DEPARTMENT OF MANAGED HEALTH CARE

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Created on July 1, 2000, the Department of Managed Health Care (DMHC) regulates the managed care industry in California. The creation of DMHC resulted from Governor Gray Davis's approval of AB 78 (Gallegos) (Chapter 525, Statutes of 1999), a bill that reformed the regulation of managed care in the state. DMHC is created in Health and Safety Code section 1341; DMHC's regulations are codified in Title 28 of the California Code of Regulations (CCR).

DMHC administers the Knox-Keene Health Care Service Plan Act of 1975, Health and Safety Code section 1340 *et seq*., which is intended to promote the delivery of health and medical care to Californians who enroll in services provided by a health care service plan. A "health care service plan" (health plan)—more commonly known as a health maintenance organization (HMO) or managed care organization (MCO)—is defined broadly as any person who undertakes to arrange for the provision of health care services to enrollees, or to pay for or reimburse any part of the cost for those services, in return for a prepaid or periodic charge paid by or on behalf of the enrollees.

In Health and Safety Code section 1342, the legislature has expressly instructed the Department Director to ensure the continued role of the professional as the determiner of the patient's health needs; ensure that enrollees[1] are educated and informed of the benefits and services available in increase consumer choice in the healthcare market; and promote effective representation of the interests of enrollees, including ensuring the best possible health care at the

[1] Enrollees, Members, and Subscribers are referred to herein as "enrollee(s)."

lowest possible cost by transferring financial risk of health care from patients to providers. The Department Director must also prosecute individuals and/or health plans who engage in fraud or misrepresent or deceive consumers; and ensure the financial stability of health plans through proper regulation health care must be accessible to enrollees and rendered in a manner to provide continuity of care, which includes a grievance process that is expeditious and thoroughly reviewed by DMHC.

The Director of DMHC is appointed by, and serves at the pleasure of, the Governor. The Department's staff of attorneys, financial examiners, health plan analysts, physicians, health care professionals, consumer service representatives, and support staff assist the DMHC Director in licensing and regulating more than 130 health plans in California. Licensed health plans include HMOs and other full-service health plans, as well as several categories of specialized health plans such as prepaid dental, vision, mental health, chiropractic, and pharmacy plans. DMHC-licensed health plans provide health care services to approximately 26 million California enrollees.

Created in Health and Safety Code section 1374.30 *et seq*., DMHC's independent medical review (IMR) system allows health plan enrollees to seek an independent review when medical services are denied, delayed, or otherwise limited by a plan or one of its contracting providers, based on a finding that the service is not medically necessary or appropriate. The independent reviews are conducted by expert medical organizations that are independent of the health plans and certified by an accrediting organization. An IMR determination is binding on the health plan, and the Department will enforce it.

SB 260 (Speier) (Chapter 529, Statutes of 1999), added section 1347.15 to the Health and Safety Code to create the Financial Solvency Standards Board (FSSB). Comprised of the DMHC Director and seven members appointed by the Director, FSSB periodically monitors and reports

on the implementation and results of those requirements and standards, and reviews proposed regulatory changes. FSSB advises the DMHC Director on matters of financial solvency affecting the delivery of health care services. FSSB develops and recommends financial solvency requirements and standards relating to plan operations.

DMHC houses the Help Center, which is open 24 hours a day, 365 days a year, and functions in many languages to help consumers who experience problems with their health plan. The Help Center educates consumers about their health care rights; resolves consumer complaints; helps consumers navigate and understand their coverage; and ensures access to appropriate health care services. The DMHC Help Center provides direct assistance to health care consumers through a call center and online access. DMHC is funded by assessments on its regulated health plans.

MAJOR PROJECTS

DMHC Rulemaking

The following are status updates on recent rulemaking proceedings that DMHC has initiated, some of which were covered in more detail in Volume 24, Number 1 of the *California Regulatory Law Reporter [24:1 CRLR 20–26]*:

♦ ***General Licensure Requirements***. On November 30, 2018, DMHC published a notice of 4th comment period to add section 1300.49, Title 28 of the CCR, which attempted to clarify the Knox-Keene Act's definition of a "health care service plan" that requires licensure by DMHC. The new regulation would have defined "health care service plan" to include an entity that takes on global risk (both institutional and professional risk) for services provided to health plan enrollees, would have set forth requirements for a restricted health plan license, as well as standards for obtaining an exemption from licensing requirements. The modified text is the result of information

received during the third comment period and the information in the Notice of Disapproval issued by the Office of Administrative Law (OAL) on October 8, 2018, and in its Decision of Regulatory Action dated October 15, 2018, which is set forth in the proposed language. *[24:1 CRLR 20–21]*

According to the final statement of reasons and its attached addendum, the proposed regulation updates the Economic Impact Analysis by providing clarity around licensure requirements of restricted health care service plans; specifies existing state law for health care service plans; simplifies the information the Director will consider when determining whether an exemption request will be granted; and identifies a process for an exemption request from DMHC.

On March 5, 2019, OAL approved the final text of the general licensure requirements to be effective July 1, 2019.

♦ ***Cancellations, Rescissions, and Non-renewals of Health Plan Enrollment, Subscription, or Contract.*** On December 28, 2018, DMHC published a notice of 2nd comment period to delete sections 1300.65, 1300.65.1, 1300.65.2, and add sections 1300.65, 1300.65.1, 1300.65.2, 1300.65.3, 1300.65.4, 1300.65.5, Title 28 of the CCR, to clarify and interpret the rights and responsibilities of plans, providers, and enrollees prior to, during, and following cancellations, rescissions, or non-renewals of an enrollee's health care coverage. The modified text is the result of information received during the initial comment period, which is set forth in the proposed language.

On February 28, 2019, DMHC published a notice of 3rd comment period affecting the same sections outlined in the prior paragraph. The revised language responds to public comments to clarify and keep consistency in the relevant terms throughout the regulation.

