

## WSR 21-12-074

## PROPOSED RULES

## DEPARTMENT OF HEALTH

[Filed May 28, 2021, 11:03 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 20-14-129.

Title of Rule and Other Identifying Information: Chapter 246-945 WAC, the department of health (department), in consultation with the pharmacy quality assurance commission (commission), is proposing three new sections of rule to move fees for all license types collected by the commission into the newly created chapter 246-945 WAC. These proposed sections are WAC 246-945-990 Pharmaceutical licensing fees and renewal cycle, 246-945-991 Hospital pharmacy associated clinics fees and renewal cycle, and 246-945-992 Fee payment. The department, in consultation with the commission, is also proposing changing licenses to a two-year renewal cycle for pharmacy professionals as requested by interested parties and adding a new fee for the registration of a remote dispensing site created by the passage of SSB 6086.

Hearing Location(s): On July 6, 2021, at 11:00 a.m. In response to the coronavirus disease 2019 (COVID-19) public health emergency, the department of health (DOH) will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington state. A virtual public hearing, without a physical meeting space, will be held instead. Register in advance for this webinar [https://us02web.zoom.us/webinar/register/WN\\_wlWRPwnXREeTRh0qrEphiA](https://us02web.zoom.us/webinar/register/WN_wlWRPwnXREeTRh0qrEphiA). After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: July 14, 2021.

Submit Written Comments to: Cori Tarzwell, 111 Israel Road S.E., Tumwater, WA 98501, email <https://fortress.wa.gov/doh/policyreview>, [HSQAfeerules@doh.wa.gov](mailto:HSQAfeerules@doh.wa.gov), by July 6, 2021.

Assistance for Persons with Disabilities: Contact Cori Tarzwell, phone 360-236-4981, TTY 711, email [hsqafeerules@doh.wa.gov](mailto:hsqafeerules@doh.wa.gov), by June 30, 2021.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The purpose of this proposal is three-fold. First, this proposal will move all existing fees for license types collected by the commission into the newly created chapter 246-945 WAC. The commission recently completed a nearly three-year project to update all the rules under the commission's authority and combine them into one streamlined chapter, chapter 246-945 WAC. As fees fall under the authority of the secretary of health (secretary), the commission could not move the fee rules as part of that original package. The proposed rule moves: Pharmaceutical licensing fees and renewal cycles in WAC 246-907-030 to 246-945-990; fees for hospital pharmacy associated clinics and renewal cycles in WAC 246-907-0302 to 246-945-991; and rules regarding fee payments in WAC 246-907-040 to 246-945-992.

Second, this proposal transitions licenses to a two-year renewal cycle for pharmacists, pharmacy technicians, pharmacy interns, and pharmacy assistants. This was requested by interested parties during the chapter update which established chapter 246-945 WAC. Effectively, licensees would still pay the same total amount over a two-year period, however licensees would pay that cost one time at the beginning of the two-year license cycle, rather than spreading it across two years.

Finally, this proposal establishes a new fee for the opioid use disorder (OUD) remote dispensing site registration in WAC 246-945-030. SSB 6086 established a registration allowing a pharmacy to apply for a registration that would extend the pharmacy's license to cover a remote dispensing site specifically for FDA-approved medications indicated for the treatment of OUD. SSB 6086 also granted the department authority to establish a fee for this registration. Department staff reviewed this registration and have proposed a fee of \$55. This aligns with fees for similar registration or licenses collected by the commission. Once this fee is in place and the department begins collecting data on the actual cost to maintain this registration, department fiscal staff will review and analyze this fee to determine if any changes are needed. Establishing a registration fee for the OUD remote dispensing sites is necessary as part of implementing SSB 6086. Furthermore, the operational costs of a profession must be fully borne by that profession by law.

Originally the CR-101 for this proposal, WSR 20-14-129, stated the department and commission would consider restructuring the drug researcher fee to allow for a noncontrolled substance researcher fee. However, the commission has determined further evaluation is necessary before a restructuring is feasible, so this item has been removed from this package at this time.

Reasons Supporting Proposal: Moving fees collected by the commission into the chapter recently created and updated by the commission will streamline the rules and make it easier for licensees to find necessary information related to their license. It also aligns the structure of the commission's rules chapter with other professions, making it easier for the public to find information. While the commission could not address the fees and transition to a two-year cycle directly in the chapter rewrite, the commission did create continuing education (CE) rules that align with a two-year renewal cycle. Those sections of the new chapter have a delayed effective date to align with this fee proposal. If this proposal is not adopted, the commission will need to perform additional rule making to adjust the CE sections accordingly.

