DEPARTMENT OF MANAGED HEALTH CARE

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reated on July 1, 2000, the Department of Managed Health Care (DMHC) regulates the managed health 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 enrollees.

In Health and Safety Code section 1342, the legislature has expressly instructed the DMHC Director to ensure the continued role of the professional as the determiner of the patient's health needs; ensure that enrollees¹ are educated and informed of the benefits and services available in and 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 lowest possible

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

cost by transferring the financial risk of health care from patients to providers. The DMHC 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. DMHC'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 DMHC 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 Releases 2018 Annual Report

In May of 2019, DMHC issued its <u>2018 Annual Report</u>, which includes an enrollment overview, statistics on the Help Center, and information on plan licensing, plan monitoring, financial oversight, rate review, and enforcement against health plans. The annual report also contains two separate appendices: one summarizing the year's consumer complaints and the other an independent medical review summary.

Enrollment Overview. In addition to the 78 full-service health plans, DMHC oversees 47 specialized health plans including chiropractic, dental, vision, psychological (behavioral health) and pharmacy. DMHC is now more evenly distributed between commercial and government enrollment with approximately 13.4 million commercial enrollees and 12.8 million government enrollees. DMHC licenses and regulates the full scope of managed care models, including all

Health Maintenance Organizations (HMO) in the state, as well as Preferred Provider Organizations (PPO), Exclusive Provider Organizations (EPO), Point-of-Service (POS) products and Medi-Cal managed care plans. They also license and conduct financial reviews of Medicare Advantage and Part D plans.

Help Center Statistics. In 2018, the DMHC Help Center assisted 142,294 health care consumers, handled 11,464 complaints, handled 7,199 provider complaints and closed 3,693 independent medical review cases. The Help Center also fielded 125,462 telephone inquiries and recovered \$3.6 million for consumers and \$11.9 million in provider payments. The DMHC Help Center continued to address the practice of "surprise balance billing" by launching an Independent Dispute Resolution Process (IDRP) in compliance with AB 72 (Bonta) (Chapter 492, Statutes of 2016). In 2018, the DMHC received 39 IDRP applications and of those, 37 were ineligible or withdrawn, and the remaining two were still pending as of December 31, 2018. Also, in 2018, the DMHC Help Center launched a new Customer Relations Management (CRM) database called "Spotlight." This interface is used to work on consumer cases with improved convenience and efficiency for both DMHC and health plans.

Plan Licensing. DMHC issues licenses to health plans in California and reviews health plan mergers to ensure adherence with the Knox-Keene Act's consumer protection and financial solvency requirements. DMHC reviews all aspects of a health plan's operations, including benefits and coverage, template contracts with doctors and hospitals, provider networks, and complaint and grievance systems. After licensure, DMHC continues to monitor health plans and any changes they make to their operations. In 2018, DMHC plan licensing issued four new licenses, reviewed 4,329 evidences of coverage, 1,342 advertisements, 45 Covered California filings reviews, and received

214 material modifications (significant changes). The Department also issued twenty All Plan Letters in 2018 on various topics. DMHC approved CVS's acquisition of Aetna, Inc. [24:2 CRLR 22–23], Optum, Inc's acquisition of DaVita Health Plan of California [24:2 CRLR 20–22], and Cigna Corporation's acquisition of Express Scripts [24:2 CRLR 23–24]. In compliance with SB 137 (Hernandez) (Chapter 649, Statutes of 2015), which became effective January 1, 2018, DMHC also established comprehensive requirements to ensure health plans publish and maintain accurate, complete and up-to-date provider directories. All health plans must have publicly available provider directories on their websites, make weekly updates to those directories, and provide consumers with simple ways to report directory errors.

Plan Monitoring. DMHC assesses and monitors health plan networks and accessibility of services to enrollees, provider-to-patient ratios, and compliance with its timely access to health care regulations. During 2018, DMHC reports that it conducted 20 routine surveys and 35 follow-up surveys. The surveys examine health plan practices related to access, utilization management, quality improvement, continuity and coordination of care, language access, and enrollee grievances and appeals. In 2018, DMHC held biweekly workgroups with health plans and the California Association of Health Plans to discuss data challenges and how to improve the mandatory methodology. DMHC will continue to work with health plans, providers, consumer advocates, and other stakeholders, to improve the usability of the timely access data and develop an acceptable rate of compliance. The December 2018 Timely Access Report is available on DMHC's website.

