Department of Managed Health Care

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Effective July 1, 2000, California's regulation of the managed care industry was transferred from the Department of Corporations (DOC) to the Department of Managed Health Care (DMHC), a new agency within the cabinet-level Business, Transportation and Housing Agency (BTH). The creation of DMHC resulted from Governor Gray Davis' approval of AB 78 (Gallegos) (Chapter 525, Statutes of 1999), one component of a 21-bill package signed by the Governor in 1999 to reform the regulation of managed care in the state. *[17:1 CRLR 7–9, 12–16]* The Department is created in Health and Safety Code section 1341; DMHC's regulations are codified in Title 28 of the California Code of Regulations (CCR).

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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 or subscribe to 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 subscribers or enrollees, or to pay for or reimburse any part of the cost for those services, in return for a prepaid or periodic charge paid by or on behalf of the subscribers or enrollees. In Health and Safety Code section 1342, the legislature has expressly instructed the Department Director to ensure the continued role of the professional as the determiner of the patient's health needs; ensure that subscribers and enrollees are educated and informed of the benefits and services available in order to make a rational consumer choice in the marketplace; prosecute malefactors who make fraudulent solicitations or who use misrepresentations or other deceptive methods or practices; help to ensure the best possible health care for the public at the lowest possible cost by transferring the financial risk of health care from patients to providers; promote effective representation of the interests of subscribers and enrollees; ensure the financial stability of health plans by means of proper regulatory procedures; ensure that subscribers and enrollees receive available and accessible health and medical services rendered in a manner providing continuity of health care; and ensure that subscribers and enrollees have their grievances expeditiously 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 and other health care professionals, consumer service representatives, and support staff assist the DMHC Director in licensing and regulating more than 100 health plans in California. Licensed health plans include HMOs and other full-service health plans, as well as several categories of specialized health plans (including prepaid dental, vision, mental health, chiropractic, and pharmacy plans). HMOs and other full-service health plans provide health care services to approximately 23.5 million California enrollees. Specialized health plans arrange for specialized services for nearly 35 million California enrollees. Total enrollment in all health plans exceeded 58 million as of May 1999.

AB 78 (Gallegos) creates several advisory committees which hold public meetings and hearings to provide a forum for public access and grievance, and which assist the DMHC Director. Under Health and Safety Code section 1347, the 22-member Advisory Committee on Managed Health Care (ACMHC) advises the Director on various issues and produces an Internet-accessible annual report that contains recommendations made to the Director by the ACMHC.

A second advisory committee, the five-member Clinical Advisory Panel (CAP) established in Health and Safety Code section 1347.1, provides expert assistance to the Director in ensuring that the Department's independent medical review (IMR) system meets quality standards necessary to protect the public interest. Created in Health and Safety Code section 1374.30 *et seq.*, the IMR system—effective January 1, 2001—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 independent of plans and certified by an accrediting organization, pursuant to conflict of interest provisions. An IMR determination is binding on the plan, and the Department will enforce it. CAP is responsible for reviewing IMR decisions and making recommendations for improvement of the IMR process.

SB 260 (Speier) (Chapter 529, Statutes of 1999) added section 1347.15 to the Health and Safety Code. Section 1347.15 creates a third advisory committee, the Financial Solvency Standards Board (FSSB), to advise the DMHC Director on matters of financial solvency affecting the delivery of health care services. Comprised of the DMHC Director

and seven members appointed by the Director, FSSB is directed to develop and recommend to the Director financial solvency requirements and standards relating to plan operations and transactions, and to periodically monitor and report on the implementation and results of those requirements and standards.

AB 78 (Gallegos) also enacted the Gallegos-Rosenthal Patient Advocate Program, and added section 1368.02(c) to the Health and Safety Code, which creates the Office of the Patient Advocate (OPA). Section 1368.02(c) requires the Patient Advocate—who is appointed by the Governor upon recommendation of the BTH Secretary and is technically independent from DMHC—to "represent the interests of enrollees served by health care service plans regulated by the department. The goal of the office shall be to help enrollees secure health care services to which they are entitled under the laws administered by the department." OPA is required to help health plan enrollees obtain information about grievance procedures, resolve consumer complaints, compile an annual HMO quality-of-care report card, and issue an annual report on the activities of the OPA.