On June 22, 2018, DMHC originally proposed amendments to the Cancellations, Rescissions, and Nonrenewals regulations, in order to impose limitations on the cancellation,

rescission, and nonrenewal of health care service plan contracts, and provide enrollees, subscribers, and group contract holders with a right to file a grievance with DMHC in certain situations consistent with federal law under the Patient Protection and Affordable Care Act (PPACA). *[24:1 CRLR 22–23]*

DMHC did not schedule a public hearing on these proposed regulatory changes, but accepted written comments until March 15, 2019. At this writing, DMHC is reviewing the comments received during the comment period and is preparing modified text of the proposed changes.

♦ ***Financial Solvency of Risk-Bearing Organizations (RBOs).*** DMHC does not directly regulate RBOs; however, it is authorized to regulate health plan contracts with RBOs. Hence, on May 25, 2018, DMHC originally proposed amendments to the Financial Solvency of RBOs regulation in a notice of proposed rulemaking. *[24:1 CRLR 23–25]* On November 15, 2018, DMHC published a notice of 3rd comment period to amend sections 1300.75.4, 1300.75.4.1, 1300.75.4.2, 1300.75.4.5, 1300.75.4.7, 1300.75.4.8, and 1300.76, Title 28 of the CCR, for an additional 15-day public comment period that ended on December 4, 2018. The third revision of the modified text addresses public comments received during the second comment period.

On January 4, 2019, DMHC published a notice of 4th comment period to continue amending the same sections outlined in the prior paragraph, for an additional 15-day public comment period that ended on January 22, 2019. The fourth revision of the text is a result of the information received during the third comment period, which is set forth in the proposed language, which is the final text submitted to OAL. According to the final statement of reasons, the proposed regulations represent the cumulative effort of DMHC to adopt rules and regulations to implement a process for reviewing and grading the financial solvency of RBOs. This includes clarifying the

financial information required from RBOs to assist in DMHC's review, including when DMHC conducts audits and when DMHC processes corrective action plans for RBOs with solvency problems. The regulations cover disclosure of relevant information from health plans to RBOs to enable the organization to be informed regarding the risks assumed under the parties' contract. The regulations also cover how health plans and RBOs file periodic reports to DMHC, ensuring confidentiality of consumers.

At its April 10, 2019 teleconference meeting, DMHC voted to adopt the final text of the regulatory action, until such time as OAL approves the regulatory action through the formal rulemaking process. A hearing on the proposed regulations is set for May 6, 2019.

Standard Prescription Drug Formulary Template

On February 20, 2019, DMHC published a notice of 2nd comment period to add section 1300.67.205, Title 28 of the CCR, a proposed regulatory action to set minimum standards for its drug formulary. The modified text is the result of comments received during the initial 45-day comment period that ended on November 13, 2018, and the public hearing held on November 13, 2018. DMHC accepted written comments relating to the modified text until March 7, 2019. Following the second comment period, DMHC released the revised text of the proposed regulation. At the time of this writing, DMHC had not scheduled a public hearing on the proposed changes and was reviewing additional comments.

DMHC also released an addendum to the Notice of Rulemaking and the Initial Statement of Reasons noticed on September 28, 2018. *[24:1 CRLR 21–22]* In the addendum, DMHC updated its Summary of Fiscal Impact contained in its initial Notice of Rulemaking, to now include the determination that there will be a fiscal impact to Medi-Cal only managed care plans to comply

with the requirements of the regulation. The estimated fiscal amount to upgrade computer systems is $13,041 per health plan, bringing the total fiscal impact to $143,452. At this writing, DMHC has not taken further action on the regulation.

DMHC Releases 2017 Timely Access Report

On December 19, 2018, DMHC published the Timely Access Report for Measurement Year (MY) 2017. The Timely Access Regulation, which became effective in 2010, "requires that health plan networks be sufficient to meet a set of standards, which include specific timeframes under which enrollees must be able to obtain care." The Timely Access Report summarizes provider appointment availability data that health plans submitted to DMHC for Measurement Year 2017. The charts within the report show provider responses to appointment availability requests.

According to the report, DMHC required full-service health and behavioral health plans to utilize external vendors to validate the health plans' Timely Access data prior to submitting them to DMHC. DMHC found some data errors in MY 2017 data that health plans were unable to correct. Although these errors limit some of the possible data representations, DMHC was able to compare MY 2017 data across health plans at a more granular level than for previously reported years. As a result, DMHC expanded the number of charts in the report and displayed data by type of health plan for the first time: Commercial; Individual/Family; and Medi-Cal.

Regarding 2017 data, some health plans continued to have issues with following the mandatory methodology, completing all of the required surveys, and achieving an acceptable statistical sample of surveyed providers. According to DMHC, ensuring that health plans provide timely access to health care services is one of its highest priorities and DMHC continues to work

with stakeholders, including health plans, providers, associations and consumer advocates to refine the provider survey methodology and develop an acceptable rate of compliance for provider appointment wait times. Furthermore, DMHC is taking the necessary steps to have mandatory methodologies for measuring compliance with the timely access standards and the acceptable rate of compliance included in regulation so that compliance results are comparable year over year.

Key Survey Findings for Full-Service Health Plans. The percentage of all surveyed providers who had appointments available within the wait time standards (urgent and non-urgent) ranged from a high of 99% to a low of 63% (Chart 1). For non-urgent appointments, the percentage of all surveyed providers who had appointments available within the wait time standards ranged from a high of 99% to a low of 70% (Chart 5). For urgent appointments, the percentage of all surveyed providers who had appointments available within the wait time standards ranged from a high of 99% to a low of 52% (Chart 9).