Financial Oversight. DMHC monitors the financial status of health plans and provider groups to make sure they can meet their financial obligations to consumers and other purchasers.

During 2018, DMHC conducted 67 financial examinations, reviewed 2,497 financial statements, ensured rebates of \$72 million to consumers whose plans failed to comply with established medical loss ratios, remediated \$1.9 million worth of disputed payments, and assessed \$314,162 in interest and penalties. In 2018, DMHC required two full-service health plans to issue rebate checks to small employers for failing to meet the minimum medical loss ratio requirement of 80% in the small group market for 2017. In April 2018, DMHC launched an internal dashboard to provide staff with easy access to financial data in one centralized application, and to improve efficiencies in reviewing health plan and risk-bearing organizations' financial statements and filings.

Rate Review. In 2018, DMHC reviewed 51 individual and small group rate filings. Although DMHC is not authorized to approve or deny rate increases, its rate review efforts hold health plans accountable through transparency. On February 7, 2018, DMHC held a public meeting to discuss the large group aggregate rate data filed by health plans in 2017. In December 2018, DMHC released the first annual report summarizing this data and the impact of prescription drug costs on health care premiums.

Enforcement. DMHC monitors and takes timely action against health plans that violate the law. In 2018, DMHC opened 1,185 cases, closed 215 of those with a penalty, and assessed \$2,975,500 in fines and penalties against health plans. For example, DMHC imposed a penalty of \$45,000 against Aetna Health of California, Inc. for numerous violations related to two different medication requests for the same enrollee. DMHC also imposed a penalty of \$100,000 against Molina Healthcare of California, Inc. for failing to pay for covered emergency services and repeatedly failing to adequately consider and rectify an enrollee's grievances. DMHC imposed a penalty of \$70,000 against Anthem Blue Cross for untrue, misleading advertising and fraudulent,

dishonest dealing. Finally, the Superior Court upheld DMHC's imposition of a \$50,000 administrative penalty against Anthem Blue Cross for delaying the Independent Medical Review process.

Agreement with Anthem Blue Cross

On June 5, 2019, DMHC and Anthem Blue Cross reached a stipulated settlement agreement in an enforcement matter before the Office of Administrative Hearings. The following day, DMHC announced in a press release that the agreement with Anthem involved the plan's processes for identifying and addressing enrollee grievances and appeals. Anthem Blue Cross agreed to pay a \$2.8 million fine and entered into a Corrective Action Plan (CAP) with DMHC so that when an enrollee call reaches a plan customer services representative, it will be categorized as a "grievance" rather than an "inquiry." DMHC took enforcement action against Anthem in 2017 related to this issue [23:2 CRLR 21–22], and the plan has invested \$8.4 million to make improvements to its grievances and appeals process. In the enforcement action, DMHC asserted that Anthem misclassified grievances as inquiries, denied enrollees their legal right to engage in the plan's and DMHC's grievance resolution process, and potentially resulted in delays or denials of care to enrollees.

Task Force on Pharmacy Benefit Management Reporting

On June 28, 2019, DMHC <u>announced</u> the development of its Task Force on Pharmacy Benefit Management Reporting as required by <u>AB 315 (Wood) (Chapter 905, Statutes of 2018)</u>. In response to the continued rise of pharmaceutical drug costs, Assembly member Jim Wood (D-Santa Rosa) authored AB 315 "to open the 'black box' of how pharmacy benefit managers operate

so that we can better understand their business model, how discounts and rebates are allocated, and who benefits. I look forward to the task force helping us ensure that PBMs are doing what's in the best interest of patients, not increasing the PBM's bottom line." [24:1 CRLR 38–40] The Task Force's purpose is to recommend what information, if any, related to pharmaceutical costs health care service plans or their contracted pharmacy benefit managers should report to DMHC. AB 315 requires the Task Force to consider wholesale acquisition costs of pharmaceuticals; rebates obtained by the health care service plan or the pharmacy benefit manager from pharmaceutical manufacturers; payments to network pharmacies; exclusivity arrangements between health care service plans or contracted pharmacy benefit managers with pharmaceutical manufacturers; and information already reported by health plans related to the costs of covered prescription drugs as required by SB 17 (Hernandez) (Chapter 603, Statutes of 2017). The Task Force held its first meeting on July 31, 2019 in Sacramento, and all meetings are open to the public. DMHC will submit a report with the Task Force's recommendations to the legislature by February 1, 2020.

