TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 17.
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

PROPOSED REGULATORY LANGUAGE:

Duty to Consult.

Legend:	Added text is indicated with an underline. Omitted text is indicated by (* * * *) Deleted text is indicated by ~~strikeout~~.

Amend section 1707.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.2. Duty to Consult.

(a) ~~A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all settings:~~Definition: "Consultation" means a discussion between a patient or patient's agent and a pharmacist regarding the patient's prescription(s) to provide information for the safe and effective use of the medication. Consultation may be provided verbally in-person, or by any other method agreed to by a patient and pharmacy, including but not limited to telephonically or by electronic means.

~~(1) upon request;~~

~~(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;~~

~~(3) whenever the prescription drug has not previously been dispensed to a patient; or~~

~~(4) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.~~

(b)~~(1) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that:~~ For the purpose of this section, a pharmacist shall exercise independent professional judgment consistent with the accepted standard of care and 42 Code of Federal Regulations (CFR) section 456.705.

~~(A) the patient receives written notice of his or her right to request consultation;~~

~~(B) the patient receives written notice of the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record; and~~

~~(C) a pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.~~

~~(2) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.~~

(c) ~~When oral consultation is provided, it shall include at least the following:~~Consultation shall be provided by a pharmacist to a patient or patient's agent in the following circumstances:

(1) ~~directions for use and storage and the importance of compliance with directions; and~~ upon request by a patient or patient's agent;

(2) ~~precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.~~upon dispensing a new prescription for a medication not previously dispensed; and

(3) when the pharmacist deems it warranted in the exercise of their professional judgment.

(d) ~~Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:~~Exceptions to Consultation Requirements: a pharmacist is not required to provide consultation to a patient or patient's agent for:

(1) ~~the name and description of the medication;~~a refill prescription;

(2) ~~the route of administration, dosage form, dosage, and duration of drug therapy;~~a refill prescription dispensed as a new prescription, solely created to apply a new prescription number;

(3) ~~any special directions for use and storage;~~a prescription delivered by common carrier, mail, curb-side pickup or other delivery method;

(4) ~~precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;~~a prescription to be administered in a physician's office, clinic or other licensed health care facility; and

(5) ~~prescription refill information;~~a prescription dispensed to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not required to consult about discharge medications if a health care facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074(e).

~~(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;~~

~~(7) action to be taken in the event of a missed dose.~~

(e) ~~Notwithstanding the requirements set forth in subsection (a) and (b),~~Declining Consultation: a pharmacist is not required to provide ~~oral~~ consultation when a patient or ~~the~~ patient's agent ~~refuses~~declines such consultation~~.~~, unless pharmacist determines, based on their professional judgement, that consultation is required. In the event a patient's agent declines consultation, licensed pharmacy personnel shall review the following information with the patient or patient's agent:

(1) the patient's right to consultation;

(2) the value of pharmacist consultation; and

(3) the pharmacy's hours of operation and how to contact a pharmacist, including a telephone number or means of electronic communication, if available, at which the patient or patient's agent may obtain future consultation from a pharmacist.

(f) Written Information Requirements: each prescription dispensed shall include the following written information, at a minimum, in addition to all federally required patient package inserts or medication guides, as applicable. This information shall be provided in writing, or electronically, if patient agrees, with each prescription dispensed regardless of whether a consultation was provided or declined.

(1) a statement regarding the patient's right to consultation with a pharmacist;

(2) a statement describing the value of pharmacist consultation;

(3) a statement on information that should be checked prior to using the medication, including:

(A) patient name on the prescription label is correct;

(B) medication matches the description on the prescription label;

(4) information on how to contact the pharmacy to speak to a pharmacist, including hours of operation, telephone number and means of electronic communication, if available.

(g) Policies and Procedures: the pharmacy shall establish policies and procedures outlining patient consultation requirements. At a minimum, the policies and procedures shall establish:

(1) how the pharmacy communicates to a patient or patient's agent that consultation is required for a prescription;

(2) when the pharmacy provides consultation, either at the time of dispensing, during prescription intake or at other designated times;

(3) consultation methods offered by the pharmacy, including electronic methods. Non-verbal methods shall be agreed to by the patient and documented in the patient's profile;

(4) how the pharmacy documents consultation with a patient or patient's agent, including when consultation was provided, what method was used, and that such documentation is readily retrievable;

(5) who is allowed to accept declination of patient consultation and how this is documented;

(6) the environment and process for ensuring confidentiality during consultation;

(7) provisions for responding to consultation requests when a patient or patient's agent contacts the pharmacy after a prescription has been dispensed, including a requirement that a pharmacist with immediate access to the patient's profile shall respond to the inquiry

(A) within 1 hour if consultation request is received during regular hours of operations, or

(B) within 2 hours of start of the next business day if the consultation request is received after hours.

(8) frequency of staff training on policies, procedures and best practices related to patient consultation and confirming patient identity, including documentation of such training; and

(9) how the pharmacy ensures adequate pharmacist staffing to provide required consultation to patients.

Note: Authority cited: Sections 4005, 4076 and 4112, Business and Professions Code. Reference: Sections 4005, 4076 and 4112, Business and Professions Code.