Annual Health Law Review for 2017

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ctivity in the California health care sector continued to move at a fast pace in 2017, despite the upheaval and uncertainty in the first year of a controversial, new presidential administration that vowed to dramatically reshape existing health care policies and systems. In some respect, the California Legislature (Legislature) took action in direct response to attacks on the Affordable Care Act and Covered California, California's individual private insurance exchange. The Legislature also enacted numerous new laws that furthered ongoing efforts to address rising health care costs and decreasing access to care, to battle America's opioid epidemic, and to address public health concerns. The California Supreme Court decided five important health care cases, while California Courts of Appeal continued to establish precedent in most major areas of the health care arena. Two of California's state regulators, the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI), kept busy promulgating new regulations to carry out the state's complex system of health care laws.

I. Notable Legislation

A. Health Insurance

1. Assemb. B. 156 (Cal. Stats. 2017, ch. 468). This new law expands the annual enrollment period for individual health benefit plans offered in California, applicable to policy years beginning on or after January 1, 2019. Health plans for individuals sold through the Covered California insurance exchange must have enrollment periods from November 1 through December 15 (consistent with federal law), but Assembly Bill 156 establishes special enrollment periods that would effectively double the federally-mandated period, from October 15 of the preceding calendar year through January 15 of the benefit year. Other health plans sold outside of Covered California similarly must have annual



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enrollment periods from October 15 of the preceding calendar year through January 15 of the benefit year.

S.B. 133 (Cal. Stats. 2017, ch. 481). 2. Also known as "Jasmine's Law," Senate Bill 133 seeks to protect consumers undergoing treatment for serious or chronic conditions when their coverage changes because the health insurer stops offering individual coverage in California. Existing law protects consumers in such situations who have coverage through employersponsored plans, by imposing strict continuity of care requirements. Senate Bill 133 extends the continuity of coverage provisions to the individual insurance market; requires insurers to notify consumers of their right to continuity of care; and allows patients who need heart transplants to continue their care before and after their surgeries. The law also requires new insurers to pay the patient's healthcare provider even if that provider is not a participating provider in the new plan.

B. Pharmacies and Prescription Drugs

- Assemb. B. 401 (Cal. Stats. 2017, ch. 548). With Assembly Bill 401, California joins a growing list of states that authorize the practice of "telepharmacy." Telepharmacy connects off-site, licensed pharmacists to remote dispensing pharmacies that are staffed by pharmacy technicians working under the supervision of the licensed off-site pharmacist. Through telepharmacy software, licensed pharmacists can perform drug use review and verify the prescriptions being filled at the remote location, as well as counsel patients in real time. Remote dispensing site pharmacies must be licensed by the California Board of Pharmacy to operate under this new law. Assembly Bill 401 seeks to increase access to pharmacy care by creating an exception to existing law that requires every pharmacy in California to have a licensed pharmacist on site at all times that drugs are being dispensed and prohibits technicians from filling prescriptions unless a pharmacist is on site.
- 2. Assemb. B. 40 (Cal. Stats. 2017, ch. 607). The Legislature enacted Assembly Bill 40 to expand the use of California's prescription drug management database, known as the Controlled Substance Utilization Review and Evaluation System (CURES), as part of California's ongoing effort to battle the opioid drug crisis. Existing law requires all health care providers who are authorized to prescribe controlled substances to register with and to

consult CURES before prescribing Schedule II, III, and IV controlled substances to a patient for the first time and annually for patients who continue a course of narcotic treatment. The mandatory consultation requirement, however, does not take effect until the California Department of Justice (DOJ) certifies that CURES is ready to meet the demands of the new laws. Assembly Bill 40 takes steps to make CURES ready to use by imposing a deadline of October 1, 2018, for the DOJ to make electronic prescription drug records in CURES accessible to providers online or through integration with existing health information technology systems. The law also requires providers' systems accessing the CURES database to meet certain confidentiality and security standards.

