



**PHARMACY
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2020 PHARMACY LAW UPDATE

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DISCLOSURE

- Robert Stein has no potential conflicts of interest to disclose.
- Keith Yoshizuka has no potential conflicts of interest to disclose.
- This presentation is intended for educational purposes only, and no attorney-client relationship is established
- This CE program is not provided by the Board of Pharmacy *and does not count towards the two hours of law and ethics required for license renewal*

LEARNING OBJECTIVES

Upon completion of this session, the participant will be able to:

- **Describe the process for pharmacist furnished PrEP and PEP**
- **Identify changes in the law regarding pharmacist initiated immunizations**
- **Identify the new requirements regarding Personal Protective Equipment (PPE)**
- **Describe actions required of the state of California to increase access to affordable prescription drugs**
- **Identify changes in CURES reporting requirements**
- **Identify the training requirements before a pharmacist may furnish PEP or PrEP according to the state protocol**

TEST QUESTIONS

1. Assuming a pharmacist is trained in pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis of HIV, which of the following is true?
 - a. Permits the pharmacist to furnish PrEP or PEP drugs if the pharmacist determines patient meets clinical criteria established by federal guidelines
 - b. The pharmacist provides no more than a 30 day supply of PrEP medication to the patient
 - c. The pharmacist provides at least a 7 day supply of PrEP medication to the patient
 - d. The patient may waive counseling

TEST QUESTIONS

2. Which of the following is the MOST correct statement regarding a new law regarding pharmacist-provided immunizations?
 - a. Permits pharmacists to independently initiate and administer vaccines authorized by FDA, regardless of ACIP recommendations
 - b. Permits pharmacists to independently initiate and administer COVID-19 vaccines authorized or approved by FDA, regardless of ACIP recommendations
 - c. Permits pharmacists to independently initiate and administer vaccines authorized or approved by FDA, consistent with ACIP recommendations
 - d. Permits pharmacists to independently initiate and administer vaccines approved by FDA, consistent with ACIP recommendations

TEST QUESTIONS

3. Which of the following is true regarding personal protective equipment (PPE)?
- a. Hospitals must supply employees with PPE necessary for protection from airborne diseases
 - b. Hospitals must maintain a supply of unexpired PPE *that is new and not previously worn or used* in an amount equal to 3 months of normal consumption
 - c. California must establish the PPE Advisory Committee (comprised of clinicians and healthcare workers) to make recommendations for the development of guidelines for procurement and distribution of PPE
 - d. a and b only
 - e. a, b and c

TEST QUESTIONS

4. As a result of a new statute, which of the following must California do?
- a. California Health and Human Services Agency (CHHSA) must enter into partnerships to increase patient access to affordable drugs
 - b. CHHSA must enter into partnerships to produce or distribute generic prescription drugs and at least three forms of insulin that result in cost savings
 - c. CHHSA must submit a report to the Legislature assessing the feasibility and advantages of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price
 - d. a and c only
 - e. a, b and c

TEST QUESTIONS

5. Effective January 1, 2021, which of the following statements regarding reporting to CURES on controlled substances dispensed is correct?

- a. Schedules II – IV must be reported to CURES weekly
- b. Schedules II – V must be reported to CURES weekly
- c. Schedules II – IV must be reported to CURES daily
- d. Schedules II – V must be reported daily
- e. Controlled substances dispensed directly by prescribers or Emergency Rooms are exempt from reporting

TEST QUESTIONS

6. Training programs required before a pharmacist may furnish PEP or PrEP pursuant to the state protocol must meet which of the following requirements? **(SELECT ALL THAT APPLY)**

- a. Must be no greater than one (1) hour in length
- b. Must be not less than 1.5 hours in length
- c. Must be not less than 3 hours in length
- d. Must include techniques to discuss sexual health
- e. Must include training on financial assistance programs for PEP & PrEP

KEYS TO CITATIONS USED THROUGHOUT THIS PRESENTATION:

- DCA – California Department of Consumer Affairs
- HSC – California Health and Safety Code
- BPC – California Business and Professions Code
- WIC – California Welfare and Institutions Code
- Ins. Code – California Insurance Code
- Civ. Code – California Civil Code
- CCR – California Code of Regulations
- Lab. Code – California Labor Code
- UIC – California Unemployment Insurance Code
- Pen. Code – California Penal Code



NEW STATUTES FOR 2020

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS¹

- Authorizes pharmacists to dispense pre-exposure (PrEP) and post-exposure (PEP) prophylaxis in specified amounts for HIV
- Requires pharmacist to furnish those drugs if certain conditions are met, including that the pharmacist determines the patient meets the clinical criteria for PrEP or PEP consistent with federal guidelines
- Requires a pharmacist to complete a training program approved by the board before furnishing PrEP or PEP

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

Board of pharmacy (BOP) has adopted regulations to implement SB 159, covered later in this presentation

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

- Health care service plans and insurers must not require prior authorization or step therapy
 - Caveat: if FDA approves additional therapeutic equivalents, plans/insurers need only cover one of them; may require pre-authorization or step therapy for others
- Health care service plans, insurers and their PBMs cannot prohibit pharmacies from furnishing PrEP or PEP
- Health care service plans and insurers shall not cover any more than a 60 day supply in any two year period (unless ordered by a prescriber)
- Health care service plans may deny coverage for PrEP/PEP in out-of-network pharmacies
- Medi-Cal must pay pharmacists 85% of what physician would receive for the services

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PrEP

Pharmacist must furnish *at least a 30 day supply, and up to a 60 day supply* if all of the following criteria are met:

- Patient is HIV negative per lab or fingerstick (CLIA* waived) blood test,
 - Pharmacist shall order test if no evidence of negative HIV test provided by patient
- Patient reports no symptoms of HIV infection on self-reported checklist
- No contraindicated meds

* Clinical Laboratory Improvement Amendments of 1988

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PrEP (continued)

- Pharmacist **must** provide counseling (MANDATORY! Patient cannot waive!)
 - On the ongoing use of PEP
 - Side effects, use during pregnancy, *timely testing*
 - Additional information necessary for safe and proper use by patient
- Advising the patient that he/she must be seen by a primary care provider to receive subsequent prescriptions for pre-exposure prophylaxis and that *a pharmacist may not furnish a 60-day supply of pre-exposure prophylaxis to a single patient more than once every two years*

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PrEP (continued)

- Pharmacist must document furnishing PrEP in the pharmacy's system
 - No specific period of retention in the law; assume at least three years (*retaining documentation longer is a best practice*)
- Pharmacist must notify the patient's primary care provider of furnishing of PrEP, or provide list of physicians and other clinicians for follow-up care

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PrEP (continued)

- Authorized PrEP meds
 - fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or
 - another drug or drug combination determined by the board to meet Centers for Disease Control and Prevention (CDC) guidelines (emtricitabine 200 mg and tenofovir alafenamide 25 mg combination [Descovy])

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PEP:

Pharmacists *must* furnish a complete supply (28 days) of PEP *if all of the following criteria are met*:

- Pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for PEP, and
 - Pharmacist provides *CLIA waived* HIV testing **or** determines the patient is willing to undergo HIV testing consistent with CDC guidelines.
 - *But*, if the patient refuses to undergo HIV testing but otherwise eligible for post-exposure prophylaxis the pharmacist *may* furnish

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PEP (continued)

- Pharmacist **must** provide counseling (MANDATORY – Patient cannot waive!)
 - On the ongoing use of pre-exposure prophylaxis
 - Side effects, use during pregnancy, timely testing
 - Additional information necessary for safe and proper use by patient
 - On the importance of timely testing and treatment for HIV and sexually transmitted diseases.
 - Inform the patient of the availability of PrEP for persons who are at substantial risk of acquiring HIV.

