California Law Supplement

to the PCT Training Manual

californiapharmacistsassociation

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INTRODUCTION

This supplement to the Michigan PCT Training Manual was prepared for technicians wishing to become certified in the state of California. This publication supplements the material on federal law contained in Chapter 30 of the PCT Training Manual and deals with the California Pharmacy Law.

We would like to thank John Cronin, PharmD, J.D. of the San Diego law firm, Fredrickson, Mazeika & Grant for his assistance in preparing and reviewing this law supplement; Melvin F. Baron, PharmD, MPA for his assistance and review on the most recent edition; the Iowa Pharmacists Association for permitting us to utilize as a guide their PCT Law Supplement; and Pete Houtekier for layout and design.

CALIFORNIA LAW SUPPLEMENT

Competencies in Legal Considerations

On completion of this section, the technician should be able to do the following:

- List the responsibilities which may be delegated to a pharmacy technician under California Law.
- Describe the types of pharmacy activities that cannot be delegated to a pharmacy technician under California Law.
- Describe the filing systems required for prescriptions.
- List required prescription record information.
- Identify when a pharmacist may use drug product selection.
- List the required components of a prescription label for an outpatient prescription.
- Describe the California law regarding the filling of prescriptions for Schedule II Controlled Substances and provisions for dispensing in an emergency.
- Describe the storage requirements for controlled substances.
- State why prescription drugs cannot be returned to a pharmacy.
- Define pharmacy access requirements.
- Describe requirements for the electronic transmission of prescriptions.

Legal Considerations

The practice of pharmacy is influenced by Federal and State laws. The major federal laws affecting pharmacy are addressed in Chapter 30 of the PCT Training Manual. State laws affecting pharmacy are the California Business and Professions Code (B&P Code) and the Health and Safety Code (H&S Code). State regulations affecting pharmacy are in the California Code of Regulations (CCR). (Included in back of this supplement are the California Board of Pharmacy's technician regulations).

State and Federal laws overlap in many areas of pharmacy practice. To determine whether state of federal law controls in a situation addressed by both, the general rule is that the more stringent law is to be followed.

In addition to federal and state laws, pharmacies located in health care institutions are subject to regulations from national and state organizations such as the Joint Commission on Accreditation of Health Care Organizations (JCAHO), the state health department and other local agencies the have a direct influence on health care institutions.

Scope and Limitations of Technician Duties

Except in very limited circumstances, no person shall act as a pharmacy technician without first being registered with the Board of Pharmacy. (B&P Code 4115(e))

Under California law, pharmacy technicians may perform packaging, manipulative, repetitive, or other non-discretionary tasks while assisting, and while under the direct supervision and control of, a pharmacist. (B&P 4115) "Non-discretionary tasks" include:

1. removing the drug or drugs from stock
2. counting, pouring or mixing pharmaceuticals
3. placing the product into a container
4. affixing the label of labels to the container

5. packaging and repackaging
   (CCR 1793.2)

In all practice settings, technicians must work under the direct supervision of a pharmacist. Except for authorized absences during break and (30 minute) meal periods (CCR 1714.1), the supervising pharmacist must be on the premises at all times and be fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records. (CCR 1793.7(b)).

Except for the preparation of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility (ie., in most outpatient settings), a pharmacy technician may perform the duties specified above only under the immediate, personal supervision and control of registered pharmacist and within the pharmacist's view. (B&P 4115(f)(1))

Any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility a pharmacist must indicate verification of the prescription, by initialing the prescription label before the medication is provided to the patient. (CCR 1793.7(a))

All duties of technicians in the preparation of prescriptions must be accomplished under the direct supervision and control of a pharmacist. In general, a pharmacist may delegate only those functions not requiring judgmental decisions. *Only a registered pharmacist, or intern pharmacist acting under the supervision of a registered pharmacist may:*

1. Receive a new prescription order orally from a prescriber or other person authorized by law.
2. Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
3. Identify, evaluate and interpret a prescription.
4. Interpret the clinical data in a patient medication record system or patient chart.
5. Consult with any prescriber, nurse or other health care professional or authorized agent thereof.
6. Supervise the packaging of drugs and check the packaging procedure and product upon completion.
7. Be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
8. Perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform.
9. Perform all functions which require professional judgment.

