

Chapter 246-XXX WAC
Prescription Monitoring Program
December 2, 2008

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NEW SECTION.

WAC 246-XXX-001 Purpose. These rules implement the prescription monitoring program, established by the Legislature in chapter 70.225 RCW, as a means to promote the public health and welfare and to detect and prevent prescription drug abuse.

NEW SECTION.

WAC 246-XXX-010 Definitions. For the purpose of this chapter and chapter 70.225 RCW, the following words and phrases will have the following meanings unless the context clearly indicates otherwise:

- (1) “CFR” means the Code of Federal Regulations.
- (2) “Controlled substance” means a drug, substance, or immediate precursor included in Schedules I through V as set forth in federal or state laws, or federal or board rules.

(3) “Authentication” means information, electronic device, or certificate provided by the Department or their designee to a dispenser or prescriber that allows the dispenser or prescriber to electronically access prescription monitoring information. The authentication may include, but are not limited to, a username, password, or an identification electronic device or certificate.

(4) “Department” means the Department of Health.

(5) “Designated contractor” means the entity or entities designated by the Department to implement and manage the prescription monitoring program under the direction and oversight of the Department.

(6) “Dispenser” means a practitioner or pharmacy that delivers a Schedule II, III, IV, or V controlled substance to the ultimate user, but does not include:

(a) A practitioner or other authorized person who only administers, as defined in RCW 69.41.010, a controlled substance; or

(b) A licensed wholesale distributor or manufacturer, as defined in chapter 18.64 RCW, of a controlled substance.

(7) “Dispenser identification number” means the provider identification number issued to dispensing pharmacies by the National Council for Prescription Drug Programs or the “Prescriber identification number” as defined in (17) for prescribers who are acting as dispensers.

(8) “Generational suffix” means the element of a patient name used to identify the patient by generation, such as but not limited to “junior,” “senior,” or “III.”

(9) “Non-Resident Pharmacy” means a pharmacy as defined in RCW 18.64.360.

(10) “Patient” means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

(11) “Patient address” means the current geographic location of the patient’s residence. If the patient’s address is in care of another person or entity, the address of that person or entity must be provided in its entirety. When alternate addresses are possible, they must be recorded in the following order of preference:

(a) The geographical location of the residence, as would be identified when a telephone is used to place a 9-1-1 call; or

(b) A post Department address issued by the United States Post Department; or

(c) The common name of the residence and town.

(12) "Patient date of birth" means a person's date of birth as recorded by vital statistics.

(13) "Patient identification number" means a unique number used to identify a particular person by the dispenser.

(14) "Patient name" means the name of the patient for whom a prescription is ordered and must be recorded in the following format: Surname, first or given name, middle initial, generational suffixes if any.

(15) "Personal representative" means a parent of a minor child, or a person who has been authorized pursuant to chapter 11.02 RCW.

(16) "Prescriber" means a licensed health care professional with authority to prescribe controlled substances.

(17) "Prescriber identification number" means the unique number issued to authorized prescribers of controlled substances by the Drug Enforcement Administration, United States Department of Justice, to authorized prescribers of controlled substances.

(18) "Prescription monitoring information" means information submitted to and maintained by the program.

(19) "Program" means the Controlled Substances Prescription Monitoring Program established under chapter 70.225 RCW.

(20) "RCW" means the Revised Code of Washington.

(21) "Surname" means the family name of a patient, including hyphenated family names.

(22) "Valid photographic identification" means:

(a) A driver's license or instruction permit issued by any U.S. state or province of Canada. If the patient's driver's license has expired, he/she must also show a valid temporary driver's license with the expired card.

(b) A state identification card issued by any U.S. state or province of Canada.;

(c) An official passport issued by any nation.

(d) A United States armed forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.

(e) A merchant marine identification card issued by the United States Coast Guard.

(f) A state liquor control identification card. An official age identification card issued by the liquor control authority of any U.S. state or Canadian province.