Establishing a registration fee for the OUD remote dispensing sites is necessary as part of implementing SSB 6086. Furthermore, the operational costs of a profession must be fully borne by that profession by law.

Statutory Authority for Adoption: RCW 43.70.110, 43.70.250; and SSB 6086 (chapter 244, Laws of 2020).

Statute Being Implemented: SSB 6086 (chapter 244, Laws of 2020).

Rule is not necessitated by federal law, federal or state court decision.

Agency Comments or Recommendations, if any, as to Statutory Language, Implementation, Enforcement, and Fiscal Matters: Not applicable.

Name of Proponent: DOH, governmental.

Name of Agency Personnel Responsible for Drafting: Cori Tarzwell, 111 Israel Road S.E., Olympia, WA 98504, 360-236-4981; Implementation: Lindsay Trant, 111 Israel Road S.E., Olympia, WA 98504, 360-236-2932; and Enforcement: Lauren Lyles, 111 Israel Road S.E., Olympia, WA 98504, 360-236-4853.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. Under RCW 34.05.328, a cost-benefit analysis is not required for fee rule making.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules set or adjust fees under the authority of RCW 19.02.075 or that set or adjust fees or rates pursuant to legislative standards, including fees set or adjusted under the authority of RCW 19.80.045.

May 27, 2021  
 Jessica Todorovich  
 Chief of Staff  
 for Umair A. Shah, MD, MPH  
 Secretary

**OTS-2987.4**

AMENDATORY SECTION (Amending WSR 18-21-123, filed 10/18/18, effective 1/1/19)

**WAC 246-907-030 Pharmaceutical licensing fees and renewal cycle.**

(1) Pharmacist, pharmacy technician, pharmacy intern, and pharmacy assistant credentials must be renewed every two years on the practitioner's birthday as provided in chapter 246-12 WAC(~~(7-Part-2)~~).

(2) Pharmacy location credentials, controlled substance researcher registration, drug dog handler K9 registration, and other Controlled Substances Act registrations will expire on June 1st of each year.

(3) All other credentials, including health care entity, will expire on October 1st of each year, except the shopkeeper endorsement which expires annually associated with a business license issued by the department of revenue.

(4) The following nonrefundable fees will be charged for pharmacy professionals:

(a) All pharmacy professionals:

Title of fee	Fee
Verification of credential	\$25.00
Duplicate credential	10.00

(b) Pharmacist:

<del>((Original))</del> <u>Initial</u> credential	<del>(\$200.00)</del> \$400.00
Renewal	<del>((265.00))</del> 530.00
Late renewal penalty	<del>((135.00))</del> 265.00
Expired credential reissuance	265.00
Inactive credential renewal	265.00
Retired <u>active</u> credential <u>status</u> application	<del>((25.00))</del> 50.00
Retired <u>active</u> credential <u>status</u> renewal	<del>((25.00))</del> 50.00

Temporary <u>practice</u> permit	100.00
Reciprocity ( <u>license by license transfer</u> )	465.00
(c) Pharmacy technician:	
(( <del>Original</del> )) <u>Initial</u> credential	(( <del>\$70.00</del> )) <u>\$140.00</u>
Renewal	(( <del>70.00</del> )) <u>140.00</u>
Late renewal penalty	(( <del>50.00</del> )) <u>70.00</u>
Expired credential reissuance	70.00

(d) Pharmacy intern:	
(( <del>Original</del> )) <u>Initial</u> credential	(( <del>\$45.00</del> )) <u>\$90.00</u>
Renewal	(( <del>45.00</del> )) <u>90.00</u>
Late renewal penalty	(( <del>45.00</del> )) <u>50.00</u>
Verification of internship hours	25.00
Expired credential reissuance	45.00

(e) Pharmacy assistant:	
(( <del>Original</del> )) <u>Initial</u> credential	(( <del>\$35.00</del> )) <u>\$70.00</u>
Renewal	(( <del>35.00</del> )) <u>70.00</u>
Late renewal penalty	(( <del>35.00</del> )) <u>50.00</u>
Expired credential reissuance	35.00

(5) The following nonrefundable fees will be charged for pharmaceutical firms:

(a) All pharmaceutical firms:	
Verification of credential	\$25.00
Duplicate credential	10.00
Facility inspection	400.00

(b) Pharmacy (includes hospital pharmacies):	
<b>Pharmacy credential</b> (for hospital pharmacy associated clinics, see WAC (( <del>246-907-0302</del> )) <u>246-945-991</u> )	
(( <del>Original</del> )) <u>Initial</u> credential	\$540.00
Renewal	540.00
Late renewal penalty	270.00
<b>Pharmacy technician utilization</b>	
(( <del>Original</del> )) <u>Initial</u> utilization	100.00
Renewal	100.00
<b>Controlled substances authority</b>	
(( <del>Original</del> )) <u>Initial</u> credential	150.00
Renewal	150.00
<b>With differential hours</b>	
(( <del>Original</del> )) <u>Initial</u> credential	55.00
Renewal	55.00