(CCR 1793.1)

The transfer of prescription information to another pharmacy must be done by a pharmacist, or intern pharmacist.

Technician to Pharmacist Ratios

The ratio of pharmacists to pharmacy technicians performing functions related to prescription filling must be one pharmacy technician on duty for the first pharmacist on duty. Then, each additional pharmacist on duty may have up to two (2) technicians. For the preparation of prescriptions for an inpatient of a hospital or skilled nursing facility, or for a patient of a licensed home health agency, the ratio must not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. (CCR 1793.7(f)) These ratios do not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority, the Department of Corrections or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services or the Department of Veterans Affairs. (B&P Code 4115(g); CCR 1793.7(f))*only one technician trainee may be supervised by a pharmacist at any time.*

Policies and Procedures and Other Requirements

Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures for utilizing technicians. The policies and procedures must be adequate to ensure compliance with the law. The pharmacy shall maintain, for at least three years from the time of making, records adequate to establish compliance with the law regulating the use of pharmacy technicians as well as compliance with the law regulating the use of pharmacy technicians as well as compliance with the pharmacy's policies and procedures. (CCR 1793.7(d))

In addition to the functions described previously, technicians may perform functions that do not involve the filling of prescriptions, such as clerical, housekeeping, bookkeeping, inventory, and other related responsibilities.

A pharmacy technician must wear identification that clearly identifies him or her as a pharmacy technician. (CCR 1793.7(c))

Prescription Record Information

Today, nearly all pharmacies utilize a computer system for processing and recording prescriptions. Although these computerized systems automatically handle all aspects of record keeping, there remain in both state and federal law specific requirements for retention and filing of pharmacy records. The regulations discussed below have been greatly modified by the use of computer systems, and technicians may not readily recognize that the systems discussed below are actually in use. However, these regulations still exist and substantial monetary penalties can result if pharmacies are not in compliance with these requirements.

All prescription records must be kept for three years.

A prescription must contain the following information (B&P Codes 4040):

1. Name or names and address of the patient or patients
2. The name and quantity of the drug or device prescribed
3. Directions for use
4. The date of issue
5. The name, address, and telephone number of the prescriber (rubber stamped, typed or printed by hand, or typeset)
6. The prescriber's license classification; and
7. The prescriber's federal registry (D.E.A.) number if a controlled substance is prescribed.

In addition to the above requirements, the following information shall be maintained for each prescription on file and shall be readily retrievable (CCR 1717 (b):

1. the date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by a pharmacist/preceptor before they are dispensed.
2. the brand name of the drug or device, or if a generic drug or device is dispensed, the manufacturer's or distributor's name which appears on the commercial package label; and
3. if a prescription for a drug or device is refilled, a record of each refill quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
4. a new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

The use of commonly used abbreviations is acceptable pursuant to California law.

Not all of the above information is required to be on the physical piece of paper that documents the prescription order.

Written Prescriptions

A written order for a dangerous drug (except for Schedule II drugs) is valid if it contains at least the name and signature of the prescriber, the name and address of the patient (as consistent with the controlled substances section below), the name and quantity of the drug prescribed, directions for use, and the date of issue as long as the additional information listed above in this records section is readily retrievable in the pharmacy. [B&P 4040(F)(2)(b)]

Orally Transmitted Prescriptions

With the exception of chart orders, an oral prescription shall be reduced to writing by the pharmacist as soon as is practical and initialed and identified as an orally transmitted prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, D.E.A. number of the prescriber, or the address of the patient or patients if the information is readily retrievable in the pharmacy. (Refer to section on Filling Prescriptions for Controlled Substances). (B&P 4070)

If the prescription is then dispensed by another pharmacist, the dispensing pharmacist must also initial the prescription to identify him or herself.

All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. (CCR 1717(c))

Electronically Transmitted Prescriptions

Prescriptions may be transmitted by electronic means from the prescriber to the pharmacy. Under California law, "electronically transmitted prescriptions" include both image transmissions (FAX) and data transmission. (B&P 4040(c)) – *Federal law does not address FAX and data transmission prescriptions.*

An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license classification and D.E.A. number may be omitted if they are on file and readily retrievable in the receiving pharmacy.