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PEP (continued)

- *Pharmacist must notify the patient's primary care provider of furnishing of PrEP, or provide list of physicians and other clinicians for follow-up care*
- Unlike PrEP, there is no explicit requirement for pharmacist to document furnishing PEP in the pharmacy's system
 - But, as a best practice, assume you should document in the pharmacy's system and *retain at least three years (retaining documentation longer is recommended)*

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

SB 159 HIV PRE- & POST-EXPOSURE PROPHYLAXIS (CONT'D)

For PEP (continued)

- PEP meds
 - Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily, or
 - Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily, or
 - Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968

AB 1264 MEDICAL PRACTICE ACT: DANGEROUS DRUGS, APPROPRIATE PRIOR EXAMINATION²

Broadens ability for physician prescribers to prescribe dangerous drugs without a physical examination and only reviewing a patient self-screening tool or questionnaire

- “An appropriate prior examination *does not require a synchronous interaction between the patient and the licensee* and can be achieved through the use of telehealth, including, *but not limited to, a self-screening tool or a questionnaire*, provided that the licensee complies with the appropriate standard of care”
- Online prescribing (*with no in-person meeting*) of controlled substances is still prohibited by federal law

2. BPC § 2242(a), 21 USC § 829(e)(2)(B)(i)

AB 714 – OPIOID PRESCRIPTION DRUGS: PRESCRIBERS³

Changes one of the parameters that determine when a prescriber must offer a naloxone prescription and/or overdose education to a patient:

- Applies to outpatient prescriptions, *not where ordered for administration to the patient or prescriptions for terminal patients*
- Now, a naloxone prescription must be offered to a patient when an opioid is prescribed within a *year from the date a prescription for benzodiazepine has been dispensed* to the patient
- Now, no patient education on overdose if patient declines or has received the education within the past 24 months
- *There are other existing requirements!* A review of amended BPC § 741 is recommended for pharmacists *who order opioids*

3. BPC § 740, 741 adopted as emergency legislation effective on governor's signature 9/6/19

SB 569 - CONTROLLED SUBSTANCE PRESCRIPTIONS IN DECLARED LOCAL, STATE, OR FEDERAL EMERGENCY⁴

Pharmacy may fill a prescription for a controlled substance in declared emergency, but only if the BoP issues notice that the board is waiving Pharmacy Law provisions during the emergency.

- Prescription must:
 - Contain all required information specified in HSC § 11164(a)
 - Contain the words “11159.3 exemption” or similar statement that patient affected by a declared emergency
 - Be written and dispensed within first two weeks of BoP notice

4. HSC § 11159.3

SB 569 - CONTROLLED SUBSTANCE PRESCRIPTIONS IN DECLARED LOCAL, STATE, OR FEDERAL EMERGENCY (CONT'D)

Pharmacist must:

- Exercise appropriate professional judgment, including reviewing the patient activity report from CURES before dispensing
- For C-II prescriptions, dispense no more than a seven day supply
- Require the patient to demonstrate to pharmacist's satisfaction of the patient's inability to access the medications.
 - Verification of residency within an evacuation area
 - Any other way for patient to demonstrate inability to access meds

4. HSC § 11159.3

AB 744 – HEALTH CARE COVERAGE: TELEHEALTH⁵

- A health care service plan cannot require in-person contact occur between a health care provider and patient in order for provider (including pharmacists) to be paid
 - If covered services appropriately provided through telehealth, subject to the terms and conditions of the contract entered into between the enrollee or subscriber and the health care service plan, and between the health care service plan and its participating providers or provider
 - Patient must consent to delivery of care via telehealth
- Requires all health care service plan contracts issued, amended or renewed after 1/1/21 to provide for payment for telehealth services at same rate as an in-person diagnosis, consultation, or treatment.

5. BPC § 2290.5; HSC § 1374, 1374.14; WIC § 10123.855, 14132.725

AB 973 – PHARMACY COMPOUNDING⁶

- Requires pharmacy compounding of drug preparations to be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance
- Authorizes the Board of Pharmacy (BoP) to adopt regulations to impose additional standards for compounding drug preparations
- Because USP <797> and <798> were not published in 2019 as expected, current USP <797> (2014) and <798> (2008) continue to apply

6. BPC § 4126.8

AB 528 CURES DATABASE⁷

- Provisions effective January 1, 2021
 - Adds C-V to controlled substance dispenses reportable to CURES
 - Requires all dispenses of controlled substances to be reported to CURES within **one** working day, reducing current requirement of within seven working days
- Delays requirement that California Department of Justice adopt regulations regarding access to CURES until January 1, 2021
- Strengthens requirements for reviewing CURES prior to prescribing C-II – C-IV and during continued therapy (but only every six months instead of current four months)

7. HSC § 11164.1, 11165, 11165.1, and 11165.4

AB 690 – PHARMACY RELOCATION AND REMOTE DISPENSING PHARMACY TECHNICIAN QUALIFICATIONS⁸

Pharmacies during declared emergency

- Authorizes pharmacy that is destroyed or severely damaged to relocate without requiring transfer of ownership
- Requires destroyed/severely damaged pharmacy to notify BoP of new premises address
- “Severely damaged” means premises are unsafe or unfit for entry or occupation

8. BPC § 4062, 4132

AB 690 – PHARMACY RELOCATION AND REMOTE DISPENSING

PHARMACY TECHNICIAN QUALIFICATIONS (CONT'D)

Remote dispensing pharmacy tech requirements

- Possess a pharmacy technician license that is in good standing
- Possess and maintain certification from BoP-approved pharmacy technician certification program
- Possess one of the following:
 - Associate degree in pharmacy technology
 - Bachelor's degree in any subject
 - Certificate of completion from a course of training specified by regulations
- Complete a minimum of **2,000** hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

SB 655 – PHARMACY GENERAL⁹

Premises license information changes

- Subject to a fee of \$100 (may increase to \$130)

Tech trainee hours

- Increases the minimum experience to 120 hours and maximum of 140 hours for any single externship
- Increases the period for a tech trainee externship that involves the *rotation between a community pharmacy and a hospital pharmacy* to 340 hours

9. BPC § 4115.5, 4163, 4200, 4211, 4400

SB 655 – PHARMACY GENERAL (CONT'D)

Reverse distributor also licensed as a wholesaler may accept returns from unlicensed source *for the sole purpose of destruction* of the dangerous drug