(g) Enrollment card issued by the governing authority of a federally recognized Indian tribe located in Washington, if the enrollment card incorporates security features comparable to those implemented by the department of licensing for Washington drivers' licenses and are recognized by the liquor control board.

NEW SECTION.

WAC 246-XXX-020 Program Management.

(1) Pursuant to the authority granted to the board of pharmacy in RCW [70.225.020](#), the board may add additional drugs to the list of drugs being monitored by the program by scheduling the drug in accordance with RCW 69.50.201 and WAC 246-887-090.

(a) The Department shall notify stakeholders of the program when a drug is going to be considered for addition to the program by the board of pharmacy.

(b) Individuals who are interested in having a drug added to the program for collection can make requests in accordance with RCW 34.05.330.

NEW SECTION.

WAC 246-XXX-030 Designated Contractor

(1) The Department may contract with another agency of this state or with a private contractor to ensure the effective operation of the program as outlined in RCW 70.225.050.

(2) Access to information by personnel of any designated contractor.

(a) Information available. Personnel of the designated contractor(s) working for the Department may obtain any prescription monitoring information necessary for establishing and maintaining the program's electronic system.

(b) Purge of information. The Department and designated contractor(s) engaged by the Department shall purge all prescription monitoring information more than seven years old.

(3) The Department shall periodically conduct an audit review of the designated contractor(s) for compliance with the terms of the contract regarding confidentiality of all program information.

NEW SECTION.

WAC 246-XXX-040 Requirements for Dispensers.

(1) Dispenser identification number(s). Dispensers must acquire and maintain identification number(s) as defined in this chapter.

(2) Submitting data. Dispensers must provide the information required by RCW 70.225.020 to the Department or the designated contractor as follows:

(a) Electronically;

(b) In the format required by the Department;

(c) In the frequency and schedule determined by the Department.

(d) Non-Resident Pharmacies are required to submit only the transactions where the patient has a Washington State zip code.

(e) Data submission requirements in this section do not apply to pharmacies operated by a county for the purpose of providing medications to offenders in county correctional institutions who are receiving pharmaceutical services from a county correctional institution's pharmacy, except that the county correctional institution's pharmacy must submit data related to each offender's current prescriptions for controlled substances upon the offender's release from a county correctional institution.

(3) The Department may grant a waiver from certain electronic submission requirements to a dispenser for good cause. Waivers cannot be granted from any requirements outlined in chapter 70.225 RCW. The dispenser requesting the waiver is responsible for establishing the basis for the requested waiver.

NEW SECTION

WAC 246-XXX-050 Waivers for Dispensers.

(1) Waivers may be granted for the following circumstances:

(a) The dispenser demonstrates that for any reason, including because the volume of controlled substances dispensed is low, financial hardship will result from being required to make electronic submissions of prescription monitoring information.

(b) Other good cause.

(2) Requests for a waiver shall be by application in writing on a form provided by the Department. The dispenser requesting the waiver may provide the Department with any reasonable supplemental materials in support of their request for a waiver, in addition to the written application. The Department may request additional information from the dispenser requesting the waiver as a condition of granting the waiver.

(3) Requests for a waiver shall be granted or denied by the Department no later than 60 days from the date the written application for waiver is submitted to the Department, or the date the last supplemental written materials are received by the Department, including any additional information requested by the Department, whichever is later.

(4) The decision of the Department to grant or deny a waiver shall constitute final agency action.

NEW SECTION.

WAC 246-XXX-060 Access to Information.

(1) By patients.

(a) Information available. A patient, or a patients' personal representative, may obtain a report listing all prescription monitoring information that pertains to the patient.

(b) Procedure for obtaining information. A patient or a patient's personal representative seeking access to the information described above must submit a written request for information in person at the Department of Health, or at any other place specified by the Department. The

written request shall be in a format established by the Department and shall contain at least, but not limited to, the following elements:

(i) The patient's full name and the full name of the patient's personal representative, if applicable;

(ii) The patient's primary and secondary address(es), and the complete physical address of the patient's personal representative, if applicable;

(iii) The patient's telephone number(s), if any, and the telephone number(s) of the personal representative, if applicable; and

(iv) The time period for which information is being requested.

