Provided below are code sections that were added or amended during the 2015 Legislative Session. Unless otherwise indicated, all of the provisions go into effect on January 1, 2016.

(Strikeout indicates text that has been removed. Underlined text indicates new or added text.)

Section 4073.5 of the Business and Professions Code is added to read:

(a) A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:

(1) The alternative biological product is interchangeable.

(2) The prescriber does not personally indicate “Do not substitute,” or words of similar meaning, in the manner provided in subdivision (d).

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists’ designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one or more of the following electronic records systems:

(1) An interoperable electronic medical records system.

(2) An electronic prescribing technology.

(3) A pharmacy benefit management system.

(4) A pharmacy record.

(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber.

(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist’s designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:

(1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.
(e) 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.

(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked “Do not substitute,” provided that the prescriber personally initials the box or checkmark.

(2) 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.

(f) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (e). A pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, as used in this subdivision, includes any professional fee that may be charged by the pharmacist.

(g) 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 Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

(i) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.

(j) For purposes of this section, the following terms shall have the following meanings:

(1) “Biological product” has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(j)).

(2) “Interchangeable” means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

(3) “Prescription,” with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).
(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.

(l) This section shall not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

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

(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 when 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 Section 4052.1, 4052.2, or 4052.6 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 Section 4052.1, 4052.2, or 4052.6.

(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 or purpose for which the drug was prescribed if the condition or purpose 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 Section 4052.1, 4052.2, or 4052.6.

(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.

(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.
**Section 4076.6 is added to the Business and Professions Code, to read:**

(a) Upon the request of a patient or patient’s representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.

(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.

(c) A dispenser shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.

(d) A dispenser may provide his or her own translated directions for use to comply with the requirements of this section, and nothing in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. This section shall not affect a dispenser’s existing responsibility to correctly label a prescription pursuant to Section 4076.

(f) For purposes of this section, a dispenser does not include a veterinarian.

**Section 4128 of the Business and Professions Code is amended to read:** *(Operative 9/2/2015)*

(a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded to contain at least the information required by pursuant to Section 4128.4.

(2) Preparing sterile compounded unit dose drugs for parenteral therapy for administration to inpatients, if each compounded unit dose drug is barcoded to contain at least the information required by pursuant to Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded to contain at least the information required by pursuant to Section 4128.4.
For purposes of this article, “common ownership” means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

Section 4128.4 of the Business and Professions Code is amended to read: (Operative 9/2/2015)

(a) Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be machine readable at the inpatient’s bedside. Upon reading the barcode, the following information shall be retrievable: bedside using barcode medication administration software.

(a) The date the medication was prepared.

(b) The components used in the drug product. barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) The lot number or control number. For purposes of this section, “barcode medication administration software” means a computerized system designed to prevent medication errors in health care settings.

(d) The expiration date.

(e) The National Drug Code Directory number.

(f) The name of the centralized hospital packaging pharmacy.

Section 4128.5 of the Business and Professions Code is amended to read: (Operative 9/2/2015)

The (a) Any label for each unit dose medication produced by a centralized hospital packaging pharmacy shall contain display a human-readable label that contains all of the following:

(a) (1) The expiration date. date that the medication was prepared.

(2) The beyond-use date.

(b) (3) The established name of the drug.

(c) (4) The quantity of the each active ingredient.

(d) (5) Special storage or handling requirements.

(6) The lot number or control number assigned by the centralized hospital packaging pharmacy.
(7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

(1) The components used in the drug product.

(2) The expiration date of each of the drug’s components.


Section 4199 of the Business and Professions Code is amended to read:

(a) Any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food producing animals from a veterinary food-animal drug retailer pursuant to this chapter is subject to the labeling requirements of Sections 4076, 4076, 4076.6, and 4077.

(b) All prescriptions filled by a veterinary food-animal drug retailer shall be kept on file and maintained for at least three years in accordance with Section 4333.

Section 4209 of the Business and Professions Code is amended to read:

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice experience before applying for the pharmacist licensure examination.

(2) This pharmacy practice experience shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education (ACPE) or with regulations adopted by the board.

(3) This pharmacy practice experience shall include 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and shall include pharmacy practice experience in both a community and institutional pharmacy practice setting.

(b) An intern pharmacist shall submit proof of his or her pharmacy practice experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such the experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours Pharmacy practice experience earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern pharmacy practice experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and has pharmacy practice experience.
in both a community and institutional pharmacy practice setting. Certification of an applicant’s licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

(d) An applicant for the examination who has graduated after January 1, 2016, from an ACPE accredited college of pharmacy or school of pharmacy recognized by the board shall be deemed to have satisfied the pharmacy practice experience requirements specified in subdivisions (a) and (b).

Section 4430 of the Business and Professions Code is amended to read:

For purposes of this chapter, the following definitions shall apply:

(a) “Carrier” means a health care service plan, as defined in Section 1345 of the Health and Safety Code, or a health insurer that issues policies of health insurance, as defined in Section 106 of the Insurance Code.

(b) “Clerical or recordkeeping error” includes a typographical error, scrivener’s error, or computer error in a required document or record.