Financial Solvency Standards Board Update, July 2019 Meeting

On July 17, 2019, the Financial Solvency Standards Board (FSSB) met in Sacramento. The agenda covered mid-year updates related to the Department of Health Care Services, regulations, federal activities, the Task Force on Pharmacy Benefit Management, provider solvency, and health plans. Director Rouillard discussed two mergers that DMHC is reviewing and analyzing in the context of AB 595 (Wood) (Chapter 292, Statutes of 2018), which requires DMHC to make a determination as to whether a merger is a "major transaction," triggering a public meeting and independent analysis of the market impact of the transaction. The first large national merger

involves Centene, a St. Louis-based parent corporation of several large health plan entities including Health Net of California, purchasing WellCare, a Florida-based Medicare-focused health plan. The second merger involves Anthem acquiring Beacon Health Options, Inc., which is the largest privately held behavioral health organization in the nation.

Highlights from the meeting included a <u>budget presentation</u>, which for fiscal year 2019–2020 is \$91 million in spending authority and 482 authorized positions, an increase of \$7 million over the prior year and 31 additional positions. The FSSB was briefed on the <u>Integrated Healthcare Association's California Regional Health Care Cost & Quality Atlas</u> program, whose mission is to create breakthrough improvements in health care services for Californians through collaboration among key stakeholders. Last, Director Rouillard announced that member Jeff Conklin had resigned from the FSSB. The next meeting is set to be held on November 17, 2019

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 2 and Volume 24, Number 1 of the *California Regulatory Law Reporter* [24:2 CRLR 13–16][24:1 CRLR 20–26]:

♦ Standard Prescription Drug Formulary Template. On June 25, 2019, OAL approved DMHC's adoption of section 1300.67.205, Title 28 of the CCR. DMHC originally noticed this regulation, the Standard Prescription Drug Formulary Template, in September 2018. According to the initial statement of reasons, this regulation was DMHC's effort to implement SB 1052 (Torres) (Chapter 575, Statutes of 2014), and was meant to "promote accessibility and transparency in prescription drug coverage" and provide "easy access to clear and comparable prescription drug information for health plan enrollees." The changes became effective on October 1, 2019.

♦ Cancellations, Rescissions, and Non-Renewals. On May 10, 2019, DMHC released its Notice of Fourth Comment Period with respect to DMHC's intent to repeal 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 to Title 28 of the CCR, regarding limitations on the cancellation, rescission, and nonrenewal of health care service plan contracts, consistent with federal law under the Patient Protection and Affordable Care Act (PPACA). The modified text results from information received during the third public comment period, which ended on March 15, 2019. [24:2 CRLR 22-23].

The newly revised <u>text</u> further clarifies language used throughout the regulation and provides greater consistency of terms. For instance, one concern related to section 1300.65.3, which defines requirements for the suspension of coverage of an enrollee in the individual market who is currently a recipient of advance payments of the premium tax credit ("APTC") pursuant to the federal Patient Protection and Affordable Care Act ("PPACA"), called an "APTC Enrollee." The new rule specifies that a qualified health plan may not take or threaten action that causes or suggests that an APTC enrollee's coverage may be suspended.

The comment period ended on May 28, 2019. On July 30, 2019, OAL <u>approved</u> the <u>final</u> <u>text</u> of the regulation.

♦ Financial Solvency of Risk Bearing Organizations. On July 10, 2019, OAL approved DMHC's proposed amendments to 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. DMHC originally noticed this regulation, Financial Solvency of Risk Bearing Organizations, in May 2018. [24:1 CRLR 23-25]. According to the initial statement of reasons, this regulation is meant to "implement, interpret and make specific the rights and requirements under Health and Safety Code section 1375.4." These

amendments allow DMHC to clarify the definition of a risk bearing organization and how these organizations are financially capable of taking on the weight of their risk-based agreements to provide health care services to health plan enrollees. The changes became effective on October 1, 2019.

LEGISLATION

AB 290 Wood, as amended September 5, 2019 and as it relates to DMHC, adds sections 1210, 1367.016, and 1385.09 to the Health and Safety Code to establish requirements related to third-party premium payments to health care plans made on behalf of patients by financially interested entities or providers. It also defines "financially interested" to include a chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization. According to the author, this bill ends the practice where companies that provide certain types of care, e.g., a dialysis company, donate money to a nonprofit that, in turn, pays for a patient's private coverage even though they qualify for coverage under Medicare or Medi-Cal, in order to receive a higher reimbursement rate. This bill will still allow providers, like dialysis companies, to donate to nonprofit organizations if they want to help provide premium assistance to patients, but it will not allow them to leverage those donations into higher reimbursement rates.