(c) Identification required. The patient or the patient's personal representative must produce valid photographic identification prior to obtaining access to the information described above. The patient or the patient's personal representative must allow photocopying of the identification.

(d) Proof of patient authorization required. Prior to obtaining access to the information described above, personal representatives must produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or in the case of persons holding power of attorney, the original document establishing the power of attorney. The patient's personal representative must allow photocopying of the documents described above. The Department may verify the patient authorization by any reasonable means prior to providing the information to the personal representative.

(2) By dispensers.

(a) Information available. A dispenser may obtain any prescription monitoring information relating to a patient of the dispenser for the purpose of providing pharmaceutical care. The information shall be provided in a format established by the Department, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication.

(b) Procedure for obtaining information. A dispenser who seeks access to the information described above may submit a request electronically using the authentication issued by the Department or the Department's designee in a manner and format established by the Department.

A dispenser may alternately submit a written request via mail or facsimile transmission in a manner and format established by the Department, to a location specified by the Department. If the authentication issued by the Department is lost, missing, or the security of the authentication is compromised, the dispenser shall cause the Department to be notified by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. The request shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

- (i) The full name and date of birth of the patient;
- (ii) The patient's address(es) and telephone number(s), if known to the dispenser;
- (iii) The time period for which information is being requested;
- (iv) The name of the dispenser;
- (v) The name and address of the dispenser's pharmacy, if applicable;
- (vi) The dispenser identification number; and
- (vii) The signature of the dispenser.

(c) Dispenser verification required. The Department shall verify the authentication and identity of the dispenser before allowing access to any prescription monitoring information.

(3) By prescribers.

(a) Information available. A prescriber or health care practitioner duly authorized by a prescriber may obtain any prescription monitoring information relating to a patient under the prescriber's care. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) Procedure for obtaining information. A prescriber or health care practitioners duly authorized by prescribers who seeks access to the information described above must submit a request electronically using the authentication issued by the Department or the Department's designee in a manner and format established by the Department. A prescriber may alternately submit a written request via mail or facsimile transmission in a manner and format established by the Department, to a location specified by the Department. If the authentication issued by the Department is lost, missing, or the security of the authentication is compromised, the prescriber shall cause the Department to be notified by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. The

request shall be in a format established by the Department or the Monitor and shall contain at least, but not limited to, the following elements for each patient:

- (i) The full name and date of birth of the patient;
- (ii) The patient's address(es) and telephone number(s), if known to the prescriber;
- (iii) The time period for which information is being requested;
- (iv) The name of the prescriber;
- (v) The name and address of the prescriber's medical practice;
- (vi) The prescriber identification number; and
- (vii) The signature of the prescriber.

(c) Prescriber verification required. The Department shall verify the authentication and identity of the prescriber or health care practitioners duly authorized by prescribers before allowing access to any prescription monitoring information.

(4) By director, or board investigator of a health professional licensing, certification, or regulatory agency or entity.

(a) Information available. A director, director's designee, compliance officer, or investigator of a health professional licensing, certification or regulatory agency or entity may obtain any prescription monitoring information as required for an investigation or compliance monitoring. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) Procedure for obtaining information. A director, director's designee, compliance officer, or investigator of a licensing board with jurisdiction over a dispenser or prescriber who seeks access to prescription monitoring information described above must submit a written request via mail, facsimile transmission, or by electronic means to a location specified by the Department. The written request shall contain a statement of facts from which the Department may make a determination of reasonable cause for the request.

(5) By local, state, and federal law enforcement or prosecutorial officials

(a) Information available. A local, state, or federal law enforcement offices and prosecutorial officials may obtain any prescription monitoring information as required for a bone fide specific investigation, with reasonable cause. The information shall be provided in a format

established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) Procedure for obtaining information. A local, state, or federal law enforcement offices and prosecutorial officials who seek access to prescription monitoring information described above must register with the Department. Once registration is approved the requester may submit a written request via mail, facsimile transmission, or by electronic means to a location specified by the Department. The written request shall contain a statement of facts from which the Department may make a determination of reasonable cause for the request.