A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality. (CCR 1717.4)

For a pharmacy that uses a computer printout or manual system for its records, the pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into the automated data processing system, or the manual record system, and the pharmacist shall create in his/her handwriting or through hand-initialing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years. (CA codes 1717 g)

Prescription Filing

A prescription order (the physical document) must be filed in one of the following three ways"

1. A pharmacy can maintain three separate files: a file for Schedule II drugs dispensed, a file for Schedules III, IV, and V drugs dispensed, and a file for prescription orders for all non-controlled drugs dispensed.
2. A pharmacy can maintain two files: a file for all Schedule II drugs dispensed and another file for all other drugs dispensed including those in Schedules III, IV, and V. If this method is used, the prescription orders in the file for Schedules III, IV, and V must be stamped with the letter "C" in red ink, not less than one inch high, in the lower right corner. This distinctive marking makes the records "readily retrievable" for inspection.*
3. A pharmacy can maintain two files: one file for all controlled drugs in all schedules and a second file for all prescription orders for non-controlled drugs dispensed. If this method is used, the prescription orders for drugs in Schedules III, IV, and V in the controlled drug prescription file must be stamped with the red letter "C" not less than one inch high in the lower right corner, as previously mentioned.*

In California, generally pharmacists keep prescriptions in filing systems 1) or 2) above and not 3), for convenience and to avoid inadvertent D.E.A. violations, which may result in substantial civil money penalties.

* Technicians should note that a 1997 DEA regulation allows an exception to the requirement that prescriptions in Schedule III-V be marked with a red "C" if the pharmacy has a computer system which permits identification by prescription number and the original documents can be retrieved. As nearly every pharmacy meets these requirements, pharmacy technicians may not see the red "C" used to identify these prescriptions. Instead, many pharmacies now use the "C" stamp to indicate that a prescription requires consultation before being dispensed to the patient.

Drug Product Selection

In California, a pharmacist may dispense a generically equivalent product if the following are observed (B&P 4073):

1. The physician has not indicated orally or has not written in his/her own handwriting the words "Do Not Substitute" or words of similar meaning.
2. Provided a prescriber has not checked and initialed a box on the prescription marked "Do Not Substitute."
3. If the drug product selected costs the patient less than the prescribed drug product.
4. When a substitution is made the use of the cost savings drug product must be communicated to the patient.
5. The brand or generic name and name of the manufacturer or distributor which appears on the commercial package label of the dispensed drug product must be indicated on the prescription label unless the prescriber orders otherwise.

Prescription Labeling

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

1. Either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer, unless the prescriber orders otherwise.
2. Directions for the use of the drug.
3. Name of the patient(s).
4. Name of the prescriber and, if applicable, the name of the nurse practitioner or physician assistant who ordered the drug while acting within their scope of practice.
5. Date of filling.
6. Name and address of the pharmacy, and prescription number or other means of identifying the prescription.
7. Strength of the drug or drugs dispensed.
8. Quantity of the drug or drugs dispensed.
9. 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.

If a pharmacist dispenses a prescribed drug using a unit dose medication system for a patient in a skilled nursing, intermediate care, or other health care facility, these requirements will be satisfied if the unit dose medication system contains the above information or the information is otherwise readily available at the time of drug administration.

Controlled Substance Requirements

The state and federal governments have classified certain drugs by abuse potential and have instituted laws and regulations based on this classification. These laws and regulations cover buying, inventory control, prescribing, dispensing, storing, destroying and using these drugs. Federal law generally parallels federal law in this area. Discussed below are the areas where California law differs from federal law.

Schedules for Controlled Substances

California uses a Schedule system that closely parallels the federal schedules. However, there are always a small number of drugs that are classified differently under the federal and California schedules. For the purpose of this document, it is not necessary to identify these drugs, but it is important for the PCT to recognize that differences do exist.

Filling Prescriptions for Controlled Substances

Tamper-resistant prescription forms for controlled substances shall be obtained from security printers approved by the Board of Pharmacy (H&S 11161.5). The prescription forms for controlled substances must be printed with the features specified under California law (H&S 11162.1).

