DEPARTMENT OF MANAGED HEALTH CARE

Director: Mary Watanabe ♦ (916) 324-8176 ♦ Help Center: (888) 466-2219 or www.HealthHelp.ca.gov ♦ Internet: www.dmhc.ca.gov

The Department of Managed Health Care (DMHC), created on July 1, 2000, 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 enrollees.

In Health and Safety Code section 1342, the legislature has expressly instructed the Department Director to ensure the continued role of the profession as the determiner of the patient's health needs; ensure that enrollees are educated and informed of the benefits and services available in order to 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 cost by transferring the 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, ensure the financial stability of health plans through proper regulation, and ensure that health care 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.

Following the retirement of previous DMHC Director Shelley Rouillard in mid-July 2020, Mary Watanabe served as the Acting Director of the Department. The Governor appointed Ms. Watanabe as the permanent Director of the Department on December 7, 2020.

On December 29, 2020, the Governor appointed Sarah L. Ream as Chief Counsel and Christin Ogden Hemann as Deputy Director of Legislative Affairs at the Department on December 29, 2020.

Dan W. Southard was appointed on March 17, 2021, as the Chief Deputy Director of the Department. Ms. Watanabe previously served as the Acting Chief Deputy Director.

At this writing, the Department is seeking a Chief Medical Officer (CMO). The Department is also still seeking five healthcare professionals to serve on the FSSB.

HIGHLIGHTS

Department Issues an All Plan Letter Requiring Full-Service Health Plans to Cover COVID-19 Vaccines

On December 11, 2020, Sarah Ream, general counsel for DMHC issued an All Plan Letter to all full-service health plans regarding health care coverage of the new COVID-19 vaccine. The Department directed health plans to cover COVID-19 vaccines with no cost-sharing to enrollees, even if the enrollee receives the vaccine from an out-of-network provider.

The first section of the letter outlines the requirements for "qualifying" vaccines. It specifies that the federal government will cover the cost of COVID-19 vaccines themselves, but that health plans must cover the cost to administer the qualifying vaccines to health plan enrollees. To "qualify" under the federal Coronavirus Aid, Relief, and Economic Security Act (CARES Act), a vaccine must either be: "evidence-based and has in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force"; or it must-have "in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved." The Department adds that health plans must begin to cover the administration of COVID-19 vaccines no later than 15 business days after a recommendation of the vaccine is made by the Advisory Committee on Immunization Practices or the U.S. Preventive Services Task Force.

The December 11 All Plan Letter also details reimbursing providers at a "reasonable" rate for the cost of administering qualifying COVID-19 vaccines. The third section in the letter, "Frequently Asked Questions," addresses potential scenarios that may arise as the vaccine

becomes available, such as how plans should determine which enrollees receive the vaccine when demand for the vaccine is greater than the supply.

On December 11, 2020, the Department also issued a press release explaining its All Plan Letter. Alongside the press release, the Department posted a fact sheet informing enrollees that they have the right to a COVID-19 vaccine with no out-of-pocket cost. Both the press release and the fact sheet inform health plan enrollees of procedures to follow should they receive a bill related to the coverage or administration of a qualifying COVID-19 vaccine. The press release also links to guidelines from the California Department of Public Health that explain California's vaccination plan and its planned phases of administering the vaccine.

Office of Administrative Law Approves DMHC's Proposed Emergency Regulation Regarding Transfer of Enrollees Pursuant to a Public Health Order

On January 12, 2021, DMHC published a notice of emergency rulemaking action with respect to its intent to adopt section 1300.67.02, Title 28 of the CCR, pertaining to the transfer of enrollees due to COVID-19. DMHC's finding of emergency includes a "non-delay statement," in which the Director explained that COVID-19 poses such an immediate and serious harm that delaying action to allow public comment would be inconsistent with the public interest. According to DMHC, the emergency regulation is necessary because of COVID-19's large impact on California and its hospitals, and "any delay in the promulgation of this regulation w[ould] exacerbate the already dire situation within the California hospital system." The finding of emergency emphasized that "this emergency regulation is crucial to ensure hospitals are able to handle the influx of patients."

The final text details the public health order and explains the requirements in place for when a health care facility transfers an enrollee. The regulation now mandates that the enrollee's health plan cannot require prior authorization or prior notice that would delay or prevent the transfer of the enrollee, and that the health plan must reimburse the receiving facility for the medically necessary services provided to the enrollee for the first 72 hours that they are treated at the receiving facility.

On January 6, 2021, Sarah Ream, Chief Counsel for DMHC, had issued an All Plan Letter informing health plans of their obligations to continue to cover emergency services even if an enrollee is transferred.

On January 15, 2021, the Office of Administrative Law (OAL) approved DMHC's proposed emergency regulation. The regulation is set to expire on November 13, 2021.

DMHC Orders Aetna To Pay Fine for Improper Denial Of Reconstructive Surgery

On February 25, 2021, DMHC's Office of Enforcement signed a letter of agreement with Aetna Health of California, Inc. (Aetna) with respect to Aetna's violations of Health and Safety Code sections 1367.63(a) and 1368(a)(1). DMHC informed Aetna in its letter that Aetna's failure to provide coverage of reconstructive surgery and failure to maintain a grievance process made Aetna subject to discipline under section 1386(b)(1) of the Health and Safety Code. DMHC fined Aetna $25,000 for the violations, and ordered it to submit a Corrective Action Plan.

