

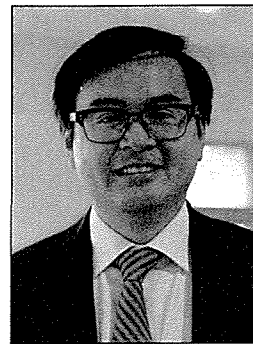
Annual Health Law Review for 2016

Long X. Do, Gabriel Ravel, Carol D. Scott, and H. Thomas Watson

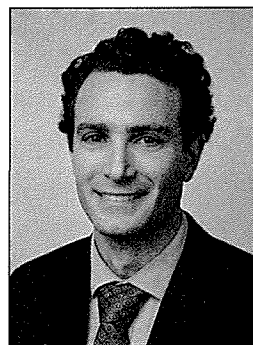
The health law sector continued to develop in significant ways in 2016. The biggest changes came at the November ballot box with California voters passing four (4) of the six (6) voter-initiated statewide propositions related to health care. Proposition 52, which passed overwhelmingly, makes permanent a hospital Medi-Cal fee program that generated nearly \$3 billion annually in federal matching funds. Proposition 55, which also passed overwhelmingly, continues high-income personal income tax rates that generated revenue allocated in part to health care. Voters passed Proposition 56 to increase the cigarette tax by \$2 per pack, and the income generated from the tax is primarily earmarked for increasing Medi-Cal provider reimbursement. Proposition 64 also passed, which legalizes and regulates the recreational use of marijuana.

In addition to the statewide propositions initiated by voters, the Legislature passed more than 150 bills in 2016 related to health care law. In particular, there was a strong focus in the Legislature on health care coverage, drug prescribing, and public health. These bills did not grab news headlines like the statewide propositions that passed in 2016 or bills that passed in 2016, which included numerous landmark legislation on controversial subjects such as end-of-life care and the elimination of a broad exemption for school vaccinations. Nonetheless, this year many significant new laws take effect and those laws will have a widespread and deep impact on the provision of health care, health care providers, and consumers.

Whereas the California Supreme Court resolved only one case involving health care law in 2015, it decided three in 2016. In *Flores v. Presbyterian Intercommunity Hospital*,¹ the court again delved into the Medical Injury Compensation Reform Act to examine the applicability of the one-year statute of limitations for professional



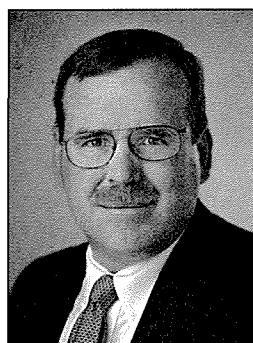
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negligence. In an opinion issued two weeks later, in *Winn v. Pioneer Medical Group, Inc.*,² the court resolved questions about the applicability of the Elder Abuse Act to outpatient settings. Rounding out the year, in *Centinela Freeman Emergency Medical Associates v. Health Net of California, Inc.*,³ the court applied tort principles in the context of health plan delegation to risk-bearing organizations to recognize a cause of action for negligent delegation and negligent continuation of a delegation.

The intermediate courts of appeal created precedents in a wide variety of health care decisions, including medical tort and MICRA, hospital - medical staff relationships, and medical confidentiality.

Finally, the state regulatory landscape has continued to shift with implementation of health care reform and other projects to modernize the health care delivery system during 2016. California's health care regulators continued to promulgate and develop important regulations.

I. Notable Legislation

A. Opioids

S.B. 482, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 708)

Senate Bill 482 reflects a continuing public concern about the number of people who die every year from prescription opioid overdoses. In order to address these concerns, California's Department of Justice has implemented a database known as the Controlled Substance Utilization Review and Evaluation System (CURES) to permit the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances. Pharmacies and other facilities that furnish these controlled substances must timely enter the prescription information into CURES, and physicians are mandated to register with the database. Senate Bill 482 imposes a new requirement on physicians to consult the CURES database and review a patient's prescription history no earlier than 24 hours, or the previous business day, before prescribing a Schedule II, III, or IV controlled substance. In addition, physicians must check the CURES database every time they prescribe a controlled substance for the first time to a patient and every four (4) months while the patient is on the drug. The bill contains certain exceptions to these requirements, such as when patients are in the hospital or undergoing certain surgical procedures, or the drug is prescribed for use on the premises of certain types of health care facilities if the quantity of the controlled substance does not exceed a nonrefillable five-day supply to be used in accordance with the directions for use.