## (c) Nonresident pharmacy:

**Pharmacy credential**

((Original)) <u>Initial</u> credential	\$540.00
Renewal	540.00
Late renewal penalty	270.00

**Controlled substances authority**

((Original)) <u>Initial</u> credential	150.00
Renewal	150.00

## (d) Controlled substance researcher:

((Original)) <u>Initial</u> credential	\$400.00
Renewal	400.00

## (e) Other controlled substances act registrations (i.e., analytical laboratories, school laboratories):

((Original)) <u>Initial</u> credential	\$360.00
Renewal	360.00

## (f) Drug dog handler K9 registration:

((Original)) <u>Initial</u> credential	\$55.00
Renewal	55.00

## (g) Health care entity:

**Health care entity credential**

((Original)) <u>Initial</u> credential	\$540.00
Renewal	540.00
Late renewal penalty	270.00

**Controlled substances authority**

((Original)) <u>Initial</u> credential	150.00
Renewal	150.00

## (h) Drug manufacturer:

**Manufacturer credential**

((Original)) <u>Initial</u> credential	\$825.00
Renewal	825.00
Late renewal penalty	300.00

**Controlled substances authority**

((Original)) <u>Initial</u> credential	150.00
Renewal	150.00

## (i) Drug wholesaler - Full line:

**Wholesaler credential**

((Original)) <u>Initial</u> credential	\$825.00
Renewal	825.00
Late renewal penalty	300.00

**Controlled substances authority**

((Original)) <u>Initial</u> credential	150.00
Renewal	150.00

## (j) Drug wholesaler - Export:

**Wholesaler credential**

	((Original)) <u>Initial</u> credential	\$825.00
	Renewal	825.00
	Late renewal penalty	300.00
(k)	Drug wholesaler - OTC only:	
	((Original)) <u>Initial</u> credential	\$465.00
	Renewal	465.00
	Late renewal penalty	235.00
(l)	Drug wholesaler - Export nonprofit humanitarian organization:	
	<b>Wholesaler credential</b>	
	((Original)) <u>Initial</u> credential	\$25.00
	Renewal	25.00
	Late renewal penalty	25.00
(m)	Legend drug sample distributor:	
	<b>Distributor credential</b>	
	((Original)) <u>Initial</u> credential	\$540.00
	Renewal	540.00
	Late renewal penalty	270.00
	<b>Controlled substances authority</b>	
	((Original)) <u>Initial</u> credential	150.00
	Renewal	150.00
(n)	Poison manufacturer/seller:	
	((Original)) <u>Initial</u> credential	\$55.00
	Renewal	55.00
	Late renewal penalty	50.00
(o)	Precursor chemicals:	
	((Original)) <u>Initial</u> credential	\$55.00
	Renewal	55.00
	Late renewal penalty	50.00
(p)	Itinerant vendor:	
	((Original)) <u>Initial</u> credential	\$55.00
	Renewal	55.00
	Late renewal penalty	50.00
(q)	Sodium pentobarbital for animal euthanization:	
	((Original)) <u>Initial</u> credential	\$55.00
	Renewal	55.00
	Late renewal penalty	50.00
(r)	Shopkeeper:	
	((Original)) <u>Initial</u> credential	\$55.00
	Renewal	55.00
<u>(s) Remote dispensing site for opioid use disorder medications registration:</u>		
	<u>Initial credential</u>	<u>\$55.00</u>
	<u>Renewal</u>	<u>55.00</u>