According to the letter of agreement, DMHC found that Aetna violated Health and Safety Code section 1367.63(a) when Aetna failed to cover electrolysis for an enrollee's gender reassignment surgery, claiming that the electrolysis was "an excluded cosmetic procedure." section

1367.63(a) mandates that every health plan cover reconstructive surgery, defined as "surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease, to do either of the following: improve function, or; create a normal appearance to the extent possible." The enrollee's surgeon informed Aetna that the enrollee had a diagnosis of gender dysphoria, met all of Aetna's requirements for gender reassignment surgery, and that the electrolysis was medically necessary as part of the gender reassignment surgery. Based on this information, DMHC stated in its letter that Aetna "failed to evaluate the clinical reasons for electrolysis being a medically necessary part of a genital reconstructive surgery," violating section 1367.63(a).

Health and Safety Code section 1368(a)(1) mandates that Aetna "maintain a grievance system that provides reasonable procedures in accordance with department regulations that shall ensure adequate consideration of enrollee grievances and rectification when appropriate." DMHC determined in its letter that Aetna's failure to conduct a clinical review for medical necessity of the enrollee's request for electrolysis as a medical procedure indicated that Aetna's grievance system "failed to adequately consider the enrollee's grievance and rectify the denial when it was appropriate to do so," violating section 1368(a)(1).

DMHC requested a Corrective Action Plan from Aetna based upon the violations. The Corrective Action Plan required, among other things, that Aetna provide written confirmation that it communicated the Gender Affirming Clinical Policy changes to its staff and medical directors, and written certification that Aetna provided training to its reviewing medical directors on the need to evaluate whether requests for cosmetic procedures are reconstructive and/or a medically necessary part of gender reassignment surgery. Aetna accepted the letter on December 18, 2020.

DMHC Issues All Plan Letter to Ensure Health Plans Comply with New Law Regarding Coverage for Mental Health and Substance Use Disorder

On January 5, 2021, DMHC issued All Plan Letter APL 21-002 to all Commercial Full-Service Health Plans and Specialized Health Care Service Plans Offering Behavioral Health Services, entitled "Implementation of Senate Bill 855, Mental Health and Substance Use Disorder Coverage." The letter provides guidance regarding implementation of SB 855 (Wiener) (Chapter 151, Statutes of 2020), effective January 1, 2021, which repeals California's mental health parity law and replaces it with a broader requirement that health plans cover medically necessary treatment of mental health and substance use disorders under the same terms and conditions applied to other medical conditions. It also establishes new requirements for medically necessary care determinations and utilization review and bans discretionary clauses in health plan contracts. *[see 26:1 CRLR 20–21, 29]*

The letter begins with an overview of SB 855 and advises that the new law requires every plan that provides hospital, medical, or surgical coverage to cover medically necessary treatment of mental health and substance use disorders that are set forth in the International Classification of Diseases ("ICD") or the Diagnostic and Statistical Manual of Mental Disorders ("DSM"). The overview also advises plans that they may not limit benefits or coverage for mental health and substance abuse disorders to short-term or acute treatment; are required to arrange coverage for out-of-network services for medically necessary treatment of a mental health or substance use disorder when services are not available in-network within geographic and timely access standards; are prohibited from limiting benefits or coverage for medically necessary services on the basis that those services may be covered by a public entitlement program; and are required to

base medical necessity determinations or utilization review criteria on current generally accepted standards of mental health and substance use disorder care.

The APL further provides plans with detailed instructions as to compliance filing dates, and offers a deadline roadmap of the notices, policies, and procedures to accommodate new coverage requirements outlined by SB 855.

The Department, in conjunction with health plans, the California Department of Insurance, and various stakeholder groups, compiled a list of the most recent versions of treatment criteria and clinical guidelines developed by nonprofit professional associations for the treatment of mental health and substance use disorders, and attached it to APL 21-002 as Attachment A. In doing so, DMHC aims to "promote consistency among health care service plans and delegated entity partners in delivering mental health and substance abuse disorder" services.

The Department also posted a fact sheet on its website to help health plan enrollees understand the changes under SB 855 and released a newsroom update on January 5, 2021, alerting health plans and enrollees of the newly-issued APL issuance. According to the update, DMHC will be strengthening its enforcement of behavioral health parity laws, including focused investigations of commercial health plans, which the Department expects to begin in the first quarter of 2021.

Department Issues Prescription Drug Cost Transparency Report for Measurement Year 2019

On December 30, 2020, DMHC released its Prescription Drug Cost Transparency Report for Measurement Year 2019. Pursuant to SB 17 (Hernandez) (Chapter 603, Statutes of 2017), Health and Safety Code section 1367.243 requires health plans that offer commercial products and

file rate information with DMHC to annually report, for all covered prescription drugs, the 25 most frequently prescribed drugs, the 25 most costly drugs by total annual spending, and the 25 drugs with the highest year-over-year increase in total annual plan spending. This provision also requires DMHC to compile the data into a report for the public and the legislature that demonstrates the overall impact of drug costs on health care premiums and post its report on its website every year on January 1. *[see 23:1 CRLR 26–27]* The most recent report looks at the impact of the cost of prescription drugs on health plan premiums compared to data over three reporting years: 2017, 2018, and 2019.