B. Mental Health

Assemb. B. 1808, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 292)

Existing law authorizes a minor who is twelve years of age or older to consent to outpatient mental health treatment or counseling services, if in the opinion of the attending professional, the minor is mature enough to participate intelligently in those services. Assembly Bill 1808 vastly extends the definition of who qualifies as a "professional person" to include a marriage and family therapist trainee; a clinical counselor trainee; a registered psychologist; a registered psychological assistant; a psychology trainee; an associate clinical social worker; and a social work intern, while working under the supervision of certain licensed professionals, as long as the professional notifies their supervisor, or an on-call supervisor at the site where they volunteer or are employed, within twenty-four hours of treating or counseling a minor.

C. Hospitals

Several new laws are directed at hospitals, ranging from the information they provide to patients to their relationship with physicians.

S.B. 1076, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 723)

Senate Bill 1076 requires hospitals to provide more accurate information to patients who are placed on observation status in hospitals. There has been a great deal of controversy over the use of observation status for patients who are unstable or have other uncertain conditions that are serious enough to require close observation in a hospital setting but not serious enough to warrant an inpatient admission. Observation status has an impact on the hospital's reimbursement rates and the patient's out-of-pocket costs (co-pays, coinsurance, etc.). Moreover, an outpatient stay will not qualify the patient for Medicare nursing home coverage, in contrast to a three-day inpatient hospital stay. Federal law already requires hospitals to tell their Medicare patients when they are an outpatient on observation status, the reasons why they have not been admitted, and the cost of care and insurance coverage implications of observation status. Senate Bill 1076 makes California law protecting health plan and health insurer patients consistent with federal

law. The new law requires all California hospitals to provide for adequate signage to advise patients that they are in an observation unit, requires hospitals to provide written notice to patients that they are under observation status and have not been formally admitted as a hospital inpatient, and requires observation units to meet minimum licensed nurse-to-patient staffing ratios.

S.B. 1365, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 501)

As medical groups are being acquired by or affiliated with hospitals or hospital systems, many physicians have shifted their practices to hospital-based clinics which are not located in the hospital. Such clinics charge a facility fee in addition to the professional fee or charge higher prices than a physician's office. In many instances, patients do not know that they are in a hospital-based clinic and not a physician's office and are surprised when they receive a bill that includes a facility fee in addition to the fees for professional services. Senate Bill 1365 requires a general acute care hospital to provide a written notice to patients treated in a hospital-based clinic notifying the patient that the services are being provided in a hospital-based clinic and may have higher costs than if the patient had obtained the services in a clinic or facility that is not hospital-based. Hospitals must also advise patients that they have the option to check with the hospital to see if the services are provided in a location that is not hospital-based or can contact their insurance company for other locations that may charge less for the services.

Assemb. B. 2024, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 496)

Most California hospitals are prohibited from directly employing physicians under a century-old law known as the bar or ban on the corporate practice of medicine. There are numerous exceptions to this prohibition, including a new one established under Assembly Bill 2024 intended to help hospitals in rural areas of California to recruit physicians. The new law, until January 1, 2024, authorizes a federally-certified critical access hospital to employ physicians or podiatrists and charge for the professional services rendered by those medical professionals. However, the critical access hospital's medical staff must concur with the employment by an affirmative vote determining that the doctor's employment is in the best interest of the communities

served by the hospital and the hospital must ensure that it does not direct or interfere with the doctor's professional judgment.

D. Health Insurance and Health Plans

Assemb. B. 1668, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 684)

Known colloquially as the "Right to Try" Act, Assembly Bill 1668 permits manufacturers of investigational drugs, biological products, and devices (that are not FDA-approved) to make such products available to eligible patients with serious or immediately life-threatening diseases or conditions, and authorizes, but does not require, health plans to provide coverage for such drugs and devices. Eligible patients are those who have considered all other treatment options currently approved by the FDA and have been unable to participate in any relevant clinical trial. The new law also prohibits state licensing boards from taking disciplinary action against a physician who recommends, prescribes, treats, or otherwise furnishes the investigational drug to a patient, so long as the physician acts consistently with protocol approved by the physician's institutional review board or an accredited institutional review board.