C. Professional Licensing

S.B. 798 (Cal. Stats. 2017, ch. 775). The Medical Board of California (MBC) must be reauthorized every four years through a legislative sunset review process. Senate Bill 798 extends the MBC's authorization through 2021. Senate Bill 798 also makes significant changes to the jurisdiction and operation of the Medical Practice Act, including: (1) adding licensed midwives to state peer review laws and the Moscone-Knox Professional Corporation Act; (2) eliminating the MBC's authority to approve American Board of Medical Specialties-equivalent boards as alternative bodies for specialist physicians to become board-certified; (3) making the Board of Podiatric Medicine independent of the MBC; (4) imposing new. hefty fines on health facilities and peer review bodies for failing to submit physician disciplinary reports pursuant to Business and Professions Code section 805.01; and (5) changing the adverse event reporting requirements for outpatient surgery settings. Also, notably, Senate Bill 798 fixed January 1, 2019, as the date for expiration of the statutory requirement for vertical prosecution of MBC cases (whereby each complaint to the MBC is assigned to an MBC investigator and to an Deputy Attorney General who advises the investigator).

D. Health Care Facilities

1. S.B. 219 (Cal. Stats. 2017, ch. 483). Entitled the LGBT Long-Term Care Facility Residents' Bill of Rights, this bill makes it unlawful for any long-term care facility to discriminate on the basis of a person's actual or perceived sexual orientation, gender identity, gender expression, or human immunodeficiency virus

(HIV) status. In particular, prohibited discriminatory actions that fall within Senate Bill 219 include refusing to use a resident's preferred name or pronoun and denying admission to a long-term care facility, transferring or refusing to transfer a resident within a facility or to another facility, or discharging or evicting a resident from a facility.

E. Public Health

- 1. Assemb. B. 1316 (Cal. Stats. 2017, ch. 507). In recognition that childhood lead poisoning is a significant issue in California, Assembly Bill 1316 requires physicians and other providers who conduct periodic health assessments for children to include a risk screening for lead poisoning. Assembly Bill 1316 also requires that health plans and insurers cover the costs of the screening.
- 2. S.B. 512 (Cal. Stats. 2017, ch. 428). Under Senate Bill 512, providers must give patients a state-mandated written notice prior to undertaking a stem cell therapy treatment that is not approved by the FDA. Patients also must be advised to consult with their primary care physician prior to undergoing such stem cell therapy.
- 3. Assemb. B. 1221 (Cal. Stats. 2017, ch. 847). California law currently prohibits bartenders, servers, and managers from serving alcohol to minors and obviously intoxicated patrons. Sponsored by the California Medical Association, Assembly Bill 1221 seeks to increase compliance with these laws by requiring bartenders, servers, and managers to undergo responsible beverage service training through a program administered or approved by the Department of Alcoholic Beverage Control or offered by an accredited training provider.

F. Reproductive Health Services

1. S.B. 743 (Cal. Stats. 2017, ch. 572). This law prohibits a Medi-Cal managed care plan from restricting a Medi-Cal patient's choice of a qualified provider for family planning services and requires the plan to reimburse out-of-network providers at the applicable in-network fee-for-service rate.

II. Significant Health Law Decisions

A. California Supreme Court Decisions

1. T.H. v. Novartis Pharmaceuticals Corp., 4 Cal. 5th 145 (2017) (Brand-name drug maker owes a

duty of care to patients who take generic form of drug, and brand name drug manufacturer can be found liable for inadequate warnings based on a generic drug maker's warning label that copies the brand warning label, even if the brand name drug manufacturer no longer makes the drug.).

Plaintiffs' mother was prescribed terbutaline, the generic bioequivalent of the brand-name drug Brethine, to suppress premature labor during her pregnancy. Plaintiffs were born full term but were diagnosed with developmental delays and autism at the age of five. Alleging they were injured in utero by terbutaline, plaintiffs sued Novartis Pharmaceuticals Corporation, the manufacturer of Brethine, for failing to warn of the risk to fetal brain development. According to plaintiffs, the generic manufacturer was legally required to follow brand-name warnings, so Novartis had continuing liability for failing to warn about Brethine's hazards. Novartis argued it owed plaintiffs no duty to warn because it had stopped manufacturing Brethine and sold its rights to the product before plaintiffs' mother received terbutaline. The trial court sustained Novartis's demurrer, but the court of appeal reversed and allowed plaintiffs leave to amend. The supreme court then granted review.