Governor Newsom signed AB 290 on October 13, 2019 (Chapter 862, Statutes of 2019).

AB 577 (Eggman), as amended August 14, 2019 and as it relates to DMHC, amends section 1373.96 of the Health and Safety Code to extend the duration of the requirement that health plans provide continuity of care for pregnant women to up to twelve months from the diagnosis or from the end of pregnancy, whichever occurs later, if the woman presents written documentation

of being diagnosed with a maternal mental health condition from the individual's treating health care provider. According to the author, maternal mental health conditions have impacts far beyond the mothers that are experiencing them; they also effect the well-being of children, families, and communities. Extending the duration of continuity of care for pregnant women with a maternal mental health condition who have had to switch health coverage plans and extending full scope Medi-Cal benefits for undocumented pregnant women will ensure that they receive important pregnancy-related and post-partum health care, including mental health care.

Governor Newsom signed AB 577 on October 12, 2019 (Chapter 776, Statutes of 2019).

AB 651 (Gravson), as amended September 9, 2019 and as it relates to DMHC, amends section 1371.55 to the Health and Safety Code to require a health insurance plan issued, amended, or renewed on or after January 1, 2020, to provide that if an individual receives covered services from a noncontracting air ambulance provider, the individual shall 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, referred to as the in-network cost-sharing amount. The bill provides that an individual would not owe the noncontracting provider more than the in-network cost-sharing amount for services. The bill also specifies the processes for advancing unpaid bills to collections and for resolving billing disputes.

Governor Newsom signed AB 651 on October 7, 2019 (Chapter 537, Statutes of 2019).

AB 731 (Kalra), as amended August 30, 2019 and as it relates to DMHC, amends sections 1374.21, 1385.01, 1385.02, 1385.045, and 1385.07 of, amends, repeals, and adds section 1385.03 of, and adds section 1385.046 to, the Health and Safety Code to expand, beginning July 1, 2020, rate filing requirements to apply to large group health insurance plans, and imposes additional rate

filing requirements on large group contracts and policies. This bill requires a health plan to disclose specified information in a rate filing by geographic region for individual, grandfathered group, and nograndfathered group contracts and policies, including the price paid compared to the price paid by the Medicare program for the same services in each benefit category. DMHC is required to determine if large group community rate changes are unreasonable or unjustified, and if so, requires health plans to notify the purchaser of an unreasonable or unjustified rate determination. According to the author, there needs to be a review from regulators to ensure premium rate increases are reasonable or justified in order to curb the skyrocketing cost of health care, which is contributing to wage stagnation and fueling income inequality.

Governor Newsom signed AB 731 on October 12, 2019 (Chapter 807, Statutes of 2019).

AB 744 (Agular-Curry), as amended September 10, 2019 and as it relates to DMHC, amends section 1374.13 of, and adds section 1374.14 to the Health and Safety Code so that effective January 1, 2021, health insurance plans reimburse treating or consulting health care providers who utilize telehealth to diagnose, consult, or treat a consumer to the same extent as inperson services. According to the author, "telehealth overcomes access and cost barriers by utilizing technology to connect patients to their physicians, no matter where they are located. Telehealth uses physicians' time and expertise more efficiently, while also improving access to all types of care for Californians. In particular, expanding access to specialty and behavioral healthcare can significantly improve health outcomes for those who currently lack providers." A University of California San Francisco report entitled "A Path to Universal Coverage and Unified Health Care Financing in California," recommends that California encourage greater use of telehealth by reimbursing providers for telehealth visits, since most telehealth services are not covered under insurance.

Governor Newsom signed AB 744 on October 13, 2019 (Chapter 867, Statutes of 2019).

AB 954 (Wood), as amended July 1, 2019, as it relates to DMHC, adds section 1374.193 to the Health and Safety Code to authorize a health plan that covers dental services to grant third-party access to a provider network contract if specified circumstances are met, such as a notification to the health care provider about the third-party access and allowing the provider to choose not to participate in third-party access to the provider network contract. 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.

Governor Newsom signed AB 954 on October 7, 2019 (Chapter 540, Statutes of 2019).