- Licensed reverse distributor & wholesaler *must get BoP approval* to perform this function
- The statute is unclear as to whether the BoP approval is “per transaction,” or allows the reverse distributor & wholesaler to perform this function indefinitely

9. BPC § 4115.5, 4163, 4200, 4211, 4400

SB 655 – PHARMACY GENERAL (CONT'D)

CPJE “Freshness”

- Requires applicants for pharmacist licensure to pass a version of California Practice Standards and Jurisprudence Examination (CPJE) based on a specified occupational analysis
- Requires applicants for pharmacist licensure to pass a version of the North American Pharmacist Licensure Examination (NAPLEX) based on a specified occupational analysis*
- Implications:
 - Effectively limits the time after passing NAPLEX* and/or CPJE to apply for pharmacist licensure
 - Mainly affects out-of-state practitioners applying for California licensure

* exception: pharmacist licensed in another state and passed NAPLEX after 1/1/04

9. BPC § 4115.5, 4163, 4200, 4211, 4400

SB 655 – PHARMACY GENERAL (CONT'D)

Advanced Practice Pharmacist (APH) Recognition Renewals

- Requires applicant for renewal of an advanced practice pharmacist recognition:
 - To maintain a current and active pharmacy license and
 - To submit satisfactory proof to the BoP the completion of 10 additional Continuing Education (CE) hours per renewal period (*but not required the first renewal cycle after obtaining APH recognition*)
 - Authorizes the BoP to issue inactive advanced practice pharmacist recognition:
 - If pharmacist's license (RPH) becomes inactive
 - For failure to submit proof of required CE (either at renewal or upon discovery during audit or investigation)

9. BPC § 4115.5, 4163, 4200, 4211, 4400

AB 824 - PRESERVING ACCESS TO AFFORDABLE DRUGS¹⁰

- Prohibits “pay for delay” by reference drug (e.g., “brand name”) manufacturers
- Assumes an agreement resolving or settling a patent infringement claim (between brand and generic manufacturers) is anticompetitive if the intent of the agreement is to limit or forego research, development, manufacturing, marketing, or sales of the generic manufacturer’s drug product for any period of time

10. HSC § 134000 et. seq.

AB 1803 – CLAIMS FOR PRESCRIPTION DRUGS SOLD FOR RETAIL PRICE¹¹

- Technical correction *delayed till 1/1/20 the requirement of pharmacies to submit the patient's co-pay or the cash price, whichever is lower, to third party payers*
- Impact: lower than co-pay cash price must be counted towards deductibles and maximum out-of-pocket limits

11. BPC § 4079

AB 1494 – MEDI-CAL: USE OF TELEHEALTH IN DECLARED STATE OF EMERGENCY¹³

- Neither face-to-face contact nor patient's physical presence on the premises is required for services provided by an enrolled community clinic to a Medi-Cal beneficiary:
 - located in the declared area *during a state of emergency and up to 90 calendar days* after the conclusion of the proclaimed state of emergency, as deemed appropriate by the Department of Health Care Services (DHCS)
 - But, requires necessary federal approvals and matching federal funds
- DHCS must publish a website page providing guidance for facilities

13. WIC § 14132.723, 14132.724

SB 583 – ACCESS TO CLINICAL TRIALS¹⁴

- Broadens the mandate to address participation in clinical trials related to any life-threatening diseases or conditions (not just cancer)
- Allows enrollee self-referral to access benefit coverage related to the clinical trial
 - Referral by a provider no longer required
- Expands the existing mandate's requirement that in-network cost sharing to apply to non-cancer trial related services

14. HSC § 1649 et. seq

SB 697 - PHYSICIAN ASSISTANTS (PAs):

PRACTICE AGREEMENT: SUPERVISION¹⁵

- Clarifies that physician supervision of PA does not require physical presence of the supervising physician (MD must be available by phone or other electronic communication when PA examines a patient)
- The PA has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered or has completed a pharmacology course as part of their academic studies
- Eliminates requirement for a patient-specific treatment plan to order Schedule II controlled substances
 - *Practice agreement must specify diagnosis or condition for which a CII med may be ordered*
- *No change to requirement that prescription is attributed to the supervising physician (PA acts as “agent of the physician”)*

SB 276 – IMMUNIZATIONS¹⁶

Requires the State Department of Public Health (DPH), by 1/1/21 to develop an electronic, standardized, statewide medical exemption request for physicians, which would be transmitted using the California Immunization Registry (CAIR)

Commencing 1/1/21, would be the only documentation of a medical exemption that a governing authority may accept

Commencing 1/1/21, requires physicians to inform a parent or guardian of the bill's requirements and to examine the child and submit a completed medical exemption request form

Commencing 1/1/21, parent or guardian must submit a copy to DPH of a medical exemption granted prior to 1/1/21 in order for the medical exemption to remain valid

16. HSC § 120370 et. seq., HSC § 120375, HSC § 12044

SB 276 – IMMUNIZATIONS (CONT'D)

- Requires DPH to:
 - annually review immunization reports from schools and institutions to identify schools with an overall immunization rate of less than 95% and schools that do not report immunization rates
 - annually review physicians and surgeons who submitted 5 or more medical exemption forms in a calendar year
 - Create a review process of all exemption requests by an MD or RN
 - Physicians who are “creating to public health risk” reported to Medical Board
- Provides parent or guardians an appeals process for denied or revoked exemptions
- Provides for excuse from attending school if child is exposed to communicable disease where child not vaccinated for that disease

16. HSC § 120370 et. seq., HSC § 120375, HSC § 12044

SB 714 – IMMUNIZATIONS¹⁷

In addition to provisions of SB 276,

- Permits exemptions issued prior to 1/1/20 to allow child to be enrolled in any primary or secondary school “until the child enrolls in the next grade span”
 - Exemptions remain valid during the grade span unless exempting physician was subject to disciplinary action by Medical/Osteopath Board
- Grade spans
 - Birth to preschool, inclusive
 - K through 6th grade, inclusive
 - Grades 7 – 12, inclusive
- Parents must get new exemptions when child transitions between grade spans

17. HSC § 120370 et. seq

AB 5 – WORKER STATUS: EMPLOYEES AND INDEPENDENT CONTRACTORS¹⁸

Creates a three part test that must be met to classify a worker as an independent contractor:

1. The person is free from the control and direction of the hiring entity in connection with the performance of the work, both under the contract for the performance of the work and in fact, *and*
2. the person performs work that is outside the usual course of the hiring entity's business, *and*
3. the person is customarily engaged in an independently established trade, occupation, or business of the same nature as that involved in the work performed.

If this test is not met, the worker is an **employee**

AB 5 – WORKER STATUS: EMPLOYEES AND INDEPENDENT CONTRACTORS (CONT'D)

- Several professions/occupations are exempted from this statute, but **not pharmacists!**
- Potential effects on pharmacists
 - “Per diem” pharmacists classified as “independent contractors” to cover shifts
 - Contract/Consultant pharmacists providing services to
 - SNFs
 - Small rural hospitals

18. Lab. Code § 2750.3, 3351; UIC § 606.5, 621

AB 5 – WORKER STATUS: EMPLOYEES AND INDEPENDENT CONTRACTORS (CONT'D)

Fortunately, there is a safe harbor that consulting/contracting pharmacists may utilize to remain contractors and not be classified as employees.

