DEPARTMENT OF MANAGED HEALTH CARE

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he 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 132 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 27.7 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. 68% of total consumer appeals (IMRs) have resulted in the consumer receiving the requested service or treatment from their health plan.

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). Composed 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. Current members include Larry deGhetaldi, M.D., Paul Durr, Jen Flory, John Grgurina, Jr., Theodore Mazer, M.D., Jeff Rideout, M.D., and Amy Yao.

AB 133 (Committee on Budget) (Chapter 143, Statutes of 2021) added section 1399.870 to the Health and Safety Code to create the Health Equity and Quality Committee (Committee). The Committee is tasked with making recommendations to the DMHC Director for standard health equity and quality measures, including annual benchmark standards for assessing equity and quality in health care delivery. The Committee is expected to convene in early 2022, but no later than March 1, 2022, and will meet at an undetermined frequency before concluding by September 30, 2022. At this writing, Committee members have yet to be announced.

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, with 2.5 million total consumers assisted in California since its creation. DMHC is funded by assessments on its regulated health plans.

HIGHLIGHTS

Department Issues an All Plan Letter Requiring No Cost Sharing on Preventative Health Services Coverage for HIV Preexposure Prophylaxis (PrEP)

On July 6, 2021, the DMHC released <u>All Plan Letter (APL) 21-018</u>, which requires health plans to provide "coverage for Human Immunodeficiency Virus (HIV) antiretroviral drugs, including preexposure prophylaxis (PrEP) or postexposure prophylaxis," and includes guidance on "prior authorization and step therapy as well as preventative health services and cost sharing." This APL followed previous <u>APL 20-026</u>, which dealt with preventive health services coverage for HIV PrEP. In that APL, released in 2020, DMHC directed health plans to cover preexposure prophylaxis, as well as follow-up treatment, with no cost sharing.

The current APL states that as of January 1, 2020, <u>SB 159 (Wiener) (Chapter 532, Statutes of 2019)</u>, which added section 1342.74 to the California Health and Safety Code, prohibited commercial and Medi-Cal plans with prescription drug benefits from requiring prior authorization or step therapy for antiretroviral drugs that are medically necessary for the prevention of HIV, including preexposure prophylaxis or postexposure prophylaxis. [24:2 CRLR 29–30] If a therapeutic equivalent drug exists, then the plan must cover at least one of the versions without prior authorization or step therapy. Under federal mandate, all group or individual plans must cover preventive health services, without cost sharing, for HIV PrEP to any individual who is determined to be at high risk of contracting HIV by the attending health care provider.

According to the APL, by August 6, 2021, all plans must submit a compliance filing that affirms full compliance with SB 159, updated formularies to reflect these changes, as well as coverage for baseline and follow-up testing and monitoring for PrEP without any share of cost. As an alternative, the plan may explain why the requirements do not apply to their circumstances.

Department Did Not Violate Weldon Amendment, According to the U.S. Department of Health and Human Services' Office for Civil Rights (OCR)

In an August 13, 2021 <u>letter</u>, the U.S. Department of Health and Human Services' Office for Civil Rights (OCR) withdrew and closed a complaint against the State of California and the DMHC finding that after review of its previous 2020 NOV decision, in light of the Weldon definition of health care entity, and the underlying investigative record, OCR determined that the violation finding cannot be sustained. The underlying complaint alleged a Weldon Amendment violation.

The Weldon Amendment, originally passed as part of the Health and Human Services (HHS) appropriations act in 2004, and has since readopted (or incorporated by reference) in each subsequent HHS appropriations act, is codified in Title 45 of the Code of Federal Regulations (CFR) section 88. The Amendment provides that "none of the funds made available [in this Act] be made available to a ... State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." The Weldon Amendment further defines "health care entity" to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance

organization, a health insurance plan, or any other kind of health care facility, organization, or plan."

According to the August 13 OCR letter and as background, on August 22, 2014, DMHC sent a <u>letter</u> to seven insurers, informing them that some of their plans limited or excluded coverage of termination of pregnancy, in violation of California law that requires that all health plans treat maternity services and legal abortion neutrally. DMHC instructed the plans to amend their plan documents to cover abortions as a basic health care service and to submit the amended materials to the state. Thereafter, three complaints were filed against DMHC, alleging that this requirement violated the Weldon Amendment. In 2016, OCR closed the complaints without finding a violation and concluding that the term "health care entity" in the Weldon Amendment did not include employers or individuals insured by a health care entity. This legal interpretation later received support through two federal court decisions.

During 2017 and 2018, OCR received five new complaints against DMHC regarding the same 2014 DMHC letter. On January 24, 2020, OCR issued its <u>Notice of Violation</u> (2020 NOV), finding that DMHC had discriminated against health care entities in violation of the Weldon Amendment.

According to the August 13, 2021 OCR letter, as described above, OCR determined that the initial 2020 NOV finding cannot be sustained because the two primary complainants, from Skyline Wesleyan Church and Missionary Guadalupanas, do not meet the definition of a "health care entity" under the Weldon Amendment. OCR determined that neither complainants are "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of

health care facility, organization, or plan." Therefore, OCR withdrew its initial determination that DMHC subjected health care entities to discrimination in violation of the Weldon Amendment, and the matter was closed.

SB 65 Becomes Law, Requiring Investigation into Serious Illness and Deaths Associated with Pregnancy and Childbirth to Reduce Racial Disparities

SB 65 (Skinner), the "California Momnibus Act," as amended September 2, 2021, adds section 123660, adds Article 4.7 (commencing with section 123635), and adds Article 4 (commencing with section 128295) to the Health and Safety Code to establish the California Pregnancy-Associated Review Committee effective August 1, 2022. This bill requires the Committee to identify and review all pregnancy-related deaths and severe maternal morbidity and authorizes the Committee to request from any related state or local health department death records, medical records, and autopsy reports to inform its review. The Committee may incorporate the membership of the California Pregnancy-Associated Mortality Review Committee and will recommend best practices to reduce maternal and infant deaths.