AB 1309 (Bauer-Kahan), as amended August 22, 2019 and as it relates to DMHC, adds section 1399.848 to the Health and Safety Code to give consumers additional time to sign up for health care coverage. This bill specifically states that a health insurer offering policies outside of the California Health Benefit Exchange (Exchange) must provide an annual enrollment period for policy years beginning on or after January 1, 2020, from November 1 of the preceding calendar year, to January 31 of the benefit year. For policy years beginning on or after January 1, 2020, a health insurer offering policies through the Exchange must provide a special enrollment period from December 16 of the preceding calendar year, through January 31 of the benefit year. An application for a health benefit plan submitted during this special enrollment period is to be treated the same as an application submitted during the annual open enrollment period.

Governor Newsom signed AB 1309 on October 12, 2019 (Chapter 828, Statutes of 2019).

AB 1622 (Carrillo), as amended September 6, 2019 and as it relates to DMHC, amends sections 1339.7, 1367.695, 101560, 123515, 127900, 128205, and 151001 of the Health and Safety Code to apply the "family physician" definition to provisions of relevant statute. Specifically, when policyholders seek obstetrical and gynecological physician services, they may do so directly from an obstetrician and gynecologist or directly from a participating family physician and surgeon designated by the plan as providing obstetrical and gynecological services. The bill refers to an individual who practices family medicine as a family physician and surgeon, and would make technical, conforming, and non-substantive changes. According to the author, family medicine encourages continuity of care and improved patient outcomes, and this bill allows family physicians to work in a capacity that reflects their training and expertise.

Governor Newsom signed AB 1622 on October 8, 2019 (Chapter 632, Statutes of 2019).

AB 1802 (Committee on Health), as amended April 11, 2019, amends sections 1358.20, 1368.015, 1368.02, 1371, and 1373.65 of the Health and Safety Code to 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.

Governor Newsom signed AB 1802 on July 12, 2019 (Chapter 113, Statutes of 2019).

SB 129 (Pan), as amended June 12, 2019, amends section 1348.95 of the Health and Safety Code to require annual health plan and insurer enrollment reporting to include enrollment data for products sold inside and outside of Covered California, any other business lines, and multiple

employer welfare arrangements. It also requires DMHC to publicly report annual enrollment data by April 15th of every year. According to the author, since the enactment of the Affordable Care Act, the health care market has undergone major transformation, as California's uninsured rate has been dramatically reduced and millions of individuals have gained coverage in the Medi-Cal program and individual and small group markets. Beginning in 2013, California tracked enrollment in different types of health care coverage products and business lines. This information helped policymakers monitor trends over time. This bill is necessary to update the insurer enrollment reporting requirement to capture additional business lines and ensure the annual availability of the data collected.

Governor Newsom signed SB 129 on September 5, 2019 (Chapter 241, Statutes of 2019).

SB 159 (Wiener), as amended September 5, 2019, amends section 1342 and adds section 1342.74 to the Health and Safety Code to prohibit a health insurer from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy. Under the bill, notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis. According to the author, data indicate that allowing access to these drugs only with a physician's prescription is blocking access for individuals who would benefit most.

Governor Newsom signed SB 159 on October 7, 2019 (Chapter 532, Statutes of 2019).

SB 343 (Pan), as amended August 12, 2019, amends sections 1385.03, 1385.045, 1385.07, 128735, 128740, and 128760 of the Health and Safety Code to require large health insurance

policies and insurers to file with DMHC the weighted average rate increase for all large group benefit designs during a twelve-month period. This bill eliminates alternative reporting requirements for plans or insurers that have no more than two medical groups or a health facility that receives the majority of its revenue from prepayment health care service plans, e.g., Kaiser Permanente. This bill results in all health care service plans reporting the same information and being held to the same standards as large health insurance plans.

Governor Newsom signed AB 343 on September 5, 2019 (Chapter 247, Statutes of 2019).

SB 407 (Monning), as amended September 5, 2019, amends sections 1358.91 and 1358.11 of the Health and Safety Code to require an issuer of a Medicare supplement contract with new or innovative benefits commencing January 1, 2020, to identify the portion of the premium attributed to a new or innovative benefit as a separate line item on the payment or invoice and extends the Medicare supplement open enrollment period to a minimum of 60 days. This bill also requires a Medicare supplement policy, certificate, or contract issuer to notify an enrollee of their open enrollment rights on any notice related to a benefit modification or premium adjustment. Additionally, DMHC must collaborate with the Department of Insurance to develop and implement policies and procedures that standardize new or innovative benefits for purposes of allowing consumer comparison of benefits, out-of-pocket costs, and premiums. According to the author, this bill sets consumer-focused standards, which protect and allow seniors to fully understand all aspects of an innovative plan they may purchase.