When filling a prescription for a controlled substance, the following requirements must be met under California law (H&S 11164).

Schedule II, III, IV and V

1. Each prescription for a controlled substance classified in Schedule II, III, IV, or V must be made on a controlled substance prescription form as specified in H&S 11162.1 and must meet the following requirements:
   (1) The Prescription must be signed and dated by the prescriber in ink and must contain the prescriber's address and telephone number; the name of the person for whom the controlled substance is prescribed; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
   (2) The prescription must also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist must write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
2. The use of commonly used abbreviations will not invalidate an otherwise valid prescription.

Schedule III, IV and V

1. Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which must be produced in hard copy form and signed and dated by the pharmacist filling the prescription of by any other person expressly authorized by the provisions of the Business and Professions Code.
2. The date of issue of the prescription and all the information required for a written prescription must be included in the written record of the prescription; the pharmacist need not include the address, telephone number license classification, or federal registry number of the prescriber or the address of the patient on the hard copy if that information is readily retrievable in the pharmacy.
3. An agent authorized by the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V if in these cases a written record of the prescription specifies the name of the agent of the prescriber transmitting the prescription.

Schedule V

1. Prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

Controlled Substance Utilization Review and Evaluation System (CURES)

The Department of Justice will maintain CURES to assist law enforcement and regulatory agencies in controlling the diversion and abuse of Schedule II and III controlled substances. For each prescription for a Schedule II, III & IV controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice (H&S 11165):

a. Full name, address, gender and date of birth of the patient.
b. The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
c. Pharmacy prescription number, license number and federal controlled substance registration number.
d. NDC (National Drug Code) number of the controlled substance dispensed.
e. Quantity of the controlled substance dispensed.
f. ICD-9 (Diagnosis code), if available.
g. Date of issue of the prescription.
h. Date of dispensing of the prescription.

Patients with a Terminal Illness

A prescription for a Schedule II controlled substance for use by a patient who has a terminal illness must meet the following requirements (H&S 11159.2):

1. Contain the information specified in Section 11164.
2. Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

Emergency Oral Prescriptions for Controlled Substances

1. Emergency Oral Prescriptions of Schedule II Controlled Substances (H&S 11167):
   a. California law states that in the event of an emergency any Schedule II controlled substance may be dispensed upon an orally (or electronically) transmitted prescription if failure to issue such a prescription might result in loss of life or intense suffering. Prior to filling an oral (electronic) prescription, the pharmacist shall reduce it to writing with all the pertinent information required by law
   b. Federal law defines a bona fide emergency as a situation in which:
      1) Immediate administration of the controlled substance is necessary for the proper treatment of the patient;
      2) There is no appropriate alternative treatment available, and
      3) It is not reasonably possible for the prescriber to provide a written prescription to the presented to the pharmacist prior to dispensing.
   c. When an emergency oral or written prescription is issued, the prescriber must provide a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order. A postmark by the seventh day following transmission of the initial order shall constitute compliance.
2. It is a federal requirement that the quantity prescribed and dispensed pursuant to the emergency oral prescriptions limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written *triplicate* prescription.
3. I the prescribing physician is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a physician, by verifying the physician's telephone number with that listed in the directory and by making other good faith efforts to insure proper identity.

4. Any controlled substance classified in Schedule III, IV or V may be dispensed upon an oral prescription, which shall be reduced to writing by the pharmacist receiving the prescription. Under California law, the prescriber's address, telephone number, category of professional licensure, or D.E.A. number need not appear on the prescription if that information is readily retrievable in the pharmacy. However, D.E.A. regulations require this information to be maintained on the file (hard) copy of the prescription. Schedule V controlled substance prescriptions may be for more than one person if they reside in the same family and have the same medical need.

Partially filling Schedule II Controlled Substance Prescriptions

A "partially filled" prescription is prescription from which only a portion of the amount for which the prescription is written is filled at any one time.

Schedule Ii controlled substances prescriptions may be partially filled if the prescription to be filled is for:

1. an inpatient of a skilled nursing facility,
2. a terminally ill patient, or
3. in a case when the pharmacist is unable to supply the quantity prescribed.