The <u>Committee</u>, comprised mostly of physicians, will also include midwives, doulas, community advocates, and a tribal representative. All proceedings, activities, and opinions of the Committee will be kept confidential. SB 65's legislative intent includes the statement that "[r]acism and racial bias in health care contribute to both the national maternal mortality and morbidity crisis and infant mortality and morbidity, in particular for pregnant and postpartum people and infants who are Black or Native American." These minority groups face

disproportionate levels of risk during childbirth as "California's Native American infant mortality rate is 11.7 deaths per 1,000 live births, followed by Black infants at 8.7 deaths per 1,000 live births," far above the "state's average of 4.2 deaths per 1,000 live births."

SB 65 builds upon SB 464 (Mitchell) (Chapter 533, Statutes of 2019), signed October 7, 2019, which works to reduce the black maternal mortality rate by requiring all perinatal health care providers to undergo implicit bias training, and the 2021–22 state budget's investments to tackle racial and ethnic disparities in maternal health outcomes by including Medi-Cal coverage for doulas, extending Medi-Cal eligibility for postpartum people, providing easier access to CalWORKs for pregnant people, and establishing a guaranteed income pilot program that prioritizes pregnant Californians with low incomes.

SB 65 impacts consumers of the Department of Managed Healthcare (DMHC) by requiring additions to Medi-Cal Managed Care Plans, such as doula care, and extending full-scope Medi-Cal to a birthing parent for 12 months postpartum.

Governor Newsom signed SB 65 on October 4, 2021 (Chapter 449, Statutes of 2021). When signing the bill, the Governor <u>stated</u> that it is "unacceptable that the maternal and infant mortality rate among Black and Indigenous communities remains significantly higher than the state average" and that "California is committed to tackling discrimination and disparity" and "both reproductive and racial justice."

DMHC Publishes Notice of Rulemaking on Transfer of Enrollees

On September 17, 2021, the Department published <u>notice</u> of its intent to adopt section 1300.67.02, Title 28 of the CCR, to permanently adopt the emergency regulation that became

effective on January 15, 2021. [see 26:2 CRLR 19–20] According to the initial statement of reasons, the proposed regulation is the Department's effort to permanently adopt, without change, the emergency regulatory action. The text of the regulation explains the requirement for health plans to transfer enrollees from hospitals that are highly impacted by patients with COVID-19 to those with available capacity. The initial statement of reasons further states that "[t]his regulation is necessary and will benefit California by allowing health plans the ability to transfer patients from one facility to another facility to ensure hospitals are able to handle the influx of patients and ensure enrollees are able to receive access to medically necessary services in a timely manner."

Notably, the proposed regulation makes the following changes: mandates that the enrollee's health plan cannot require prior authorization or prior notice that would delay or prevent the transfer of the enrollee; requires that the health plan cover the medically necessary costs of moving the enrollee between the transferring facility and the receiving facility; provides 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; and after the first 72 hours, the health plan must continue to reimburse the receiving facility for all medically necessary services provided to the enrollee under specified conditions.

The proposed regulation further specifies that if the health plan does not have a contract with the receiving facility, the health plan must reimburse the receiving facility for the "reasonable and customary value" of the services the enrollee receives at the receiving facility and defines what this term means. Finally, an enrollee transferred pursuant to a covered public health order must not be liable for more than the cost the enrollee would have incurred if the enrollee had remained in a

contracting health facility. These last changes amount to financial protections for plan participants/consumers.

The public comment period on the proposed regulations expired on November 2, 2021.

AB 570 Expands Dependent Coverage to Qualified Parents and Stepparents

AB 570 (Santiago), as amended August 26, 2021, and as it applies to the DMHC, amends section 1399.845 and adds section 1374.1 to the Health and Safety Code to require health care service plans, issued or renewed after January 1, 2023, to make dependent coverage available to qualified parents or stepparents.

Currently, dependent coverage is only available to children added to their parent's health care plans. This bill expands the definition of "dependent" to parents and stepparents who meet the definition of qualifying relative under section 152(d), Title 26 of the United States Code, and who live in the health care plan's service area. This includes dependent parents who are undocumented immigrants. According to the author, this bill will save working families significant costs and expand health care access across California.

Under current law, the Health Insurance Counseling and Advocacy Program (HICAP) only provides those with Medicare and those eligible for Medicare with health insurance counseling. This bill requires health care plans, insurers, or the California Health Benefit Exchange to provide written notice to applicants (those seeking to add a parent or stepparent as a dependent) that the HICAP provides free health insurance counseling to seniors. The newly required notice must include the specified contact information of HICAP, including the name, address, and phone number of the local HICAP program and the statewide HICAP program phone number.

According to the sponsor of the bill, allowing dependent parents of adult children to be covered in the same health insurance policy will reduce overall health care costs for the family by pooling these costs and making coverage more affordable, especially during the COVID-19 pandemic. Opponents argued that the bill will cause health care costs to increase and that "the availability of Medi-Cal already provides health care coverage for these individuals," in addition, if the individuals are 65 or older, they qualify for Medicare.

AB 570 makes willful violations of the bill by health care service plans a crime. Also, the change in law does not apply to specialized health plans, Medicare supplement insurance, CHAMPUS supplement insurance, or TRICARE supplement insurance, or to hospital-only, accident-only, or specified disease insurance policies that reimburse for hospital, medical, or surgical benefits.

Governor Newsom signed AB 570 on October 4, 2021 (Chapter 468, Statutes of 2021).