In a 4-3 decision, the supreme court affirmed the court of appeal's decision. The supreme court majority explained that, under federal law, the manufacturer of Brethine (brand-name) controlled both the form and content of the terbutaline (generic) warning label. The court therefore concluded that plaintiffs could allege a cause of action against Novartis for failing to warn. Because the same warning label must appear on the brand-name drug and its generic bioequivalent, a brandname drug manufacturer owes a duty of reasonable care in ensuring that the label includes appropriate warnings, regardless of whether the end user has been dispensed the brand-name drug or its generic bioequivalent. The majority also endorsed plaintiffs' predecessor liability theory. The majority explained that, if the person exposed to the generic drug can reasonably allege that the brandname drug manufacturer's failure to update its warning label foreseeably and proximately caused physical injury, then the brand-name manufacturer's liability for its own negligence does not automatically terminate merely because the brand-name manufacturer transferred its rights in the drug to a successor.

Three justices dissented in part, disagreeing with the court's holding that predecessor manufacturers have a duty to warn their successors' customers about risks of a product they no longer make or sell. According to the dissenters, this "theory of 'predecessor liability' represents a substantial and unprecedented expansion of tort duties. The majority cites no case holding a predecessor manufacturer liable for failing to warn about injuries caused by its successor's product."

2. Lewis v. Superior Court, 3 Cal. 5th 561 (2017) (Medical Board does not violate patient privacy right by warrantless access of prescription records in CURES database.).

As part of its investigation into a patient complaint against petitioner Dr. Lewis, the Medical Board of California obtained the prescription records of Dr. Lewis's patients from California's Controlled Substance Utilization Review and Evaluation System (CURES) without patient authorization, a warrant, or a subpoena. The board then filed an accusation against Dr. Lewis, who unsuccessfully moved to dismiss on the ground that the board had violated his patients' privacy rights. An administrative law judge recommended staying revocation of Dr. Lewis's license and placing him on probation. Dr. Lewis filed an unsuccessful petition for writ of administrative mandamus in superior court reasserting his patients' privacy rights, then he filed a petition for writ of mandate in the court of appeal on the same issue. The court of appeal denied writ relief.

The supreme court granted Dr. Lewis's petition for review, and affirmed the denial of writ relief in a unanimous opinion by Justice Liu. The court held that (1) Dr. Lewis had standing to assert his patient's privacy rights, (2) the board's conduct should be assessed under the general balancing test, rather than the compelling state interest test, because its actions did not intrude on a fundamental autonomy right, and (3) under that general balancing test, the board's conduct did not violate the constitutional privacy rights of Dr. Lewis's patients. The court reasoned that the balance of interests tipped in favor of the board because it had a legitimate interest in protecting the public from unlawful use of dangerous prescription drugs and from negligent or incompetent physicians. The court explained that the board need not use the least intrusive means of achieving those legitimate objectives, in part because patients' privacy

interest in their prescription records is "less robust" than their privacy interest associated with their full medical records, and in part because statutes governing CURES limited access to and distribution of that information. The court further reasoned that imposing on the board the requirement to show good cause was infeasible because it would compromise the board's ability to swiftly identify and stop dangerous prescribing practices.

Justice Liu also authored a concurring opinion, joined by Justice Kruger. He explained that the court's opinion had assumed, arguendo, that Dr. Lewis had satisfied the threshold elements of an invasion of privacy claim, and he wrote separately to state his belief that Dr. Lewis had satisfied the elements of that claim: (1) his patients had a legally recognized privacy interest in their prescription records; (2) the patients had a reasonable expectation of privacy because their prescription records could reveal underlying medical conditions; and (3) disclosure of sensitive medical information by a government agency could not be dismissed as trivial.

3. People v. Superior Court, 3 Cal. 5th 230 (2017) (Statute prohibiting self-interested transactions by public officials can apply to doctors working at public hospitals who are independent contractors.).

