

MIEC New Law Alert

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New Law Alert – California

INSIDE

DEA reschedules hydrocodone combination products from Schedule III to Schedule II effective October 6, 2014.....1

Continuing medical education: sexual orientation, gender identity, and gender expression2

Medi-Cal managed care: language assistance services2

Medical care: electronic treatment authorization.....2

Telehealth.....2

Personal information: privacy.....2

Medical information.....3

Hypodermic needles and syringes ...3

Medical Assistants3

Medical Board of California.....3

End-of-life-care: patient notification4

Physician Assistants: disability certifications.....4

All laws are effective January 1, 2015, unless otherwise specified.

DEA reschedules hydrocodone combination products from Schedule III to Schedule II effective October 6, 2014

Federal Register/Vol. 79, No. 163/21 C.F.R. Part 1308; Friday, August 22, 2014/Rules and Regulations; Cal. Bus. & Prof. Code §3501.2; 16 C.C.R. §1399.545

The Drug Enforcement Agency has issued new regulations, effective October 6, 2014, that classify all hydrocodone combination products (HCPs) as Schedule II drugs. HCPs are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. All pharmaceuticals containing hydrocodone currently on the market in the United States are now considered to be Schedule II drugs. These products are approved for marketing for the treatment of pain and for cough suppression.

As a reminder, prescriptions for Schedule II drugs are subject to detailed requirements, and may not be faxed, e-mailed, or orally prescribed except under emergency and certain other circumstances. In addition, Schedule II prescriptions are valid for six months from the date of issuance by the prescriber and cannot be refilled. State and

federal law allow a physician under specified conditions to issue multiple prescriptions authorizing the patient to receive a total of up to a ninety-day supply of Schedule II controlled substances provided that the individual practitioner writes instructions on each prescription indicating the earliest date on which a pharmacy may fill each prescription.

Physicians who supervise PAs, who issue drug orders for HCPs on a physician’s behalf, should update their written supervisory protocols to include HCPs as Schedule II drugs. Each supervising physician who delegates the authority to issue a drug order to a PA shall first prepare and adopt, or adopt, a written, practice-specific formulary and protocols that specify all criteria for the use of a particular drug or device and any contraindications for the selection. Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or the condition for which the Schedule II controlled substance is being administered, provided, or issued. The medical record of any patient for whom a PA has issued a Schedule II drug order must be reviewed and countersigned by a supervising physician within 7 days. California law provides that the supervising physician shall be responsible for all medical services provided by a PA under his or her supervision.

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For further information, contact Imelda L. Paredes, Office of Diversion Control, DEA, Telephone (202) 598-6812

Continuing medical education: sexual orientation, gender identity, and gender expression

AB 496 (Gordon)
Business & Professions Code §2190.1

Under the existing Medical Practice Act, a physician and surgeon is required to demonstrate satisfaction of continuing education requirements, including curriculum on cultural and linguistic competency. Cultural competency is defined as a set of integrated attitudes, knowledge, and skills that enables a health care professional or organization to care effectively for patients from diverse cultures, groups, and communities. Existing law recommends that instruction on cultural competency, at a minimum, include among other things, understanding and applying cultural and ethnic data to the process of clinical care. The new law expands on the concept of “cultural and ethnic data” to include, as appropriate, information pertinent to the appropriate treatment of, and provision of care to, the lesbian, gay, bisexual, transgender, and intersex communities.

Medi-Cal managed care: language assistance services

AB 505 (Nazarian)
Welfare & Institutions Code §§14029.91, 14712

This new law requires all managed care plans contracting with the State Department of Health Care Services (DHCS) to provide language assistance services to limited-English-proficient (LEP) Medi-Cal beneficiaries who are mandatorily enrolled in managed care. The statute defines an LEP person as one who “speaks English

less than very well.” Oral interpretation services must be provided in any language on a 24-hour basis at key points of contact. Translation services must be provided to the language groups identified by the Department. The Department must determine when an LEP population meets the requirement for translation services using a defined numeric threshold.

This provision does not apply to managed mental health plans for Medi-Cal beneficiaries.