Department Issues an All Plan Letter Reminding Health Plans of Their Obligation to Cover Influenza Vaccines and Prepare to Provide COVID Vaccines for Children Aged 5-11

On November 1, 2021, the DMHC issued an <u>All Plan Letter</u> to all full-service health care service plans regarding health care coverage of the influenza vaccines and COVID-19 vaccines for children aged 5-11. In the letter, DMHC reminds health plans of their obligation to cover influenza vaccines with no cost-sharing to enrollees, and also encourages health plans to proactively prepare for the administration of COVID-19 vaccines to children upon recommendation by the Centers for Disease Control and Prevention (CDC).

The first section of the letter directs health plans to take steps to provide easy access to the influenza vaccine by enrollees. It specifies that health plans should take steps to relax the use management requirements and similar policies to lessen barriers to receiving the vaccine. The letter also encourages health plans to conduct outreach activities that encourage enrollee vaccination.

The second section of the letter expresses DMHC's belief that the CDC will likely issue an Emergency Use Authorization for the COVID-19 vaccine for those aged 5–11 within the next few days. In fact, on November 2, 2021, the day after DMHC issued this All Plan Letter, the CDC Advisory Committee on Immunization Practices met and recommended, by unanimous vote, the use of the Pfizer-BioNTech vaccine for children 5–11 years of age. In the recommendation, the FDA requires that vaccination providers "report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine." The CDC also reports that it has developed a smartphone-based tool (available at https://www.cdc.gov/vsafe) where parents or guardians can register their children and communicate by text and online surveys to provide health check-ins after receipt of the COVID-19 vaccine.

DMHC's All Plan Letter further explains that health plans should take immediate steps to prepare to provide access to the COVID-19 vaccine for pediatric plan enrollees as soon as the CDC authorizes its use. DMHC recommends that this be done by preparing the claims processing systems to avoid delays in reimbursement to providers and informing enrollees of the availability of the vaccine to pediatric enrollees.

Department Proposes the Formal Adoption of Dental Benefits and Coverage Disclosure Matrix Regulations

On July 23, 2021, the DMHC published <u>notice</u> of rulemaking action pertaining to the formal adoption of section 1300.63.4, Title 28 of the California Code of Regulations (CCR), "Summary of Dental Benefits and Coverage Disclosure Matrix" (SDBC). As provided in the <u>Initial Statement of Reasons</u>, section 1300.63.4 was first adopted on December 29, 2020 as an emergency regulation. The <u>emergency regulation</u> included a uniform benefits and coverage disclosure matrix to be used by health care service plans that cover dental services and are provided to consumers for transparency. The emergency regulation outlined the medical providers who would have to provide the matrix, to whom the matrix must be provided, and the acceptable methods of delivery for the matrix. The emergency regulation also provided the matrix itself and the Instruction Guide for SDBC. The Office of Administrative Law (OAL) <u>approved</u> the emergency regulation, and this change became effective on January 25, 2021. [26:2 CRLR 33]

On September 7, 2021, DMHC issued a Notice of Readoption of Emergency Rulemaking Action, and on September 22, 2021, it issued a Notice of Approval. DMHC now proposes to formally adopt the emergency regulations, with the changes found in the text of the proposed regulation. According to DMHC in its initial statement of reasons, this proposed regulation is necessary as it "sets forth and clarifies the requirements of Health and Safety Code section 1363.04 and implements the goals of SB 1008 by providing a comprehensive and easily understandable SDBC for consumers."

According to the notice, DMHC anticipates that the proposed formal adoption of the regulation will provide significant benefits for consumers pertaining to dental health care services

and that the formal adoption will provide clarification to medical providers by simplifying the task of completing the SDBC by identifying who must provide the SDBC and to whom they must provide it to. This would ensure that the public "ha[s] access to useful and comparable information regarding the extent of coverage and costs of dental services offered by various health plans and dental plans," and allow consumers to better compare different dental plans.

Though the proposed regulation remains largely the same as the emergency regulation, minor changes have been made. It is now proposed that the regulations shall apply to "health care service plans or specialized health care service plans, issuing, selling, renewing, or offering a contract on or after January 1, 2022, that covers the provision of dental services." Changes made include a new requirement that a paper copy of the SDBC be made available free of charge, and that providers must inform the group, rather than an enrollee, how to contact the plan for a paper copy or with any questions. Other subdivisions were amended for consistency with references to federal and state law throughout the text of the proposed regulation. Finally, health care and specialized health care service plans must affirm their compliance with the proposed regulation by April 1, 2022.

The written public comment period ended on September 8, 2021. At the time of this writing, no further action has been taken on the rulemaking package.

California COVID-19 Emergency Testing Regulations Imposed By DMHC without Notice Ruled Improper

California Association of Health Plans v. Mary Watanabe, et al., Case No. 20STCP03773 (Super. Ct., Los Angeles County). On May 5, 2021, after consideration of the arguments and evidence presented at trial by Petitioner California Association of Health Plans

("CAHP") and Respondents Mary Watanabe and the California Department of Managed Health Care (collectively, "DMHC") relative to section 1300.76.01, subdivision (d), Title 28 of the CCR, and having entered its April 13, 2021 order finding Respondents failed to comply with the Administrative Procedure Act, the Court entered judgment. This judgment held that DMHC failed to comply with the California Administrative Procedure Act (APA) when promulgating the relevant emergency regulation (subdivision (d)).

Section 1300.67.01, Title 28 of the CCR, the regulation in dispute, was enacted by DMHC on July 17, 2020, as an emergency regulation without notice, public comment period, or public hearing. Among other changes, subdivision (c), the Coverage Mandate, of the regulation required that all COVID-19 tests for essential workers be covered by health plans as a medically necessary basic health care service regardless of a lack of symptoms or potential exposure. Subdivision (d) of the regulation prohibited health care plans from relying on previously negotiated contracts with their health care providers to allocate the costs of COVID-19 testing provided under the Coverage Mandate. Rather, health care plans were to renegotiate the allocation of such costs with the health care providers. According to the Court's April 13 order, DMHC stated that this subdivision was necessary, as the enactment of the Coverage Mandate would lead to confusion as to who would cover the cost of testing, which would then lead to confusion as to when and how enrollees could be tested for COVID-19.