Assemb. B. 72, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 492)

Assembly Bill 72 tackles a problem colloquially known as "surprise bills" when a patient receives treatment at in-network hospitals. Although the hospital may be a part of the patient's insurance of health plan network, various individual providers who render service to the patient (e.g., an anesthesiologist on the surgery team) may not be part of the network. Patients thus may incur significant, unintended out-of-network costs even though they are receiving services at an in-network facility. Assembly Bill 72 provides that the patient would only be responsible for in-network copays or coinsurance amounts for nonemergency services in these circumstances, including services provided by out-of-network providers. In addition, the patient would be responsible for out-of-network costs only if he or she provides written consent. Assembly Bill 72 also establishes a process for determining how out-of-network providers in these situations are to be paid by the patient's

health plan or insurer and creates an independent dispute resolution process for claim disputes.

E. Physician Health and Well-Being

S. B. 1177, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch.591)

Sponsored by the California Medical Association, Senate Bill 1177 authorizes the Medical Board of California (MBC) to establish a nondisciplinary Physician and Surgeon Health and Wellness Program designed for early identification and intervention of substance abuse in physicians and to provide for appropriate monitoring and support for physician rehabilitation if substance abuse is identified. While the MBC is given leeway in designing the details of the program, the new law requires that program participants must enter into strict agreements that specify treatment protocol, monitoring, and laboratory tests, and that the monitoring and tests are to be paid by the participating physician. The law also provides that failure to satisfy these requirements could lead to investigation and disciplinary action by the MBC against the physician.

F. Public Health

Assemb. B. 1554, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 742)

S.B. 819, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 778)

A couple of new laws are directed at the growing problem with powdered alcohol, an unregulated substance that is sold or provided in crystalline form. Powdered alcohol, which can be taken directly or mixed with water, can be extremely potent and susceptible to overdose. Assembly Bill 1554 prohibits the California Department of Alcoholic Beverage Control (ABC) from issuing a license to anyone or entity to manufacture, distribute, or sell powdered alcohol. The new law also broadly prohibits the possession, purchase, sale, distribution, manufacture, or use of powdered alcohol. Senate Bill 819 contains similar prohibitions concerning powdered alcohol and requires the ABC to revoke the license of any licensee who manufactures, distributes, or sells powdered alcohol.

Assemb. B. 1954, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 495)

Assembly Bill 1954, also known as the Direct Access to Reproductive Health Care Act, is an important law for access to health care services in that it prohibits health care service plans and health insurers from requiring an enrollee to obtain a referral as a condition for payment for reproductive and sexual health care services.

S.B. x2-5, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 7)

S.B. x2-7, 2015-2016 Reg. Sess. (Cal. Stats. 2016, ch. 8)

Tobacco and electronic cigarettes remain a focus of public health and medical professionals. Two new laws focus on these products, particularly in regard to minors under the age of 21. Senate Bill x2-5 expands the definitions of “smoking” and “tobacco products” under the Stop Tobacco Access to Kids Enforcement Act to include electronic devices, such as electronic cigarettes, that deliver nicotine or other vaporized liquids. This new law now makes it a misdemeanor to furnish e-cigarettes to minors. Senate Bill x2-7 also extends the applicability of the Stop Tobacco Access to Kids Enforcement Act to e-cigarettes and authorizes the California Department of Public Health to conduct random, onsite sting inspections of tobacco product retailers.

II. Significant Health Law Decisions

A. California Supreme Court Decisions

1. *Centinela Freeman Emergency Medical Associates v. Health Net of California, Inc.*, 1 Cal. 5th 994 (2016) (HMOs owe common-law duties when delegating the obligation to make payments to emergency care providers for enrollees' care)

Emergency healthcare providers are required to treat patients regardless of their ability to pay under both federal and state law, and therefore they sometimes treat enrollees of an HMO with whom they have no contractual relationship. In that event, California law obligates the HMO to reimburse the providers for the emergency treatment, but the HMO is permitted by statute to delegate this obligation to individual practice associations (IPAs).