In a press release issued by the Department, DMHC Director Mary Watanabe is quoted as stating, "[t]he amount health plans paid for prescription drugs has increased by $1 billion since 2017, the cost of prescription drugs is continuing to grow rapidly every year, which is having a real impact on the cost of premiums and the affordability of health care. This report provides greater transparency into prescription drug costs and the impact on health plan premiums." Other key findings indicated that health plans paid more than $9.6 billion for prescription drugs in 2019, an increase of almost $600 million or 6.3% from 2018. The Department found that Prescription drugs accounted for 12.8% of total health plan premiums in 2019, a slight increase from 12.7% in 2018. Prescription drugs accounted for 12.9% of total health plan premiums in 2017.

Health plans' prescription drug costs increased by 6.3% in 2019, whereas medical expenses increased by 5.2%. Overall, total health plan premiums increased by 5.3% from 2018 to 2019. Manufacturer drug rebates totaled approximately $1.205 billion, up from $1.058 billion in 2018 and $922 million in 2017, representing about 12.5% of the $9.6 billion spent on prescription drugs in 2019.

According to the report, while specialty drugs accounted for only 1.5% of all prescription drugs dispensed, they accounted for 56.1% of total annual spending on prescription drugs. Generic drugs accounted for 88.5% of all prescribed drugs but only 20.9% of the total annual spending on prescription drugs. Brand name drugs accounted for 10% of prescriptions and constituted 23% of the total annual spending on prescription drugs. The 25 Most Frequently Prescribed Drugs represented 47.4% of all drugs prescribed and approximately 44.9% of the total annual spending on prescription drugs. For the 25 Most Frequently Prescribed Drugs, enrollees paid 2.9% of the cost of specialty drugs, 11.5% of the cost of brand name drugs, and 53% of the cost of generics. Of the 12.8% of total health plan premium that was spent on prescription drugs, the 25 Most Costly Drugs accounted for 7.1%. Overall, health plans paid 92.4% of the cost of the 25 Most Costly Drugs across all three categories (generic, brand name, and specialty).

DMHC Issues Enforcement Action Against Blue Cross of California

On February 26, 2021, the Office of Enforcement within DMHC concluded its investigation of Blue Cross of California concerning the Plan's violations of the Knox-Keene Health Care Service Plan Act of 1975 and other regulations, fining Blue Cross $10,000. In a Letter of Agreement issued by the Office of Enforcement Deputy Director and Chief Counsel Sonia Fernandez, DMHC outlines the factual summary, liability analysis, suspected violations, and Corrective Action Plan. Blue Cross of California accepted receipt of the agreement on March 10, 2021.

According to the letter, on October 30, 2018, a Blue Cross enrollee went into labor required transportation to a medical center in Los Angeles by an out-of-network ambulance company. The

enrollee's Evidence of Coverage (EOC) covers emergency ambulance services at a 50% coinsurance rate for non-emergency out-of-network ambulance services and a 30% coinsurance rate for emergent ambulance services whether in-network or out-of- network. Blue Cross charged the enrollee with a 50% coinsurance rate. The enrollee filed a grievance with Blue Cross on April 16, 2019, asking for an adjustment because the transportation was for an emergency.

Blue Cross acknowledged the appeal and upheld its decision on April 24, 2019, in a letter without addressing whether the transportation was emergent or non-emergent. The enrollee filed a grievance with DMHC's Help Center on September 24, 2019. The Blue Cross's response to the Help Center stated that it incorrectly classified the transportation as a non-emergency. It agreed to adjust the claim according to the enrollee's out-of-network level of benefits for emergency transportation, leaving the enrollee with a 30% coinsurance rate.

The liability analysis cited Blue Cross for suspected violations of Health and Safety Code section 1386, subdivision (b)(1), acting at variance with the terms of a document filed with DMHC, and Health and Safety Code section 1368, subdivision (b)(6), failure to adequately consider and respond to an enrollee grievance. Here, the enrollee was charged at the 50% coinsurance rate for out-of-network non-emergent services, but the Plan admitted that this was an error in its September 27, 2019, letter. DMHC also found that Blue Cross's April 24, 2019 response to the enrollee's grievance was inadequate because it failed to address whether the ambulance was emergent or non-emergent and failed to provide a clear explanation of the reasons for the Plan's response, subjecting it to administrative penalties.

In addition to the $10,000 fine, the Corrective Action Plan outlined Blue Cross of California's agreement with DMHC to utilize this enforcement matter as a case study at the

Grievances and Appeals Quality Circle held September 24, 2020, where DMHC retrained its California Grievances and Appeals associates on the importance of properly escalating, clinically reviewing, addressing and auditing grievances that indicate an immediate clinical need, to ensure that the Plan responds to enrollees' medical needs. Blue Cross was ordered to submit proof that it completed this deliverable within 10 days of its execution of the Letter of Agreement.