On November 13, 2020, CAHP <u>petitioned</u> for a writ of prohibition, mandamus, or judicial declaration "directing [DMHC] from enforcing [Subdivision (d)] as it was . . . enacted in violation of [the APA] and California Constitution." CAHP focused on subdivision (d), asserting that DMHC did not make an emergency finding sufficient to waive the minimum of five-day notice,

public comment period, or public hearing as required by the APA. CAHP did not dispute the Coverage Mandate.

On April 13, 2021, the Court ruled that the DMHC's enactment of subdivision (d) did not comply with the APA requirement that the DMHC's emergency addressed by their regulation "clearly poses . . . an immediate, serious harm that delaying action to allow public comment would be inconsistent with the public interest." The Court allowed for each subdivision of the regulation to be reviewed individually. The Court then noted that there "must be some sufficient relationship between the emergency and *both* the Coverage Mandate and Subdivision (d) to justify an adoption of the [specific] rule without public notice and comment."

The Court rejected that there may be a connection between who was to pay for COVID-19 testing and easy access to testing by the public, stating that "[s]ubdivision (d) could only conceivably address any confusion that might have been generated between the health care providers and the health care plans over financial allocation." The Court further stated that DMHC did not have evidence that there was any confusion between health care plans and health care providers about the allocation of costs for COVID-19 testing under their capitated contracts, and they did not have evidence that such confusion occurring would prevent the testing of essential workers in the first place. DMHC had, therefore, failed to demonstrate that there was an emergency that could justify the enacting of subdivision (d) without any notice period, and the Court held that subdivision (d) was invalid.

On March 8, 2021, the parties stipulated that the action be bifurcated for trial into two phases, with Trial Phase 1 limited to whether DMHC's promulgation of subdivision (d) on an emergency basis complied with the APA and Trial Phase 2 addressing all remaining issues. On

26

April 29, 2021, the parties further stipulated that Trial Phase 2 was unnecessary as a result of the Court's April 13, 2021 order, and that judgment in the action be entered in Petitioner's favor. These stipulations became part of the Court's May 5, 2021 judgment and concluded this matter.

Department Provides Independent Analysis of the Competitive Effects of Centene's Proposed Acquisition of Magellan Health

On October 12, 2021, Deborah Haas Wilson, Ph.D., who was retained by the Office of the California Attorney General on behalf of DMHC, published her independent analysis of the anti-competitive impact on subscribers and enrollees of a proposed acquisition between two major health insurance companies. This analysis, titled Competitive Effects Analysis of Centene's Proposed Acquisition of Magellan Health, examined the competitive effects of Centene Corporation's (Centene) proposed acquisition of Magellan Health, Inc. (Magellan), which was filed on January 12, 2021. Under Health and Safety Code section 1399.65(b), DMHC is permitted to "disapprove [a proposed] transaction or agreement if the director finds the transaction or agreement would substantially lessen competition in health care service plan products or create a monopoly in this state, including, but not limited to, health coverage products for a specific line of business."

On October 27, 2021, DMHC held a public <u>meeting</u> specifically to address this acquisition. As stated in the <u>notice of public meeting</u>, the acquisition in question proposes a "change of control through the acquisition of [Human Affairs International of California (HAI-CA) and Magellan Health Services of California, Inc. - Employer Service's (MHSC)] indirect parent, Magellan Health, Inc. by Centene Corporation ... through its subsidiary Mayflower Merger Sub, Inc."

Centene and Magellan both sell behavioral-specific healthcare financing services, pharmacy benefit management (PBM) services, specialty pharmacy services, and employee assistance programs (EAPs) in California. Additionally, Centene sells healthcare financing services, and Magellan sells behavioral-specific healthcare financing services, PBM services, and specialty pharmacy services to sellers of healthcare financing services that compete with Centene. If the acquisition is completed, Centene would own "100% of the issued and outstanding shares of capital stock of Magellan, HAI-CA, and MHSC."

The analysis addresses the potential anti-competitive concerns that could occur because of the proposed acquisition and sets forth various recommendations. It first states that the proposed acquisition is unlikely to lessen horizontal competition for behavioral-specific healthcare financing services in a substantial manner because Centene and Magellan have different enrollee pools and thus little "head-to-head" competition for business. The analysis then concludes that horizontal competition for EAPs will likely be lessened by the proposed acquisition because of the already small number of EAP sellers with statewide provider networks in California, such as the ones provided by Centene and Magellan. The analysis, therefore, recommends that Centene or Magellan be required to divest its EAP business in California and that enrollees of the group who do not divulge their EAP business be given the option to switch to the other group on "same or better terms" for a short period. The analysis also states that the proposed acquisition will likely have little effect on the competition for PBM services and specialty pharmacy services due to Centene and Magellan having small national shares in these markets.

As for vertical competition concerns, the analysis found that there would likely be little change to competition as a result of the acquisition but identified potential issues that may occur.

According to the analysis, some interviewees expressed concern that they would not be able to provide adequate coverage for enrollees without access to the Magellan network of providers. The analysis, therefore, recommends that "the Centene-Magellan combined entity be prohibited from making any contractual arrangements with behavioral care providers that restrict behavioral care providers' ability to contract with direct purchasers of healthcare services." The analysis further recommends that the merging groups should not be able to share "[their] employees, processes, information technology systems, or data [with the other]" and that a third party should ensure this does not occur.