Key Survey Findings for Behavioral Health Plans. The percentage of all surveyed providers who had appointments available within the wait time standards (urgent and non-urgent) ranged from a high of 83% to a low of 64% (Chart 13). For non-urgent appointments, the percentage of all surveyed providers who had appointments available within the wait time standards ranged from a high of 87% to a low of 71% (Chart 17). For urgent appointments, the percentage of all surveyed providers who had appointments available within the wait time standards ranged from a high of 80% to a low of 57% percent (Chart 21).

Key Audit Findings for Full-Service Health Plan, Kaiser Permanente. The percentage of all audited providers meeting appointment wait time standards across all provider types and appointment types (urgent and non-urgent) was 92% (Chart 25). The percentage of all audited

providers meeting non-urgent appointment standards was 91% (Chart 29). The percentage of all audited providers meeting urgent appointment standards was 98% (Chart 33).

DMHC Releases 2017 Prescription Drug Cost Transparency Report

Despite undecided legal challenges to the constitutionality of the 2017 legislation *[see* LITIGATION*]*, on December 27, 2018, DMHC released its Prescription Drug Cost Transparency Report (SB 17). SB 17 (Hernandez) (Chapter 603, Statutes of 2017), as codified in Health and Safety Code section 1367.243, requires health plans that file rate information with DMHC to annually report specific information related to the costs of covered prescription drugs. Prescription drug data was submitted by 25 health plans for measurement year 2017. DMHC states that it will continue to collect and report on the data required by SB 17, which will enable the public to understand how prescription drugs impact health care premiums over time.

This report looks at the impact of the cost of prescription drugs on health plan premiums. According to the report, DMHC considered the total volume of prescription drugs prescribed by health plans and the total cost paid by health plans for these drugs, on both an aggregate spending level and a per member per month basis (PMPM). DMHC also analyzed how the 25 most frequently prescribed drugs, the 25 most costly drugs, and the 25 drugs with the highest year-over-year increase in total annual spending impacted premiums.

Key Findings. According to the report, health plans paid nearly $8.7 billion for prescription drugs in 2017. Prescription drugs accounted for 13.1% of total health plan premiums. Health plans' prescription drug costs increased by 5% in 2017, whereas medical expenses increased by 5.9%. Overall, total health plan premiums increased 4.8% from 2016 to 2017. Manufacturer drug rebates equaled approximately $915 million, or about 10.5%, of the $8.7 billion spent on prescription

drugs. While specialty drugs accounted for only 1.6% of all prescription drugs, they accounted for over half (51.5%) of total annual spending on prescription drugs. Generic drugs accounted for nearly 90% (87.8%) of all prescribed drugs but only 23.6% of the total annual spending on prescription drugs. Brand name drugs accounted for 10.6% of prescriptions and constituted 24.8% of the total annual spending on prescription drugs. The 25 Most Frequently Prescribed Drugs represented 47.7% of all drugs prescribed and approximately 42.8% of the total annual spending on prescription drugs. For the 25 Most Frequently Prescribed Drugs, enrollees paid approximately 3% of the cost of specialty drugs and over half (56.6%) the cost of generic drugs. Overall, plans paid over 90% of the cost of the 25 Most Costly Drugs across the three categories (generic, brand name, and specialty).

As reported by DMHC, the impact of prescription drug costs on health plan premiums is significant. Health plans paid nearly $8.7 billion for prescription drugs in 2017, which accounted for 13.1% of the total health plan premium in 2017. This amount is primarily related to the cost of specialty drugs. Overall, specialty drugs accounted for just over 1% of the total number of drugs prescribed, and represented over half of the health plans' total annual spending on prescription drugs. Generic drugs made up nearly 90% at of all the drugs prescribed in 2017 but represented only about one-quarter of total annual spending on prescription drugs.

Recent Enforcement Actions

Following are recent enforcement actions taken by DMHC:

♦ ***DMHC Approves Optum's Acquisition of DaVita.*** On November 28, 2018, DMHC approved Optum, Inc.'s acquisition of DaVita Health Plan of California, as contained in a document setting forth the conditions of the merger. DMHC's approval includes several conditions

that will protect enrollees and support behavioral health services. Optum and DaVita agree to not increase premiums as a result of acquisition costs, and keep premium rate increases to a minimum. The plans also agree to invest at least $58 million in California as follows: (1) $40 million in philanthropic activities in California; (2) $10 million to one or more areas that include support for scholarships through the United Health Foundation Diverse Scholars Initiative, medical grants for California families, investments to help address social determinants of health and other health and wellness initiatives; and (3) $8 million to support behavioral health services by providing scholarships to those seeking to become a psychiatrist or psychiatric nurse practitioner in the field of Child and Adolescent psychiatry. The health plans will also support activities and implement programs to address the opioid crisis. This includes educating providers on substance abuse detection and prescribing naloxone and buprenorphine.

According to DMHC Director Rouillard, there has been rapid consolidation in the health care industry, including health plan mergers, and "[a]s the primary state regulator of health plans, [DMHC's] job is to protect the health care rights of impacted enrollees and ensure a stable health care delivery system." In response to DaVita's notice of the proposed acquisition by Optum in early 2018, DMHC conducted a comprehensive review of the transaction to ensure compliance with the Knox-Keene Act. DMHC examined both parties' organization and corporate structures, administrative capacity changes, health care delivery system changes, product or subscriber changes, the effect of the transaction on the financial viability of DHMC licensed plans, the financing for the transaction, and its impact on consumers. DMHC's Financial Solvency Standards Board (FSSB) held a public meeting on the acquisition back in April, 2018. At the meeting, Director Rouillard reiterated that the Department's primary focus in reviewing these mergers is to

ensure compliance with the strong consumer protections and financial solvency requirements of the Knox-Keene Act.

♦ ***LA Care Grievance Process Violations Result in $280,000 Fine.*** On November 6, 2018, DMHC announced it would fine LA Care $280,000 for systemic grievance process violations. DMHC Director Rouillard stated that health plans are required by law to have a grievance process in place to resolve consumers' complaints and ensure access to appropriate care. DMHC found that "LA Care failed to comply with laws surrounding the grievance and appeals system and must correct their deficiencies to ensure consumers know their health care rights and how to act on them."

