



PROPOSED RULE MAKING

CR-102 (December 2017) (Implements RCW 34.05.320)

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STATE OF WASHINGTON
FILED

DATE: July 30, 2018

TIME: 10:49 AM

WSR 18-16-075

Agency: Department of Health

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR ; or

Expedited Rule Making--Proposed notice was filed as WSR ; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

Proposal is exempt under RCW .

Title of rule and other identifying information: (describe subject) WAC 246-907-030 Pharmaceutical licensing periods-Fees and renewal cycle; 246-907-0301 Pharmacy assistant licensing periods and fees-Fees and renewal cycle; and 246-907-0302 Hospital pharmacy associated clinics licensing periods and fees-Fees and renewal cycle. The department is proposing fee increases for many of the pharmacy program fees, including pharmacy professions and pharmaceutical firms. The department is also proposing a few fee decreases to simplify the fee schedule, and changes to duplicate credential, verification of credential, and late renewal penalties to align them with standards for all health professions. The proposal includes repeal of WAC 246-907-0301 and moving fees for pharmacies assistants to WAC 246-907-030.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
9/4/2018	1:00 p.m.	Department of Health Town Center 2 111 Israel Road SE Room 158 Tumwater, WA 98501	

Date of intended adoption: 09/14/2018 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Sherry Thomas, Policy Coordinator
Address: PO Box 47850
Olympia, WA 98504-7850
Email: <https://fortress.wa.gov/doh/policyreview>
Fax: 360-236-2901
Other:
By (date) 09/04/2018

Assistance for persons with disabilities:

Contact Sherry Thomas
Phone: 360-236-4612
Fax:
TTY: (360) 833-6388 or 711
Email: sherry.thomas@doh.wa.gov
Other:
By (date) 08/27/2018

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Current fees are not generating sufficient revenue to keep the program self-supporting as required in the law. The pharmacy program budget is currently in a \$1 million deficit that is anticipated to grow to \$12 million by 2025 if fees are not increased. This deficit is caused by a number of factors that included a large increase in complaint volume and multiple legislative changes that: increased inspection and enforcement activities, created newly regulated facilities, and converted the pharmacy board from a 7-member board to a 15-member commission, all of which have contributed to the need for more investigators and other staff. In addition, the pharmacy program must increase staffing to address the current and projected workload of the

commission, which includes substantial revision and consolidation of 30 current WAC chapters and related procedures to address changes in technology and the health care system. Chapter 1, laws of 2017(219)(16) provided additional spending authority to the commission that has been pending adoption of these proposed fee rules.

The department is proposing increases to initial credential and renewal fees for many of the pharmacy credentials to include pharmacy professions and pharmaceutical firms. The fees for controlled substances researcher are not changing because they were substantially increased in 2016. The department anticipates these changes will best help the program recover from the current large deficit and reach the desired fund balance of 15 percent over an eight-year period. The department is also proposing adjustments to standardize fees for late renewal, verification of credentials, and duplicate credentials, a few small fee decreases to simplify the fee schedule, and formatting changes to help credential holders determine which fees they are required to pay. In addition, the department is proposing including the pharmacy assistant fees in WAC 246-907-030 and repealing WAC 246-907-0301.

Reasons supporting proposal: RCW 43.70.250 requires the cost of each licensing program to be fully borne by the profession's/program's members and licensing fees to be based on licensure costs. Increasing fees to the proposed levels will allow this program's revenues to align with current and projected expenses and avoid the anticipated \$12 million budget deficit over an eight-year period. The other fee adjustments and formatting changes will simplify the fee schedule and create consistency in the fees for functions that require similar staff time to complete across all health professions/programs.

The commission and the department will continue to monitor the budget and identify efficiencies where possible to attempt to lower the expenditure growth rate of 7 percent down to 3.5 percent. The process to identify potential efficiencies is anticipated to begin in August of 2018.

Statutory authority for adoption: RCW 43.70.250

Statute being implemented: RCW 43.70.250, 43.70.280, Chapter 18.64 RCW, and Chapter 18.64A RCW

Is rule necessary because of a:

Federal Law? Yes No
Federal Court Decision? Yes No
State Court Decision? Yes No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Department of Health Private
 Public
 Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Sherry Thomas	111 Israel Road SE, Tumwater, WA 98501	360-236-4612
Implementation:	Sherry Thomas	111 Israel Road SE, Tumwater, WA 98501	360-236-4612
Enforcement:	Sherry Thomas	111 Israel Road SE, Tumwater, WA 98501	360-236-4612

Is a school district fiscal impact statement required under RCW 28A.305.135? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:

Other:

Is a cost-benefit analysis required under RCW 34.05.328?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(vi) exempts rules that set or adjust fees or rates pursuant to legislative standards.