- A business-to-business contract for services is not affected by the bill
- Establish your consulting practice as a business
 - Sole proprietorship
 - LLC
 - S corporation
- You contract using your business entity with your client

18. Lab. Code § 2750.3, 3351; UIC § 606.5, 621



NEW STATUTES FOR 2021

AB-1710 PHARMACY PRACTICE: VACCINES¹⁹

- Authorizes a pharmacist to independently initiate and administer COVID-19 vaccines approved by the federal Food and Drug Administration (FDA) in addition to vaccines approved by FDA and recommended by the federal Advisory Committee on Immunization Practices (ACIP) for persons 3 years of age or older

19. BPC § 4052.8

AB-2537 PERSONAL PROTECTIVE EQUIPMENT: HEALTH CARE EMPLOYEES²⁰

- Requires public and private employers of workers who provide direct patient care in a hospital setting to supply those employees with the personal protective equipment (PPE) necessary to comply with regulations related to the nature and use personal protective equipment and practices in health care facilities connected with aerosol transmissible diseases
- Requires an employer to ensure that the employees use the PPE supplied to them
- Requires that an employer in this context maintain a supply of unexpired PPE *that is new and not previously worn or used* in an amount equal to 3 months of normal consumption and to provide an inventory of its stockpile to the Division of Occupational Safety and Health upon request
- Requires a hospital to report to the State the hospital's highest 7-day consecutive daily average of consumption of PPE during 2019

20. Lab. Code § 6403.3

SB 275 HEALTH CARE/ESSENTIAL WORKERS PROTECTION ACT: PERSONAL PROTECTIVE EQUIPMENT²¹

- Requires the State Department of Public Health to establish a PPE stockpile to be at least sufficient for a 90-day pandemic or other health emergency.
- Requires providers, health care employers, including clinics, health facilities, and home health agencies, to maintain a 45-day stockpile of new, unexpired PPE for use in the event of a declared state of emergency starting the later of 1/1/23 or the adoption of implementation regulations
- Allows exemptions for supply chain disruptions
- Establishes the PPE Advisory Committee (comprised of clinicians and healthcare workers) to make recommendations for the development of guidelines for procurement and distribution of PPE

AB-890 NURSE PRACTITIONERS:

PRACTICE WITHOUT STANDARDIZED PROCEDURES²²

- Creates the Nurse Practitioner Advisory Committee (NPAC) to advise and give recommendations to the Board of Registered Nursing (BRN) on matters relating to nurse practitioners
- Requires the BRN, by regulation, to define minimum standards for a nurse practitioner to transition to practice independently
- Authorizes a nurse practitioner who meets certain education, experience, and certification requirements to perform, *in certain settings or organizations*, specified functions without standardized procedures, including ordering, performing, and interpreting diagnostic procedures, certifying disability, and prescribing, administering, dispensing, and furnishing controlled substances

22. BPC § 650.01; 805, 805.5; 2837.100 et. seq.

AB-890 NURSE PRACTITIONERS:

PRACTICE WITHOUT STANDARDIZED PROCEDURES (CONT'D)

- Authorizes, beginning 1/1/23 a nurse practitioner to perform those functions without standardized procedures *outside of specified settings or organizations* in accordance with specified conditions and requirements if the nurse practitioner holds an active certification issued by the board
- Requires the BRN, by regulation, to define minimum standards for a nurse practitioner to transition to practice without the routine presence of a physician and surgeon.
independently Requires NP to inform patients that the NP is not a physician and surgeon
- Forbids referrals by NP to laboratory, diagnostic nuclear medicine, and physical therapy, if the NP or his/her immediate family has a financial interest with the person or in the entity that receives the referral

22. BPC § 650.01; 805, 805.5; 2837.100 et. seq.

SB-1237 NURSE-MIDWIVES: SCOPE OF PRACTICE²³

- Authorizes a certified nurse-midwife (CN-M) to attend to low-risk pregnancy and childbirth in an out-of-hospital setting if consistent with specified provisions
- Authorizes a CN-M to attend to provide prenatal, intrapartum, and postpartum care, including family-planning services, interconception care, and immediate care of the newborn
- Requires a CN-M to refer all emergencies to a physician and surgeon immediately, and authorizes a CN-M to provide emergency care until the assistance of a physician and surgeon is obtained

23. BPC § 650.01, 2746.2, 2746.5, 2746.51, 2746.52, 2746.54, 2746.55; HSC § 102415, 102426, 102430

SB-1237 NURSE-MIDWIVES: SCOPE OF PRACTICE (CONT'D)

- Permits CN-M to furnish or order most drugs *without physician supervision*, and would authorize a CN-M to furnish drugs or devices incidentally to the provision of care and services
- Schedule II or III controlled substances furnished or ordered by a certified nurse-midwife for any condition to be furnished or ordered in accordance with a patient-specific protocol approved by a physician and surgeon
- CN-M must register with CURES before prescribing or furnishing controlled substances
- Forbids referrals by CN-M to laboratory, diagnostic nuclear medicine, and physical therapy, if the NP or his/her immediate family has a financial interest with the person or in the entity that receives the referral

23. BPC § 650.01, 2746.2, 2746.5, 2746.51, 2746.52, 2746.54, 2746.55; HSC § 102415, 102426, 102430

SB-852 HEALTH CARE: PRESCRIPTION DRUGS²⁴

- Requires the California Health and Human Services Agency (CHHSA) to enter into partnerships, in consultation with other state departments as necessary to, among other things, increase patient access to affordable drugs.
- Requires CHHSA to enter into partnerships to produce or distribute generic prescription drugs and at least one form of insulin that results in cost savings
- Requires CHHSA to submit a report to the Legislature prior to 7/1/23 that assesses the feasibility and advantages of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price.

24. HSC § 127690 et. seq.

SB-878 DEPT OF CONSUMER AFFAIRS: APPLICATION PROCESSING TIMEFRAMES²⁵

- Beginning July 1, 2021, would require each board within the department that issues licenses, on at least a quarterly basis, to:
 - Prominently display on its website either the current average timeframes for processing initial and renewal license applications or the combined current average timeframe for processing both initial and renewal license applications
 - Prominently display on its website either the current average timeframes for processing each license type that the board administers or the combined current average timeframe for processing all license types that the board administers

AB-2077 HYPODERMIC NEEDLES AND SYRINGES²⁶

- Extends the current statute (BPC § 4145.5) allowing for pharmacists to dispense needles and syringes to any person 18 years of age or older without requiring the recipient provide a legitimate need for needles and syringes to January 1, 2026
- Repeals BPC § 4326 (criminalizing possession of needles and syringes for unauthorized purposes) and HSC § 121285 (Disease Prevention Demonstration Project of 2013)

26. BPC § 4145.5; HSC § 11364

AB-2164 TELEHEALTH²⁷

- Permits a federally qualified health center (FQHC) service and rural health clinic (RHC) service to use telehealth technology to establish a patient who is located within the FQHC's or RHC's federal designated service area using synchronous interaction or asynchronous store and forward as of the date of service
- Provides that an FQHC or RHC "visit" includes an encounter between an FQHC or RHC patient and a health care provider using telehealth by synchronous interaction or asynchronous store and forward