(CA codes 1745 & CFR 1306.13 (a)):

In the case of inpatients of skilled nursing facilities and terminally ill patients, the remaining quantities may be dispensed, in whole or in part, for a period not to exceed 30 days from the day the prescription is issued. The pharmacist shall record the date and amount of each partial filling in a readily retrievable form and on the original prescription and shall also record the initials of the pharmacist dispensing the prescription. In no case may a the total amount dispensed exceed the amount originally prescribed.

In the case of partially filling a schedule II due to an ability to supply the complete amount, the remaining portion of the prescription must be filled within 72 hours of the first partial fill or a new prescription is required. If the remaining quantity cannot be filled within 72 hours, the balance of the prescription may not be dispensed and the pharmacist shall notify the prescriber of the fact.

Refilling Prescriptions for Controlled Substances

Prescriptions for Schedule II controlled substances may not be refilled. Schedule III or IV controlled substance prescriptions shall not be filled or refilled more than six months after the date on which the prescription was issued.

No Schedule III or IV controlled substance prescriptions shall be filled more than five times or in an amount, for all refills of that prescription taken together, that exceeds a 120 day supply, without a new authorization from the prescriber (H&S 11200). Schedule a V controlled substances may be refilled as authorized by the prescriber. A record of each refill must be entered on the back of the prescription or otherwise be readily retrievable.

Records for Controlled Substances in County or Licensed Hospitals

1. An order for controlled substances for use by a patient in a county or licensed hospital is exempt from the requirements for a prescription for a controlled substance. However, chart (medication) orders must be (H&S 11159):
   a. in writing on the patient's record,
   b. signed by the prescriber,
   c. dated, and
   d. must state the name and quantity of the controlled substance ordered and the quantity actually administered.
   e. In addition, the records of such orders shall be maintained as a hospital record for a minimum of seven years.

Storage of Controlled Substances

Controlled substances in a community or institutional pharmacy may be stored in a substantially constructed locked cabinet, or they may be distributed throughout the general stock I such a fashion that they are not easily recognizable. In addition, institutional hospitals pharmacies may store controlled substances outside the pharmacy, in a nursing station, for instance. However, when outside the pharmacy these substances must be kept in a substantially-constructed, double-locked cabinet with appropriate disposition record; they may not be distributed throughout the general floor (ward) stock.

Return or Exchange of Drugs and Devices

For the protection of the public health and safety, prescriptions drugs and/ or device which have been removed from the original container or packaging may not be returned to the pharmacy or exchanged for resale. This is because once the drug is out of its control, the pharmacy cannot vouch for the handling or storage conditons to which the drug may have been exposed. A pharmacy may have a business policy of allowing the return of prescription drugs or devices, but the items cannot be resold and should be disposed of properly.

However, drugs dispensed in single unit, unit dose, or unit of issue packaging in a hospital setting may be returned to the pharmacy stock if proper identity had been maintained such as lot number, etc.

Maximum Allowable Cost Program (MAC)

In the mid-1970s, the federal government, Department of Health, Education, and Welfare or Dept. of Health and Human Services (DHHS), became concerned about the rising cost of the Medicaid drug program. The government believed that the amount reimbursed to pharmacists by the state Medicaid Agencies was to high. To address this, the government established the Maximum Allowable Cost Program (MAC). MAC was defined as the maximum amount the pharmacies can receive as reimbursement for the cost of selected drugs. MAC was based on commonly provided dosing or manufacturing units (#30, #60, #100, etc.) at list price. After 1987 amendments to MAC established FUL, the Federal Upper Limit, which states that the reimbursement price for FUL drugs must be equal to 150 percent of the published price for the least costly therapeutic equivalent. In California, the Medi-Cal[1] provider manual refers to the federal upper limit, Maximum allowable Ingredients Cost (MAIC).

Generic drugs play an important role in cost containment because they stimulate competition and in many instances are less expensive than the original brand name product. This is especially important to the pharmacist in product selection where MAC or other fee regulation requirements exist.