Medical care: electronic treatment authorization

SB 1457 (Evans)
Welfare & Institutions Code §14133.01; Health & Safety Code §§123929 and 125185
Effective July 1, 2016, or a later date determined by DHCS

Will require requests for authorization for treatment of services in the Medi-Cal program, California Children’s Services (CCS) Program, and the Genetically Handicapped Persons Program (GHPP) to be submitted in an electronic format determined by the Department of Health Care Services (DHCS) via DHCS’ website or other electronic means designated by DHCS. Will require DHCS to implement an alternate format for submission when DHCS’ website is unavailable due to a system disruption.

Telehealth

AB 809 (Logue)
Business & Professions Code §2290.5
Effective September 18, 2014

Existing law required a health care provider at the originating site [where the patient is located] to verbally inform the patient that telehealth may be used and obtain verbal consent from the patient for this use.

The new law eliminates the requirement that consent be obtained only at the originating site. Consent must now be obtained by the health care provider “initiating the use of telehealth.” Consent may be given either verbally or in writing, but must still be documented in the patient’s chart. The provider must inform the patient about the use of telehealth and obtain consent for the use of telehealth as an acceptable mode of delivering health care services and public health. This eliminates the need to receive consent for each individual use of telehealth and instead apply that one-time consent to further treatment.

Personal information: privacy

AB 1710 (Dickinson)
Civil Code §1798.82

California law requires that in the event a person or business who owns or licenses computerized data that includes personal information discovers a breach in security of the data, the breach must be disclosed to any California resident whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person. Notifications of breach must meet several requirements, such as providing notice in plain language and including the types of personal information breached.

Under the new law, the security and reporting requirements are extended to persons and entities that maintain such information. In addition, if the information breached includes the California resident’s name and social security number, and the person or business providing the notice was the ‘source of the breach,’ then the notification must include an offer to provide appropriate identity theft prevention and mitigation services for not less than 12 months at no

cost to the affected person. For entities covered by HIPAA, however, the content of the notification need only comply with federal law, which does not require an offer for free identity theft protection.

Medical information

AB 1755 (Gomez)
Health & Safety Code §1280.15

Existing law requires a clinic, health facility, home health agency, or hospice to prevent unauthorized access, use or disclosure of patients' medical information, and breaches must be reported to the patient (or the patient's representative) and to the State Department of Public Health. The new law extends the deadline for reporting from five business days to no later than fifteen business days after the breach is detected. The new law authorizes the report made to the patient or patient's representative by alternative means, including e-mail, but only if the patient has previously agreed in writing to those alternative means of notification.

The Department now has full discretion to determine whether to investigate reported breaches and determine whether any administrative penalty should be imposed.

(Note: Clinic, health facility, home health agency and hospice are defined in Health & Safety Code §§1204; 1250; 1727; and 1746.)

Hypodermic needles and syringes

AB 1743 (Ting)
Business & Professions Code §4145.5; Health & Safety Code §11364

Existing law provides that it is unlawful to possess an opium pipe or any device used for unlawfully injecting controlled substances, with the exception of properly containerized hypodermic needles or syringes. A person age 18 or

older may be provided with hypodermic needles and syringes by a pharmacist or physician solely for his or her personal use if the person is known to the furnisher and the furnisher has previously been provided with a prescription or other proof of legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment. Previous law allowed possession or furnishing of up to 30 hypodermic needles for personal use as a public health measure to prevent the spread of bloodborne diseases.

The new law provides that there is no upper limit to the number of hypodermic needles or syringes that may be provided or possessed for personal use, if acquired from a physician, pharmacist, hypodermic needle exchange program, or any other source authorized by law to provide sterile syringes or hypodermic needles without a prescription.

In addition, pharmacies and needle exchange programs must now counsel consumers on safe disposal, as well as provide one or more specified disposal options. The new law is in effect until January 1, 2021.

Medical Assistants

AB 1841 (Mullin)
Business & Professions Code §§2069(b)(4)(B), 4180, 4190

The Medical Practice Act currently authorizes a medical assistant to administer medication only by intradermal, subcutaneous, or intramuscular injections and to perform skin tests and additional technical support services upon the specific authorization and supervision of a licensed physician and surgeon, a licensed podiatrist, a physician assistant, a nurse practitioner, or a certified nurse midwife.