27. WIC § 14132.100

AB 1976 MENTAL HEALTH SERVICES: ASSISTED OUTPATIENT TREATMENT²⁸

- Requires a county or group of counties to offer specified mental health programs including access to medications, unless a county or group of counties opts out, stating the reasons for opting out and any facts or circumstances relied on in making that decision.
- Authorizes a county to instead offer those mental health programs in combination with one or more counties
- Prohibit a county or group of counties implementing these provisions from reducing existing voluntary mental health programs serving adults, or children's mental health programs

28. WIC § 5346, 5347, 5348, 5349, 5349.1

AB 732 INCARCERATED PREGNANT PERSONS²⁹

- Requires the county jail or state prison provide incarcerated persons identified as possibly pregnant or capable of becoming pregnant:
 - To offer a pregnancy test upon intake or request, and in the case of a county jail, within 72 hours of arrival at the jail
 - To provide a pregnancy examination with a physician, nurse practitioner, certified nurse midwife, or physician assistant within 7 days of a positive pregnancy test
 - To ensure incarcerated pregnant persons receive prenatal care visits

29. Pen. Code § 3405, 3406, 3408, 3409; 4023.5, 4023.6, 4023.8, 4028

AB 732 INCARCERATED PREGNANT PERSONS (CONT'D)

- To provide specified prenatal services and a referral to a social worker and access to community-based programs serving pregnant, birthing, or lactating inmates
- To allow an incarcerated pregnant person to elect to have a support person present during childbirth
- To provide a postpartum examination one week, and as needed up to 12 weeks postpartum
- To prohibit the use of tasers, pepper spray, or other chemical weapons against incarcerated pregnant persons

29. Pen. Code § 3405, 3406, 3408, 3409; 4023.5, 4023.6, 4023.8, 4028

AND NOW, A MOMENT OF RESPECT FOR ALL THE OTHER BILLS SUPPORTED, OPPOSED OR WATCHED BY CSHP (THAT DIED IN SECOND SESSION)

- AB 1467 (Salas) Optometrist additional' Scope under agreement with Ophthalmologist
- AB 1639 (Gray) Age to Purchase Tobacco or apparatus to smoke or ingest a controlled substance
- AB 1936 (Rodriguez) Rx and OTC medication access during an emergency POWER SHUT OFF
- AB 2100 (Wood) Medi-Cal: Pharmacy Benefits (passed legislature but vetoed by the governor)
- AB 1938 (Eggman) 340B Discount Drug Purchasing Program
- AB 2177 (Kalra) Pharmacy at Horse Racing Facility
- AB 2203 (Nazarian) Limit Pt charge for Insulin
- AB 2549 (Salas) Military DCA temporary licensees
- AB 2794 (Mathis) Pharmacist Employee vs. Contractor status
- AB 2857 (Low) BoP Member removal
- AB 2983 (Holden) Prohibit automated refill request to prescribers
- AB 2984 (Daly) Rx "Drug Cost Sharing"
- AB 3042 (Limon) Dietary Supplement restrictions
- AB 3082 (Gabriel) Nurse to patient ratios.
- AB 3342 (Bauer-Kahan) EpiPens for child daycare
- AB 362 (Eggman) Safe injection venues - OD prevention
- AB 531 (Friedman) Extended housing options and Psychotropic mediations for Foster Children





NEW REGULATIONS FOR 2020

CCR §1749 FEE SCHEDULE³⁰ (EFFECTIVE 4/1/20)

- Issuance of a pharmacy license has increased to \$570 and a renewal has increased to \$930
- Issuance and renewal of a pharmacy technician license has increased to \$195
- Application fee for the pharmacist licensing examination has increased to \$285
- Issuance of a pharmacist license has increased to \$215 and a renewal has increased to \$505
- Issuance of a centralized hospital packaging pharmacy license has increased to \$1,125
- Issuance of an outsourcing facility license has increased to \$3,180 and renewal to \$1,855

30. CCR §1749

CCR §1746.3 NALOXONE FACT SHEET³¹ (EFFECTIVE 4/1/20)

Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board approved fact sheet. ~~This~~ The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.

31. CCR §1746.3

CCR §1747 EMERGENCY REGULATION – HIV PREEXPOSURE AND POSTEXPOSURE PROPHYLAXIS FURNISHING³² (EFFECTIVE 4/30/20)

A pharmacist must complete a training program approved by the board or provided by a provider accredited by an approved accreditation agency prior to furnishing PEP or PrEP

- Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
 - (A) HIV preexposure and postexposure prophylaxis pharmacology.
 - (B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

CCR §1747 EMERGENCY REGULATION – HIV PREEXPOSURE AND POSTEXPOSURE PROPHYLAXIS FURNISHING (CONT'D)

- (C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
- (D) Patient referral resources and supplemental resources for pharmacists.
- (E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
- (F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

CCR §1747 EMERGENCY REGULATION – HIV PREEXPOSURE AND POSTEXPOSURE PROPHYLAXIS FURNISHING (CONT'D)

- (2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.
- (b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

32. CCR § 1747

CCR 1714.3 COMMUNITY PHARMACY STAFFING ³³

EFFECTIVE 9/15/20

- (a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee currently working, the pharmacy shall make another person who is an employee of the establishment within which the pharmacy is located available to assist the pharmacist. The pharmacy shall:
- (1) Designate the name(s) of one or more persons who will be available to assist the pharmacist;
 - (2) Ensure that each designated person is able, at a minimum, to perform the duties of nonlicensed pharmacy personnel as specified in section 1793.3;
 - (3) Ensure that each designated person qualifies to have access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;
 - (4) Ensure that a designated person responds and is able to assist the pharmacist within five minutes after the pharmacist's request.

CCR 1714.3 COMMUNITY PHARMACY STAFFING (CONTINUED)

(b) A pharmacy shall have and maintain policies and procedures that address the following:

- (1) How a pharmacist on duty will be able to identify the person(s) designated as available to assist them, and the required criteria and training for those designated person(s)
- (2) (2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy.

(c) All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section. “Impacted pharmacy employees” means any employee of the pharmacy, whether the person works within or for the pharmacy owner, who has any duties to prepare for or to execute how or when a pharmacist may seek or obtain assistance, including any pharmacist, any person who creates or approves pharmacy employees’ work schedules, or who designates persons who may assist the pharmacist pursuant to this section.

(d) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format.

CCR §1706.2 ABANDONMENT OF APPLICATION FILES ³⁴

EFFECTIVE 10/1/20

- Consolidates language such that an applicant for a premises license (pharmacy, wholesaler, clinic, veterinary food drug retailer, out-of-state distributor, or to furnish hypodermic syringes and needles) who fails to complete the application within 60 days of notice of deficiencies will be deemed as abandoned (rather than naming every licensing category).
- Expands scope from pharmacy technician to EVERY personal license such that failure to complete the application within 60 days of notice of deficiencies will be deemed as abandoned

34. CCR § 1706.2

CCR §1707.2 DUTY TO CONSULT ³⁵ (EFFECTIVE 10/1/20)

- Adds requirements for consultation when the prescription is delivered or mailed
- The patient shall receive written notice of his or her right to consultation
- The notice shall include the hours of availability and the telephone number
- (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.