A delegation absolves the HMO of statutory liability for unpaid claims by the delegated IPA.⁴

In *Centinela Freeman*, noncontracting emergency service providers whose fees were not paid by financially struggling (and later insolvent) IPAs sued HMOs for negligently delegating to those IPAs the HMOs' obligation to pay for the emergency services provided to the HMOs' enrollees. The superior court sustained the HMOs' demurrers. The court of appeal reversed, holding in part that providers could properly plead claims against the HMOs for negligent initial delegation, and negligent failure to continually monitor IPAs' fulfillment, of the obligation to pay for HMO enrollees' emergency medical expenses.

The supreme court granted review and affirmed the court of appeal. The supreme court noted that the providers had no direct cause of action against the HMOs under the Knox-Keene Act, subsequent legislative amendments, or implementing regulations. But the supreme court rejected an argument that this scheme of statutes and regulations displaced common-law remedies. Instead, the supreme court held that the HMOs owe providers common-law tort duties based on the factors identified in *Biakanja v. Irving*,⁵ because: (1) the HMOs' delegation to the IPAs was intended to affect providers; (2) the harm to the providers was foreseeable because the HMOs knew or should have known the IPAs were struggling or insolvent; (3) the injury to the providers (non-payment) was undisputed; (4) the HMOs' delegation was closely connected to that injury; (5) the HMOs' conduct was morally blameworthy; and (6) recognizing a common-law duty would advance the public policy of preventing future economic harm to noncontracting emergency care providers.

2. *Flores v. Presbyterian Intercommunity Hospital*, 63 Cal. 4th 75 (2016) (The limitations period for professional, not ordinary, negligence applies to injury resulting from equipment used to implement doctor's orders)

Code of Civil Procedure section 340.5, the statute of limitations for actions based on alleged professional negligence enacted as part of the Medical Injury Compensation Reform Act of 1975 (MICRA), is three years after the date of injury, or one year after the plaintiff discovers, or reasonably should have discovered, the

injury, whichever occurs first. For claims of general negligence, the statute of limitations under Code of Civil Procedure section 335.1 is two years.

In *Flores*, the plaintiff sued a hospital for negligence, seeking damages for injuries she sustained (more than one year before filing suit) when a side rail on her hospital bed collapsed and she fell. The hospital demurred, arguing that MICRA's one-year statute of limitations for professional negligence barred the action. The trial court sustained the hospital's demurrer without leave to amend. Plaintiff appealed, arguing that the accident amounted to general (not professional) negligence, which is subject to the two-year statute of limitations. The court of appeal reversed, holding that the action was based on general negligence because the bed rail did not collapse while the hospital was rendering professional services.

The California Supreme Court granted review and reversed the court of appeal. The supreme court held that "if the act or omission that led to the plaintiff's injuries was negligence in the maintenance of equipment that, under the prevailing standard of care, was reasonably required to treat or accommodate a physical or mental condition of the patient, the plaintiff's claim is one of professional negligence under section 340.5." Under this test, the supreme court indicated that professional negligence would not apply if a person was injured when a chair collapsed in a hospital waiting room. However, the bed rail collapse in this case was different because a doctor had assessed plaintiff's condition and made a medical decision to order the rails on her bed raised. Accordingly, the court applied the professional negligence statute of limitations, which barred plaintiff's claim.

3. *Winn v. Pioneer Medical Group, Inc.*, 63 Cal. 4th 148 (2016) (An elder abuse neglect claim may not be asserted unless the defendant assumed significant responsibility for attending to the basic needs of an elder or dependent adult)

Under the Elder Abuse Act, liability for neglect is based on "[t]he negligent failure of any person having the care or custody of an elder or a dependent adult to exercise that degree of care that a reasonable person in a like position would exercise."⁶

In *Winn*, the defendants provided outpatient medical care to plaintiffs' mother, who suffered from vascular

disease. Although her condition worsened over two years, defendants never referred her to a vascular specialist. Ultimately, she developed gangrene, underwent amputations, and died from complications. The plaintiffs sued for elder abuse. The trial court sustained the defendants' demurrer, ruling that plaintiffs failed to adequately allege that the defendants denied their mother needed care in a reckless manner, and that the professional negligence allegations could not support an elder abuse action. The court of appeal reversed, holding that an elder abuse claim does not require the defendant healthcare provider to have a custodial relationship with the patient, and that plaintiffs had sufficiently alleged reckless conduct such that the issue should be decided by a jury.