Finally, the analysis addresses the issue of disruption of care to Magellan or Magellan customers who are Centene's competitors and could no longer agree to contract with Magellan. The analysis states that this could lead to a lapse in the continuity of care. The analysis, therefore, recommends that enrollees of Magellan network plans "be required to continue to provide access to these services for a period of two years at prices that increase by no more than the prior year's inflation rate."

The public comment period concluded on November 3, 2021.

MAJOR PUBLICATIONS

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

ALL PLAN LETTERS

COVID-19 All Plan Letters

• <u>APL 21-023</u> – Flu Vaccines; Preparation for COVID-19 Vaccines – November 1, 2021 (Issued to all full-service health care service plans, reminding health plans of their obligation

to cover immunizations recommended by the Center for Disease Control without any cost-sharing, and encouraging health care service plans to take proactive steps in preparation for the administration of COVID-19 vaccines to children between age 5 to 11 (see HIGHLIGHTS)).

- <u>APL 21-20</u> Continued Coverage of COVID-19 Diagnostic Testing July 26, 2021 (Issued to all full-service health care service plans, reminding health plans that they must cover COVID-19 testing for their enrollees when the testing provides an individualized assessment of whether the enrollee is infected with COVID-19; reminds health plans they may not impose authorization or cost-sharing requirements and must cover the testing even if the testing is performed in or out of network, the enrollee is asymptomatic, or the enrollee has recent known or suspected exposure to COVID-19).
- <u>APL 21-021</u> Transfer of Hospitalized Enrollees per Regulation Section 1300.67.02 August 17, 2021 (Issued to all full-service health care service plans, reminding health plans of their obligations to comply with section 1300.67.02, Title 28 of the CCR, which directs plans to remove barriers and specifies how plans must be reimbursed for enrollee transfers between hospitals when those transfers are made pursuant to a public health order; reminds health care service plans they must comply with the <u>Public Health Order</u> issued by the California Department of Public Health, which requires hospitals to accept transfer of patients without the patient's insurance status or ability to pay when certain conditions are met).
- <u>APL 21-022</u> Hospital Surges; Continued Applicability of COVID-19 Requirements October 26, 2021 (Issued to all health care service plans and risk-bearing organizations; advises health plans that they may be in violation of the Knox-Keene Act if their administrative processes unnecessarily impede a hospital's ability to efficiently admit, discharger

or transfer patients, which results in the hospital being unable to provide appropriate care to its patients; directs health plans to examine their administrative staffing levels, wait times for hospital staff to speak with plan representatives, and the amount of time it takes the plan to respond to hospitals' requests for admissions, transfers and/or discharges; provides a chart listing the APL number, titles, summaries, and termination dates for all of the COVID-19 APLs the DMHC issued to date, and provides whether each APL is still in effect.)

- <u>APL 21-017</u> Large Group Renewal Notice Requirements July 6, 2021 (Provides guidance to health plans on the timing and content requirements for renewal notices and states that health plans must comply with the new requirements no later than the January 1, 2022 renewals or renewal notices sent after September 1, 2021, whichever occurs earlier).
- <u>APL 21-016</u> Continued Coverage of COVID-19 Diagnostic Testing June 7, 2021 (Issued to All Full-Service Commercial and Medi-Cal Health Care Service Plans, informing them that health plans must continue to cover COVID-19 diagnostic testing, regardless of whether enrollees access such tests through in- or out-of-network providers, may not require any type of prior authorization for testing, and may not impose medical management/utilization management criteria on testing, pursuant to federal law (The Families First Coronavirus Response Act (FFCRA) and Coronavirus Aid, Relief, and Economic Security Act (CARES Act)).).
- <u>APL 21-015</u> Block Transfer Portal Updates—June 7, 2021 (The Block Transfer team updated the portal in an effort to streamline the Block Transfer filing submission process for health plans, as well as the review process for the DMHC).
- <u>APL 21-014</u> COVID-19 Vaccinations for Homebound Enrollees May 3, 2021 (Issued to All Full-Service Commercial and Medicare Advantage Health Plans, informing them

that all individuals 16 years or older are eligible to be vaccinated against COVID-19, that all health plans must arrange for vaccines for individuals receiving "home health services," as defined by section 1374.10, and that plans should refer homebound enrollees that want to be vaccinated or lack transportation to a vaccination site to MyTurn online appointment request system to request an in-home vaccination.).

Licensure and Guidance All Plan Letters

• <u>APL 21-019</u> — Guidance Regarding Assembly Bill (AB) 2118 Reporting Requirements — July 13, 2021 (Issued to all full service health care service plans, provides guidance on the filing requirements needed to comply with <u>AB 2118 (Kalra) (Chapter 277, Statutes of 2020)</u>, which requires health plans to annually report specified rate information on premiums, cost-sharing, benefits, enrollment, and trend factors for products in the individual and small group markets for grandfathered and non-grandfathered products).

RULEMAKING

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

• Timely Access to Non-Emergency Health Care Services: On April 16, 2021, DMHC issued a notice for a third 45-day public comment period on the modified text of its proposed amendments to section 1300.67.22 and adoption of section 1300.67.23, Title 28 of the CCR regarding Timely Access to Non-Emergency Health Care Services. DMHC initially gave notice of its intent to amend and add these sections on June 12, 2020, and released modified text for an additional 45-day comment period on December 4, 2020. [26:1 CRLR 27; 26:2 CRLR 32]. 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 codify a process outlined in 2019 for health plans to gather and interpret provider network data that plans would then report to DMHC. The third public comment period expired on May 3, 2021. At this writing, no further action has been taken.

LEGISLATION

• <u>SB 524 (Skinner)</u>, as amended August 30, 2021, and as it applies to DMHC, would have added section 1367.44 to the Health and Safety Code to prohibit a health care service plan from engaging in patient steering, a practice in which health care plans and their agents limit what pharmacy can be used, even when the patient's preferred pharmacy is in the patient's health plan network. According to the author, this bill would have protected patients' ability to choose a pharmacy that best serves their health care needs.