35. CCR §1707.2



BOARD OF PHARMACY WAIVERS FOR DECLARED STATE OF EMERGENCY

STAFFING RATIO OF PHARMACISTS TO INTERN PHARMACISTS AND GENERAL SUPERVISION - IMMUNIZATIONS - BPC SECTION 4114³⁶

The ratio of pharmacists to intern pharmacists may increase to allow for one additional intern pharmacist for each supervising pharmacist under the following conditions:

The additional intern pharmacist is administering immunizations consistent with the provisions of Pharmacy Law.

The pharmacy maintains a readily retrievable record documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver and the staff operating under the waiver. Records must be maintained for one year following the end of the declared emergency.

Effective: July 23, 2020

Expiration: October 20, 2020

36. Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision - Immunizations - BPC section 4114;
<https://www.pharmacy.ca.gov/licensees/waivers/4114.shtml>

DUTY TO CONSULT ³⁷

If the pharmacist-in-charge makes the determination that oral consultation places the public and/or personnel at risk for exposure to COVID-19, in-person oral consultation may be waived under the following conditions:

1. The patient or patient's agent receives a verbal and prominently written notice of his or her right to request consultation by telephone.
2. The written notice includes the telephone number to call and the hours of availability during which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's records.
3. A pharmacist is readily available to speak to the patient or patient's agent during any regular hours of operation, unless additional hours of availability are provided and a return call is scheduled to occur within that time in the same business day, if acceptable to the patient. The pharmacist must make two good faith attempts to contact the patient by telephone and document the attempts or consultation. Documentation shall include the name of patient or prescription number, date, time and identification of pharmacist who provided consultation.

DUTY TO CONSULT (CONTINUED)

4. A pharmacist may provide oral consultation to the patient or patient's agent prior to the sale or delivery of a prescription.
5. The pharmacy has policies and procedures in place to ensure compliance with the requirements of this waiver prior to implementation.
6. A pharmacist may consult with patients or patients' agents using telephone, video chat or other method as acceptable to the patient.
7. If a pharmacist deems consultation is warranted in the exercise of his or her professional judgment or if there is an adverse drug therapy warning deemed necessary after the review, consultation must occur prior to the patient or the patient's agent receiving the prescription.
8. Documentation required by this waiver shall be maintained and readily retrievable for one year following the end of the declared emergency.

Effective: April 1, 2020

Expiration: December 28, 2020

USE OF PPE IN CERTAIN COMPOUNDING ASEPTIC ISOLATORS OR COMPOUNDING ASEPTIC CONTAINMENT ISOLATORS ³⁸

Provisions of Title 16, California Code of Regulations, section 1751.5(a)(1)-(3) related to the requirement to don PPE garb (including masks, gowns, head, and shoe covers) when compounding in a compounding aseptic isolator or compounding aseptic containment isolator May be waived under the following conditions:

1. The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain garbing requirements established in the regulation.
2. The isolator manufacturer has provided written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required. This documentation must be readily retrievable by the licensed location.
3. A policy is developed that details the revised conditions for use of PPE for compounding pursuant to this waiver.

USE OF PPE IN CERTAIN COMPOUNDING ASEPTIC ISOLATORS OR COMPOUNDING ASEPTIC CONTAINMENT ISOLATORS (CONTINUED)

4. Applicable pharmacy staff are trained on the policy and the training is documented prior to implementation.
5. Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.
6. Surface sampling schedule will be reviewed for the possible need to increase the frequency.
7. Documentation indicating the duration of time the pharmacy is operating under the waiver approval is maintained.

Note: This waiver not does extend to the requirements for the use of sterile gloves.

Effective: April 1, 2020

Expiration: December 28, 2020

REMOTE PROCESSING ³⁹

For the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy.

Remote processing means most of the activities involved in evaluating and approving a prescription. The waiver does not include the dispensing of a drug or final product verification by remote processing.

Further, this waiver allows for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

39. Remote Processing – Effective through October 31, 2020 –

https://www.pharmacy.ca.gov/licensees/waivers/4071_1_a.shtml

REMOTE PROCESSING (CONTINUED)

Pharmacy and Pharmacist Remote Processing Waiver Conditions

Pharmacists are permitted to conduct remote processing as permitted by this waiver if in compliance with the following:

- The pharmacist must be a California-licensed pharmacist who either processes medication orders or prescriptions from a remote site or on the premises of a California licensed-pharmacy.
- A California-licensed pharmacy may allow staff to engage in remote processing provided the pharmacy has policies and procedures that outline the authorized functions to be performed. These policies and procedures must assure compliance with HIPAA standards. Such policies must be readily retrievable and provided to the Board upon request (i.e. be able to be produced within three business days of request).

39. Remote Processing – Effective through October 31, 2020 –
https://www.pharmacy.ca.gov/licensees/waivers/4071_1_a.shtml

REMOTE PROCESSING (CONTINUED)

Pharmacy and Pharmacist Remote Processing Waiver Conditions (cont)

- A pharmacy utilizing remote processing must assure training of all staff, and at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy must ensure that any pharmacist performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site pharmacist has access to when the pharmacy is open.
- All record keeping requirements for pharmacies, including capturing the positive identification of the pharmacist.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

39. Remote Processing – Effective through October 31, 2020 –

https://www.pharmacy.ca.gov/licensees/waivers/4071_1_a.shtml

REMOTE PROCESSING (CONTINUED)

Pharmacy Intern and Pharmacy Technician Remote Processing Waiver Conditions

Pharmacy interns and pharmacy technicians are permitted to conduct **nondiscretionary tasks** related to remote processing as permitted by the waiver if in compliance with the following:

- The pharmacy intern or pharmacy technician must be licensed by the Board.
- A pharmacy utilizing remote processing shall ensure that all pharmacy interns and pharmacy technicians are trained on the policies and procedures, and at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

REMOTE PROCESSING (CONTINUED)

Pharmacy Intern and Pharmacy Technician Remote Processing Waiver Conditions (continued)

- A pharmacy shall ensure that any pharmacy intern or pharmacy technician performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems to which an on-site pharmacy intern or pharmacy technician has access when the pharmacy is open.
- Each remote entry record must comply with all record keeping requirements for pharmacies.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

Effective: March 18, 2020

Expiration: October 31, 2020, or until the emergency declaration is lifted, whichever is sooner.

39. Remote Processing – Effective through October 31, 2020 –

https://www.pharmacy.ca.gov/licensees/waivers/4071_1_a.shtml

SIGNATURE REQUIREMENT FOR RECEIPT OF DELIVERY OF DRUGS ⁴⁰

Waive the signature requirement for the receipt of the delivery of drugs as required in BPC 4059.5 under the following conditions:

The delivery personnel confirm that the employee accepting the delivery is a pharmacist.