Late renewal penalty50.00

[Statutory Authority: RCW 43.70.250, 43.70.280 and chapters 18.64 and 18.64A RCW. WSR 18-21-123, § 246-907-030, filed 10/18/18, effective 1/1/19. Statutory Authority: RCW 69.50.302, 43.70.250. WSR 16-18-087, § 246-907-030, filed 9/6/16, effective 10/7/16. Statutory Authority: RCW 43.70.110, 43.70.250, and 2011 1st sp.s. c 50. WSR 11-20-092, § 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, § 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, § 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, § 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, § 246-907-030, filed 6/1/01, effective 7/2/01. Statutory Authority: RCW 43.70.250. WSR 98-10-052, § 246-907-030, filed 4/29/98, effective 5/30/98. Statutory Authority: RCW 43.70.280. WSR 98-05-060, § 246-907-030, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.040. WSR 97-06-019, § 246-907-030, filed 2/25/97, effective 3/28/97. Statutory Authority: RCW 18.64.005. WSR 94-05-036, § 246-907-030, filed 2/8/94, effective 3/11/94; WSR 93-18-015, § 246-907-030, filed 8/24/93, effective 9/24/93; WSR 93-05-045 (Order 334), § 246-907-030, filed 2/17/93, effective 3/20/93. Statutory Authority: RCW 43.70.250. WSR 92-07-099 (Order 256), § 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 § 246-907-030, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 43.70.250. WSR 91-13-002 (Order 173), § 360-18-020, filed 6/6/91, effective 7/7/91. Statutory Authority: RCW 18.64.005. WSR 89-04-015 (Order 222), § 360-18-020, filed 1/23/89; WSR 88-14-042 (Order 216), § 360-18-020, filed 6/30/88; WSR 88-07-011 (Order 209), § 360-18-020, filed 3/3/88; WSR 87-18-066 (Order 207), § 360-18-020, filed 9/2/87. Statutory Authority: RCW 18.64.005(4). WSR 85-22-033 (Order 196), § 360-18-020, filed 10/31/85; WSR 85-06-010 (Order 193), § 360-18-020, filed 2/22/85. Statutory Authority: RCW 18.64.005. WSR 84-17-142 (Order 189), § 360-18-020, filed 8/22/84; WSR 84-04-030 (Order 184), § 360-18-020, filed 1/25/84; WSR 83-22-034 (Order 177), § 360-18-020, filed 10/26/83. Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 83-18-021 (Order 175), § 360-18-020, filed 8/30/83. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), § 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), § 360-18-020, filed 6/26/80, effective 9/30/80; WSR 80-05-074 (Order 154, Resolution No. 4/80), § 360-18-020, filed 4/28/80.]

AMENDATORY SECTION (Amending WSR 18-21-123, filed 10/18/18, effective 1/1/19)

**WAC 246-907-0302 Hospital pharmacy associated clinics fees and renewal cycle.** (1) Parent hospital pharmacy licenses with one or more hospital pharmacy associated clinics (HPAC) expire on June 1st of each year.

(2) A parent hospital pharmacy must submit fees for HPACs in addition to fees set in WAC (~~(246-907-030(4))~~) 246-945-990(5). HPAC fees

are due annually, except as provided under subsection (3) (d) of this section.

(3) A parent hospital pharmacy must submit the following nonrefundable fees based on category and number of HPACs as defined in WAC ((246-873A-020)) 246-945-233(3) added to the parent hospital pharmacy license.

(a) **Category 1 HPAC.** A parent hospital pharmacy must submit the Category 1 HPAC fee according to the number of Category 1 HPACs under the parent hospital pharmacy license.

HPAC tier	Number of Category 1 HPACs under parent hospital pharmacy license	Total annual fee
A	1-10	\$895.00
B	11-50	\$2,240.00
C	51-100	\$3,125.00
D	Over 100	\$4,025.00

(b) **Category 2 HPAC.** A parent hospital pharmacy must submit the Category 2 HPAC fee for each Category 2 HPAC under the parent hospital pharmacy license.

Category 2 HPAC fee	\$755.00
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(c) The department charges a processing fee of fifty-five dollars for an amended license to change the number of HPACs.

(d) If at any time a parent hospital pharmacy submits an addendum increasing the number of HPACs on the parent hospital pharmacy license, which changes the applicable HPAC tier to a higher fee amount, the parent hospital pharmacy shall submit the difference in fees with the addendum.

(e) The department will not refund fees when a tier reduction occurs between renewal periods.

[Statutory Authority: RCW 43.70.250, 43.70.280 and chapters 18.64 and 18.64A RCW. WSR 18-21-123, § 246-907-0302, filed 10/18/18, effective 1/1/19. Statutory Authority: RCW 43.70.250 and 2016 c 118. WSR 16-18-069, § 246-907-0302, filed 9/2/16, effective 9/8/16.]

AMENDATORY SECTION (Amending WSR 91-19-028, filed 9/10/91, effective 10/11/91)

**WAC 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 for pharmacy professionals are charged on ((an annual)) a biennial basis and will not be prorated.



(4) All fees for pharmaceutical firms 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 § 246-907-040, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 18.64.005. WSR 88-07-011 (Order 209), § 360-18-025, filed 3/3/88.]

NEW SECTION

The following sections of the Washington Administrative Code are decodified and recodified as follows:

Old WAC Number	New WAC Number
246-907-030	246-945-990
246-907-0302	246-945-991
246-907-040	246-945-992