The Office of Enforcement handles DMHC litigation needs by investigating alleged violations of the Knox-Keene Act. The Office of Enforcement exercises its jurisdiction to prosecute violators in an administrative action before the Director of the DMHC, the Office of Administrative Hearings, or in the California Superior Courts. When the DMHC finds the Knox-Keene Act is violated, the Director is authorized to take a variety of actions, including, assessing administrative penalties and issuing a cease-and-desist order requiring the subject of the order to stop the offending action. All subjects are afforded appropriate due process protections. The Enforcement Action Database allows a user to search enforcement actions posted since July 1, 2000. A user can search by health plan name, organization name, action date(s), penalty amount(s), document category, or violation section (California Health and Safety Code and Title 28 of the California Code of Regulations).

MAJOR PUBLICATIONS

The following reports or studies have been conducted by or about DMHC during this reporting period:

Reports

- ***Prescription Drug Cost Transparency Report for 2019*** – December 30, 2020 (pursuant to Health and Safety Code section 1367.243, provides a compilation of mandated data into a report for the public and the legislature that demonstrates the overall impact of drug costs on health care premiums and post its report on its website every year on January 1) (see HIGHLIGHTS).

COVID-19 All Plan Letters

- ***APL20-039*** – COVID-19 Vaccine Coverage – December 11, 2020 (Issued to All Full-Service Health Care Service Plans, outlines federal CARES Act coverage requirements generally and addresses questions health plans may have as COVID-19 vaccines are developed, approved for use and distributed.).

- ***APL21-012*** – COVID-19 Vaccine Prioritization – March 12, 2021 (Issued to All Health Plans and All DMHC-Registered Risk Bearing Organizations, to ensure health care service plans take all appropriate steps to help enrollees at the very highest risk to receive COVID-19 vaccinations in a timely and efficient manner. Requires health plans to coordinate with their contracted health care providers to engage in outreach to high-risk enrollees; Updated March 24, 2021, in a Follow-up Email to Plans Regarding APL 21-012 reminding health plans to take all appropriate steps to help ensure enrollees at the highest risk from COVID-19 receive the vaccine as soon as possible.).

- ***APL21-011*** – New Federal Guidance Regarding COVID-19 Testing – March 10, 2021 (Issued to All Health Care Service Plans, provides an overview of new federal guidance released on February 26, 2021, by the federal Centers for Medicare & Medicaid Services in

conjunction with the Department of Labor and the Department of the Treasury, making it easier for enrollees to obtain diagnostic COVID-19 testing and clarifying when health plans must cover such testing for their enrollees. The APL also explains how the federal guidance and the DMHC's emergency regulation regarding COVID-19 work together to ensure enrollees have ready access to COVID-19 testing at no cost to the enrollee.).

- ***APL20-042*** – Removal of Administrative Burdens on Hospitals – December 16, 2020 (Issued to all full-service health care service plans, directing health plans to take immediate steps to reduce or remove unnecessary barriers to the efficient admission, transfer, and/or discharge of health plan enrollees.).

- ***APL20-043*** – Health Plan Reporting Regarding PPE and Related Support to Providers – December 16, 2020 (Issued to all full-service health care service plans, instructing health plans to report information to DMHC regarding the support they have provided to their contracted providers to ensure that providers have sufficient COVID-19 supplies and personal protective equipment to safely deliver services to the plan's enrollees.).

- ***APL21-003*** – Transfer of Enrollees Per State Public Health Officer Order – January 6, 2021 (Issued to all full-service commercial plans, emphasizing that due to California's surge in COVID-19 positive cases and hospitalizations, it is important to maximize the capacity of hospitals in the state by allowing for the quick transfer of patients from the most highly impacted hospitals to hospitals with more available capacity.).

- ***APL21-004*** – Transfer of Unstable or Destabilized Enrollees – January 6, 2021 (Issued to all full-service commercial plans, reminding plans of their continuing obligations under Health and Safety Code section 1371.4 to cover emergency services and care provided to plan

enrollees, including reimbursement for appropriate transfers of unstable enrollees between hospitals.).

- ***APL20-040*** – Network Stability REVISED – January 28, 2021 (Issued to all full-service health care service plans, instructing health plans to report to the DMHC information regarding contracted primary care practices, closures or sales of the health plans' contracted primary care practices, and how those closures and/or sales may impact the plan's ongoing ability to provide services to enrollees. The APL is to remain in effect until the Governor declares that the California State of Emergency regarding COVID-19 is over, or the DMHC terminates the APL, whichever is earlier.).

- ***APL21-008*** – Special Enrollment Period; Coverage Effective Dates – January 28, 2021 (Issued to all commercial full-service health plans offering individual market products, informing them that California Health Benefits Exchange (Covered California) launched a special enrollment period on February 1, 2021, to offer individual health insurance coverage to all Californians negatively impacted by COVID-19.).

Dental All Plan Letters

- ***APL21-007*** – Dental Plan Reporting Regarding PPE and Related Support to Providers – January 26, 2021 (Issued to all specialized health care service plans that cover dental services, directing dental plans to report to the DMHC information regarding the support they have provided to their contracted providers to ensure that providers have sufficient PPE and COVID-19 supplies to safely deliver services to the plan's enrollees.).