A district attorney criminally charged a surgeon under California Government Code section 1090, which prohibits public officers and employees from making contracts in which they have a financial interest when they act in their official capacities. The surgeon was a member (and sometimes chief of staff) of a public hospital's medical staff, a member of the hospital's medical executive committee, and an independent contractor at the hospital, and had negotiated professional service contracts on behalf of the hospital. The surgeon negotiated a contract with an anesthesiologist whereby the hospital would pay the anesthesiologist \$36,000 per month plus benefits to work at the hospital. Then the surgeon allegedly pressured the hospital into hiring the anesthesiologist for \$48,000 per month plus benefits and arranged to receive the greater sum and remit the lesser sum to the anesthesiologist. (The hospital was allegedly unaware of this arrangement.) The trial court dismissed the section 1090 count, ruling (under People v. Christiansen, 216 Cal. App. 4th 1181 (2013)) that the statute covers employees only, and independent contractors, like the surgeon, cannot be held criminally liable. The court of appeal affirmed.

The supreme court granted review and reversed. The court held that section 1090 is not limited to public employees or governed by employee/independent contractor distinctions applicable in tort law. Disapproving Christiansen, the court examined the legislative history of section 1090 and an attorney general opinion interpreting the statute, and found that the Legislature intended the statute to cover certain independent contractors—those that, according to the court, "have duties to engage in or advise on public contracting that they are expected to carry out on the government's behalf." The court rejected an argument by the California Medical Association (as amicus) that section 1090 should not be applied to members of a medical staff because of the unique nature of their relationships with hospitals. The court explained that section 1090 would not criminalize much of what physicians currently do, because related statutes exempt personal financial interests "that are remote or minute." The court added there was nothing unreasonable about subjecting physicians to criminal liability under section 1090 if they enter into more significant self-interested transactions. The court also dismissed the surgeon's arguments for strict construction of penal statutes, such as section 1090, and remanded to allow the court of appeal to consider the surgeon's fallback argument that (due to his own lapsed contract) he was not even an independent contractor when he negotiated the anesthesiologist's contract.

4. Dhillon v. John Muir Health, 2 Cal. 5th 1109 (2017) (Final administrative mandamus order remanding for further administrative proceedings is appealable.).

Following a verbal altercation at a staff meeting, the medical executive committee at John Muir Health required plaintiff Dr. Dhillon and another physician to attend anger management classes. Dr. Dhillon refused to attend, and requested a judicial review committee hearing. John Muir responded by informing Dr. Dhillon he was not entitled to a hearing, and suspended his clinical privileges for fourteen days when he refused to comply. Dr. Dhillon then filed a petition for writ of administrative mandamus in the superior court. He alleged that John Muir had violated its bylaws by imposing the discipline without a hearing.

The superior court denied most writ relief sought by Dr. Dhillon, but ruled that he was entitled to a hearing

and remanded the matter for John Muir to conduct it. John Muir filed a writ petition in the court of appeal and a notice of appeal. The court of appeal summarily denied the writ petition and later dismissed the appeal, holding that the superior court's remand order was not appealable.

The California Supreme Court granted review and reversed, holding that the superior court's remand order was appealable because it marked the end of the mandamus proceeding. Because the superior court had granted or denied each of Dr. Dhillon's claims and did not reserve its jurisdiction to consider additional issues, nothing remained to be decided in that court. In deciding Dhillon, the supreme court did not enact a categorical rule that remand orders for further administrative proceedings are always appealable. Instead, the court held that the appealability of a ruling hinges on the extent to which issues are (or are not) left for future consideration. The supreme court also rejected Dr. Dhillon's alternative argument that (even if the remand order were appealable) John Muir had received the functional equivalent of an appeal by filing a writ petition and obtaining a denial. The supreme court noted that appellants have important rights unavailable to writ petitioners, such as the right to oral argument and a written opinion.

5. Shaw v. Superior Court, 2 Cal. 5th 983 (2017) (No statutory right to jury trial of California Health and Safety Code section 1278.5 claims.).