An acronym that has impacted pharmacy drug cost is DRG (Diagnostic Related Group). Under the DRG system, hospitals and nursing homes receive a fixed payment for each patient and admission based on diagnosis, regardless of length of stay. Because the institution receives a fixed amount, all costs incurred to make a patient well, including drug costs, are critically important.

Mailing of Prescription Drugs

U.S. Postal regulations permit mailing of all medications. Any preparation which could escape from its container and cause damage, discomfort, destruction or soiling must be packed either in leak-proof receptacles or sealed in durable, leaked outer containers. United Parcel Service (UPS) may also be used to ship prescription medications.

Prescribing by Medical Interns and Residents

Prescriptions written by unlicensed persons lawfully practicing medicine (residents and interns) must be filled in the hospital pharmacy in the institution where such person is practicing.

Physician Assistants and Nurse Practitioners

Technically, neither physician assistants or nurse practitioner “prescribe.” However, both groups have limited authority to “furnish” drugs and “transmit” orders. This means that pharmacies may dispense drugs pursuant to drugs orders issued by physician assistants and nurse practitioners functioning within their scope of practice.

Physician Assistant[1]

Physician assistants function under the supervision of a physician. A physician may delegate to a physician assistant under their supervision the authority to issue a drug order if done in compliance with a written, practice specific formulary and protocol. When issuing a drug order, the physician assistant is acting on behalf of and as and agent for a supervising physician. A drug order issued by a physician assistant is treated in the same manner as prescription or order of the supervising physician. Any drug order issued by the physician assistant shall either be based on the protocol or shall be approved by the supervising physician.

Any written drug order issued by a physician assistant, except a written drug order in a patient’s medical record in a health facility or medical practice, must include the printed name, address and phone number of the supervising physician, the printed or stamped name and license number of the physician assistant, and the signature of the physician assistant.

A physician assistant may issue a drug order for a controlled substance only if he or she has obtained the advanced approval by a supervising physician for the particular patient. Any drug order issued by a physician assistant for a controlled substance, except a written drug order in a patient’s medical record in a health facility or medical practice, must also include the name of the supervising physician and the name of the physician assistant.

When filling a drug order issued by a physician assistant, the prescription label must include the name of the supervising physician and the name of the physician assistant.

Nurse Practitioner[2] and Nurse Midwife[3] Furnishing (Ordering) Drugs

Like physician assistants, nurse practitioners and nurse midwives function under the supervision of a physician, Drug orders may be issued by nurse practitioners and nurse midwives if done in compliance with a standardized procedure or protocol developed with the supervising physician. Pharmacies may dispense drugs or devices upon the order of nurse practitioner or nurse midwife provided:

1) the nurse practitioner or nurse midwife is certified by the Board of Registered Nursing;
2) they possess current furnishing numbers from that Board and their number is included on the transmittal (prescription) order along with the name of the supervising physician;
3) that the orders are only for drugs and devices that are specified in standardized procedures
4) that the orders are for essentially healthy person who seek:
    a) routine health care
    b) prenatal care
    c) family planning

Any written drug order issued by a nurse practitioner or nurse midwife must include the name, address and telephone number of the supervising physician, the name and license number of the nurse practitioner or nurse midwife and the signature of the nurse practitioner or nurse midwife. An drug order for a controlled substance issued by a nurse practitioner must include the DEA registration number of the nurse practitioner.

When filling a drug order issued by a nurse practitioner or nurse midwife, the prescription label must include the name of the supervising physician and the name of the nurse practitioner or midwife.

The prescriptions received from physician assistants, nurse practitioners and nurse midwives should be reviewed carefully to assure that all requirements of the law are met. Any problems should be resolved before filling the prescriptions.