- ***APL21-009*** – Dental Plan Reporting Regarding Network Stability – February 16, 2021 (Issued to all specialized health care service plans that cover dental services, requiring dental

plans to report to the DMHC information regarding (1) contracted dental practices identified to be "priority practices"; (2) closures or sales of their contracted dental practices; and, (3) how those closures and/or sales may impact the plan's ongoing ability to provide service to enrollees. The APL is to remain in effect until the Governor declares the California State of Emergency regarding COVID-19 over, or until the DMHC terminates the APL, whichever is earlier.).

General Administration

- ***APL20-038*** – General Licensure Regulation 3rd Phase-in Period – December 3, 2020 (Issued to all Health Care Service Plans and all Risk Bearing Organizations, extends the phase-in period during which entities seeking exemption from licensure requirements may take advantage of an expedited exemption request process; Revises APL19-014, issued June 13, 2019, and APL20-017 issued April 16, 2020.).
- ***APL21-002*** – Implementation of SB 855, MH/SUD Coverage – January 5, 2021 (Issued to All Commercial Full-Service Health Plans and Specialized Health Care Service Plans offering Behavioral Health Services, provides guidance regarding implementation of SB 855 (Wiener) (Chapter 151, Statutes of 2020) effective January 1, 2021, as well as filing and compliance requirements for all full service and certain specialized health care service plans.) (*see* HIGHLIGHTS).

RULEMAKING

The following is a status update on recent rulemaking proceedings that DMHC has initiated:

- ***Timely Access to Non-Emergency Health Care Services:*** On December 4, 2020, DMHC issued a notice for its second comment period on the modified text of its proposed amendments to section 1300.67.22 and proposed adoption of section 1300.67.23, Title 28 of the CCR regarding Timely Access to Non-Emergency Health Care Services. DMHC initially noticed its intent to amend and add these sections on June 12, 2020. *[see 26:1 CRLR 27]* According to the Initial Statement of Reasons, the proposed regulations are meant to clarify the timely access to care and annual network reporting requirements for health plans, and codifies a process set forth in 2019 for health plans to gather and interpret provider network data that plans would then report to DMHC. The text was modified and released for an additional 45-day comment period after the Department received comments during the first public comment period that two forms and three taps from a third form were missing from the documents made available during the initial comment period, although they were fully described in the Initial Statement of Reasons. The second public comment period expired on January 21, 2021. At this writing no further action has been taken.

- ***Emergency Regulation Regarding Transfer of Enrollees Pursuant to Public Health Order***: On January 12, 2021, DMHC published a notice of emergency rulemaking action with respect to its intent to adopt section 1300.67.02, Title 28 of the CCR, pertaining to the transfer of enrollees due to COVID-19. The emergency regulation mandates that an enrollee's health plan cannot require prior authorization or prior notice that would delay or prevent the transfer of an enrollee. It also requires that the health plan reimburse the receiving facility for the medically necessary services provided to the enrollee for the first 72 hours that they are treated at the receiving facility. This emergency regulation is set to expire on November 13, 2021 (see HIGHLIGHTS).

- ***Summary of Dental Benefits and Disclosure Matrix:*** On December 13, 2020, DMHC published a Notice of Emergency Rulemaking covering a summary of the proposed adoption of section 1300.63.4 in Title 28 of CCR. The proposed emergency regulation implements, interprets, and makes specific Health and Safety Code section 1363.04. According to the Notice of Emergency Rulemaking, this regulation is meant to allow DMHC to develop a uniform benefits and coverage disclosure matrix to be used by health care service plans that cover dental services. The emergency regulation clarifies the requirements of the statute by identifying those persons who must provide the matrix, persons to whom it must be provided, and methods of delivery of the matrix. OAL approved the proposed emergency regulation on January 25, 2021, effective immediately, and is set to expire on September 25, 2021.

LEGISLATION

- **SB 245 (Gonzalez)**, as amended April 12, 2021, and as it applies to DMHC, would add section 1367.251 to the Health and Safety Code to prohibit a health care service plan that is issued, amended, renewed, or delivered on or after January 1, 2022, from imposing a deductible, coinsurance, copayment, or any other cost-sharing requirement on coverage for all abortion and abortion-related services. According to the author, this bill would ensure that no Californian is denied their right to abortion services due to the cost. *[S. Appr]*

- **SB 250 (Pan)**, as amended March 11, 2021, and as it applies to DMHC, would add sections 1363.6 and 1371.57 to the Health and Safety Code to authorize DMHC to review a plan's clinical criteria, guidelines, and utilization management policies to ensure compliance with existing law. If the criteria and guidelines are not in compliance, the bill would require DMHC's Director to issue corrective action and to send the matter to enforcement if necessary. According

to the author, COVID-19 has shown the impact that traditional health administrative procedures have on delaying access to care, and this bill would address that delay by creating a simpler billing process for patients. *[S. Appr]*

- **SB 255 (Portantino)**, as introduced January 26, 2021, and as it applies to DMHC, would amend section 1357.503 of the Health and Safety Code. This bill would authorize an association of employers to offer a large group health care service plan contract consistent with the Employment Retirement Income Security Act of 1974 (ERISA) if certain requirements are met. According to the author, this bill would help prevent freelance employees in the entertainment industry from losing their insurance while ensuring high insurance standards. *[S. Health]*