Governor Newsom signed SB 407 on October 7, 2019 (Chapter 549, Statutes of 2019).

SB 600 (Portantino), as amended September 5, 2019, adds section 1374.551 to the Health and Safety Code to require that standard fertility preservation services are covered as basic health

services when a covered treatment may directly or indirectly cause iatrogenic infertility, with the exemption of Medi-Cal managed care plans and clarifying that these services are basic health care services with respect to health plans. New section 1374.551 defines "iatrogenic infertility" to mean infertility caused directly or indirectly by surgery, chemotherapy, radiation, or other medical treatment.

Governor Newsom signed SB 600 on October 12, 2019 (Chapter 853, Statutes of 2019).

SB 714 (Pan), as amended September 6, 2019, amends sections 120370, 120372, and 120372.05 of the Health and Safety Code to allow a child who has a medical exemption for certain vaccinations issued before January 1, 2020, to be allowed to continue enrollment until the child enrolls in the next grade span. This bill prohibits, on and after July 1, 2021, a governing authority from unconditionally admitting or readmitting to these institutions, or admitting or advancing any pupil to 7th grade level, unless the pupil has been immunized or has a medical exemption through a procedure that includes the completion of a compliant statewide form. The bill removes the requirement that the statewide form be signed under penalty of perjury by an eligible physician or surgeon, and specifies which physicians and surgeons are eligible to issue a medical exemption. According to the author, SB 714 provides technical revisions necessary for the Department of Public Health to implement SB 276 (Pan) (Chapter 278, Statutes of 2019).

Governor Newsom signed SB 714 on September 9, 2019 (Chapter 281, Statutes of 2019).

SB 784 (Committee on Health), as amended June 3, 2019 and as it applies to DMHC, amends sections 1358.91 and 1358.11 of, and adds sections 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

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Specifically, the bill amends section 1358.91 to clarify that, effective January 1, 2020, the standardized Medicare supplement benefit plan D can now also be offered to any individual who was eligible for Medicare prior to the effective date. Amended section 1358.11 requires that for all contracts sold or issued on or after January 1, 2020, the issuer shall offer new Medicare beneficiaries additional Medicare supplement benefit plan options if the applicant's original supplement is unavailable. According to the author, the policy changes need to be in place prior to the 2020 plan year so this bill contains an urgency clause.

Governor Newsom signed SB 784 on July 30, 2019 (Chapter 157, Statutes of 2019). Due to the urgency clause the bill became effective immediately.

AB 993 (Nazarian), as amended September 4, 2019, would have added section 1367.693 to the Health and Safety Code to allow patients to designate HIV specialists as eligible primary care physicians. According to the author, by allowing HIV specialists to serve as primary care providers for their patients, this bill eliminates administrative impediments, such as ordering tests or making additional referrals, maintains continuity of care for a disease that has become manageable today, and protects the patient against unintentionally errant treatment.

Governor Newsom <u>vetoed</u> AB 993 on October 12, 2019 stating that the bill was unnecessary because existing law already permits specialists to serve as primary care physicians.

AB 1249 (Maienschein), as amended August 30, 2019, would have added and repealed 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 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 have been conducted under the voluntary employees' beneficiary association (VEBA) with more than 100,000 enrollees. The bill would have required each health care provider participating in a pilot program to report to DMHC with information on cost savings and clinical patient outcomes. New section 1343.3 would have required the DMHC to report those findings to the legislature by June 1, 2026.

On September 27, 2019, Governor Newsom <u>vetoed</u> AB 1249, stating that "this bill would authorize a pilot program that would exempt risk-bearing provider groups taking on global risk from full licensure under the Knox-Keene Act. This proposed pilot project would undermine the fundamental purpose of the Knox-Keene Act by permitting such entities to operate in the State without providing the strong consumer protections guaranteed under the Act."

SB 382 (Neilsen), as amended on September 3, 2019, would have added section 14197.6 to the Welfare and Institutions Code to require Medi-Cal managed care health plans (MCPs) to ensure that members who remain in a general acute care hospital continue to receive medically necessary post-acute care services at the general acute care hospital, during a Governor-declared state of emergency, if specified requirements are met.

On October 12, 2019, Governor Newsom <u>vetoed</u> SB 382 stating, "[w]hile the intent of this bill to ensure the MCP members who are impacted by an emergency continue to receive medically necessary care is admirable, it is also unnecessary...[t]o the extent that there are scenarios where a MCP has not appropriately reimbursed a general acute care hospital, I encourage the Legislature to work with my administration to address any such issues."