Pharmacy Security

Access to the pharmacy area. Access to the licensed pharmacy area is restricted. Only a registered pharmacist, an intern pharmacist, an authorized officer of the law or a prescriber is permitted in the area where controlled substances or dangerous drugs are stored, compounded, or repackaged. However, other individuals may enter the pharmacy for the purposes of receiving consultation from the pharmacist or for performing clerical, inventory control, housekeeping, delivery, maintenance or similar functions relating to the pharmacy if the pharmacist is present and is responsible for them. (B&P Code Section 4116)

One exception exists to the above rule. A pharmacist may leave the pharmacy area without closing the pharmacy in order to take a break or meal period as authorized under the labor law in California. In order to remain open during these periods, the pharmacy must have in place a written policy and procedure for maintaining the security of the pharmacy while the pharmacist is temporarily absent. During the pharmacist's absence, non-licensed personnel may remain in the pharmacy, but may only perform non-discretionary tasks and may not dispense any medication that has not been checked by the pharmacist or that requires patient consultation. The pharmacy's policy and procedure must allow the pharmacist to close the pharmacy if he or she feels it is required for any reason.

Possession of keys to the pharmacy. Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices.

Responsibility for security of the pharmacy. Each pharmacist whole on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices.

Hospital Pharmacy Security

No person other than a pharmacist, an intern pharmacist, a pharmacy technician, and authorized officer of the law, a person authorized to prescribe, a registered nurse, a licensed vocational nurse, a person who enters the pharmacy for purposes of receiving consultation from a pharmacist, or a person authorized by the pharmacist in charge to perform clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy shall be permitted in that area, place, pr premises described in the license issued by the board to a licensed hospital wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.
(B&P Code Section 4117)

Patient Medication Profiles

A pharmacy shall maintain medication profiles on any patient who has prescriptions filled in the pharmacy except when the pharmacist has a reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy. A patient medication record shall be maintained in an automated data processing or manual record mode such that it readily retrievable during the pharmacy's normal hours of operation. The patient medication record shall contain at least:

1) The patient's full name and address, telephone number, date of birth (or age) and gender;
2) For each prescription dispensed by the pharmacy:
   a) The name, strength, dosage form, route of administration (if other than oral), quantity and directions for use of any drug dispensed
   b) The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;
   c) The date on which a drug was dispensed or refilled;
   d) The prescription number for each prescription;
   e) The name or initials of the dispensing pharmacist; and
   f) Required information if the prescription is transferred to another pharmacy.
3) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, medications and relevant devices, or medical conditions which are communicated by eh patient to the patient's agent.
4) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

CALIFORNIA PHARMACY TECHNICIAN REGULATIONS

Article 11. Ancillary Personnel

1793. Definitions

"Pharmacy technician" means an individual who, under the direct supervision and control of a registered pharmacist, performs packaging, manipulative, repetitive, or other non-discretionary task related to the processing of a prescription in a licensed pharmacy, but who does not perform duties restricted to a registered pharmacist under section 1793.1.

1793.1 Duties of a registered Pharmacist

Only a registered pharmacist, or an intern pharmacist acting under the supervision of a registered pharmacist, may:

a. Receive a new prescription order orally from a prescriber or other person authorized by law.
b. Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
c. Identify, evaluate and interpret a prescription.
d. Interpret the clinical data in a patient medication record system or patient chart.
e. Consult with any prescriber, nurse or other health care professional or authorized agent thereof.
f. Supervise the packaging of drugs and check the packaging procedure and product upon completion.
g. Be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
h. Perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform.
i. Perform all functions which require professional judgment.

1793.2 Duties of a Pharmacy Technician

Pharmacy technicians may perform packaging, manipulative, repetitive, or other non-discretionary tasks, while assisting, and while under the direct supervision and control of, a registered pharmacist. "Non-discretionary task" as used in Business and Professions code section 4115, include:

a. removing the drug or drugs from stock;
b. counting, pouring, or mixing pharmaceuticals;
c. placing the product into a container;
d. affixing the label or labels to the container;
e. packaging and repackaging.

1793.3. Other Non-Licensed Pharmacy Personnel

In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription

record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

(b) A pharmacist may supervise the number of non-licensed personnel performing the duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her professional judgment, does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law.

(c) A pharmacist who, exercising his or her professional judgment pursuant to subdivision (b), refuses to supervise the number of non-licensed personnel scheduled by the pharmacy, shall notify the pharmacist-in-charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the non-licensed personnel that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule.

1793.5. Application for Registration

The application for registration (Form 17A-5 Rev. 9/94) as a pharmacy technician required by this section is available from the Board of Pharmacy upon request.

