. Code 246-905-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-905**. Pharmacy-Home Dialysis Program
➡➡ **246-905-030. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-905-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-06-026 (Order 210), S 360-60-020, filed 2/25/88.

WAC 246-905-030, WA ADC 246-905-030

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Wash. Admin. Code 246-905-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-905**. Pharmacy-Home Dialysis Program
➡➡ **246-905-040. 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.

Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-905-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-06-026 (Order 210), S 360-60-030, filed 2/25/88.

WAC 246-905-040, WA ADC 246-905-040

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Wash. Admin. Code 246-905-050

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-905**. Pharmacy-Home Dialysis Program
➡➡ **246-905-050. 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 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as S 246-905-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-06-026 (Order 210), S 360-60-040, filed 2/25/88.

WAC 246-905-050, WA ADC 246-905-050

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Wash. Admin. Code Ch. 246-907 Disp Table

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-907**. Pharmaceutical Licensing Periods and Fees
➡➡ **Ch. 246-907 DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

246-907-020. Licensing periods. (Statutory Authority: RCW 43.70.040. WSR 97-06-019, S 246-907-020, filed 2/25/97, effective 3/28/97. Statutory Authority: RCW 18.64.005. WSR 94-14-038 S 246-907-020, filed 6/29/94, effective 7/30/94. Statutory Authority: RCW 43.70.250. WSR 92-07-099 (Order 256), S 246-907-020, filed 3/18/92, effective 4/18/92. Statutory Authority: RCW 43.70.040. WSR 91-19-028 (Order 194), recodified as S 246-907-020, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 18.64.005. WSR 88-14-042 (Order 216), S 360-18-010, filed 6/30/88. Statutory Authority: RCW 18.64.005, 18.81.080 and 42.17.290. WSR 83-01-083 (Order 171), S 360-18-010, filed 12/17/82. Statutory Authority: RCW 18.64.005 (4) and (11). WSR 80-05-074 (Order 154, Resolution No. 4/80), S 360-18-010, filed 4/28/80.) Repealed by WSR 98-05-060, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.280.

246-907-995. Conversion to a birthday renewal cycle. (Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-907-995, filed 2/13/98, effective 3/16/98.) Repealed by WSR 05-12-012, filed 5/20/05, effective 7/1/05. Statutory Authority: RCW 43.70.250, (43.70.)280 and 43.70.110.

WAC Ch. 246-907 Disp Table, WA ADC Ch. 246-907 Disp Table

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END OF DOCUMENT

Wash. Admin. Code 246-907-030

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-907**. Pharmaceutical Licensing Periods and Fees (Refs & Annos)
➡➡ **246-907-030. Pharmaceutical licensing periods and fees-Fees and renewal cycle.**

(1) Pharmacist, pharmacy technician, and pharmacy intern licenses must be renewed every year on the practitioner's birthday as provided in chapter 246-12 WAC, Part 2.

(2) Pharmacy location, controlled substance registration (pharmacy), pharmacy technician utilization, and shopkeepers differential hours licenses will expire on June 1 of each year.

(3) All other licenses, including health care entity licenses, registrations, permits, or certifications will expire on October 1 of each year.

(4) The following nonrefundable fees will be charged for pharmacy location:

| **Title of fee** | **Fee** |
|---|---|
| Original pharmacy fee | $370.00 |
| Original pharmacy technician utilization fee | 65.00 |
| Renewal pharmacy fee | 405.00 |
| Renewal pharmacy technician utilization fee | 75.00 |
| Penalty pharmacy fee | 205.00 |

(5) The following nonrefundable fees will be charged for vendor:

| | |
|---|---|
| Original fee | 75.00 |
| Renewal fee | 75.00 |
| Penalty fee | 50.00 |

(6) The following nonrefundable fees will be charged for pharmacist:

| | |
|---|---|
| Original license fee | 145.00 |
| Renewal fee, active and inactive license | 190.00 |
| Renewal fee, retired license | 25.00 |
| Penalty fee | 100.00 |

| | |
|---|---|
| Expired license reissuance (active and inactive) | 90.00 |
| Reciprocity fee | 335.00 |
| Certification of license status to other states | 30.00 |
| Retired license | 25.00 |
| Temporary permit | 65.00 |

(7) The following nonrefundable fees will be charged for shopkeeper:

| | |
|---|---|
| Original fee | 40.00 |
| Renewal fee | 40.00 |
| Penalty fee | 40.00 |
| Shopkeeper - with differential hours: | |
| Original fee | 35.00 |
| Renewal fee | 35.00 |
| Penalty fee | 35.00 |

(8) The following nonrefundable fees will be charged for drug manufacturer:

| | |
|---|---|
| Original fee | 590.00 |
| Renewal fee | 590.00 |
| Penalty fee | 295.00 |

(9) The following nonrefundable fees will be charged for drug wholesaler - Full line:

| | |
|---|---|
| Original fee | 590.00 |
| Renewal fee | 590.00 |
| Penalty fee | 295.00 |

(10) The following nonrefundable fees will be charged for drug wholesaler - OTC only:

| | |
|---|---|
| Original fee | 330.00 |
| Renewal fee | 330.00 |
| Penalty fee | 165.00 |

(11) The following nonrefundable fees will be charged for drug wholesaler - Export:

| | |
|---|---|
| Original fee | 590.00 |
| Renewal fee | 590.00 |
| Penalty | 295.00 |

(12) The following nonrefundable fees will be charged for drug wholesaler - Export nonprofit humanitarian organization.

| | |
|---|---|
| Original fee | 25.00 |
| Renewal fee | 25.00 |
| Penalty | 25.00 |

(13) The following nonrefundable fees will be charged for pharmacy technician:

| | |
|---|---|
| Original fee | 60.00 |
| Renewal fee | 50.00 |
| Penalty fee | 50.00 |
| Expired license reissuance | 50.00 |