According to DMHC, this enforcement action is a result of 21 cases involving 63 consumer grievance violations that occurred during 2014 through 2017. In these cases, LA Care deprived enrollees of their rights to medical care in that it failed to identify, timely process, and resolve consumer grievances. Additionally, LA Care did not comply with statutory timeframes to provide DMHC information during investigation of member complaints. The plan has acknowledged its failure to comply with the law, and DMHC has determined that an administrative penalty and Corrective Action Plan are warranted. The corrective actions include employee training and increased oversight of the grievance and appeals system.

DMHC Approves CVS-Aetna Merger

On November 15, 2018, DMHC Director Rouillard issued a statement of approval for the CVS-Aetna merger. DMHC placed conditions on the approval of the merger. CVS and Aetna agreed to not increase premiums as a result of acquisition costs and to keep premium rate increases to a minimum. The plans also agree to invest nearly $240 million in California's health care

delivery system. As part of DMHC's conditions, CVS and Aetna confirmed the sale of Aetna's Medicare Part D Individual Prescription Drug business to WellCare in compliance with the conditional approval by the U.S. Department of Justice. Additionally, until the divestiture is completed, CVS and Aetna will guarantee Aetna's Medicare Part D Individual Prescription Drug business in California continues to be a viable and competitive plan for 2019.

On April 5, 2019, Judge Richard Leon of the U.S. District Court for the District of Columbia heard argument from parties as to what, if any, witnesses should be called at any hearing on the Government's Motion for Entry of Final Judgment. Pending Judge Leon's approval, CVS agreed to temporarily allow Aetna to independently make critical product, pricing and personnel decisions.

Prior editions of the Reporter have covered the proposed acquisition in January of 2018, through DMHC's examination of CVS' and Aetna's structures, including a public hearing in May of 2018. *[23:2 CRLR 18–19]* On October 10, 2018, the Department of Justice conditionally approved the CVS-Aetna merger. *[24:1 CRLR 27–28]*

DMHC Approves Cigna-Express Scripts Merger

On December 13, 2018, the Cigna-Express merger was approved by the New York Department of Financial Services and DMHC. Further, the New York Superintendent, Maria Vullo, cancelled the hearing that was scheduled for January 10, 2019 after receiving commitments from the applicants to conditions of approval that address anti-competitive concerns.

On December 13, 2018, Director of DMHC Rouillard issued a statement of approval for the Cigna-Express acquisition. DMHC placed conditions on the approval of the merger, including agreement to not increase premiums as a result of acquisition costs and to keep premium rate

increases to a minimum. Both companies will also invest over $60 million in California healthcare initiatives, including the opioid crisis and healthcare delivery.

The U.S. Department of Justice approved the Cigna-Express acquisition in September of 2018. *[24:1 CRLR 28–29]*

LEGISLATION

AB 1802 (Committee on Health), as amended April 11, 2019, would amend sections 1358.20, 1368.015, 1368.02, 1371, and 1373.65 of the Health and Safety Code, relating to health care service plans. The bill would clarify that the obligation of a health plan to comply with claims reimbursement obligations is not deemed to be waived if the plan requires its medical groups, independent practice associations, or other contracting entities to pay claims for covered services. According to the Committee on Health, this bill reverts language back to its original statutory language to apply to all health plans and updates DMHC telephone and internet website addresses in specified materials. *[A. Health]*

AB 1174 (Wood), as amended March 25, 2019, would add sections 1341.46 and 1371.32 to the Health and Safety Code, relating to anesthesia services. According to the author, this bill would ensure that health plans and health insurers have a contractual relationship with anesthesiologists such that enrollees will have access to these types of providers at contracted facilities. This bill would require a health plan to notify DMHC before the expiration or termination of an anesthesia services contract. This bill would also require DMHC to make a finding that the health plan have contracts in place that meet the following: 1) the health plan has a contract with at least one individual health professional who is licensed by the state to deliver or furnish anesthesia services (individual health professional) for each of its contracted facilities; and 2) an

enrollee requiring anesthesia services has access to contracted individual health professional at all times and for all procedures at each of the contracted facilities. *[A. Appr]*

AB 651 (Grayson), as amended April 8, 2019, would add section 1371.55 to the Health and Safety Code, relating to air ambulance services. This bill would require a health plan contract to provide that if an enrollee receives covered services from a noncontracting air ambulance provider, the individual would pay no more than the same cost sharing that the individual would pay for the same covered services received from a contracting air ambulance provider, as specified. Among other things this bill would, commencing January 1, 2020, and to the extent that federal financial participation is available and federal approvals have been obtained, require the department to set and maintain the Medi-Cal fee rate for air ambulance services provided by either fixed or rotary wing aircraft that is equal to a percentage of the rural Medicare rates for those services. This would be a rate increase for air ambulance providers that, according to the sponsor, is necessary to maintain adequate coverage of services across the state. *[A. Health]*

AB 1611 (Chiu), as introduced February 22, 2019, would amend section 1317.2a of, and add sections 1317.11, 1317.12, 1371.6, 1371.7, and 1385.035 to, the Health and Safety Code, relating to hospital service costs. This bill would prohibit a hospital from charging more than the greater of the average contracted rate or 150% of the amount Medicare reimburses on a fee for service basis for the same or similar hospital services in the general geographic region in which the services were rendered, as specified, for emergency care or post-stabilization care. This bill would also require a health plan contract amended or renewed on or after January 1, 2020, to provide that if an enrollee receives covered services from a noncontracting hospital, the enrollee is prohibited from paying more than the same cost sharing that the enrollee would pay for the same covered services received from a contracting hospital. *[A. Health]*