Under the new law, the scope of practice for medical assistants

working at certain clinics authorized to purchase and dispense wholesale prescription drugs has been expanded to specify that a medical assistant may "hand to a patient" a properly labeled and prepackaged prescription drug, other than a controlled substance, ordered by a licensed physician, podiatrist, physician assistant, nurse practitioner, or certified nurse midwife. In "every instance," however, prior to handing the medication to a patient, the properly labeled and prepackaged prescription drug must have the patient's name affixed to the package and a licensed physician, podiatrist, physician assistant, nurse practitioner or certified nurse midwife must verify that it is the correct medication and dosage for that specific patient and must provide the appropriate patient consultation regarding use of the drug.

Medical Board of California

AB 1886 (Eggman)
Business & Professions Code §§2027, 2233

This new law makes a number of revisions to the information about physicians that will be posted on the website of the Medical Board of California (The Board). The revisions include:

- Settlements will now be posted for five, instead of ten, years, if there are three or more settlements within the last five years for licensees in the "low risk" categories, and four or more settlements for licensees in the "high risk" category.
- The Board will post information related to the "current" status of all current and former licensees, including whether or not the licensee is in good standing, current Board certification status, and enforcement actions and proceedings to which the

licensee is “actively subjected,” including temporary restraining orders, interim suspension orders, restrictions ordered by other states or jurisdictions, and current accusations.

- The Board will post “historical” information concerning current and former licensees indefinitely, including approved postgraduate training, revocations, suspensions or probation imposed in California or other jurisdictions, malpractice judgments, summary of final discipline by hospitals, and felony and certain misdemeanor convictions, public letters of reprimand issued within the last ten years, and citations issued within the last three years.

End-of-life-care: Patient notification

AB 2139 (Eggman)
Health & Safety Code §§442.5 and 442.7

Existing law provided that when a patient is diagnosed with a terminal illness, the health care provider must provide the patient, upon request, with “comprehensive information and counseling regarding legal end-of-life care options” as described by statute. The new law requires that when a terminal illness diagnosis is made, the health care provider must advise the patient (or patient’s representative) of their right to receive comprehensive information and counseling, whether the patient asks or not. This notification may be made at the time of diagnosis or at a subsequent visit in which the provider discusses treatment options. Of course, the comprehensive information and counseling must still be provided if requested by the patient or patient’s representative.

As before, the information and counseling must include information related to:

- Hospice care at home or in a health care setting.
- A prognosis with and without the continuation of disease-targeted treatment.
- The patient’s right to refusal of or withdrawal from life-sustaining treatment.
- The patient’s right to continue to pursue disease-targeted treatment, with or without concurrent palliative care.
- The patient’s right to comprehensive pain and symptom management at the end of life, including, but not limited to, adequate pain medication, treatment of nausea, palliative chemotherapy, relief of shortness of breath and fatigue, and other clinical treatments useful when a patient is actively dying.
- The patient’s right to give individual health care instruction pursuant to Probate Code § 4670, which provides the means by which a patient may provide written health care instruction, such as an advance health care directive, and the patients’ right to appoint a legally recognized health care decision maker.
- The new law has also clarified that the notification of the right to receive information and counseling need not be made if the patient or authorized decision maker has already received it. These requirements will not be construed to interfere with the clinical judgment of a health care provider in recommending a course of treatment.
- As before, if the health care provider does not wish to provide information on end-of-life options to the patient or the patient’s designated decision

maker, the provider must refer or transfer the patient to another health care provider that shall provide the information and provide the patient or the patient’s representative with information on procedures to transfer to another health care provider.

Physician Assistants: disability certifications

SB 1083 (Pavley)
Business & Professions Code §3502.3; Unemployment Insurance Code §2708(e)(2)(B)

Existing law requires a claimant for unemployed compensation disability benefits to establish medical eligibility for each uninterrupted period of disability by filing a first claim for disability benefits supported by the certificate of a treating physician or practitioner that establishes the sickness, injury, or pregnancy of the employee, or the condition of the family member that warrants the care of the employee. Physician Assistants are now included in the definition of a “practitioner” authorized to certify disability. The certification may be done after performance of a physical examination under the supervision of a physician and surgeon pursuant to a delegation of services agreement.

We thank Sonja Dahl, Esq. of Donnelly Nelson Depolo & Murray, APC, Walnut Creek, California, for her review of this edition of New Law Alert.