

Requirements for Prescriptions

BUSINESS AND PROFESSIONS CODE

SECTION 4070-4078

4070. (a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

(b) A pharmacy receiving an electronic transmission prescription shall not be required to reduce that prescription to writing or to hard copy form if, for three years from the last date of furnishing pursuant to that prescription or order, the pharmacy is able, upon request by the board, to immediately produce a hard copy report that includes for each date of dispensing of a dangerous drug or dangerous device pursuant to that prescription or order: (1) all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040, and (2) the name or identifier of the pharmacist who dispensed the dangerous drug or dangerous device. This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's computer system shall not permit the received information or the dangerous drug or dangerous device dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law once the information has been received by the pharmacy and once the dangerous drug or dangerous device has been dispensed. Once a dangerous drug or dangerous device has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall impair the requirement to have an electronically transmitted prescription transmitted only to the pharmacy of the patient's choice or to have a written prescription. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

4071. Notwithstanding any other provision of law, a prescriber may

authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order.

This section shall not apply to orders for Schedule II controlled substances.

4071.1. (a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500). This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(b) Nothing in this section shall reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) No dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

4072. (a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

(b) In enacting this section, the Legislature recognizes and affirms the role of the Department of Health Services in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

4073. (a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and

accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and provided the drug is determined by the board pursuant to subdivision (b) to be a drug or drug type for which this warning shall be given.

(b) The board may by regulation require additional information or labeling.

(c) This section shall not apply to drugs furnished to patients in conjunction with treatment or emergency services provided in health facilities or, except as provided in subdivision (d), to drugs furnished to patients pursuant to subdivision (a) of Section 4056.

(d) A health facility shall establish and implement a written policy to ensure that each patient shall receive information

regarding each medication given at the time of discharge and each medication given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each medication, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other provision of law shall be construed to require that only a pharmacist provide this consultation.

4075. No prescription for a controlled substance transmitted by means of an oral or electronically transmitted order shall be furnished to any person unknown and unable to properly establish his or her identity. The board may by regulation establish procedures to prevent unauthorized persons from receiving prescription drugs furnished to a patient or a representative of the patient.

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

4076.5. (a) The board shall promulgate regulations that require, on

or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

- (1) Medical literacy research that points to increased understandability of labels.
- (2) Improved directions for use.
- (3) Improved font types and sizes.
- (4) Placement of information that is patient-centered.
- (5) The needs of patients with limited English proficiency.
- (6) The needs of senior citizens.
- (7) Technology requirements necessary to implement the standards.

(d) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

4077. (a) Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

(b) Physicians, dentists, podiatrists, and veterinarians may personally furnish any dangerous drug prescribed by them to the patient for whom prescribed, provided that the drug is properly labeled to show all information required in Section 4076 except the prescription number.

(c) Devices that bear the legend "Caution: federal law restricts this device to sale by or on the order of a _____," or words of similar meaning, are exempt from the requirements of Section 4076, and Section 111480 of the Health and Safety Code, when provided to patients in skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(d) The following notification shall be affixed to all quantities of dimethyl sulfoxide (DMSO) prescribed by a physician, or dispensed by a pharmacy pursuant to the order of a physician in California: "Warning: DMSO may be hazardous to your health. Follow the directions of the physician who prescribed the DMSO for you."

(e) The label of any retail package of DMSO shall include appropriate precautionary measures for proper handling and first aid treatment and a warning statement to keep the product out of reach of children.

4078. (a) (1) No person shall place a false or misleading label on

a prescription.

(2) No prescriber shall direct that a prescription be labeled with any information that is false or misleading.

(b) Notwithstanding subdivision (a), a person may label a prescription, or a prescriber may direct that a prescription be labeled, with information about the drug that is false under either of the following circumstances:

(1) If the labeling is a necessary part of a clinical or investigational drug program approved by the federal Food and Drug Administration or a legitimate investigational drug project involving a drug previously approved by the federal Food and Drug Administration.

(2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.

(c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and retain for three years from the date of making, a record stating the manner in which the information on the prescription label varies from the actual drug in the container and documenting the order of the prescriber to so label the container. The prescriber shall make, and retain for at least three years, a record of his or her order to so label the container.