DMHC houses the HMO Help Center, which is open 24 hours a day, 365 days a year, and functions in 150 languages to help consumers with HMO problems. The Help Center is staffed with 100 HMO rights experts and customer services representatives. The OPA monitors the Help Center and helps identify systemic consumer problems being reported to the Help Center as well as throughout the state so the Department can act quickly and efficiently. The OPA also makes sure the Center provides the highest levels of quality and service.

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DMHC also houses the Office of Plan and Provider Relations (OPPR), which is designed to open the lines of communication between the Department and health plans, hospitals, physicians, and other providers to assure early intervention for the resolution of consumer issues.

From the physician's point of view, the problem stems from unmanageably low capitation rates, lack of information, and inequality in the contract negotiation process with HMOs.

Finally, more than 300 employees at the Department (based in Sacramento and Los Angeles) work on seven teams: Consumer Resources and Support, Enforcement, Technology and Innovation, Legal Services, Oversight Standards and Research, Health Plan Oversight, and Staff Leadership.

Governor Davis has appointed Daniel Zingale as the first Director of DMHC. From 1997–99, Zingale served as executive director of Washington, D.C.-based AIDS Action; before that, he was public policy director of the Human Rights Campaign, the nation's largest gay and lesbian civil and human rights organization. From 1987–91, Zingale was a deputy controller and chief of staff to then-Controller Gray Davis.

In July 2000, Governor Davis appointed Angela Mora as the Patient Advocate for DMHC and BTH. Since 1991, Mora has served as executive director of Amigos Volunteers in Education and Services, a community-based nonprofit organization in Texas that provides health care services for the underserved and at-risk populations in a 13-county area. In that capacity, she designed and implemented one of the most innovative outreach programs in Texas and increased access to medical care for underserved communities.

MAJOR PROJECTS

DMHC Releases Emergency Financial Solvency Regulations

DMHC's Financial Solvency Standards Board was created in SB 260 (Speier) (Chapter 529, Statutes of 1999) to focus on a pressing problem affecting health care in California—the increasing number of medical groups, medical corporations, independent physician associations (IPAs), and other "middlemen" that assume financial risk for the medical care of a health plan's enrollees (also called "risk-bearing organizations" or "RBOs") that are declaring bankruptcy, leaving physicians unpaid for medical services already rendered and patients stranded and forced to change physicians. According to the California Medical Association (CMA), the problem is very serious: A 1999 study commissioned by CMA found that 113 medical groups had gone out of business during the prior three years, another 34 would go bankrupt within a year, and 70% of the remaining medical groups are in "serious financial trouble." *[17:1 CRLR 11]*

In California, the problem has manifested itself to the detriment of patients and physicians for several years. FPA Medical Management went bankrupt in 1998, leaving (according to CMA) 1,600 physicians unpaid for $60 million in services rendered. *[16:1 CRLR 29]* In March 1999, DOC seized MedPartners Provider Network and placed it in bankruptcy under the jurisdiction of a conservator—temporarily stranding 1,000 physicians and 1.3 million Californians. *[16:2 CRLR 7–8]* Just two months after receiving a $30 million bailout loan from eight HMOs to help it pay its creditors (mostly physicians), Anaheim-based KPC Medical Management filed for bankruptcy in November 2000, disrupting care for 300,000 patients. And those are just the largest failures. El Dorado Medical Associates and the San Mateo Individual Practice Association folded in September 2000; the Family Health Care Medical Group, serving 135,000 patients in Ventura County, closed its doors in October 2000; and other smaller medical groups have closed or moved in recent months.