- **SB 306 (Pan)**, as amended March 24, 2021, and as it applies to DMHC, would amend sections 120582, 120685, and 120917 of, as well as add section 1367.32 to, the Health and Safety Code, requiring health care service plans to provide coverage for home test kits for sexually transmitted diseases (STDs) and the laboratory costs for processing those kits, since home test kit coverage has been limited due to the COVID-19 pandemic. According to the author, this bill would address the broader problem of the disproportionate impact of STDs on California's youth, people of color, and gay, bisexual, and transgender people. *[S. BP&ED]*

- **SB 326 (Pan)**, as introduced February 5, 2021, would amend sections 1357.51, 1357.503, 1357.512, 1367.005, 1399.849, and 1399.855 of the Health and Safety Code. This bill would remove provisions in existing law that would make health plan preexisting condition protections, premium rating limitations, and other antidiscrimination requirements inoperative if portions of the Affordable Care Act were repealed or no longer applied. [*S. Appr*]

- **SB 368 (Limón)**, as amended March 22, 2021, and as it applies to DMHC, would add section 1367.0061 to the Health and Safety Code to require health care service plans to monitor an enrollee's accrual balance toward their annual deductible and out-of-pocket maximum for covered benefits. This bill would allow an enrollee to request their most up-to-date accrual balances from their health insurer at any time, because, according to the author, no state law currently requires health plans to inform consumers about where their accrual balance falls. *[S. Appr]*

- **SB 428 (Hurtado)**, as introduced February 12, 2021, and as it applies to DMHC, would add section 1367.32 to the Health and Safety Code, and would require that health care service plan contracts issued, amended, or renewed on or after January 1, 2022, provide coverage for adverse childhood experiences screenings. Adverse childhood experiences, according to the author, are related to a decline in an individual's long-term health outcomes, and this bill seeks to alleviate these outcomes. *[S. Health]*

- **SB 510 (Pan)**, as amended April 12, 2021, and as it applies to DMHC, would add sections 1342.2 and 1342.3 to the Health and Safety Code to require a health care service plan contract to cover the costs for COVID-19 testing and health care services related to testing for COVID-19, or a future disease when declared a public health emergency by the Governor. The bill would also require a contract or policy to cover without cost-sharing or prior authorization an item, service, or immunization intended to prevent or mitigate COVID-19. The author intends for this bill to help counteract problems with insurers and providers inappropriately charging enrollees for COVID-19 testing. [*S. Appr*]

- **SB 523 (Leyva)**, as amended March 16, 2021, and as it applies to DMHC, would amend section 1367.25 of the Health and Safety Code to prohibit a religious employer from discriminating or retaliating against an employee for independently obtaining contraceptives outside of the employer's plan. According to the author, this bill would help to modernize and expand California's contraceptive equity laws to reduce structural inequities people face in attempting to access birth control. *[S. Health]*

- **SB 535 (Limón)**, as introduced February 17, 2021, and as it applies to DMHC, would amend section 1367.665 of the Health and Safety Code to prohibit an individual or group health care service plan contract issued, amended, delivered, or renewed on or after January 1, 2022, from requiring prior authorization for biomarker testing for an enrollee or insured with advanced or metastatic stage 3 or 4 cancer. According to the author, this bill would improve access to targeted therapy for advanced cancer patients. *[S. Health]*

- **SB 562 (Portantino)**, as amended March 15, 2021, and as it applies to DMHC, would amend section 1374.73 of the Health and Safety Code. This bill would revise the definition of behavioral health treatment to require that the services and treatment programs provided be based on behavioral, developmental, relationship-based, or other evidence-based models. It would also expand the definition of a "qualified autism service professional" to include behavioral service providers who meet specified educational and professional or work experience qualifications. According to the author, changes to the existing law are needed to ensure that Californians with autism spectrum disorder will receive coverage for medically necessary treatments. *[S. Health]*

- **SB 718 (Bates)**, as amended March 9, 2021, and as it applies to DMHC, would amend section 1357.503 of the Health and Safety Code. This bill would authorize an association

of employers to offer a large group health care service plan contract to small group employer members of the association consistent with ERISA if certain requirements are met. In the author's opinion, this bill would allow small emerging companies to compete with global biopharmaceutical or medical device companies by not asking an employee to sacrifice their quality of health coverage for the opportunity to work at a small company. *[S. Health; S. Appr]*

- **SB 568 (Pan)**, as introduced February 18, 2021, and as it applies to DMHC, would add section 1342.75 to the Health and Safety Code. This bill would prohibit a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2022, from imposing a deductible requirement for a covered prescription drug and certain equipment and supplies for the management and treatment of insulin used to treat a chronic disease. According to the author, this bill aims to level out cost sharing throughout the year by eliminating deductible requirements for patients with chronic disease. *[S. Health]*

- **AB 32 (Aguiar-Curry)**, as amended February 12, 2021, and as it applies to DMHC, would amend section 1374.14 of the Health and Safety Code to requires health plans to reimburse for audio-video, audio-only and other virtual communication on the same basis and to the same extent that the plan is responsible for reimbursement for the same service through in-person diagnosis, consultation, or treatment (referred to as "payment parity"). According to the author, this bill would extend the telehealth flexibilities that were put in place during the COVID-19 pandemic, and ensure that these services are available to patients, regardless of their insurance. It would also help individuals who have geographic, transportation, childcare, or work-related concerns be able to access affordable and reliable access to healthcare. *[A. Health]*

