ASSEMBLY BILL No. 2660

Introduced by Assembly Member Leno

February 20, 2004

An act to amend Sections 4040, 4052, 4060, 4061, and 4076 of the Business and Professions Code, and to amend Section 11150 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 2660, as introduced, Leno. Prescriptions: issuance by a pharmacist.

Existing law, the Uniform Controlled Substances Act, authorizes a pharmacist in specified circumstances to write or issue a prescription. The Pharmacy Law, which provides for the licensure and regulation by the California State Board of Pharmacy of pharmacy practices, defines a prescription, in part, as being issued by designated healing arts practitioners, not including a pharmacist. The Pharmacy Law prohibits distribution of a complimentary sample of a dangerous drug or dangerous device, as defined, without the written request of designated healing arts practitioners. A knowing violation of the Pharmacy Law is punishable as a misdemeanor offense.

This bill would revise the definition of ''prescription'' to include a pharmacist, as specified, among those practitioners who are authorized issuers. The bill would also authorize a pharmacist, as specified, to request and sign for the receipt of a complimentary sample of a dangerous drug or a dangerous device.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4040 of the Business and Professions Code is amended to read:

4040. (a) ''Prescription'' means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, ~~or~~ physician assistant*, or pharmacist* who issues a drug order pursuant to Section 2746.51, 2836.1, ~~or~~ 3502.1*, or 4052, respectively.*

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, ~~or~~ 3502.1, *or 4052,* by a certified nurse-midwife, nurse practitioner, or physician assistant*, or pharmacist* licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner

consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) ''Electronic transmission prescription'' includes both image and data prescriptions. ''Electronic image transmission prescription'' means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. ''Electronic data transmission prescription'' means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

SEC. 2. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) (A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California

in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations

before initiating emergency contraception drug therapy pursuant to this paragraph.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) *Initiating or adjusting drugs or devices by a pharmacist under this section is an act of ordering or making a pharmaceutical agent available to the patient in accordance with approved policies, procedures, and protocol. A pharmacist who is authorized to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.*

(d) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

~~(d)~~

(e) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 3. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a

physician, dentist, podiatrist, optometrist, or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, ~~or~~ a physician assistant pursuant to Section 3502.1*, or a pharmacist pursuant to Section 4052*. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, *pharmacist,* physician, podiatrist, dentist, optometrist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.

SEC. 4. Section 4061 of the Business and Professions Code is amended to read:

4061. (a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, *pharmacist,* or veterinarian. However, a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, ~~or~~ a physician assistant who functions pursuant to a protocol described in Section 3502.1, *or a pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052,* may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725 or 3502.1, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, ~~or~~ physician assistant*, or pharmacist* shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified

nurse-midwife, nurse practitioner, ~~or~~ physician assistant, *or pharmacist* if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

(c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, ~~or~~ physician assistant*, or pharmacist*.

SEC. 5. Section 4076 of the Business and Professions Code is amended to read:

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, ~~or~~ the physician assistant who functions pursuant to Section 3502.1*, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to 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 ~~and~~ *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, ~~or~~ the physician assistant who functions pursuant to Section 3502.1*, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to 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, ~~or~~ the physician assistant who functions pursuant to Section 3502.1*, or the pharmacist who*

functions pursuant to a policy, procedure, or protocol pursuant to 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.

SEC. 6. Section 11150 of the Health and Safety Code is amended to read:

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 *or within the scope of Section 4052 of the Business and Professions Code*, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

the meaning of Section 6 of Article XIII B of the California Constitution.

O