The supreme court granted review and reversed the court of appeal. It held that the Elder Abuse Act required the existence of a custodial relationship to establish a cause of action for neglect, and no custodial relationship was established by the defendants providing patients with medical treatment at an outpatient facility. The supreme court explained that a caretaking or custodial relationship under section 15610.57 of the Welfare and Institutions Code arises when an elder or dependent adult depends on another for the provision of some or all of his or her fundamental needs that a fully competent adult would ordinarily be capable of managing without assistance. It rejected the plaintiff's argument that the Elder Abuse Act neglect standard applied whenever a physician provides medical treatment to an elderly patient at an outpatient facility, believing that "[r]eading the act in such a manner would radically transform medical malpractice liability relative to the existing scheme." Accordingly, because plaintiffs' complaint failed to include sufficient factual allegations showing that the decedent "relied on defendants in any way distinct from an able-bodied and fully competent adult's reliance on the advice and care of his or her medical providers," the complaint was insufficient to support an elder abuse cause of action.

B. Select California Court of Appeal Decisions

1. Medical tort liability

Glennen v. Allergan, Inc., 247 Cal. App. 4th 1 (2016), holds that state-law claims involving medical devices are preempted by the federal Food, Drug, and

Cosmetics Act (the "FDCA") unless the claim is premised on conduct that both violates the FDCA and would give rise to recovery under state law even in the absence of the FDCA.

Fenimore v. Regents of the University of California, 245 Cal. App. 4th 1339 (2016), held that a colorable elder abuse claim may be based on a hospital's pattern of understaffing in violation of applicable regulations.

Tenet Healthsystem Desert, Inc. v. Blue Cross of California, 245 Cal. App. 4th 821 (2016), held that a colorable fraud claim may be asserted against an insurer that repeatedly authorized a hospital to provide a patient with services and made misleading communications regarding coverage before denying coverage for the services.

Pipitone v. Williams, 244 Cal. App. 4th 1437 (2016), held that physicians who treated the victim of a future domestic homicide for a foot injury owed no duty to report domestic abuse where there was no evidence they harbored any reasonable suspicion of abuse.

2. Medical Injury Compensation Reform Act (MICRA)

Drexler v. Petersen, 4 Cal. App. 5th 1181 (2016), found that, where defendants allegedly fail to diagnose a preexisting condition, there is no "injury" for purposes of the MICRA statute of limitations until "the plaintiff first experiences appreciable harm as a result of the misdiagnosis, which is when the plaintiff first becomes aware that a preexisting disease or condition has developed into a more serious one."

Nava v. Saddleback Memorial Medical Center, 4 Cal. App. 5th 285 (2016), held a tort claim stemming from a patient's fall from a gurney sounded in professional negligence because gurney transfer was integrally related to medical diagnosis or treatment, and therefore the applicable limitations period was one-year from the injury under Code of Civil Procedure section 340.5.

3. Medical staff, employment, and agency

Markow v. Rosner, 3 Cal. App. 5th 1027 (2016), held that a non-emergency patient who signed numerous forms stating that his treating physician was an independent contractor could not recover from the hospital on ostensible agency theory.

Armin v. Riverside Community Hospital, 5 Cal. App. 5th 810 (2016), held that a doctor is permitted to file a whistleblower claim under Health and Safety Code section 1278.5 before peer review proceedings are complete, but such claims may only be filed against a hospital or hospital medical staff as an entity, not against individual physicians involved in the peer review.

Unilab Corporation v. Angeles-IPA, 244 Cal. App. 4th 622 (2016), held that an independent physician association (IPA) is not responsible for the cost of laboratory tests on specimens that were misdirected to non-contracted laboratories due to physician oversight or error.

4. Medical confidentiality

Kirchmeyer v. Phillips, 245 Cal. App. 4th 1394 (2016), held that the medical records of a patient who allegedly had a sexual relationship with her psychiatrist were protected from discovery by the psychotherapist-patient privilege because the medical board failed to show a compelling interest justifying production of medical records where other non-privileged evidence of the sexual relationship was available.