◆ ***The Problem.*** From the physician's point of view, the problem stems from unmanageably low capitation rates, lack

of information, and inequality in the contract negotiation process with HMOs. CMA states that five health plans control at least 75% of California's managed care market, so physicians and physician groups—in order to practice medicine—are forced to accept whatever capitation rates and other terms those plans dictate. Further, physicians say plans are not forthcoming with information about the enrollees for whose care the physician groups are assuming responsibility. When physician groups strapped by low capitation rates and high-cost patient populations get into financial trouble, the incentives to delay or deny care to patients are momentous, and quality of care suffers.

For their part, health plans dispute the physicians' allegations of widespread market concentration by a few HMOs and unequal bargaining power in the negotiation process. Plans emphasize their legal duties to delegate the care of their enrollees only to RBOs that are able to bear the risk, and to monitor the continuing solvency and stability of those with whom they contract. To satisfy these legal duties (and preclude potential civil liability and DMHC disciplinary action), plans claim they need detailed information about the books and financial solvency of the RBOs with whom they contract, both during contract negotiations and throughout the term of the contract. Plans insist that they themselves should be able to verify the solvency of those with whom they contract, to protect themselves and their enrollees.

The state—caught in the middle and paying dearly through public health care programs when the private sector fails—must navigate in an area where it has no express jurisdiction: Medical groups and other RBOs are not licensed or regulated in any way (yet). Further, the HMO-medical group contractual negotiation is a private transaction into which the state is not generally authorized to interfere, and it sometimes involves proprietary information (or at least information that the parties to the negotiation would like to keep confidential).

◆ ***The Statute***. To attempt a resolution of this thorny problem, SB 260 (Speier) created the FSSB and a regulatory framework that is intended to ensure the fiscal solvency of medical groups and other RBOs. In this regard, the bill added new section 1375.4 to the Health and Safety Code, which requires contracts between health plans and RBOs after July 1, 2000 to include: (1) a requirement that the RBO furnish financial information to the health plan "and meet any other financial requirements that assist the health...plan in maintaining the financial viability of its arrangements for the provision of health care services in a manner that does not adversely affect the integrity of the contract negotiation process"; (2) a requirement that the health plan disclose information to the RBO that enables the RBO to be informed regarding the financial risk assumed under the contract; and (3) a requirement that health plans provide payments of all risk arrangements, excluding capitation, within 180 days after close of the fiscal year.

SB 260 also required the DMHC Director to adopt regulations (as recommended by FSSB) in the following areas on or before June 30, 2000 (a deadline which became impossible to meet as DMHC was not created until July 1, 2000):

• Under Health and Safety Code section 1375.4(b)(1)(A), the regulations must establish a process for the review or "grading" of an RBO based on four specified criteria: (1) the extent to which it reimburses, contests, or denies claims for health care services for which it is financially responsible in accordance with the timeframes and other requirements in Health and Safety Code section 1371 and in accordance with any other applicable state and federal laws and regulations; (2) the extent to which it properly estimates its liability for "incurred but not reported" (IBNR) claims (that is, sums it owes to doctors who have not yet filed their claim), records that estimate at least quarterly as an accrual in its books and records, and appropriately reflects this accrual in its financial statements; (3) the extent to which it maintains "at all times a positive tangible net equity" (TNE) as defined in section 1300.76(e), Title 28 of the CCR; and (4) the extent to which it maintains "at all times a positive level of working capital (excess of current assets over current liabilities)."

• The review or grading process must be based upon information provided by the RBO— including balance sheets, claims reports, and designated annual, quarterly, or monthly financial statements prepared in accordance with generally accepted accounting principles (GAAP)—"to a single external party as approved by the director to the extent that it does not adversely affect the integrity of the contract negotiation process between the health care service plan and the risk-bearing organizations."

• Audits of the financial statements of an RBO must be conducted in accordance with generally accepted auditing standards (GAAS) and in a manner that avoids duplication of review of the RBO.

• The regulations must establish a process for corrective action plans (CAPs)—which must be "mutually agreed upon" by the health plan and the RBO and approved by the DMHC Director—for cases where the review or grading indicates deficiencies that need to be corrected by the RBO, and must set forth contingency plans to ensure the delivery of health care services if the CAP fails.