AB 1670 (Holden), as amended March 18, 2019, would add section 1371.85 to the Health and Safety Code, relating to health care coverage. This bill would authorize a provider that contracts with a health plan to bill an enrollee for a service that is not a covered benefit if the enrollee consents in writing and that written consent meets specified criteria. The bill would require a contracting provider to provide an enrollee with a written estimate of the person's total cost, based on the standard rate the provider would charge for the service, if the service sought is not a covered benefit under the person's health plan. The bill would require these documents to be in the language spoken by the enrollee as specified. A willful violation of the bill's requirements relative to health plans would be a crime. *[A. Health]*

AB 744 (Aguiar-Curry), as introduced February 19, 2019, would amend section 2290.5 of the Business and Professions Code, and amend section 1374.13 of, and add section 1374.14 to the Health and Safety Code, relating to health care coverage. This bill would require a contract between a health plan and a healthcare provider to specify that the health plan reimburse a healthcare provider for the diagnosis, consultation, or treatment of an enrollee, delivered through telehealth services on the same basis and to the same extent that the health plan is responsible for reimbursement for the same service through in-person diagnosis, consultation, or treatment. *[A. Health]*

AB 954 (Wood), as amended March 27, 2019, would add section 1374.193 to the Health and Safety Code, relating to dental services. According to the author, network leasing arrangements present numerous problems for dentists and their patients because plans that lease or purchase networks do not have any responsibility to be transparent about which fee schedules are in effect for their patients. To address the need for transparency, the bill would authorize a health plan that issues, sells, renews, or offers a contract covering dental services to grant third

party access to a provider network contract entered into, amended, or renewed on or after January 1, 2020, or access to services or discounts provided pursuant to that provider network contract if certain criteria are met. *[A. Appr]*

AB 767 (Wicks), as amended April 9, 2019, would amend section 1374.55 of the Health and Safety Code, relating to infertility. Requires every health plan contract policy that is issued, amended, or renewed on or after January 1, 2020, to provide coverage for in vitro fertilization (IVF), as a treatment of infertility, and mature oocyte cryopreservation (OC). This bill would delete the exemption for religiously affiliated employers and health plans, from the requirements relating to coverage for the treatment of infertility, thereby imposing these requirements on these employers and plans. This bill would also delete the requirement that a health plan contract provide infertility treatment under agreed upon terms that are communicated to all group contractholders and prospective group contractholders. *[A. Health]*

SB 600 (Portantino), as introduced February 22, 2019, would add section 1374.551 to the Health and Safety Code, relating to fertility preservation. This bill would clarify that a health plan contract that covers hospital, medical, or surgical expenses include coverage for standard fertility preservation services when a medically necessary treatment may cause infertility to an enrollee. This bill would also prohibit a health plan from denying coverage of standard fertility preservation services based on medical necessity of an enrollee's treatment plan, as specified. As outlined in the Bill Analysis, "DMHC has initiated enforcement action, and DMHC no longer approves plan documentation that purports to exclude medically necessary fertility preservation. DMHC has communicated this to health plans and has conducted individual plan-by-plan conferences to explain DMHC's position and expectation for compliance." *[S. Health]*

SB 163 (Portantino), as amended April 9, 2019, would amend section 1374.73 of the Health and Safety Code, to expand the definition of behavioral health treatment (BHT) and expand the provider qualifications to include more provider types that can provide BHT under the mandate that health plans and insurers cover BHT for pervasive developmental disorder or autism. The bill would prohibit the setting, location, or time of treatment recommended by a qualified autism services provider from being used as the only reason to deny or reduce coverage for medically necessary services, and requires the setting be consistent with the standard of care for BHT. This bill would also require the intervention plan designed by the qualified autism service provider, when clinically appropriate, to include parent or caregiver participation that is individualized to the patient and takes into account the ability of the parent or caregiver to participate in therapy sessions and other recommended activities. Notably, the bill would bring health plans in the Medi-Cal program into compliance with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). *[S. HumanS]*

SB 11 (Beall), as introduced December 3, 2018, would add sections 1374.77 and 1374.78 to the Health and Safety Code, to require a health plan to submit an annual report to DMHC, certifying compliance with state and federal mental health parity laws, as specified. The bill would require DMHC to review the reports submitted by health plans to ensure compliance with relevant laws, and would require DMHC to make the reports and the results of the reviews available publicly, including posting on its website. The bill would also require the California State Auditor to review DMHC and the Department of Insurance's implementation of this bill and report its findings to the Legislature. The addition of section 1374.78 would prohibit prior authorization or step therapy requirements on any prescription medication approved by the federal Food and Drug Administration for the treatment of substance use disorders. *[S. Health]*

AB 731 (Kalra), as amended March 20, 2019, would amend sections 1385.01, 1385.02, 1385.03, and 1385.07 of the Health and Safety Code, relating to DMHC's rate review of health plans. According to the author, "[m]any [consumers] are struggling with ever rising co-pays and health insurance premiums that have risen 249% since 2002, more than six times the increase in the state's overall inflation." This bill would expand the existing requirement—that health plans offering a contract or policy in the individual or small group market file specified information with DMHC—to apply to large group health plan contracts. The bill would require a plan to disclose specified information by geographic region, including annual medical trend factor assumptions by aggregate benefit category and the top 25 procedures in each benefit category. This bill would also require a health plan that fails to provide all the information required, to be determined an unjustified rate. To effectuate its purpose, the bill would eliminate confidentiality protections for contracted rates between a health plan and a large group. *[A. Appr]*

AB 1309 (Bauer-Kahan), as introduced February 22, 2019, would add section 1399.848 to the Health and Safety Code, to require a health plan, for policy years beginning on or after January 1, 2020, to provide a special enrollment period to allow individuals to enroll in individual health benefits plans through the Exchange from December 16 of the preceding calendar year, to January 31 of the benefit year. The bill would also require, for health plans offered outside of the Exchange, that the annual open enrollment period for policy years beginning on or after January 1, 2020, extend from October 15 of the preceding calendar year, to January 31 of the benefit year. *[A. Appr]*