(14) The following nonrefundable fees will be charged for pharmacy intern:

| | |
|---|---|
| Original registration fee | 30.00 |
| Renewal registration fee | 30.00 |

(15) The following nonrefundable fees will be charged for Controlled Substances Act (CSA):

| Registrations | |
|---|---|
| Dispensing registration fee (i.e. pharmacies and health care entities) | 80.00 |
| Dispensing renewal fee (i.e. pharmacies and health care entities) | 65.00 |
| Distributors registration fee (i.e. wholesalers) | 115.00 |
| Distributors renewal fee (i.e. wholesalers) | 115.00 |
| Manufacturers registration fee | 115.00 |
| Manufacturers renewal fee | 115.00 |
| Sodium pentobarbital for animal euthanization registration fee | 40.00 |
| Sodium pentobarbital for animal euthanization renewal fee | 40.00 |

| | |
|---|---|
| Other CSA registrations | 40.00 |

(16) The following nonrefundable fees will be charged for legend drug sample - Distributor:

| | |
|---|---|
| Registration fees | |
| Original fee | 365.00 |
| Renewal fee | 265.00 |
| Penalty fee | 135.00 |

(17) The following nonrefundable fees will be charged for poison manufacturer/seller - License fees:

| | |
|---|---|
| Original fee | 40.00 |
| Renewal fee | 40.00 |

(18) The following nonrefundable fees will be charged for facility inspection fee:

| | |
|---|---|
| | 200.00 |

(19) The following nonrefundable fees will be charged for precursor control permit:

| | |
|---|---|
| Original fee | 65.00 |
| Renewal fee | 65.00 |

(20) The following nonrefundable fees will be charged for license reissue:

| | |
|---|---|
| Reissue fee | 30.00 |

(21) The following nonrefundable fees will be charged for health care entity:

| | |
|---|---|
| Original fee | 365.00 |
| Renewal | 265.00 |
| Penalty | 135.00 |

Statutory Authority: RCW 43.70.110, 43.70.250, and 2011 1st sp.s. c 50. WSR 11-20-092, S 246-907-030, filed 10/4/11, effective 12/1/11. Statutory Authority: RCW 43.70.110, 43.70.250, 2008 c 329. WSR 08-15-014, S 246-907-030, filed 7/7/08, effective 7/7/08. Statutory Authority: RCW 43.70.250, (43.70.)280 and 43.70.110. WSR 05-12-012, S

246-907-030, filed 5/20/05, effective 7/1/05. Statutory Authority: RCW 43.70.250, 2001 2nd sp.s. c 7 and RCW 18.64.310, 18.64A.010. WSR 01-23-101, S 246-907-030, filed 11/21/01, effective 1/21/02. Statutory Authority: RCW 43.70.040, 42.70.250, and 18.64.310. WSR 01-12-052, S 246-907-030, filed 6/1/01, effective 7/2/01. Statutory Authority: RCW 43.70.250. WSR 98-10-052, S 246-907-030, filed 4/29/98, effective 5/30/98. Statutory Authority: RCW 43.70.280. WSR 98-05-060, S 246-907-030, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.040. WSR 97-06-019, S 246-907-030, filed 2/25/97, effective 3/28/97. Statutory Authority: RCW 18.64.005. WSR 94-05-036, S 246-907-030, filed 2/8/94, effective 3/11/94; WSR 93-18-015, S 246-907-030, filed 8/24/93, effective 9/24/93; WSR 93-05-045 (Order 334), S 246-907-030, filed 2/17/93, effective 3/20/93. Statutory Authority: RCW 43.70.250. WSR 92-07-099 (Order 256), S 246-907-030, filed 3/18/92, effective 4/18/92. Statutory Authority: RCW 43.70.040. WSR 91-19-028 (Order 194), recodified as S 246-907-030, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 43.70.250. WSR 91-13-002 (Order 173), S 360-18-020, filed 6/6/91, effective 7/7/91. Statutory Authority: RCW 18.64.005. WSR 89-04-015 (Order 222), S 360-18-020, filed 1/23/89; WSR 88-14-042 (Order 216), S 360-18-020, filed 6/30/88; WSR 88-07-011 (Order 209), S 360-18-020, filed 3/3/88; WSR 87-18-066 (Order 207), S 360-18-020, filed 9/2/87. Statutory Authority: RCW 18.64.005(4). WSR 85-22-033 (Order 196), S 360-18-020, filed 10/31/85; WSR 85-06-010 (Order 193), S 360-18-020, filed 2/22/85. Statutory Authority: RCW 18.64.005. WSR 84-17-142 (Order 189), S 360-18-020, filed 8/22/84; WSR 84-04-030 (Order 184), S 360-18-020, filed 1/25/84; WSR 83-22-034 (Order 177), S 360-18-020, filed 10/26/83. Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 83-18-021 (Order 175), S 360-18-020, filed 8/30/83. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), S 360-18-020, filed 5/28/82. Statutory Authority: RCW 18.64.005 (4) and (11). WSR 80-08-035 (Order 155, Resolution No. 6/80), S 360-18-020, filed 6/26/80, effective 9/30/80; WSR 80-05-074 (Order 154, Resolution No. 4/80), S 360-18-020, filed 4/28/80.

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Wash. Admin. Code 246-907-040

Washington Administrative Code Currentness
Title 246. Health, Department of
Chapter **246-907**. Pharmaceutical Licensing Periods and Fees (Refs & Annos)
➡➡ **246-907-040. 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 43.70.040. WSR 91-19-028 (Order 194), recodified as S 246-907-040, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 18.64.005. WSR 88-07-011 (Order 209), S 360-18-025, filed 3/3/88.

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