(a) Each application for registration as pharmacy technician shall include:
  (1) Information sufficient to identify the applicant.
  (2) A description of the applicant's qualifying experience or education, and supporting documentation for that experience or education. Examples of supporting documentation shall include: a certificate of completion issued by the training course provider showing the date of issuance and the number of theoretical and practical hours completed, transcripts, or an experience affidavit (Form 17a-6 or 17A-9 9/94) signed by the pharmacist having direct knowledge of the applicants experience.
  (3) A criminal background check that will require two completed fingerprint cards and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.
  (4) The twenty –five dollar ($25) registration fee which is effective until June 30, 1995. This registration fee shall be fifty dollars ($50) effective July 1, 1995. *May have increased again since then. (not material to be tested on)*

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days whether the application is complete or deficient; and what is needed to correct the deficiency. Once the application is complete, the board will notify the applicant within 60 days of a permit decision.

(d) Upon review and approval of the application, the board shall issue a certificate of registration as a pharmacy technician for at least one year. Before expiration of the initial certificate of registration, a pharmacy technician must renew the registration certificate with the board. Upon payment of the twenty-five dollar ($25) fee which is effective until June 30, 1995, the board shall issue a renewal certificate for two years. Effective July 1, 1995, the fee is fifty dollars ($50) and the penalty for failure to renew is

(e) twenty-five dollars ($25).

1793.6 Training Courses Specified by the Board

A course of training that meets the requirements of section B&P 4202 (a) (2) is:

(a) Any pharmacy technician training program accredited by the American society of Health-System Pharmacists,

(b) Any Pharmacy technician training program provided by a branch of the federal armed services for which the applicant posses a certificate of completion, or
(c) Any other course that provides a training period of at least 240 hours of theoretical and practical instruction, provided that at least 120 of these hours are in theoretical instruction in a curriculum that provides:\
    1. Knowledge and understanding of different pharmacy practice settings
    2. Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
    3. Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
    4. Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
    5. Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
    6. Knowledge of and ability to perform the manipulative and record keeping functions involved in and related to dispensing prescriptions.
    7. Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

1793.7. Requirements for pharmacies Employing Pharmacy Technicians

a. Any function performed by a pharmacy technician in connection with dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.
b. Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is full aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
c. A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
d. Any pharmacy employing or using pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.
e. A pharmacist shall be responsible for all activities of pharmacy technicians eo ensure that all such activities are performed completely, safely and without risk of harm to patients.
f. For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ration shall not be less than one pharmacist on duty of a total of two pharmacy technicians on duty. Pursuant to Business and Professional Code section 4115 (g) 91), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Addendum to PCT Training Manual

Chapter 9, Consultant Pharmacy

Add at page 61, at the end of the section "Utilization of Pharmacy Technicians"

Under California law, long term care facilities must have secured emergency pharmaceutical supplies available at each nursing station in the facility, Each of these emergency "kits" may have up to 24 different drugs of either oral or suppository dosage form as and up to four doses of any one of these drugs (B&P Section 4119 and H&S section 1261.5)

As an alternative to the emergency kits, the pharmacy may supply emergency medications via an "automated drug delivery system," which is a device that collects, controls and maintains information about drugs added to or dispensed from the device. Access to the drugs must be controlled by a pharmacist and the system must be adequate to ensure security, accuracy and accountability of drugs handled through it.

There are several requirements for drugs dispense through an automated drug delivery system. Of importance to technicians, nearly all the activities surroundings the use of one of these systems requires some activity by a pharmacist. the stocking of the systems with removable pockets or drawers may be performed by a pharmacy technician under the supervision of a pharmacist if:

1. The restocking is done in the pharmacy and is checked by a pharmacist.
2. The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container; and
3. The facility and pharmacy have developed policies and procedures to ensure that the pockets or drawers properly placed into the automated drug delivery system.

Finally, drugs dispense from an automated drug delivery system to not need to be labelled in the same way as regular prescriptions if the drugs are in unit dose or unit of use packaging and if the information that would otherwise appear on the label is readily available at eh time of the drug administration.

Contact Information

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Pharmacy Technician Certification Board
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californiapharmacistsassociation