SB 159 (Weiner), as amended April 11, 2019, would add section 1342.74 to the Health and Safety Code, to preclude health plans from requiring a prior authorization or step therapy for combination antiretroviral drug treatments that are medically necessary for the prevention of

AIDS/HIV, including pre-exposure prophylaxis or post-exposure prophylaxis. This bill would also require Medi-Cal to reimburse pharmacies for initiating and furnishing pre-exposure prophylaxis or post-exposure prophylaxis, and permits a pharmacist to furnish these treatments in accordance with protocols established by the bill. According to the author, allowing pharmacists to furnish these treatments without a prescription "will expand access, help increase the number of individuals who use these HIV preventatives, and will help California achieve its goal to end new HIV infections." *[S. Health]*

AB 1249 (Maienschein), as amended March 18, 2019, would add and repeal section 1343.3 to the Health and Safety Code, to require the DMHC Director, by May 1, 2020, to authorize two pilot programs, one in northern California and one in southern California. The purpose of the pilot programs is to demonstrate the control of costs for health care services and the improvement of health outcomes and quality of service when compared against a sole fee-for-service provider reimbursement model. Each pilot program would be conducted under the voluntary employees' beneficiary association (VEBA) with more than 100,000 enrollees. The bill would further require each health care provider participating in a pilot program to report to DMHC with information regarding cost savings and clinical patient outcomes. New section 1343.3 would require the DMHC to report those findings to the legislature by June 1, 2026. *[A. Health]*

SB 612 (Pan), as introduced on February 22, 2019, would add section 1348.7 to the Health and Safety Code, to require health plans, health insurers, and medical groups, on or before January 1, 2021, to annually report to the Office of Statewide Health Planning and Development (OSHPD) in its participation in a list of health care programs and activities. New section 1348.7 would create requirements for the data that needs to be included, such as detailed descriptions of enrollees, demographic profiles, numbers and types of participating providers, lengths of participation of

enrollees, lengths of carrier participation, and performance measures and outcomes. According to the author, "[t]his bill provides baseline data to policymakers, purchasers, and the public on the extent to which health plans, health insurers, and medical groups are participating in activities that provide high quality care and improve outcomes for Californians with chronic disease." *[S. Appr]*

SB 129 (Pan), as amended on February 26, 2019, would amend section 1348.95 of the Health and Safety Code, to require health plans and insurers to annually report enrollment data for products sold inside and outside of Covered California, any other business lines, and multiple employer welfare arrangements. New section 1348.95 would require DMHC to publicly report annual enrollment data no later than April 15 of each year. According to the author, this bill is necessary to update the annual health plan and insurer enrollment reporting requirements that are required under the Affordable Care Act. *[S. Appr]*

SB 406 (Pan), as introduced on February 20, 2019, would amend section 1348.96 of the Health and Safety Code, to require DMHC (and the Department of Insurance) to each prepare, in coordination with the other department, an annual summary report that describes the impact of the risk adjustment program on premium rates in the state. The bill would also require the reports to be posted on the departments' respective public websites no later than seven months after the risk adjustment year. The federal Patient Protection and Affordable Care Act (PPACA), which enacted various health care coverage market reforms, requires a state, using criteria and methods developed by the United States Secretary of Health and Human Services, to implement a risk adjustment program under which a charge is assessed on low actuarial risk plans and a payment is made to high actuarial risk plans. This bill effectuates the federal legislation. *[S. Health]*

SB 407 (Monning), as amended on March 28, 2019, would amend sections 1358.11 and 1358.91 of the Health and Safety Code, to extend the Medicare supplement annual open enrollment

period 30 additional days (for a total of 60 days or more), commencing with the individual's birthday. The bill eliminates a restriction that an individual may only purchase coverage during the annual open enrollment period under specified circumstances, and allowing an individual to choose any Medicare supplement coverage during the annual open enrollment period. Amended section 1358.91 would require an issuer of a Medicare supplemental contract with new or innovative benefits, which is advertised, solicited, or issued for delivery in California on or after January 1, 2020, to offer the new or innovative benefits only as a rider to the Medicare supplemental contract, thus creating guaranteed renewability for consumers. *[S. Health]*

SB 784 (Pan), as introduced on March 7, 2019, would amend sections 1358.91 and 1358.11 of, and add section 1358.92, to the Health and Safety Code, to make conforming changes in California law to the requirements and standards that apply to Medicare supplement contracts and policies, for the purpose of complying with the federal laws affecting contracts delivered or issued after January 1, 2020. This bill contains an urgency clause to ensure that the provisions of the bill go into immediate effect upon enactment. Supporters of this bill argue that it makes necessary amendments to California's laws governing Medicare Supplement to protect seniors and ensure that the state maintains the ability to regulate this product. *[S. Health]*

AB 1268 (Rodriguez), as introduced on February 21, 2019, would amend sections 1363.5 and 1367.01 of the Health and Safety Code, to require a health care service plan that prospectively reviews and approves, modifies, delays, or denies services, based in whole or in part on medical necessity, to report to DMHC the number of times in the previous year the service was approved, modified, delayed, or denied. According to the author, "we cannot begin to address the problem [prior authorizations delaying necessary medical care] without information and facts, and this bill will ensure that the detailed data is collected and made available to stakeholders …." *[A. Health]*

SB 260 (Hurtado), as amended on March 26, 2019, would amend section 1366.50 of the Health and Safety Code, relating to automatic health care coverage enrollment. Amended section 1366.50 would require, no later than July 1, 2020, Covered California to use specified information to enroll an individual who was terminated from a health coverage program administered by the Department of Health Care Services, in the lowest cost silver plan available, or in the individual's previous managed care plan before the termination date of Medi-Cal coverage, under specified circumstances. This bill would further require a health plan to annually notify an enrollee that when the enrollee terminates coverage that their contact information will be provided to Covered California to assist in obtaining other coverage, or that they may opt out of this transfer of information. *[S. Appr]*