Legislative Bills That Died

The following bills reported in Volume 24, No. 2 (Spring 2019) died in committee or otherwise failed to be enacted during 2019: AB 598 (Bloom), which would have required a health care plan to include coverage for hearing aids for an enrollee under 18 years of age; AB 648 (Nazarian), which would have established rules that govern wellness programs instituted by health plans, insurers and employers such as prohibiting an employer from requiring an employee to participate in a wellness program as a condition of employment; AB 767 (Wicks), which would have required Covered California to develop options for the inclusion of in vitro fertilization coverage as part of, or as supplementary to, coverage currently offered through Covered California; AB 1174 (Wood), which would have required health plans to have contracts in place with anesthesia providers and ensure enrollees could access a contracted anesthesia provider; AB 1268 (Rodriguez), which would have required entities that perform utilization review or utilization management functions to report the number of services denied or approved. It also would have required plans to report the information to DMHC to determine compliance with existing law; AB 1656 (Gallagher), which would have clarified that a physician or authorized hospital staff may administer or dispense narcotic drugs in a hospital to maintain or detoxify a person incidental to medical or surgical treatment of conditions other than addiction; AB 1670 (Holden), which would have authorized 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; AB 1676 (Maienschein), which would have required health plans, by January 1, 2021, to establish a telehealth consultation program that allowed providers who treat children and pregnant and postpartum persons access to a psychiatrist during standard provider hours; SB 11 (Beall), which would have required health plans that provide prescription drug benefits for the treatment of substance use disorders to place prescription medications approved by the federal Food and Drug Administration (FDA) for the treatment of substance use disorders on the lowest cost-sharing tier of the plan's prescription drug formulary; SB 163 (Garcia), which would have required the California Department of Social Services to create a facilities liaison position within its Immigration Services Unit to assist state-licensed resource facilities that service undocumented immigrant youth in connecting with appropriate supports and services; SB 406 (Pan), which would have rewritten existing law that requires health plans to cover preventive services without cost sharing by deleting federal statutory citations and replacing those citations with the actual federal provisions that impose the requirements; SB 612 (Pan), which would have required a health plan to report on its participation in specified collaboratives and activities, including whether the supportive and therapeutic needs of an enrollee are addressed in a holistic fashion, to the Office of Statewide Health Planning and Development (OSHPD), and would have required OSHPD to compile and publish the information on its website; and SB 746 (Bates), which would have required health plans to cover medically necessary anti-cancer medical devices designed for use outside of a medical treatment facility.

LITIGATION

♦ Pharmaceutical Research & Manufacturers of America v. Brown, Case No. 2:17-cv-02573-MCE-KJN (E.D. Cal.). On July 31st, 2019, District Judge Morrison C. England, Jr. denied Defendant California's Motion to Dismiss and granted Defendant's Request for Judicial Notice. As reported previously, on September 28, 2018, Plaintiff PhRMA submitted its <u>first amended complaint</u> alleging that SB 17 (Hernandez) (Chapter 603, Statutes of 2017) 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 due to its various notice, reporting, and justification obligations for prescription drug manufacturers. [24:1 CRLR 44–45]

♦ Missionary Guadalupanas of Holy Spirit Inc. v. Rouillard, Case No. C083232 (Cal. App.). On August 6, 2019, Judge Blease of the Third Appellate District Court of California upheld the trial court's judgment finding that Michelle Rouillard, Director of DMHC, did not violate the Administrative Procedure Act by directing seven health plans to comply with California law in their coverage of abortion services. The issue in this case was whether a "voluntary" abortion is a "medically necessary" procedure that health plans are required to cover. Judge Blease held that the appellant, Missionary Guadalupanas of the Holy Spirit, Inc., "attempt[ed] to limit coverage of most abortions by health care service plans in California" by "setting up a false choice between 'voluntary' and 'medically necessary' abortions."

Judge Blease found that "medically necessary" covers not only lifesaving treatments, but women's reproductive health, and recognized that abortion is "both a recognized treatment for the medical condition of a patient's pregnancy, and a treatment every woman in California has the legal right to choose." Furthermore, abortion services are included in "basic health care services" under Health and Safety Code section 1345(b), and the California Constitution prohibits health plans from discriminating against women who choose to terminate a pregnancy.

On October 4, 2019 Plaintiff-Appellants filed a petition for review with the Supreme Court Case No. S258380.

