



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health- Board of Pharmacy

- 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)

Chapter 246-870 WAC and WACs 246-887-020 and -030, Electronic Transmission of Prescription Information, Uniform Controlled Substances Act, and Dispensing Schedule V Controlled Substances. Implementing Substitute Senate Bill 5416 and House Bill 1609 (chapters 276 and 19, laws of 2013), to (1) redefine electronic communication of prescription information; (2) revise prescription dispensing requirements for Schedule II through V controlled substances; and (3) replace the name Board of Pharmacy with Pharmacy Quality Assurance Commission.

Hearing location(s): Department of Health
Point Plaza East
Room 152/153
310 Israel Road SE
Tumwater, Washington 98501

Date: January 29, 2015

Time: 10:00 a.m.

Submit written comments to:

Name: Peggy Crain
Address: P.O. Box 47852
Olympia, WA 98504-7852
e-mail: <http://www3.doh.wa.gov/policyreview/>
fax (360) 236-4626 by (date) 01/08/2015

Assistance for persons with disabilities: Contact

Peggy Crain by 01/15/2015

TTY (800) 833-6388 or () 711

Date of intended adoption: 01/29/2015

(Note: This is **NOT** the **effective** date)

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

SSB 5416 (chapter 276, Laws of 2013) redefined electronic communication of prescription information. To be consistent with the law, the Pharmacy Quality Assurance Commission (commission) is proposing to amend chapter 246-870 WAC to align rules with statutes. Also as a result of SSB 5416, the commission is proposing to amend WAC 246-887-020 and -030 to clarify prescription dispensing requirements for Schedule II through Schedule V controlled substances.

Additionally, HB 1609 (chapter 19, Laws of 2013) renamed the Board of Pharmacy with Pharmacy Quality Assurance Commission. Therefore, while these rules are open the commission is proposing to change Board of Pharmacy to Pharmacy Quality Assurance Commission in the WAC sections that pertain to electronic communication and scheduled drugs.

Language is being moved and other minor edits are being made that do not change the effect of the rules.

Reasons supporting proposal:

SSB 5416 and HB 1609 (chapters 276 and 19, laws of 2013) amended state statutes that require changes to administrative rules to implement the new laws. These changes are consistent with SSB 5416 and HB 1609.

Statutory authority for adoption:

RCW 18.64.005; SSB 5416, C276, L2013; HB1609, C19, L2013

Statute being implemented:

RCW 18.64.005; SSB 5416, C276, L2013; HB1609, C19, L2013

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: November 26, 2014

TIME: 2:36 PM

WSR 14-24-076

DATE 11/25/14

NAME (type or print)

Chris Humberson, R.Ph.

TITLE

Executive Director

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None.

Name of proponent: (person or organization)	Pharmacy Quality Assurance Commission	<input type="checkbox"/> Private
		<input type="checkbox"/> Public
		<input checked="" type="checkbox"/> Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Chris Humberson	111 Israel Road SE, Tumwater, WA 98504	360-236-4853
Implementation....Chris Humberson	111 Israel Road SE, Tumwater, WA 98504	360-236-4853
Enforcement.....Chris Humberson	111 Israel Road SE, Tumwater, WA 98504	360-236-4853

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)(c and d), a SBEIS is not required for proposed rules that adopt or incorporate by reference without material change Washington state statutes or for rules that only clarify language of a rule without changing its effect.

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: A cost benefit analysis was not prepared. Under RCW 34.05.328 (5)(b)(iii and iv), a cost-benefit

analysis is not required for proposed rules that adopt or incorporate by reference without material change Washington state statutes or for rules that only clarify language of a rule without changing its effect.

AMENDATORY SECTION (Amending WSR 03-24-070, filed 12/1/03, effective 1/1/04)

WAC 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))~~ "Commission" means the Washington state pharmacy quality assurance commission.

(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 communication of prescription information" means the transmission of a prescription or refill authorization for a drug of a practitioner using computer systems. The term does not include a prescription or refill authorization transmitted verbally by telephone nor a facsimile manually signed by the practitioner.

(5) "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))~~ (6) "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.

AMENDATORY SECTION (Amending WSR 03-24-070, filed 12/1/03, effective 1/1/04)

WAC 246-870-030 What is included in the electronic (~~transmission and transfer~~) communication of prescription information? The electronic (~~transfer~~) communication of prescription information includes the communication of prescription (~~information~~) or refill authorization by computer(~~, fax, or other electronic means~~). It in-

cludes the transfer of original and refill prescriptions and the transfer of prescription information from one pharmacy to another pharmacy.

~~((Transmission))~~ (1) Electronic communication of original prescriptions must include:

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

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

~~((3))~~ (c) Date of issuance;

~~((4))~~ (d) Patient's name and address;

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

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

~~((7))~~ (g) Refills or renewals authorized, if any;

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

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

~~((10))~~ (j) Any other requirements consistent with laws and rules pertaining to prescription content and form, RCW 69.41.120 and ~~((21 Code of Federal Regulations))~~ Title 21 C.F.R. Parts 1300, 1304, 1306, and 1311; and

~~((11))~~ (k) Identification of the electronic system readily retrievable for ~~((board of pharmacy))~~ commission inspection.

~~((Transfer))~~ (2) Electronic communication of refill 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.

AMENDATORY SECTION (Amending WSR 03-24-070, filed 12/1/03, effective 1/1/04)

WAC 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 certified or paid by medicare under Title XVIII of the federal Social Security Act, 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)) by fax.~~

AMENDATORY SECTION (Amending WSR 11-12-036, filed 5/25/11, effective 6/25/11)

WAC 246-870-060 What are the ((beard)) commission's requirements for electronic prescription ((transmission)) communication systems?

(1) Systems for the electronic ((transmission)) communication of prescription information must be approved by the ((beard)) commission. ((Beard)) Commission approval of systems will be for a period of three years. The ((beard)) commission 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 ((beard)) commission approval.

(3) Each system shall have policies and procedures on the electronic ((transmission)) communication 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 as required 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 prescriptions electronically 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~~) commission 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.

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

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

AMENDATORY SECTION (Amending WSR 03-24-070, filed 12/1/03, effective 1/1/04)

WAC 246-870-070 What are the (~~board~~) commission's requirements for pharmacies using electronic prescription (~~transmission~~) communication 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.

AMENDATORY SECTION (Amending WSR 03-24-070, filed 12/1/03, effective 1/1/04)

WAC 246-870-080 Can prescription records be stored electronically? Prescription records for legend drugs can be stored electronically if they are in compliance with chapter 246-875 WAC (~~((patient medication record systems))~~) and are readily retrievable by the ~~((board))~~ commission, or its agent for inspection. Controlled substance prescriptions must be maintained in accordance with state and federal regulations.

AMENDATORY SECTION (Amending WSR 03-24-070, filed 12/1/03, effective 1/1/04)

WAC 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))~~ must meet the requirements for security and confidentiality in WAC ~~((246-870-020))~~ 246-870-060.

WAC 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~~) pharmacy quality assurance commission 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~~) commission, 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~~) commission, 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~~) commission;

(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))~~ commission.

(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.

(7) A prescription for a substance included in Schedule II may not be refilled.

(8) A prescription for a substance included in Schedule II may not be filled more than six months after the date the prescription was issued.

(9) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule III, IV, or V, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written, oral, or electronically communicated prescription of a practitioner. Any oral prescription must be promptly reduced to writing. The prescription for a substance included in Schedule III, IV, or V may not be filled or refilled more than six months after the date issued by the practitioner or be refilled more than five times, unless the practitioner issues a new prescription.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-887-030 Dispensing Schedule V controlled substances.