The delivery personnel input the pharmacist's name and license number conveyed to them by the pharmacist directly into their signature capture device in lieu of the pharmacist physically signing the tablet as part of the delivery process.

Note: This waiver applies only to the **signature** requirement for the pharmacist accepting delivery.

Effective: March 17, 2020

Expiration: December 21, 2020, or until the emergency declaration is lifted, whichever is sooner.

40. Signature Requirement for Receipt of Delivery of Drugs – Effective through December 21, 2020 –
https://www.pharmacy.ca.gov/licensees/waivers/4059_5.shtml

PRESCRIBER DISPENSING MEDICATION TO EMERGENCY ROOM PATIENT ⁴¹

Waive provisions related to the prohibition against a prescriber to dispensing medications to an emergency room patient if the medication dispensed is a short-acting, beta-agonist inhalation product.

Effective: March 27, 2020

Expiration: December 21, 2020, or until the emergency declaration is lifted, whichever is sooner.

41. Prescriber Dispensing Medication to Emergency Room Patient – Effective through December 21, 2020 – https://www.pharmacy.ca.gov/licensees/waivers/4068_a_1_4068_a_5_and_4068_a_6.shtml

USP <797> REQUIREMENTS RELATED TO USE OF PERSONAL PROTECTIVE EQUIPMENT ⁴²

Waive USP <797> requirements related to the use of personal protective equipment (PPE) in that a PPE mask and gown may be reused by staff performing sterile compounding under the following conditions:

- The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain the single-use provisions established in USP <797>.
- The pharmacy has developed a policy that details the conditions under which PPE may be reused. Such policies shall be consistent with standards of practice used during emergency situations.

42. Requirements Related to PPE – Effective through December 21, 2020 -
https://www.pharmacy.ca.gov/licensees/waivers/4126_8.shtml

USP <797> REQUIREMENTS RELATED TO USE OF PERSONAL PROTECTIVE EQUIPMENT (CONTINUED)

- Documented training on the policy is provided to all staff.
- Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.
- Surface sampling schedule was reviewed for the possible need to increase the frequency.
- Documentation is maintained indicating the duration of time the pharmacy is operating under the waiver approval.

Effective: March 17, 2020

Expiration: September 22, 2020

42. https://www.pharmacy.ca.gov/licensees/waivers/4126_8.shtml

GOVERNOR NEWSOM'S EXECUTIVE ORDERS

EXECUTIVE ORDER N-39-20⁴³

California Department of Consumer Affairs and State Board of Pharmacy will allow pharmacists to collect specimens for COVID-19 tests and order tests for consumers. The specimens will be delivered to and processed at public health, university or commercial labs.

Multiple independent pharmacies, CVS, Sharp Healthcare, and Ralph's Supermarkets (1 location) commenced collecting specimens to be tested for COVID in an effort to increase the number of persons tested for COVID, part of the criteria for reopening the state.

43. <https://www.gov.ca.gov/2020/05/12/governor-newsom-announces-california-has-conducted-over-1-million-diagnostic-tests-for-covid-19-as-testing-capacity-ramps-up/>

EXECUTIVE ORDER N-75-20⁴⁴

Performing Point-Of-Care CLIA-Waived Tests For The Presence Of SARS-CoV-2 Without A Laboratory Director

Pursuant to the Governor's Executive Orders and the applicable DCA waiver, and as discussed in more detail below, pharmacists and pharmacy technicians may perform on individual patients point-of-care clinical laboratory tests or examinations for the presence of the virus SARS-CoV-2 that are deemed or classified as waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), in settings without a laboratory director, including a pharmacy.

Such tests are limited to tests authorized by the United States Food and Drug Administration (FDA) and performed consistent with the provisions of any applicable Emergency Use Authorization.

Pharmacies where tests are performed must still comply with any other applicable federal requirements, including CLIA certificate of waiver requirements. For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decision making is the pharmacist-in-charge.

EXECUTIVE ORDER N-75-20 (CONTINUED)

- Pharmacies where tests are performed must also register with the Department of Public Health to perform waived tests, but need not identify a laboratory director. Such pharmacies must also comply with disease reporting requirements applicable to laboratories.
- There are currently several waived tests for the presence of SARS-CoV-2 that may be performed in a clinical laboratory with a federal CLIA certificate of waiver and a California clinical laboratory registration. More information about the current list of available tests receiving FDA Emergency Use Authorization is available here: <https://www.fda.gov/medical-devices/emergency-situations-medicaldevices/emergency-use-authorizations-medical-devices>
- For further information about the circumstances under which a test can be performed, please refer to the appropriate FDA-EUA approved manufacturers test kit's "Instructions for Use" literature

EXECUTIVE ORDER N-75-20 (CONTINUED)

Pharmacists May Order And Collect Specimens For All CLIA Categories Of Authorized COVID-19 Tests, And They May Perform and Interpret the Results for Authorized CLIA-Waived COVID-19 Tests

Pursuant to the Governor's Executive Orders and the applicable DCA waiver, pharmacists may order and collect specimens for all CLIA categories of tests for the presence of SARS-CoV-2 in individual patients, including waived, moderate- and high-complexity tests.

Pharmacists may also perform and interpret results for point-of-care tests for the presence of SARS-CoV-2 that are deemed or classified as CLIA waived. The DCA waiver does not, however, authorize pharmacists to perform and interpret results for moderate- or high-complexity tests.

Pharmacists must be competent and trained to collect the particular specimen and perform the particular test, and the specimen must be collected, and the test performed, consistent with any applicable Emergency Use Authorization. Pharmacists that supervise pharmacy technicians are responsible for the testing duties the pharmacy technicians perform under their supervision. Pharmacists must also comply with disease reporting requirements applicable to health care

EXECUTIVE ORDER N-75-20 (CONTINUED)

Pharmacy Technicians In Pharmacies May Collect Specimens And Perform Authorized CLIA-Waived COVID-19 Tests

Pursuant to the Governor's Executive Orders and the applicable DCA waiver, pharmacy technicians in a pharmacy may collect specimens through the use of nasal, nasopharyngeal, or throat swabs, and perform, point-of-care tests for the presence of SARS-CoV-2 that are deemed or classified as CLIA waived. Pharmacy technicians must be competent and trained to collect the particular specimen and perform the particular test, and the specimen must be collected, and the test performed, consistent with any applicable Emergency Use Authorization. Pharmacy technicians collecting specimens and performing tests, as specified, must remain under the direct supervision and control of a pharmacist.

44. https://www.dca.ca.gov/licensees/dca_20_45_guidance.pdf

EXECUTIVE ORDER N-75-20 (CONTINUED)

Pharmacists Serving As Laboratory Personnel Performing COVID-19 Tests In A Licensed Laboratory

For the duration of the COVID-19 emergency, persons may perform testing for SARS-CoV-2, the virus that causes COVID-19, without holding a California license to perform such testing, if they meet the requirements specified in federal regulations for high-complexity testing personnel.

