

Chapter 246-875 WAC

PHARMACY—PATIENT MEDICATION RECORD SYSTEMS

WAC

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DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-875-090	Effective date. [Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-100, filed 1/9/84.] Repealed by 92-12-035 (Order 277B), filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005.
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WAC 246-875-001 Purpose. The purpose of this chapter shall be to insure that a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place, in order to insure the health and welfare of the patients served. This system will consist of certain patient and prescription information, and shall provide the pharmacist within the pharmacy means to retrieve all new prescription and refill prescription information relevant to patients of the pharmacy. It shall be designed to provide adequate safeguards against the improper manipulation or alteration of records, and to provide an audit trail. It may be either a manual system or an automated data processing system for the storage and retrieval of prescription and patient information. If an automated data processing system is utilized, an auxiliary recordkeeping procedure shall be available for documentation of new and refill prescriptions in case the automated system is inoperative for any reason. Establishment of a patient medication record system is intended to insure that the information it contains will be reviewed by the pharmacist in a manner consistent with sound professional practice when each prescription is filled.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-010, filed 1/9/84.]

WAC 246-875-010 Definitions. Terms used in this chapter shall have the meaning set forth in this section unless the context clearly indicates otherwise:

- (1) "Address" means the place of residence of the patient.
- (2) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the

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prescription order, and authorization of subsequent modifications of that order.

(3) "Auxiliary recordkeeping procedure" means a back-up procedure used to record medication record system data in case of scheduled or unscheduled down-time of an automated data processing system.

(4) "Hard copy of the original prescription" shall include the prescription as defined in RCW 18.64.011(8) and/or the medical records or chart.

(5) "Therapeutic duplication" means two or more drugs in the same pharmacological or therapeutic category which when used together may have an additive or synergistic effect.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-020, filed 1/9/84.]

WAC 246-875-020 Minimum required information in an automated patient medication record system. An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system.

(1) All automated patient medication record systems must maintain the following information with regard to ambulatory patients:

- (a) Patient's full name and address.
- (b) A serial number assigned to each new prescription.
- (c) The date of all instances of dispensing a drug.
- (d) The identification of the dispenser who filled the prescription.
- (e) The name, strength, dosage form and quantity of the drug dispensed.
- (f) Any refill instructions by the prescriber.
- (g) The prescriber's name, address, and DEA number where required.
- (h) The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050.

(i) Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

(j) Authorization for other than child-resistant containers pursuant to WAC 246-869-230, if applicable.

(2) All automated patient medication record systems must maintain the following information with regard to institutional patients:

- (a) Patient's full name.
- (b) Unique patient identifier.
- (c) Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization. If there is no

patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

- (d) Patient location.
- (e) Patient status, for example, active, discharge, or on-pass.
- (f) Prescriber's name, address, and DEA number where required.
- (g) Minimum prescription data elements:
 - (i) Drug name, dose, route, form, directions for use, prescriber.
 - (ii) Start date and time when appropriate.
 - (iii) Stop date and time when appropriate.
 - (iv) Amount dispensed when appropriate.
- (h) The system shall indicate any special medication status for an individual prescription, for example, on hold, discontinued, self-administration medication, investigational drugs, patient's own medications, special administration times, restrictions, controlled substances.
- (i) The system shall indicate on the labeling, and in the system, (for the pharmacist, nursing and/or physician alert) any special cautionary alerts or notations deemed necessary by the dispenser for the patient safety.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-020, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-030, filed 1/9/84.]

WAC 246-875-030 Minimum required information in a manual patient medication record system. A manual patient medication record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.

- (1) All manual patient medication record systems must maintain the following information with regard to ambulatory patients:
 - (a) Patient's full name and address.
 - (b) A serial number assigned to each new prescription.
 - (c) The date of all instances of dispensing a drug.
 - (d) The identification of the dispenser who filled the prescription.
 - (e) The name, strength, dosage form and quantity of the drug dispensed.
 - (f) The prescriber's name, address and DEA number where appropriate.
 - (g) Any patient allergies, idiosyncrasies or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.
- (2) All manual patient medication record systems must maintain the following information with regard to institutional patients:
 - (a) Patient's full name.
 - (b) Unique patient identifier.
 - (c) Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.