Plaintiff Deborah Shaw, a former human resources coordinator, sued her former employers, Kindred Hospital and related entities, for retaliation under Health and Safety Code section 1278.5 and for wrongful termination in violation of public policy under *Tameny v. Atlantic Richfield Co.*, 27 Cal. 3d 167 (1980). She claimed her employment was terminated after she raised complaints about the quality of patient care. The trial court ruled that Shaw was entitled to a jury trial on her *Tameny* claim, but not on her section 1278.5 claim. Shaw petitioned for a writ of mandate. The court of appeal held that Shaw had a right to a jury trial on her section 1278.5 claim.

The California Supreme Court granted review, and unanimously reversed the court of appeal. The supreme court first resolved a split of authority on a procedural issue, holding that an order denying a request for a jury trial is amenable to writ review. Turning to the merits, the court noted that section 1278.5 is silent on whether a section 1278.5 claim is to be tried to a jury or judge.

The court inferred from textual clues in the statute that the Legislature did not intend to confer a jury trial right. Section 1278.5 lists several equitable remedies (including reinstatement of employment), and equitable claims are typically tried to courts, not juries. The supreme court also analyzed the structure and legislative history of a 2007 statutory amendment to section 1278.5, when language was added authorizing a court to fashion "any remedy deemed warranted by the court [emphasis added]," which the supreme court interpreted as a reference to a judge. Having concluded Shaw had no statutory right to a jury trial, the supreme court declined to address whether she had a constitutional right to a jury trial on a section 1278.5 claim, because Shaw could obtain a jury trial on her closely related Tameny claim. The supreme court also held that, to avoid depriving a plaintiff of her jury trial right, any trial should be sequenced so that a jury trial on the Tameny claim precedes an adjudication of the section 1278.5 claim.

B. Select California Court of Appeal Decisions

1. Medi-Cal

Hoag Memorial Hosp. Presbyterian v. Price, 866 F.3d 1072 (9th Cir. 2017) (U.S. Department of Health and Human Services cannot approve Medi-Cal rate reduction without first comparing Medi-Cal beneficiaries' and the general public's access to medical services).

2. Medical Tort Liability

Bigler-Engler v. Breg, Inc., 7 Cal. App. 5th 276 (2017) (exception to strict liability for providers dispensing products, the learned intermediary defense, and the interplay between MICRA and Proposition 51).

Brenner v. Universal Health Services of Rancho Springs, Inc., 12 Cal. App. 5th 589 (2017) (patient's family members who complain about quality of care issues have no standing to assert retaliation claim under Health and Safety Code section 1278.5).

3. Medical Billing

Pacific Bay Recovery, Inc. v. California Physicians' Services, Inc., 12 Cal. App. 5th 200 (2017) (Evidence of Coverage contract limits health insurer's obligation to pay provider for out-of-network, nonemergency services to insured).

Goel v. Regal Medical Group, Inc., 11 Cal. App. 5th 1054 (2017) (courts may consider Medicare rates

and other doctors' charges in assessing value of medical services).

YDM Management Co., Inc. v. Sharp Community Medical Group, Inc., 16 Cal. App. 5th 613 (2017) (noncontracting provider whose bills were coded for nonemergency services may not seek reimbursement for emergency services).

4. Medical Privacy

Lemke v. Sutter Roseville Medical Center, 8 Cal. App. 5th 1292 (2017) (statements to the Nursing Board reporting misconduct are absolutely privileged whether or not made in good faith).

Cross v. Superior Court, 11 Cal. App. 5th 305 (2017) (psychotherapist-patient privilege no bar to Medical Board subpoena for patient records during investigation of psychiatrist).

Julian v. Mission Community Hospital, 11 Cal. App. 5th 360 (2017) (person involuntarily detained for mental health evaluation has no private right of action for violation of certain Lanterman-Petris-Short Act provisions).

5. MICRA (Medical Injury Compensation Reform Act)

Cuevas v. Contra Costa County, 11 Cal. App. 5th 163 (2017) (MICRA collateral source statute applies to future medical expense awards, which must be measured by likely market value).

Johnson v. Open Door Community Health Centers, 15 Cal. App. 5th 153 (2017) (MICRA limitations period does not apply to lawsuit implicating general duty to maintain premises safe for public visitors).

6. Procedural Issues

Kumari v. Hospital Committee for the Livermore-Pleasanton Areas, 13 Cal. App. 5th 306 (2017) (informal notice of intent to sue prevents later notice from tolling MICRA statute of limitations).