AB 1656 (Gallagher), as amended on March 21, 2019, would amend section 11217 of the Health and Safety Code, to clarify that a physician or authorized hospital staff may administer or dispense controlled substances in a hospital to maintain or detoxify a person related to medical or surgical treatment of conditions other than addiction, or to treat people with pain for which a significant relief or cure has not been possible after reasonable efforts. *[A. Health]*

AB 290 (Wood), as amended on March 5, 2019, would add section 1367.016 to the Health and Safety Code, to institute requirements for third-party payments of health insurance premiums, and implement a prohibition on assistance that is conditioned on the use of a specific facility or provider. New section 1367.016 would require that third-party payers disclose payments to health plans and requires health plans to report this information to DMHC. According to the author, this bill addresses concerns that dialysis companies, through a third party, may be veering patients away from Medicare or Medi-Cal by indirectly paying a patient's premiums, for the company's

own financial benefit. This bill will still allow providers, like dialysis companies, to donate to nonprofit organizations if they want to help provide premium assistance to patients. *[A. Appr]*

AB 648 (Nazarian), as amended on March 28, 2019, would add section 1367.13 to the Health and Safety Code, to establish rules that govern wellness programs instituted by health plans. New section 1357.13 would require a health plan to comply with data privacy protections, limit sharing of data and destroy data upon conclusion of the program, and provide clear written explanations about program parameters, data collection, and enrollee rights. *[A. Appr]*

AB 1676 (Maienschein), as introduced on February 22, 2019, would add 1367.626 to the Health and Safety Code, to require that health plans and insurers, by January 1, 2021, establish a telehealth consultation program and maintain records surrounding certain patient's telehealth mental health data. The bill requires a health plan or insurer to communicate information relating to the telehealth program and its availability to contracting medical providers who treat children and pregnant and postpartum persons, including pediatricians, obstetricians, and primary care providers, at least twice a year in writing. *[A. Health]*

SB 746 (Bates), as introduced on February 22, 2019, would add 1367.667 to the Health and Safety Code, to require every health plan contract and health insurance policy issued, amended, or renewed in California on or after January 1, 2020, that provides coverage for chemotherapy or radiation therapy for the treatment of cancer, to also provide coverage for anticancer medical devices. *[S. Health]*

AB 993 (Nazarian), as amended on April 11, 2019, would add 1367.693 to the Health and Safety Code, to require that if the HIV specialist meets the plan's criteria, then the health plan must allow an HIV specialist who is a physician, physician assistant, or nurse practitioner to be eligible as a primary care provider. According to the author, "Californians living with HIV should have

access to care from physicians and other providers with the training and experience required to meet their complex needs." *[A. Appr]*

AB 598 (Bloom), as introduced on February 14, 2019, would add 1367.72 to the Health and Safety Code, to require a health plan to include overage for hearing aids for an enrollee who is under the age of 18 years. *[A. Health]*

SB 382 (Nielsen and Stern), as amended on March 26, 2019, would add section 1368.7 to the Health and Safety Code, to require a health care service plan contract or health insurance policy entered into, amended, or renewed on or after January 1, 2020, to provide reimbursement for care provided to enrollees who remain in acute care hospitals, and no longer meet the medical necessity criteria for care in an acute care hospital, due to a lack of access to post-acute care services during a state of emergency. This bill would require daily reimbursement rates to be no lower than the Medi-Cal administrative day rate, unless the plan or insurer has otherwise contracted with the acute care hospital for reimbursement during a state of emergency. According to the author, "[i]n order to avoid leaving patients in limbo regarding their health care coverage and questions about access during an emergency, this bill would ensure that individuals and families with health insurance can access health care regardless of availability of services outside of an acute care facility." *[S. Health]*

LITIGATION

***Pharmaceutical Research & Manufacturers of America v. Brown*, Case No. 2:17-cv-02573-MCE-KJN (E.D. Cal.).** On October 26, 2018, on the Court's own motion and pursuant to Local Rule 230(g), U.S. District Judge Morrison C. England, Jr. of the Eastern District of California vacated the December 13, 2018, hearing on Defendant's Motion to Dismiss without

appearance and argument. (This case involves the constitutionality of SB 17 (Hernandez) (Chapter 603, Statutes of 2017), a bill challenged by Petitioner PhRMA in this lawsuit, which attempts to provide transparency in regard to prescription drug pricing, including requiring drug manufacturers to provide advance information on and a justification for prescription drug price increases.) The order also provided that the opposition or statement of non-opposition and reply shall be filed in accordance with the original motion hearing date and, if the court determines that oral argument is needed, it will be scheduled at a later date. To date, oral argument has not been scheduled. At this writing, motions and responses have been submitted by both parties and are pending.

As reported previously, on September 28, 2018, Petitioner PhRMA submitted its first amended complaint. PhRMA alleges that SB 17 is unconstitutional in that it compels them to speak about potential price increases when they would prefer not to communicate that information (thus violating these corporation's asserted first amendment rights); additionally, PhRMA alleges that the bill interferes with interstate commerce. In its prayer for relief, PhRMA seeks an injunction to prevent California from implementing and enforcing SB 17, and a declaration that the statute is unconstitutional. *[24:1 CRLR 44–45]*

Other pharmaceutical companies have followed PhRMA's lead and filed lawsuits to prevent the enforcement of SB 17. On December 11, 2018, Petitioner Amgen Inc., filed a Petition for Writ of Mandate and declaratory and injunctive relief in superior court to prevent disclosure of its confidential, proprietary, and trade secret drug pricing information that it was required to provide to the California Correctional Health Care Services (CCHCS) in ***Amgen Inc. v. The California Correctional Health Care Services,*** **No. 18STCP03147 (Super. Ct. Los Angeles)**. According to the petition, in November and December 2018, CCHCS, informed Amgen that it had

received Californian Public Records Act (CPRA) requests for the potential price changes that Amgen had provided to the agency. According to Amgen's petition, SB 17 does not require drug manufacturers to publicly disclose potential increases in drug prices, nor does it modify the CPRA in any way.