- **AB 97 (Nazarian)**, as amended March 30, 2021, and as it applies to DMHC, would amend section 1367.51 of the Health and Safety Code to prohibit a health care service plan contract from imposing a deductible on an insulin prescription drug. According to the author, this bill is intended to address the burden of the high cost of insulin on individuals with diabetes who require insulin to live. *[A. Health]*

- **AB 326 (Rivas)**, as introduced January 26, 2021, would amend section 1348.9 of the Health and Safety Code to make permanent in existing law the DMHC Director's authority to establish the Consumer Participation Program. This program allows the Director to award reasonable advocacy and witness fees to a person or organization that represents consumers and has made a substantial contribution on behalf of consumers to the adoption of a regulation or with regard to an order or decision impacting a significant number of enrollees. *[A. Floor]*

- **AB 342 (Gipson)**, as amended March 25, 2021, and as it relates to DMHC, would add section 1367.668 to the Health and Safety Code. The bill would prohibit a health care service plan contract from imposing cost sharing on an individual who is between 50 and 75 years of age for colonoscopies conducted for specified purposes. The bill would also provide that it does not require a health care service plan to provide benefits for items or services delivered by an out-of-network provider and does not preclude a health care service plan or health insurer from imposing cost-sharing requirements for items or services that are delivered by an out-of-network provider. According to the author, this bill, which is sponsored by the American Cancer Society Cancer Action Network and the California Colorectal Cancer Coalition, will remove cost barriers to colonoscopies, helping to catch cases of colorectal cancer earlier and improving survival. *[A. Appr]*

- **AB 347 (Arambula)**, as amended April 8, 2021, and as it relates to DMHC, would amend sections 1367.241 and 1367.244 of, and add section 1367.206 to, the Health and Safety Code to establish standards for exceptions to "step therapy," where patients are required to try a specified drug and fail before coverage is granted for the prescribed drug. Specifically, this bill would require a health care service plan to expeditiously grant a step therapy exception if specified criteria are met; authorize an enrollee to file an appeal of a prior authorization or the denial of an exception request; require a health care service plan to designate a clinical peer to review; require a health care service plan to annually report specified information about exception and prior authorization requests to DMHC; and deem a prior authorization request or step therapy exception request to have been granted if a health plan fails to send an approval or denial within a specified timeframe. According to the author, health plans use utilization management solely based on cost, which limits a health care provider's ability to tailor care to individual patient needs, and more than 20 states have implemented standard exceptions to step therapy. [*A. Appr*]

- **AB 454 (Rodriguez)**, as amended April 8, 2021, and as it applies to DMHC, would add section 1367.55 to the Health and Safety Code to authorize the DMHC Director to require a health care service plan to provide specified payments and support to a provider during and at least 60 days after the end of a declared state of emergency or other circumstance. The bill would require that, when determining the appropriate amount and type of support to be provided, the Director must take specified factors into consideration, including whether the plan providers have received support from the Federal Emergency Management Agency. According to the author, this bill is intended to address the fact that many health care providers suffered financially during the

pandemic due to lower patient volume, while health plans have profited from collecting premiums but not having claims to payout. *[A. Health]*

- **AB 457 (Santiago)**, as amended April 8, 2021, and as it applies to DMHC, would add section 1374.141 to the Health and Safety Code to enact the Protection of Patient Choice in Telehealth Provider Act. Specifically, the bill would require a health plan to arrange for the provision of a service via telehealth to an enrollee through a third-party corporate telehealth provider only if the service is not available to the enrollee via telehealth through a contracting individual health professional, a contracting clinic, or a contracting health facility, consistent with existing timeliness standards, when specified conditions are met. According to the author, this bill would make sure patients have all the information they need to make informed decisions when accessing telehealth services from direct-to-consumer third party providers. *[A. Health]*

- **AB 570 (Santiago)**, as amended March 18, 2021, and as it applies to DMHC, would amend sections 1357, 1357.500, 1357.600, and 1399.845 of, and add section 1374.1 to, the Health and Safety Code to require a group or individual health care service plan contract, issued or renewed after January 1, 2022, that provides dependent coverage to make that coverage available to a qualified dependent parent or stepparent. The bill would also expand the definition of "dependent" for an individual or small employer health care service plan contract to include a qualified dependent parent or stepparent. According to the author, this bill would provide health coverage to more Californians by ensuring that dependent parents, including undocumented immigrants, are covered, and by allowing adult children to add their dependent parents to their health care plans, working families will save a significant amount each year on healthcare costs. *[A. Health]*

- **AB 752 (Nazarian)**, as amended April 15, 2021, and as it applies to DMHC, would add section 1367.207 to the Health and Safety Code to require a health care service plan to furnish specified information in real time about a prescription drug upon request by an enrollee or their health care provider. The bill would also prohibit a health care service plan from restricting a health care provider from sharing the information furnished about the prescription drug or penalizing a provider for prescribing a lower cost drug. According to the author, information about prescription drugs will help consumers make better-informed choices about costs, allow pharmacy benefit managers to better negotiate prices, and therefor reduce the cost of prescription drugs for consumers. *[A. Appr]*