Baker v. Italian Maple Holdings, 13 Cal. App. 5th 1152 (2017) (MICRA arbitration agreements may be enforced if party dies during thirty-day rescission period).

III. Notable Regulatory Actions

A. Essential Health Benefits (EHB)

Both the California Department of Insurance (CDI) and the Department of Managed Health Care (DMHC) issued regulations packages designed to conform existing

regulations to statutory changes. In regulations issued in late 2014, the U.S. Department of Health and Human Services stipulated that states may update their Essential Health Benefits (EHB) package pursuant to the Affordable Care Act (ACA) beginning in plan year 2017. The EHB is the menu of benefits that must be offered by every nongrandfathered product in the individual and small group markets, and is based on what is covered by the state's benchmark plan. In the federal regulations, states were given the opportunity to change their benchmark plan to one of a specified group of products in existence in the first quarter of 2014. Pursuant to Senate Bill 43, enacted in 2015, the California Legislature selected the same Kaiser Small Group 30 product that was the existing benchmark plan for plan years 2014-2017, updated to the first quarter of 2014. Some key changes had been made to the benchmark plan, requiring DMHC and CDI to update their existing regulations¹ to reflect these changes.

Some of the important differences included:

- Pediatric dental EHB includes Medi-Cal Early Period Screening, Diagnosis, and Treatment (EPSDT);
- The per se age limit on aphakia lens coverage is eliminated;
- The definition of habilitative and rehabilitative services is changed to comport with statutory amendments; and
- Prescription drug EHB coverage is provided in accordance with state and federal law by modifying the Prescription Drug Benefit Worksheet.

Emergency regulations had been previously adopted to implement these changes in November 2016. The CDI and DMHC regulation packages making the emergency regulations permanent became effective July 1, 2017.

B. Prescription Drug Prior Authorization and Step Therapy Exception Form

In 2011, the Legislature enacted Senate Bill 866, which required every prescribing health care provider to use a standard form when requesting prior authorization for a prescription medication from a health plan or insurer. The initial regulation implementing the bill became effective in 2014. In response to implementation difficulties, in 2016 the Legislature passed, and the Governor signed, Senate Bill 282 and Assembly Bill 374, which required CDI and DMHC to consult affected

stakeholders and update the standard form by January 1, 2017. The DMHC and CDI implemented the statutes by amending the regulations to:

- Promote uniformity across health plans and insurers regarding prior authorization process and forms;
- Increase efficiency by allowing for new technology and alternative methods for transmitting prescription drug prior authorization requests;
- Exempt specified medical groups from the requirement to use the form; and
- Expand the form to include step-therapy exception requests.

The DMHC's and CDI's amended regulations² became effective on July 1, 2017, and plans and providers were required to use the new form as of January 1, 2018.

C. Risk/Jurisdiction

In the fall of 2017, DMHC issued notice of a proposed new regulation (section 1300.49 to title 28 of the Code of California Regulations) for public comment addressing the level of risk an entity could take without requiring licensure as a health care service plan and the requirements and licensing procedure for restricted health care service plan licenses. DMHC has always stated that an entity that accepts both professional and institutional risk meets the definition of a health care service plan, and must obtain a Knox-Keene license. The proposed new regulation would codify that requirement. The regulation package also would codify the requirements for restricted health care service plan licenses, which are health plans that accept global risk from other plans and do not market to the public.

The first public comment period for these regulations ended in December 2017. The DMHC is preparing its response to the comments received and expects to finalize the regulation in 2018.³

Endnotes

- * Peter Batalden and H Thomas Watson prepare bulletins on appellate health law decisions for the California Society for Healthcare Attorneys (CSHA), which are republished with CSHA's permission as State Bar Health Law Committee e-bulletins. The case summaries in the annual review article are derived from these same case summaries (with some minor editing).
- 1 Cal. Code Regs. tit. 28 § 1300.67.005; id. tit. 10 § 2594.3.
- 2 CAL. CODE REGS. tit. 28 § 1300.67.241; id. tit. 10 § 2218.30.
- 3 See DMHC regulation package control no. 2017-5220.