Fett v. Medical Board of California, 245 Cal. App. 4th 211 (2016), found that the trial court may enforce an administrative investigative subpoena seeking medical records where the evidence is needed to determine whether records were missing or altered, no exclusionary rule prevented improperly obtained evidence from being used to launch an administrative investigation, the government's compelling interest in protecting the public by ensuring medical care provided by board-certified practitioners meets the industry's standard of care outweighed the patients' privacy interests, and the subpoena sought only three years of records.

5. Medical billing

Moran v. Prime Healthcare Management, Inc., 3 Cal. App. 5th 1131 (2016), held that an uninsured patient adequately alleged facts supporting his claim that unconscionably excessive hospital bills for self-pay patients violated California's Unfair Competition Law (UCL) and Consumer Legal Remedies Act (CLRA), but his price discrimination claim was barred by a safe harbor provision in Business and Professions Code section 17042.

6. Procedural issues

Humboldt County Adult Protective Services v. Super. Ct., 4 Cal. App. 5th 548 (2016), held that a trial court abused its discretion by refusing to award attorney fees to a respondent who successfully moved to dismiss a petition under the Health Care Decisions Law to revoke her dying husband's advance care directive that was based on concealed evidence, an incomplete discussion of law, and exhibits containing multiple level of hearsay that lacked proper foundation.

Sutter Health v. Eden Township Healthcare District, 6 Cal. App. 5th 60 (2016), held that evidence a healthcare district would be forced into bankruptcy if required to satisfy a lump sum judgment constitutes an unreasonable hardship that allowed it to satisfy the judgment in installment payments at a reduced interest rate under the Government Code, but the lower interest rate applied prospectively only and did not affect interest that already accrued on the initial judgment at the higher rate.

III. Regulations Update

Some highlights from actions by the Department of Managed Health Care (DMHC), which regulates licensees under the Knox-Keene Act, are listed below.

A. Consumer Participation Program

The DMHC updated its regulations respecting its Consumer Participation Program, whereby it provides compensation to entities that assist the DMHC in significant proceedings on behalf of consumers. This program was initially authorized by the Legislature in 2002. The new regulation streamlined and simplified the process to apply for eligibility to participate and to request an award of fees. These changes went into effect January 1, 2016.

B. Financial Solvency Regulations

The DMHC updated its financial solvency regulations to increase the required deposit for specialized plans from \$50,000 to \$150,000, in order to more accurately reflect the cost of providing continuity of care for enrollees, reimbursing providers, and financing an orderly wind-down of a specialized plan in the event of failure. Additionally, the regulations replaced references to outdated accounting methodologies and forms. These changes became effective April 1, 2016.

C. Essential Health Benefits

The DMHC's Essential Health Benefits regulations were amended to comply with requirements from the new benchmark plan selected under Senate Bill 43, 2015-2016 Reg. Sess. and to implement federal guidance regarding nondiscrimination. Specifically, the pediatric oral, pediatric vision, and habilitative services benefits were amended to comply with state legislation, and the per se age limit on aphakia lens benefits was removed. The emergency regulation package that included these amendments became effective on November 28, 2016.

D. Consumer Participation Program

The regulation concerning the Prescription Drug Prior Authorization and Step Therapy Exception Request Standard Form is in its second regulatory comment period. While prior authorization has been shown to be effective in controlling prescription drug costs, the lack of uniformity between health plans' prior authorization processes can delay and negatively impact patient care. Previous law established a standardized prior

authorization form and process, but it did not account for new technology and alternative methods of transmitting prior authorization requests. This proposed regulation package in process will allow providers to use an electronic process for transmitting prior authorization information that meets the NCPDP's SCRIPT standards. Additionally, the new regulation will exempt certain delegated provider groups from the requirement to use the standard form. The second comment period closed on December 29, 2016, and the DMHC expects the revised regulation to become effective early in 2017.

Endnotes

- 1 63 Cal. 4th 75 (2016).
- 2 63 Cal. 4th 148 (2016).
- 3 1 Cal. 5th 994 (2016).
- 4 *See Ochs v. PacifiCare of Cal.*, 115 Cal. App. 4th 782, 790-91 (2004).
- 5 49 Cal. 2d 647 (1958).
- 6 CAL. WELF. & INST. CODE § 15610.57.

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