- **AB 935 (Maienschein)**, as introduced February 17, 2021, and as it relates to DMHC would add section 1367.626 to the Health and Safety Code to establish the Mothers and Children Mental Health Support Act of 2021 and require health care service plans, by July 1, 2022, to provide access to a telehealth consultation program that meets specified criteria and provides providers who treat children and pregnant and certain postpartum persons with access to a mental health consultation program. According to the author, given the prevalence of maternal and children's mental health issues, which has been exacerbated by the pandemic, this bill aims to increase the capacity of screening primary care providers to treat mental health disorders, and open access to mental health treatment. *[A. Health]*

- **AB 1162 (Villapudua)**, as introduced February 18, 2021, and as it applies to DMHC, would amend sections 1368.7, 1371, and 1371.35 of, and to add section 1371.15 to, the Health and Safety Code to require a health care service plan to provide access to medically necessary health care services to its enrollees that are displaced or otherwise affected by a state of

emergency. The bill would also allow the Department to suspend requirements for prior authorization during a state of emergency. According to the author, this bill would modernize the law to prevent unnecessary payment delays to hospitals and other healthcare providers and ensure adequate finances to secure all things patients need during emergencies such as the COVID-19 pandemic. *[A. Health]*

- **AB 1468 (Cunningham)**, as introduced February 19, 2021, and as it applies to DMHC, would amend section 1367.01 of, and add section 1367.26 to, the Health and Safety Code to require a health care service plan that implements an automated prior authorization system to use evidence-based clinical guidelines to program the system and to make the algorithms used for the system available for download. The bill would also require a plan that implements an automated prior authorization system to ensure that a licensed health care professional makes the decision to deny or modify a request by examining the request specific to the enrollee and does not simply ratify an automated response. According to the author, this bill is designed to address the practice of third parties attempting to control utilization of physical therapy and other services and denying care that was determined to be medically necessary by a patient's health care provider. *[A. Health]*

- **AB 1520 (Levine)**, as amended April 14, 2021, and as it applies to DMHC, would amend section 1367.64 of the Health and Safety Code to prohibit a health care service plan contract from applying cost-sharing for specified screening services for prostate cancer for an enrollee who is 55 years of age or older, or is 40 years of age or older and is high risk, as determined by their health care provider. *[A. Health]*

- **SB 221(Wiener)**, as amended March 22, 2021, and as it applies to DMHC, would amend sections 1367.03 and 1367.031 of the Health and Safety Code to codify the regulations adopted by DMHC to provide timely access standards for health care service plans. Specifically, the bill would require a health care service plan to ensure that appointments with nonphysician mental health and substance use disorder providers are subject to the timely access requirements. The bill would also require a health care service plan to ensure that an enrollee that is undergoing a course of treatment for an ongoing mental health or substance use disorder condition is able to get a follow-up appointment with a nonphysician mental health care or substance use disorder provider within 10 business days of the prior appointment. *[S. Appr]*

- **SB 242 (Newman)**, as amended April 13, 2021, as it applies to DMHC, would add section 1374.192 to the Health and Safety Code, to require a health care service plan to contract with its health care providers to reimburse, at a reasonable rate, their business expenses that are medically necessary to comply with a public health order to render treatment to patients, to protect health care workers, and to prevent the spread of diseases causing public health emergencies. The bill contains an urgency clause; if passed, it would take effect immediately. *[S. Appr]*

LITIGATION

- ***Doe v. United Behavioral Health, et al.,* Case No. 4:19-cv-07316, — F.Supp.3d — (N.D. Cal. 2001).** On March 5, 2021, U.S. District Judge Yvonne Gonzalez Rogers issued an order granting plaintiff's motion for partial summary judgment and holding that UnitedHealth's refusal to cover behavioral therapies such as applied behavioral analysis, which is a common form of autism treatment, flouted the federal Mental Health Parity and Addiction Equity Act. Judge Rogers ruled that UnitedHealth could not justify its exclusion of applied behavioral

analysis because it doesn't maintain comparable exclusion of coverage for treatment of physical ailments. At this writing, the matter is in the discovery phase, which is set to close on July 30, 2021.

- ***Stone v. UnitedHealthCare Insurance Co.*, Case No. 19-16227, 979 F.3d 770 (9th Cir. 2020)**. On November 9, 2020, the U.S. Court of Appeals for the Ninth Circuit issued its opinion holding that defendants' denial of coverage did not violate the Mental Health Parity Act because the plan's exclusion of coverage for out-of-state treatment applied equally to mental and physical illnesses. The Ninth Circuit court affirmed the judgment. On December 21, 2020, the rehearing was denied.

- ***DaVita Inc. v. Amy's Kitchen, Inc.*, Case No. 19-15963, 981 F.3d 664 (9th Cir. 2020)**. On November 24, 2020, the U.S. Court of Appeals for the Ninth Circuit issued its opinion upholding the District Court's dismissal of DaVita's claim that the health plan administered by Defendant Amy's Kitchen violated the Medicare as Secondary Payer provisions of the Social Security Act and ERISA when it provided a lower reimbursement rate for dialysis than it did for other services. Reviewing the motion de novo, the Ninth Circuit agreed with the lower court that the health care plan did not violate federal law with regard to reimbursement because, among other things, it treated all dialysis the same. On February 2, 2021, the rehearing was denied.