On February 1, 2019, after consideration of the parties' briefs and argument, in an eight-page order (the "PI Order"), the court granted Amgen's preliminary injunction motion and ordered that Amgen's SB 17 notice should not be disclosed pursuant to a CPRA request until Petitioner effectuates a price increase for the medications in the notice. At this writing, Defendant CCHCS's appeal is pending.

A similar ruling was also granted in ***Ipsen Biopharmaceuticals, Inc. v. California Public Employees' Retirement System, et al.*, No. CPF-18-516445 (Super. Ct. San Francisco)**. On December 13, 2018, the superior court judge granted Ipsen Biopharmaceuticals, Inc.'s order to show cause and temporary restraining order against defendants The California Public Employees' Retirement System (CalPERS), and the California Correctional Health Care Services (CCHCS). CalPERS and CCHCS are ordered to show cause why a preliminary injunction should not be ordered, pending trial in this action, restraining and enjoining defendants from disclosing the content of any Ipsen confidential pricing information submitted in accordance with the section 127677 of the Health and Safety Code, as responsive to the CPRA request received or to be received requesting such information.

On February 27, 2019, the court issued an order on joint stipulation regarding stay of proceedings in this action. The court stated that there is "substantial overlap between the claims, issues, and parties involved in this case and the Los Angeles litigation (*Amgen Inc. v. The California Correctional Health Care Services*); and therefore, the outcome of proceedings relating

to the preliminary injunction motion in the Los Angeles case will affect the scope and conduct of this case. According to the order, the parties stipulate and agree that all proceedings in this litigation shall be stayed while the preliminary injunction in the Los Angeles litigation remains in effect and the stay will automatically expire if the preliminary injunction in the Los Angeles litigation is terminated. The order also stipulates, in the event that an order issued terminates the preliminary injunction in the Los Angeles litigation, CalPERS and CCHCS shall continue to withhold Ipsen's allegedly confidential and proprietary information for a period of 21 days from the issuance of the order. If Ipsen moves for a preliminary injunction during that 21-day period, CalPERS and CCHCS shall continue to withhold Ipsen's allegedly confidential and proprietary information until a ruling on that motion is issued.

Not all parties requesting preliminary injunctions against agencies are being granted so quickly. On October 26, 2018, the Plaintiffs' motion for preliminary injunction was heard and taken under advisement in ***Association for Community Affiliated Plans, et al. v. United States Department of Treasury, et al.,*** **Case No. 1:18-cv-02133-RJL (D.D.C.)**. The court stated that it would not be possible to complete an opinion in this case within a few weeks because it's too complicated, too large, and too consequential, and then the court went into recess.

On November 12, 2018, upon consideration of Plaintiffs' notice of withdrawal of motion for a preliminary injunction and motion for expedited briefing schedule, and defendants' response, the court ordered a hearing on the parties' cross-motions for summary judgment to be held on February 19, 2019. However, on December 31, 2018, Judge Richard J. Leon granted the Defendants' motion to stay proceedings in light of a lapse of appropriations to the Department of Justice. On March 1, 2019, Judge Leon ordered that the stay in this case be lifted and Defendants'

motion to modify the briefing schedule be granted. At this writing, all parties and numerous *amici curiae* are briefing the case; no further arguments have been held.

Update on Federal Government Actions

♦ ***Texas, et al. v. United States of America*, 300 F. Supp. 3d 810 (2019)**. In *Texas v. United States of America*, twenty Republican state attorneys general and two individual plaintiffs challenged the constitutionality of the individual mandate and with it, the entire Affordable Care Act (ACA). The states brought an action alleging that the United States, United States Department of Health and Human Services (HHS), HHS Secretary, Internal Revenue Service (IRS), and its Commissioner, effectively required states to pay Health Insurance Providers Fees (HIPF) imposed by the ACA in order to receive Medicaid funds, thus, violated the vesting clause, the Administrative Procedure Act (APA), and the spending clause. Plaintiffs sought declaratory judgment and a permanent injunction to prevent the defendants from prospectively collecting the provider fees. The parties in the action filed cross-motions for summary judgment.

On March 5, 2019, Judge Reed O'Connor held that the ACA is unconstitutional. The ruling is currently being appealed and several stakeholders have been filing amicus briefs during the past several months, including The National Women's Law Center, National Partnership for Women and Families, and the Black Women's Health Initiative.

♦ ***State of New York, et al. v. U.S. Department of Labor,* Civ. Action No. 18-1747, (D.D.C.).** The following is a status update on *State of New York, et al. v. U.S. Department of Labor* has been covered previously in Volume 24, No. 1 (Fall 2018) of the *California Regulatory Law Reporter [24:1 CRLR 46]*:

On March 28, 2019, United States District Judge Bates entered an order granting the motion for summary judgment for the plaintiff and denying motion for summary judgement and motion to dismiss for the defendant. On August 23, 2018, Plaintiffs filed a memorandum of law in support of a motion for summary for judgment. Plaintiffs argue that the administration is violating the ACA's purpose of establishing minimum insurance protections. Defendants filed a counter memorandum of law in support of their position for summary judgment in conjunction with a motion to dismiss. In defendant's memorandum for summary judgement it is argued that loosening of health plans allows for more affordable health care, and more covered Americans.

On July 26, 2018, the complaint was filed by 12 state attorneys general entitled *State of New York, et al. v. U.S. Department of Labor*, in the U.S. District Court for the District of Columbia. This complaint challenges the Trump administration's regulation issued this year that makes it easier for individuals and small employers to band together to purchase health care coverage through association health plans (AHPs) that do not meet ACA standards.