- (d) Patient location.
- (e) Patient status, for example, active, discharge, or on-pass.
- (f) Prescriber's name, address and DEA number where required.
- (g) Minimum prescription data elements:
 - (i) Drug name, dose, route, form, directions for use, prescriber.
 - (ii) Start date and time when appropriate.
 - (iii) Stop date and time when appropriate.
 - (iv) Amount dispensed when appropriate.
- (h) The system shall indicate any special medication status for an individual prescription, for example, on hold, discontinued, self-administration medication, investigational drugs, patient's own medications, special administration times, restrictions, controlled substances.
- (i) The system shall indicate on the labeling, and in the system, (for the pharmacist, nursing and/or physician alert) any special cautionary alerts or notations deemed necessary by the dispenser for the patient safety.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-040, filed 1/9/84.]

WAC 246-875-040 Minimum procedures for utilization of a patient medication record system. Upon receipt of a prescription or drug order, a dispenser must examine visually or via an automated data processing system, the patient's medication record to determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication, and to determine improper utilization of the drug and to consult with the prescriber if needed. Any order modified in the system must carry in the audit trail the unique identifier of the person who modified the order. Any change in drug name, dose, route, dose form or directions for use which occurs after an initial dose has been given requires that a new order be entered into the system and the old order be discontinued, or that the changes be accurately documented in the record system, without destroying the original record or its audit trail.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-050, filed 1/9/84.]

WAC 246-875-050 Auxiliary recordkeeping procedure. If an automated data processing system is used to maintain a patient's medication record, an auxiliary recordkeeping procedure must be available for use when the automated data system is temporarily inoperative due to scheduled or unscheduled system interruption. The auxiliary recordkeeping procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. Upon restoration of operation of the automated system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. This section does not require that a permanent dual recordkeeping system be maintained.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-060, filed 1/9/84.]

WAC 246-875-060 Retrieval of information from an automated system. All automated patient medication record systems must provide within 72 hours, via CRT or hard copy printout, the information required by WAC 246-875-020 and by 21 CFR § 1306.22(b) as amended July 1, 1980. Any data purged from an automated patient medication record system must be available within 72 hours.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-070, filed 1/9/84.]

WAC 246-875-070 Confidentiality and security of data. (1) Information contained in patient medication record systems shall be considered to be a part of prescription records maintained in accordance with RCW 18.64.245 and shall be maintained for a period of at least two years in the same manner as provided for all prescription records (see WAC 246-869-100).

(2) The information in the patient medication record system which identifies the patient shall be deemed confidential and may be released to persons other than the patient or a pharmacist, or a practitioner authorized to prescribe only on written release of the patient. If in the judgment of the dispenser, the prescription presented for dispensing is determined to cause a potentially harmful drug interaction or other problem due to a drug previously prescribed by another practitioner, the dispenser may communicate this information to the prescribers.

(3) Security codes or systems must be established on automated medication record systems to prevent unauthorized modification of data.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-080, filed 1/9/84.]

WAC 246-875-080 Extension of time for compliance. The rules regarding patient medication record systems contained in chapter 246-875 WAC shall apply to all pharmacists practicing pharmacy in the state of Washington upon the effective date of the chapter unless an extension is granted by the board pursuant to this rule. In order to seek an extension that will allow compliance with this chapter to be delayed, good cause for granting such extension must be shown. The board shall consider requests for extensions and if, in the board's judgment good cause is shown, the board may grant an extension for a period of time, specifying those portions of the rules with respect to which an extension is being granted.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-875-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-875-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 84-03-016 (Order 181), § 360-19-090, filed 1/9/84.]