On October 8, 2021, Governor Newsom <u>vetoed</u> SB 524, stating that "[w]hile offering consumers a choice in pharmacies within their health plan or insurer networks is a worthwhile goal," it is "unclear what business relationships between health plans, insurers, and their agents are intended to be affected because the bill does not define 'agent' or 'corporate affiliate'" and it is "unclear what it means to 'limit an enrollees' (or insureds') access' to certain pharmacy providers."

• SB 255 (Portantino), as amended September 2, 2021, and as it applies to DMHC, amends section 1357.503 of the Health and Safety Code to authorize an association of employers to offer a large group health care service plan contract or large group health insurance policy consistent with the federal Employee Retirement Income Security Act of 1974 (ERISA) if certain requirements are met, including that the association is headquartered in this state, is a multiple

employer welfare arrangement (MEWA) as defined under ERISA, and was established as a MEWA prior to March 23, 2010, and has been in continuous existence since that date. The bill requires the MEWA, on or before June 1, 2022, to file an application for registration with DMHC and to annually file evidence of ongoing compliance with the bill's requirements with the Department. Governor Newsom signed SB 255 on October 8, 2021 (Chapter 725, Statutes of 2021).

- SB 306 (Pan), as amended September 7, 2021, and as it applies to DMHC, adds section 1367.34 to the Health and Safety Code to provide greater testing and treatment for sexually transmitted infections (STIs) through expanded access to STI testing remotely at home and in the community, increase access to STI treatment for patients and their partners, and require every licensed health care professional engaged in providing prenatal care or attending a birthing patient at the time of delivery to provide congenital syphilis screenings. Governor Newsom signed SB 306 on October 4, 2021 (Chapter 486, Statutes of 2021).
- <u>SB 326 (Pan)</u>, as amended September 1, 2021, and as it applies to DMHC, amends sections 1357.51, 1357.503, 1357.512, 1367.005, 1399.849, and 1399.855 of the Health and Safety Code to indefinitely extend the operation of the Patient Protection and Affordable Care Act (PPACA), the individual federal mandate, the federal coverage guarantee, and federal essential health benefits coverage requirements. Governor Newsom signed SB 326 on October 9, 2021 (Chapter 764, Statutes of 2021).
- SB 368 (Limón), as amended July 15, 2021, and as it applies to DMHC, adds section 1367.0061 to the Health and Safety Code to require health care service plan contracts or health insurance policies issued, amended, or renewed on or after July 1, 2022, in the individual

or group market, to monitor an enrollee's or insured's accrual balance toward their annual deductible and out-of-pocket maximum, if any, for every month in which benefits were used. Governor Newsom signed SB 368 on October 6, 2021 (Chapter 602, Statutes of 2021).

- <u>SB 428 (Hurtado)</u>, as amended September 3, 2021, and as it applies to DMHC, adds section 1367.34 to the Health and Safety Code to require a health care service plan contract issued, amended, or renewed on or after January 1, 2022, to provide coverage for pediatric services and preventative care to additionally include coverage for adverse childhood experiences screenings. Governor Newsom signed SB 428 on October 7, 2021 (Chapter 641, Statutes of 2021).
- SB 510 (Pan), as amended September 3, 2021, and as it applies to DMHC, adds sections 1342.2 and 1342.3 to the Health and Safety Code to require a health care service plan contract that provides coverage for hospital, medical, or surgical benefits, excluding a specialized health care service plan contract, to cover the costs for COVID-19 diagnostic and screening testing and health care services related to the testing for COVID-19, or a future disease when declared a public health emergency by the Governor of the State of California, and prohibits that contract from imposing cost-sharing or prior authorization requirements for that coverage. Governor Newsom signed SB 510 on October 8, 2021 (Chapter 729, Statutes of 2021).
- SB 535 (Limón), as amended July 8, 2021, and as it applies to DMHC, amends section 1367.665 of the Health and Safety Code to prohibit health care insurers that already cover biomarker testing from requiring prior authorization for patients with advanced or metastatic stage 3 or 4 cancer. Governor Newsom signed SB 535 on October 6, 2021 (Chapter 605, Statutes of 2021).

- SB 242 (Newman), as amended on August 30, 2021, and as it applies to DMHC, adds section 1374.192 to the Health and Safety Code to impose a state-mandated local program requiring health care service plans to reimburse contracting health care providers for their business expenses accrued in preventing the spread of the respiratory-transmitted infectious diseases causing public health emergencies declared on or after January 1, 2022. Governor Newsom signed SB 242 on October 5, 2021 (Chapter 538, Statutes of 2021).
- AB 789 (Low), as amended on June 28, 2021, and as it applies to DMHC, adds section 1316.7 to the Health and Safety Code to require adult patients receiving primary care services to be offered hepatitis B and hepatitis C screening tests to the extent that the screenings are covered under the patient's health insurance. If a patient's screening test is positive, health care providers must offer the patient follow-up health care or a referral to a provider who can provide adequate care. Health care providers are not required to offer hepatitis testing if the patient has recently been tested for hepatitis, is receiving emergency treatment, or cannot consent to the testing. Governor Newsom signed AB 789 on October 4, 2021. (Chapter 470, Statutes of 2021).
- AB 451 (Arambula), as amended on August 31, 2021, amends section 1317 of the Health and Safety Code to require psychiatric units within a general acute care hospital, psychiatric health facilities, and acute psychiatric hospitals to provide emergency services to treat a person with a psychiatric emergency medical condition regardless of whether the facility operates as an emergency department. This is contingent upon the treating physician determining and noting that the patient is medically stable and appropriate for treatment in a psychiatric setting, and the facility has an available bed and proper facilities and personnel available to care for the patient. Governor Newsom signed AB 451 on October 1, 2021 (Chapter 438, Statutes of 2021).