Pharmacists are not specifically included in the referenced section of the Code of Federal Regulations, but in the Board of Pharmacy's view, a pharmacist would satisfy those requirements by virtue of the education required for licensure. Accordingly, Executive Order N-25-20 and LFS's guidelines separately enable pharmacists to serve as laboratory personnel and perform COVID-19 testing under the guidelines issued by the LFS

44. https://www.dca.ca.gov/licensees/dca_20_45_guidance.pdf

TEST QUESTION #1

1. Assuming a pharmacist is trained in pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis of HIV, which of the following is true?
 - a. Permits the pharmacist to furnish PrEP or PEP drugs if the pharmacist determines patient meets clinical criteria established by federal guidelines
 - b. The pharmacist provides no more than a 30 day supply of PrEP medication to the patient
 - c. The pharmacist provides at least a 7 day supply of PrEP medication to the patient
 - d. The patient may waive counseling

TEST QUESTION #2

Which of the following is the MOST correct statement regarding a new law regarding pharmacist-provided immunizations?

- a. Permits pharmacists to independently initiate and administer vaccines authorized by FDA, regardless of ACIP recommendations
- b. Permits pharmacists to independently initiate and administer COVID-19 vaccines authorized or approved by FDA, regardless of ACIP recommendations
- c. Permits pharmacists to independently initiate and administer vaccines authorized or approved by FDA, consistent with ACIP recommendations
- d. Permits pharmacists to independently initiate and administer vaccines approved by FDA, consistent with ACIP recommendations

TEST QUESTION #3

Which of the following is true regarding personal protective equipment (PPE)?

- a. Hospitals must supply employees with PPE necessary for protection from airborne diseases
- b. Hospitals must maintain a supply of unexpired PPE *that is new and not previously worn or used* in an amount equal to 3 months of normal consumption
- c. California must establish the PPE Advisory Committee (comprised of clinicians and healthcare workers) to make recommendations for the development of guidelines for procurement and distribution of PPE
- d. a and b only
- e. a, b and c

TEST QUESTION #4

As a result of a 2020 statute, which of the following must California do?

- a. California Health and Human Services Agency (CHHSA) must enter into partnerships to increase patient access to affordable drugs
- b. CHHSA must enter into partnerships to produce or distribute generic prescription drugs and at least three forms of insulin that result in cost savings
- c. CHHSA must submit a report to the Legislature assessing the feasibility and advantages of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price
- d. a and c only
- e. a, b and c

TEST QUESTION #5

5. Effective January 1, 2021, which of the following statements regarding reporting to CURES on controlled substances dispensed is correct?

- a. Schedules II – IV must be reported to CURES weekly
- b. Schedules II – V must be reported to CURES weekly
- c. Schedules II – IV must be reported to CURES daily
- d. Schedules II – V must be reported daily
- e. Controlled substances dispensed directly by prescribers or Emergency Rooms are exempt from reporting

TEST QUESTION #6

6. Training programs required before a pharmacist may furnish PEP or PrEP pursuant to the state protocol must meet which of the following requirements? **(SELECT ALL THAT APPLY)**

- a. Must be no greater than one (1) hour in length
- b. Must be not less than 1.5 hours in length
- c. Must be not less than 3 hours in length
- d. Must include techniques to discuss sexual health
- e. Must include training on financial assistance programs for PEP & PrEP



REFERENCE LIST

(WHERE A URL IS NOT OTHERWISE LISTED, THE CITED CODES CAN BE FOUND AT

[HTTPS://WWW.PHARMACY.CA.GOV/LAWS REGS/LAWBOOK.PDF](https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) .)

1. BPC § 4052, 4052.02, 4052.03; HSC § 1342.71; Ins. Code § 10123.1933; WIC § 14132.968
2. BPC § 2242(a), 21 USC § 829(e)(2)(B)(i)
3. BPC § 740, 741 adopted as emergency legislation effective on governor's signature 9/6/19
4. HSC § 11159.3
5. BPC § 2290.5; HSC § 1374, 1374.14; WIC § 10123.855, 14132.725
6. BPC § 4126.8
7. HSC § 11164.1, 11165, 11165.1, and 11165.4
8. BPC § 4062, 4132
9. BPC § 4115.5, 4163, 4200, 4211, 4400
10. HSC § 134000 et. seq.
11. . BPC § 4079
12. WIC § 14197.6
13. WIC § 14132.723, 14132.724
14. HSC § 1649 et. Seq
15. BPC § 3500 et. seq.
16. HSC § 120370 et. seq., HSC § 120375, HSC § 12044
17. HSC § 120370 et. seq
18. Lab. Code § 2750.3, 3351; UIC § 606.5, 621
19. BPC § 4052.8
20. Lab. Code § 6403.3
21. HSC 131021, Lab. Code 6403.1
22. BPC § 650.01; 805, 805.5; 2837.100 et. seq.
23. BPC § 650.01, 2746.2, 2746.5, 2746.51, 2746.52, 2746.54, 2746.55; HSC § 102415, 102426, 102430
24. HSC § 127690 et. seq.
25. BPC § 139.5
26. BPC § 4145.5; HSC § 11364
27. WIC § 14132.100
28. WIC § 5346, 5347, 5348, 5349, 5349.1
29. Pen. Code § 3405, 3406, 3408, 3409; 4023.5, 4023.6, 4023.8, 4028
30. CCR §1749
31. CCR §1746.3
32. CCR §1747

REFERENCE LIST (CONTINUED)

(WHERE A URL IS NOT OTHERWISE LISTED, THE CITED CODES CAN BE FOUND AT

[HTTPS://WWW.PHARMACY.CA.GOV/LAWS REGS/LAWBOOK.PDF](https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) .)

33. CCR § 1714.3
34. CCR §1706.2
35. CCR §1707.2
36. Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision - Immunizations – Effective through October 20, 2020 -
<https://www.pharmacy.ca.gov/licensees/waivers/4114.shtml>
37. Duty to Consult – Effective through December 28, 2020 -
https://www.pharmacy.ca.gov/licensees/waivers/1707_2_a.shtml
38. Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators – Effective through December 28, 2020 -
https://www.pharmacy.ca.gov/licensees/waivers/1751_5.shtml
39. Remote Processing – Effective through October 31, 2020 –
https://www.pharmacy.ca.gov/licensees/waivers/4071_1_a.shtml
40. Signature Requirement for Receipt of Delivery of Drugs – Effective through December 21, 2020 –
https://www.pharmacy.ca.gov/licensees/waivers/4059_5.shtml
41. Prescriber Dispensing Medication to Emergency Room Patient – Effective through December 21, 2020 –
https://www.pharmacy.ca.gov/licensees/waivers/4068_a_1_4068_a_5_and_4068_a_6.shtml
42. Requirements Related to PPE – Effective through December 21, 2020 -
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43. <https://www.gov.ca.gov/2020/05/12/governor-newsom-announces-california-has-conducted-over-1-million-diagnostic-tests-for-covid-19-as-testing-capacity-ramps-up>
44. Guidance on COVID-19 Testing Under Executive Orders N-25-20, N-39-20 and N-75-20, and DCA Waiver DCA-20-
https://www.dca.ca.gov/licensees/dca_20_45_guidance.pdf

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