(6) By the Department of Social and Health Services

(a) Information available. An authorized practitioner of the Department of Social and Health Services may obtain any prescription monitoring information regarding Medicaid program recipients. The information shall be provided in a format established by the Department.

(b) Procedure for obtaining information. An authorized practitioner of the Department of Social and Health Services who seeks access to prescription monitoring information described above must submit a request to the Department.

(7) By the Department of Labor and Industries

(a) Information available. The director or director's designee of the Department of Labor and Industries may obtain any prescription monitoring information regarding worker's compensation claimants. The information shall be provided in a format established by the Department.

(b) Procedure for obtaining information. The director or director's designee of the Department of Labor and Industries who seeks access to prescription monitoring information described above must submit a request to the Department.

(8) By the Department of Corrections

(a) Information available. The director or director's designee of the Department of Corrections may obtain any prescription monitoring information regarding offenders committed to the Department of Corrections. The information shall be provided in a format established by the Department.

(b) Procedure for obtaining information. The director or director's designee of the Department of Corrections who seeks access to prescription monitoring information described above must submit a request to the Department.

(9) By County Coroners and Medical Examiners

(a) Information Available. A local, state, or federal coroner or medical examiner may obtain any prescription monitoring information regarding investigations of deaths. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) Procedure for obtaining information. A local, state, or federal coroner or medical examiner who seeks access to prescription monitoring information described above must register with the Department. Once registration is approved the requester may submit a written request via mail, facsimile transmission, or by electronic means to a location specified by the Department. The written request shall contain a statement of facts from which the Department may make a determination of reasonable cause for the request.

(10) By other state's prescription monitoring programs

(a) Information Available. Other state's prescription monitoring programs may obtain any prescription monitoring information for requests from within their state that do not violate the provisions of this chapter or chapter 70.225 RCW. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) Procedure for obtaining information. Another state prescription monitoring program seeking access to prescription monitoring information must first establish a data sharing agreement (inter-state compact) with the department. The agreement will specify what information may be made available, to what individuals or organizations, how requests are to be made, how quickly requests should be processed, and the format the information should be provided in.

(11) By public or private entities for statistical, research, or educational purposes

(a) Information available. Any public or private entity may obtain any prescription monitoring information after information that could be used to identify any person has been removed. The information shall be provided in a format established by the Department, which

may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.

(b) Procedure for obtaining information. Any public or private entity who seeks access to prescription monitoring information described above must submit a written request via mail, facsimile transmission, or by electronic means to a location specified by the Department. The written request shall contain a statement of facts from which the Department may make a determination of reasonable cause for the request.

(12) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must match the intent as outlined in RCW 70.225.040 and this section.

NEW SECTION.

WAC 246-XXX-070 Confidentiality.

(1) Pursuant to RCW 70.225.040, prescription monitoring information is confidential in accordance with RCW 70.02 and federal health care information privacy requirements.

NEW SECTION.

WAC 246-XXX-080 Penalties and Sanctions.

(1) Civil penalties. A person who intentionally or knowingly uses or discloses prescription monitoring information in violation of chapter 70.225 RCW is subject to civil penalty.

(2) A dispenser or practitioner acting in good faith is immune from any civil, criminal, or administrative liability for requesting, receiving, or using information from the program in accordance with RCW 70.225.240.

(3) Administrative sanctions. A dispenser who knowingly fails to submit prescription monitoring information to the Department as required by these rules and by statute is subject to disciplinary action under chapter 18.130 RCW.

(4) Departmental actions. If the department determines a person has intentionally or knowingly used or disclosed prescription monitoring information in violation of RCW chapter 70.225 RCW the following action(s) may be taken:

- (a) Termination of access to prescription monitoring information.
- (b) Complaint(s) filed with appropriate health licensing and credentialing entities.
- (c) Report violation(s) to law enforcement.

Discussion Document