- <u>AB 474 (Chau)</u>, as amended on August 16, 2021, and as it applies to DMHC, enacts numerous conforming and technical changes to <u>AB 473 (Chau)</u>. AB 473 was signed by Governor Newsom on October 7, 2021, as amended on August 16, 2021 (Chapter 614, Statutes of 2021), and recodifies and reorganizes the California Public Records Act. The California Public Records Act requires that state and local agencies make their records available for public inspection unless an exemption applies. Governor Newsom signed AB 474 on October 7, 2021 (Chapter 615, Statutes of 2021).
- AB 1042 (Jones-Sawyer), as amended on September 3, 2021, amends sections 1324.22, 1325.5, and 1437.5 of, and adds section 1424.3 to the Health and Safety Code, establishing shared standards of liability for long-term health care facilities in which a licensee and a related party share a controlling interest of 5% or more, and allows the State Department of Public Health to take appropriate legal action to recover specified unpaid penalties, such as funds used from the Health Facilities Citation Penalties Account and unpaid quality assurance fees, from the licensee provider's financial interest in the related party. Governor Newsom signed AB 1042 on October 4, 2021 (Chapter 475, Statutes of 2021).
- AB 532 (Wood), as amended on August 31, 2021, amends sections 1339.585 and 127410 of the Health and Safety Code, requiring that the written notice hospitals provide to patients about the hospital's discount payment and charity care programs include the website of a specific health consumer assistance entity, the website for the hospital's list of shoppable services, and information regarding Covered California and Medi-Cal eligibility. This notice must be provided to patients at the time of service if possible. Additionally, hospitals are required to post notice of their policy for financially qualified and self-pay patients in observation units, and that

hospitals are automatically required to provide patients with estimates and an application for financial assistance or charity care without specific requests needed. Governor Newsom signed AB 532 on October 4, 2021 (Chapter 465, Statutes of 2021).

- AB 133 (Committee on Budget), as amended on July 11, 2021, and as it applies to DMHC, is a budget bill that amends various sections of the Health and Safety Code to, among other things, require DMHC to convene a Health Equity and Quality Committee that would make recommendations for standard health equity and quality measures. Health care service plans are required to submit equality and quality data and information reports to ensure compliance with the established DMHC measures. DMHC is authorized to take action against health care service plans not complying with the requirements of the bill. DMHC is required to publish a health equity and quality compliance report beginning in 2025, and health plans that contract with the Department of Health Care Services must have accreditation from the National Committee for Quality Assurance by 2026. Governor Newsom signed AB 133 on July 27, 2021 (Chapter 143, Statutes of 2021).
- SB 718 (Bates), as amended September 2, 2021, and as it applies to DMHC, amends, repeals, and adds section 1357.503 to the Health and Safety Code regarding the regulation of health care service plan coverage. Section 1357.503 addresses which health care service contracts apply to small employer groups. New section 1357.503 authorizes an association of small employer groups to access large group health care service plan contracts until January 1, 2026, if the employer meets certain requirements. According to the author, SB 718 "will provide for the continuation of high-quality small employer health care service plan contracts." Governor Newsom signed SB 718 on October 8, 2021 (Chapter 736, Statutes of 2021).

- AB 326 (Luz Rivas), as amended September 3, 2021, amends section 1348.9 of the Health and Safety Code regarding the Consumer Participation Program managed by DMHC. Section 1348.9 requires the Director of DMHC to establish the Consumer Participation Program, which includes annually awarding organizations and people who substantially contribute on behalf of consumers and who substantially impact enrollees, beginning March 1, 2004, and annually thereafter, until January 1, 2024. SB 326 now indefinitely extends the Consumer Participation Program and changes the annual reporting requirement from submissions of reports to specified legislative committees to instead posting updates on DMHC's website beginning March 1, 2022. Governor Newsom signed AB 326 on October 9, 2021 (Chapter 741, Statutes of 2021).
- AB 342 (Gipson), as amended July 5, 2021, and as it applies to DMHC, adds section 1367.668 to the Health and Safety Code regarding health care service plan coverage for screening tests. New section 1367.668 requires health plans that are issued, amended, or renewed on or after January 1, 2022, to provide coverage, without any cost-sharing, for colorectal cancer screening tests and required colonoscopies resulting from a positive test result, unless the underlying test or procedure was a colonoscopy. Governor Newsom signed AB 342 on October 1, 2021 (Chapter 436, Statutes of 2021).
- <u>AB 347 (Arambula)</u>, as amended September 3, 2021, and as it applies to DMHC, amends sections 1367.241 and 1367.244 and adds section 1367.206 to the Health and Safety Code regarding health plan guidelines for patient treatment, specifically through step therapy. Step therapy is a process whereby health plans can require patients to try medications chosen by the plans before agreeing to cover the medication prescribed by the patient's physician. Section 1367.241 requires the step therapy exception request be approved for the

duration of the prescription if the health plan does not send an approval or denial within a particular timeframe. Section 1367.244 requires health plans to provide step therapy exceptions. New section 1367.206 requires health plans to expeditiously grant step therapy exceptions if the health care provider submits the necessary justification and documentation and allows the provider, enrollee, or enrollee's designee to appeal the denial of an exception request. Governor Newsom signed AB 347 on October 9, 2021 (Chapter 742, Statutes of 2021).