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

RCW 34.05.310 (4)(b)
(Internal government operations)

RCW 34.05.310 (4)(e)
(Dictated by statute)

RCW 34.05.310 (4)(c)
(Incorporation by reference)

RCW 34.05.310 (4)(f)
(Set or adjust fees)

RCW 34.05.310 (4)(d)
(Correct or clarify language)

RCW 34.05.310 (4)(g)
((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's analysis showing how costs were calculated.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

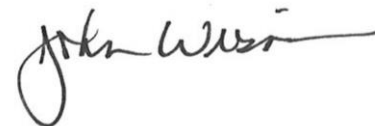
- Name:
- Address:
- Phone:
- Fax:
- TTY:
- Email:
- Other:

Date: 07/27/2108

Name: John Wiesman, DrPH, MPH

Title: Secretary of Health

Signature:



WAC 246-907-030 Pharmaceutical licensing (~~(periods and fees)~~) fees and renewal cycle. (1) Pharmacist, pharmacy technician, ~~((and))~~ pharmacy intern ~~((licenses)), and pharmacy assistant credentials~~ 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))~~ credentials, controlled ((Substances Act)) substance researcher registration, ((pharmacy technician utilization, and shopkeepers differential hours licenses)) drug dog handler K9 registration, and other Controlled Substances Act registrations will expire on June 1st of each year.

(3) All other ~~((licenses))~~ credentials, including health care entity ~~((licenses, registrations, permits, or certifications))~~ 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 ~~((location))~~ professionals:

((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
Researchers registration fee	400.00
Researchers renewal fee	400.00
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
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~~(21) The following nonrefundable fees will be charged for health care entity:~~

Original fee	365.00
Renewal	265.00
Penalty	135.00))

(a) All pharmacy professionals:

<u>Title of fee</u>	<u>Fee</u>
<u>Verification of credential</u>	<u>\$25.00</u>
<u>Duplicate credential</u>	<u>10.00</u>

(b) Pharmacist:

<u>Original credential</u>	\$200.00
<u>Renewal</u>	265.00
<u>Late renewal penalty</u>	135.00
<u>Expired credential reissuance</u>	265.00
<u>Inactive credential renewal</u>	265.00
<u>Retired credential application</u>	25.00
<u>Retired credential renewal</u>	25.00
<u>Temporary permit</u>	100.00
<u>Reciprocity</u>	465.00

(c) Pharmacy technician:

<u>Original credential</u>	\$70.00
<u>Renewal</u>	70.00
<u>Late renewal penalty</u>	50.00
<u>Expired credential reissuance</u>	70.00

(d) Pharmacy intern:

<u>Original credential</u>	\$45.00
<u>Renewal</u>	45.00
<u>Late renewal penalty</u>	45.00
<u>Verification of internship hours</u>	25.00
<u>Expired credential reissuance</u>	45.00

(e) Pharmacy assistant:

<u>Original credential</u>	\$35.00
<u>Renewal</u>	35.00
<u>Late renewal penalty</u>	35.00
<u>Expired credential reissuance</u>	35.00

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

(a) All pharmaceutical firms:

<u>Verification of credential</u>	\$25.00
<u>Duplicate credential</u>	10.00
<u>Facility inspection</u>	400.00

(b) Pharmacy (includes hospital pharmacies):

Pharmacy credential (for hospital pharmacy associated clinics, see WAC 246-907-0302)

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

Pharmacy technician utilization

<u>Original utilization</u>	100.00
<u>Renewal</u>	100.00

Controlled substances authority

<u>Original credential</u>	150.00
<u>Renewal</u>	150.00

With differential hours

<u>Original credential</u>	55.00
<u>Renewal</u>	55.00

(c) Nonresident pharmacy:

Pharmacy credential

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

Controlled substances authority

<u>Original credential</u>	<u>150.00</u>
<u>Renewal</u>	<u>150.00</u>

(d) Controlled substance researcher:

<u>Original credential</u>	<u>\$400.00</u>
<u>Renewal</u>	<u>400.00</u>

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

<u>Original credential</u>	<u>\$360.00</u>
<u>Renewal</u>	<u>360.00</u>

(f) Drug dog handler K9 registration:

<u>Original credential</u>	<u>\$55.00</u>
<u>Renewal</u>	<u>55.00</u>

(g) Health care entity:

Health care entity credential

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

Controlled substances authority

<u>Original credential</u>	<u>150.00</u>
<u>Renewal</u>	<u>150.00</u>

(h) Drug manufacturer:

Manufacturer credential

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

Controlled substances authority

<u>Original credential</u>	<u>150.00</u>
<u>Renewal</u>	<u>150.00</u>

(i) Drug wholesaler - Full line:

Wholesaler credential

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

Controlled substances authority

<u>Original credential</u>	<u>150.00</u>
<u>Renewal</u>	<u>150.00</u>

(j) Drug wholesaler - Export:

Wholesaler credential

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

AMENDATORY SECTION (Amending WSR 16-18-069, filed 9/2/16, effective 9/8/16)

WAC 246-907-0302 Hospital pharmacy associated clinics (~~licensing periods and fees~~) 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). 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(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	\$(640.00) 895.00
B	11-50	\$(1,600.00) 2,240.00
C	51-100	\$(2,240.00) 3,125.00
D	Over 100	\$(2,880.00) 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	\$(540.00) 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.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-907-0301 Pharmacy assistant licensing periods and fees—Fees and renewal cycle.