♦ Association of American Physicians & Surgeons, Inc. v. Rouillard, Case No. No. 2:16-cv-02441-MCE-EFB (E.D. Cal.). On June 13, 2019, District Court Judge Morrison C. England Jr. granted Defendant's motion to dismiss this litigation for failure to state a claim, holding that the plaintiffs failed to allege requisite standing to pursue claims; failed to plead a property interest deprivation for a due process claim; even if plaintiffs had pleaded a property interest deprivation, they failed to allege that they were denied due process; and also, plaintiffs failed to state a takings claim. The Judge granted this motion but allowed plaintiffs one last attempt to properly assert a claim in the form of an amended complaint.

This case involves AB 72 (Bonta) (Chapter 492, Statutes of 2016), which adds several new sections to the Health and Safety Code and the Insurance Code to limit the rights of reimbursement for out-of-network physicians. The change in law, effective July 1, 2017, requires the following for out-of-network physicians:

[U]nless otherwise agreed to by the noncontracting individual health professional and the plan, the plan shall reimburse the greater of the average contracted rate or 125 percent of the amount Medicare reimburses on a fee-for-service basis for the same or similar services in the general geographic region in which the services were rendered. For the purposes of this section, "average contracted rate" means the average of the contracted commercial rates paid by the health plan or delegated entity for the same or similar services in the geographic region.

AB 72, section 2 (adding section 1371.31 to the Health and Safety Code). According to plaintiffs, the effective of the change in law prohibits an out-of-network physician from recovering fully on his or her claims for services lawfully rendered.

The District Court held, however, that the plaintiffs failed to establish an injury, or imminent harm to find standing when it stated, "[n]oticeably absent, however, are any allegations addressing the Court's concerns, as set forth in its prior Order, that Plaintiffs need to allege facts demonstrating: '(1) the inability of out-of-network providers to reach agreements for reasonable compensation with health care service plans; (2) the setting of unreasonable rates of reimbursement; and (3) unsuccessful appeals pursuant to AB 72's independent dispute resolution process." In essence, plaintiffs failed to set forth any facts creating a nexus between their assertions and any provision of the Act, leaving their claims "speculative at best." Furthermore, even if standing was found, the Judge states that the plaintiffs do not currently have a valid takings or preemption claim, due to the lack of causality.

It is for these reasons that Defendant's Motion to Dismiss was granted with one final leave to amend, that was to be submitted no later than thirty (30) days following the date of the Order, filed June 14, 2019. On August 21, 2019, Judge England dismissed this action without prejudice in its entirety.

♦ Children's Hospital Association of Texas, et al. v. Azar, Case No. No. 1:17-cv-00844 (D.D.C), Case No. 18-5135 (D.C. Cir.), 933 F.3d 764 (D.C. Cir. 2019). Under the Medicaid Act, the federal government provides states with funds to distribute to hospitals that treat a disproportionate number of low-income patients. These funds are called Disproportionate Share Hospital (DSH) payments. DSH payments may not exceed the "costs incurred" by these hospitals in serving low-income patients. In 2017, the Secretary of the U.S. Department of Health and Human Services implemented a regulation defining "costs incurred" to mean that the payments

made by Medicaid and uninsured people must be subtracted out when calculating a hospital's incurred costs ("2017 Rule"). 82 C.F.R. § 16,114; 16,122 (Apr. 3, 2017). In *Children's Hospital Association of Texas v. Azar*, the plaintiffs, a group of children's hospitals that receive DHS payments, argued that the regulatory definition of "costs incurred" conflicted with the Medicaid Act. The dispute centered on the question of whether payments made by Medicare and private insurers should also be subtracted out of DHS payment calculations. The district court agreed with the plaintiffs and vacated the 2017 Rule.

On August 13, 2019, Judge Henderson of the D.C. Circuit Appellate Court reversed the district court's ruling. Judge Henderson held that the 2017 Rule was reasonable because while Medicare and private insurers are not specifically mentioned, there is nothing in the Medicaid Act's text that suggests Congress meant for these related sources of income to be excluded. Judge Henderson found that the 2017 Rule is

consistent with the statute's context and purpose, both of which suggest DSH payments are meant to assist those hospitals that need them most by covering only those costs for which DSH hospitals are in fact uncompensated. ... By requiring the inclusion of payments by Medicare and private insurers, the 2017 Rule ensures that DSH payments will go to hospitals that have been compensated least and are thus most in need.

933 F.3d 764, 772. The 2017 Rule is therefore consistent with the Medicaid Act.