- AB 457 (Santiago), as amended September 3, 2021, and as it applies to DMHC, amends section 1374.14 and adds section 1374.141 to the Health and Safety Code regarding telehealth services. Section 1374.14 requires health plans to apply the telehealth reimbursement requirement, whereby health plans reimburse health care providers for the treatment of enrollees to the same extent as they would for in-person services, to all contracts between health plans and providers. New section 1374.141 specifies notice and consent requirements and requires health plans to comply with these requirements if they offer telehealth services to enrollees through third-party telehealth providers. This bill enacts and is knowns as the Protection of Patient Choice in Telehealth Provider Act. Governor Newsom signed AB 457 on October 1, 2021 (Chapter 439, Statutes of 2021).
- SB 221 (Wiener), as amended September 3, 2021, and as it applies to DMHC, amends sections 1367.03 and 1367.031 of the Health and Safety Code regarding timely health care access. Section 1367.03 requires health plans to comply with timely access requirements by providing enrollees with the care needed within specified timeframes and following up with DMHC to maintain compliance. Section 1367.031 requires health plans to notify enrollees of information relating to the standards for timely access. Governor Newsom signed SB 221 on October 8, 2021 (Chapter 724, Statutes of 2021).

The following bills reported in Volume 26, No. 2 (Spring 2021) died in committee or otherwise failed to be enacted during 2021: AB 32 (Aguiar-Curry), relating to the exemption of Medi-Cal managed care plans from telehealth services; AB 97 (Nazarian), relating to deductibles on insulin prescription drugs; AB 454 (Rodriguez), relating to health care service plans providing payments and support to health care providers; AB 752 (Nazarian), relating to health care service plans providing requested information about prescription drugs to enrollees; AB 935 (Maienschein), relating to providing telehealth mental health consultation for pediatric, pregnant, and postpartum patients; AB 1162 (Villapudua), relating to health care services for enrollees who are displaced or affected by a state of emergency; AB 1468 (Cunningham), relating to health plan and health provider usage of automated prior authorization systems for health care services; AB 1520 (Levine), relating to coverage for screening services for prostate cancer; SB 245 (Gonzalez), relating to coverage for abortion and abortion-related services; SB 250 (Pan), relating to DMHC's review of health plan's clinical criteria, policies, and guidelines to ensure compliance; SB 523 (Leyva), relating to coverage for contraceptive drugs, devices, and products; SB 562 (Portantino), relating to coverage for behavioral health treatment for autism; and SB 568 (Pan), relating to deductible requirements and coverage for prescription drugs.

LITIGATION

• Gray v. Dignity Health, Case No. CGC-19-574074, 70 Cal. App. 5th 225 (2021). On October 13, 2021, the First District Court of Appeals affirmed the trial court's dismissal of the plaintiff's claim that a hospital operated by defendant Dignity Health violated the Unfair Competition Law or the Consumer Legal Remedies Act when it failed to disclose, prior to providing emergency medical treatment, that its billing would include an emergency room charge.

The Court held that the complaint did not adequately identify a practice that violates established public policy or is immoral, unethical, oppressive, or unscrupulous to sufficiently state a claim for either violation. The Court denied rehearing on November 8, 2021.

• California v. Texas, Case No. 19-840, 141 S. Ct. 2104 (2021). On June 17, 2021, the U.S. Supreme Court held that Plaintiffs lacked standing to challenge section 5000A(a) minimum essential coverage provision because they had not shown a past or future injury fairly traceable to defendants' conduct enforcing the specific statutory provision they attacked as unconstitutional.

The Patient Protection and Affordable Care Act, as enacted in 2010, required most Americans to obtain minimum essential health insurance coverage and imposed a monetary penalty upon most individuals who failed to do so. Amendments to the Act in 2017 effectively nullified the penalty by setting its amount to \$0. Subsequently, Texas brought suit against federal officials, claiming that without the penalty, the Act's minimum essential coverage provision, codified at 26 U. S. C. §5000A(a), is unconstitutional. They sought a declaration that the provision is unconstitutional, a finding that the rest of the Act is not severable from section 5000A(a), and an injunction against enforcement of the rest of the Act. The District Court determined that the individual plaintiffs had standing. It also found section 5000A(a) both unconstitutional and not severable from the rest of the Act. The Fifth Circuit agreed as to the existence of standing and the unconstitutionality of section 5000A(a). Still, it concluded that the District Court's severability analysis provided insufficient justification to strike down the entire Act. Petitioner California and other States intervened to defend the Act's constitutionality and to seek further review.

The Supreme Court vacated and reversed the Fifth Circuit's judgment in respect to standing and remanded with instructions to dismiss.

• Foothill Church v. Watanabe, Case No. 19-15658, 3 F.4th 1201 (9th Cir. 2021).

On July 19, 2021, the U.S. Court of Appeals for the Ninth Circuit issued its opinion vacating and remanding plaintiffs' Free Exercise and Equal Protection claims. Specifically, the Court stated that the Director of DMHC requires that plaintiff churches offer elective abortions as part of their group health plans for church employees. The churches maintain that this violates their sincerely held religious beliefs. But the district court dismissed the churches' Free Exercise Clause claim, applying only deferential rational basis review under Employment Division, Department of Human Resources of Oregon v. Smith, 494 U.S. 872 (1990). The Court vacated the district court's order and remanded it for further consideration in light of the Supreme Court's recent decision in Fulton v. City of Philadelphia, 141 S. Ct. 1868 (2021). The Ninth Circuit stated, "[t]he Court's order is a small step in the right direction. But it does not go nearly far enough—or move nearly fast enough—to address the significant constitutional violation that the churches plead and the patent legal error in the decision below."

• United States ex rel. Osinek v. Kaiser Permanente, Lead Case No. 3:13-cv-03891 (N.D. Cal.). On July 29, 2021, the United States intervened in six complaints alleging that members of the Kaiser Permanente consortium violated the False Claims Act by submitting inaccurate diagnosis codes for its Medicare Advantage Plan enrollees in order to receive higher reimbursements. At this writing, the claims in which the United States has intervened are allegations only, and there has been no determination of liability.