(c) “Extrapolation” means the practice of inferring a frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors actually measured in a sample of claims.

(d) “Health benefit plan” means any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. “Health benefit plan” includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of the Health and Safety Code, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer.

(e) “Maximum allowable cost” means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.

(f) “Maximum allowable cost list” means a list of drugs for which a maximum allowable cost has been established by a pharmacy benefit manager.

(g) “Obsolete” means a drug that may be listed in national drug pricing compendia but is no longer available to be dispensed based on the expiration date of the last lot manufactured.

(h) “Pharmacy” has the same meaning as provided in Section 4037.

(i) “Pharmacy audit” means an audit, either onsite or remotely, of any records of a pharmacy conducted by or on behalf of a carrier or a pharmacy benefits manager, or a representative thereof, for prescription drugs that were dispensed by that pharmacy to beneficiaries of a health benefit plan pursuant to a contract with the health benefit plan or the issuer or administrator thereof. “Pharmacy audit” does not include a concurrent review or
desk audit that occurs within three business days of transmission of a claim, or a concurrent review or desk audit where no chargeback or recoupment is demanded.

(a) [j] “Pharmacy benefit manager” means a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

Section 4432 of the Business and Professions Code is amended to read:

Notwithstanding any other law, a contract that is issued, amended, or renewed on or after January 1, 2013, between a pharmacy and a carrier or a pharmacy benefit manager to provide pharmacy services to beneficiaries of a health benefit plan shall comply with the provisions of this chapter. This chapter shall not apply to contracts authorized by Section 4600.2 of the Labor Code.

Section 4440 is added to the Business and Professions Code to read:

(a) A pharmacy benefit manager that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis shall comply with this section.

(b) A pharmacy benefit manager shall include in a contract, initially entered into, or renewed on its scheduled renewal date, on or after January 1, 2016, with the contracting pharmacy information identifying any national drug pricing compendia or other data sources used to determine the maximum allowable cost for the drugs on a maximum allowable cost list.

(c) A pharmacy benefit manager shall make available to a contracting pharmacy, upon request, the most up-to-date maximum allowable cost list or lists used by the pharmacy benefit manager for patients served by that pharmacy in a readily accessible, secure, and usable Web-based format or other comparable format.

(d) A drug shall not be included on a maximum allowable cost list or reimbursed on a maximum allowable cost basis unless all of the following apply:

(1) The drug is listed as “A” or “B” rated in the most recent version of the federal Food and Drug Administration’s approved drug products with therapeutic equivalent evaluations, also known as the Orange Book, or has an “NA,” “NR,” or “Z” rating or a similar rating by a nationally recognized pricing reference, such as Medi-Span or First DataBank.

(2) The drug is generally available for purchase in the state from a national or regional wholesaler.
(3) The drug is not obsolete.

(e) For contracts initially entered into, or renewed on the scheduled renewal date, on or after January 1, 2016, a pharmacy benefit manager shall review and shall make necessary adjustments to the maximum allowable cost of each drug on a maximum allowable cost list using the most recent data sources available at least once every seven days.

(f) For contracts initially entered into, or renewed on the scheduled renewal date, on or after January 1, 2016, a pharmacy benefit manager shall have a clearly defined process for a contracting pharmacy to appeal the maximum allowable cost for a drug on a maximum allowable cost list that includes all of the following:

(1) A contracting pharmacy may base its appeal on either of the following:

(A) The maximum allowable cost for a drug is below the cost at which the drug is available for purchase by similarly situated pharmacies in the state from a national or regional wholesaler.

(B) The drug does not meet the requirements of subdivision (d).

(2) A contracting pharmacy shall be provided no less than 14 business days following receipt of payment for the claim upon which the appeal is based to file an appeal with a pharmacy benefit manager. The pharmacy benefit manager shall make a final determination regarding a contracting pharmacy’s appeal within seven business days of the pharmacy benefit manager’s receipt of the appeal.

(3) If an appeal is denied by a pharmacy benefit manager, the pharmacy benefit manager shall provide to the contracting pharmacy the reason for the denial and the national drug code (NDC) of an equivalent drug that may be purchased by a similarly situated pharmacy at the price that is equal to or less than the maximum allowable cost of the appealed drug.

(4) If an appeal is upheld by a pharmacy benefit manager, the pharmacy benefit manager shall adjust the maximum allowable cost of the appealed drug for the appealing contracting pharmacy and all similarly situated contracting pharmacies in the state within one calendar day of the date of determination. The pharmacy benefit manager shall permit the appealing pharmacy to reverse and resubmit the claim upon which the appeal was based in order to receive the corrected reimbursement.

(g) A contracting pharmacy shall not disclose to any third party the maximum allowable cost list and any related information it receives either directly from a pharmacy benefit manager or through a pharmacy services administrative organization or similar entity with which the contracting pharmacy has a contract to provide administrative services for that pharmacy.

Section 11165.1 of the Health and Safety Code is amended to read: (Operative 10/11/15)

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before January July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration,
whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before January 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be
considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient’s controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

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