



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- 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).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

WAC 246-907-030 pharmaceutical licensing periods - fees and renewal cycle. Proposing a separate registration category and separate application and renewal fees for Controlled Substances Act (CSA) researchers. CSA researchers are under the "Other CSA registrations" fees in the current rule.

Hearing location(s): Department of Health
Town Center 2
111 Israel Road, Room 158
Tumwater, WA 98501

Date: 7/6/2016

Time: 1:30 PM

Submit written comments to:

Name: Sherry Thomas
Address: PO Box 47850
Olympia, WA 98504-7850
e-mail: <https://fortress.wa.gov/doh/policyreview>
fax 360-236-4626 by (date) 07/06/2016

Assistance for persons with disabilities: Contact

Sherry Thomas by 06/24/2016

TTY (800) 833-6388 or () 711

Date of intended adoption: 07/13/2016

(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

Current licensing fees do not generate sufficient revenue to cover the costs of administering the CSA researcher registration. This registration is issued to an individual, but applies to a specific lab at which other authorized individuals conduct research using controlled substances named in the application. Much of the costs are incurred through initial and ongoing inspections of the research laboratory. The department is proposing to increase application and renewal fees to cover the average costs of the inspections. In addition, we are proposing to separate the CSA researcher registration fee from the "Other CSA registrations" category because it is much more costly to administer than the other registrations in this category. This "other" category also includes registrations for dog handlers/trainers who use dogs for drug detection, analytical laboratories, and school laboratories, for which the current \$40 fees are adequate.

Reasons supporting proposal:

RCW 43.70.250 requires the cost of each licensing program to be fully borne by the profession's members and licensing fees to be based on the licensing program's costs. Revenue from the current CSA researcher registration fee does not support the cost of the unique inspections required to maintain the credential, meaning other pharmacy program funds supplement this activity. The proposed fees cover the average costs of conducting the inspections for this registration. See Attachment A for additional information.

Statutory authority for adoption:

RCW 69.50.302, RCW 43.70.250

Statute being implemented:

RCW 43.70.250

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 25, 2016

TIME: 1:19 PM

WSR 16-12-044

DATE 05/25/2016

NAME (type or print)

John Wiesman, DrPH, MPH

SIGNATURE

_____, DrPh, MPH

TITLE

Secretary of Health

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, Tumwater, WA 98501	360-236-4612
Implementation....Sherry Thomas	111 Israel Road, Tumwater, WA 98501	360-236-4612
Enforcement.....Doreen Beebe	111 Israel Road, Tumwater, WA 98501	360-236-4834

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(f), a SBEIS is not required for proposed rules that set or adjust fees or rates pursuant to legislative standards.

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

e-mail

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.

Attachment A
CR-102 Controlled Substance Researcher
WAC 246-907-030

Reasons supporting the proposal

Continued from CR-102:

In addition to the costs to issue and renew the controlled substance researcher credential, the inspection process requires additional costs. Most CSA researchers conduct unique research, leading to great variation in the expertise needed and a lengthier inspection process than the standard inspections for facilities such as pharmacies. The CSA researcher registration requires an inspection upon application and regular inspections thereafter. Those inspections consist of:

Initial applications

Require up to six hours of a pharmacy investigator's time, at a rate of \$110 per hour, which consists of technical assistance to help the researcher develop:

- Compliant record systems;
- Security and handling; and
- Storage and disposal of drugs used in the research project.

Ongoing inspections

Require up to four hours of an investigator's time, at \$110 per hour, which consists of:

- Auditing of records regarding procurement, storage, use and disposal of drugs;
- Inspection of security and environmental measures implemented for storage of drugs;
- A review of written policies and procedures implemented by the researcher regarding procurement, compliant record systems, security and handling, storage and disposal of drugs used in the research project. This includes review of which personnel are authorized to access drugs; and
- Technical assistance to give guidance on how to correct any deficiencies found during the inspection.

It can also involve a review of updated written policy and procedures that have been implemented post-inspection as a result of deficiencies noted during the inspection.

Given their current annual growth rate of 12.2 percent, regulation of CSA researchers will place an ever greater burden on the pharmacy program. The number of CSA researchers is growing, as an increasing number of privately owned biotech and pharmaceutical firms are opening in Washington.

AMENDATORY SECTION (Amending WSR 11-20-092, filed 10/4/11, effective 12/1/11)

WAC 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), Controlled Substances Act researcher registration, 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 - <u>With differential hours</u> :	
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
<u>Researchers registration fee</u>	<u>400.00</u>
<u>Researchers renewal fee</u>	<u>400.00</u>
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