• The regulations must require health plans to disclose specified information to the RBO that enables the RBO to be informed regarding the risk assumed under the contract.

• Health plans must provide periodic reports to the Director that include information concerning the RBOs and the type and amount of financial risk assumed by them. Further, "if deemed necessary and appropriate by the Director," DMHC must create a registration process for RBOs.

• The regulations must ensure the confidentiality of financial and other records to be produced, disclosed, or otherwise made available, "unless as otherwise determined by the Director."

◆ ***DOC's Draft Regulations***. In May 2000, before DMHC was officially created, DOC released draft regulations in response to the mandate in SB 260. Characterized as a "start-

ing point" intended to stimulate comments by interested parties, the draft regulations attempted to accomplish seven goals:

• *Plan Disclosures to RBOs*. In every contract with an RBO, a plan must agree to provide the RBO with detailed information on enrollees, the risk-sharing arrangement between the plan and the RBO, and the amount of payment for each and every service to be provided under the contract.

• *Minimum Standards for RBOs*. In every contract with a plan, an RBO must agree to: (1) reimburse, contest, or deny every claim for health care services it has provided, arranged for, or for which it is otherwise financially responsible within the timeframes established in Health and Safety Code sections 1371 and 1371.35; (2) estimate its liability for IBNR claims on a monthly basis pursuant to one of two specified methods; (3) maintain at all times a positive TNE of at least $50,000; and (4) maintain at all times a positive level of working capital of at least $25,000 in excess of current liabilities.

• *RBO Information and Audits*. In every contract with a plan, an RBO must agree to prepare quarterly reports containing specified financial information and (on an annual basis) undergo a certified financial audit containing specified financial information. These reports must be submitted to "an external party." In addition, the RBO must agree to notify the external party immediately if it repeatedly fails to reimburse, contest or deny claims, fails to estimate or document IBNR claims, or fails to maintain the required TNE and working capital levels; permit the external party to "make any examination it deems necessary" to determine whether the RBO is satisfying the rules; and allow the plan to terminate the contract if the RBO fails to provide the required reports or notices to the external party.

• *Review of an RBO's Performance*. In every contract with a plan, an RBO must agree to allow the external party to review or grade it; prepare periodic reports describing the RBO's overall performance in meeting the required criteria; maintain a public file of reports and nonproprietary information concerning the RBO and make that file available to plans, other RBOs, DMHC, and other interested parties; and allow a plan to terminate the contract if the RBO fails to comply with the evaluation process. A plan that contracts with an RBO must review any reports and nonproprietary information made available by the external party to determine whether the RBO is meeting the regulatory criteria, and must notify the external party immediately if any of its RBOs repeatedly fails to reimburse, contest or deny claims, fails to estimate or document IBNR claims, or fails to maintain the required TNE and working capital levels.

• *Corrective Action Plans for RBOs*. In every contract, a plan and an RBO must agree to comply with a process administered by the external party for corrective action plans. The plan and the RBO must agree to propose recommendations for CAPs upon request of the external party; meet with and advise the external party regarding the recommended corrective action; permit the external party to prepare a CAP, taking into account the recommendations of the plan and the RBO; resolve any disputes concerning the CAP pursuant to a resolution mechanism established by the external party; and submit the CAP to the DMHC Director for approval. Plans and RBOs must also agree to adhere to any contingency plan for the continuous delivery of health care services to the plan's enrollees, if the CAP fails.

• *Periodic Reports from Plans*. Plans are required to submit a report to the DMHC Director, not more than 45 days after the close of each quarter, containing a list of all its contracting RBOs and describing in detail all of their risk-sharing arrangements.

• *Disciplinary Action for Plans*. A plan that complies with all of the provisions of these regulations shall be deemed to have satisfied its obligations under section 1300.70(b)(2)(H)(1), Title 28 of the CCR, to ensure that the RBO has the financial capacity to meet its contractual obligations. Any failure of the plan to comply with the requirements of Health and Safety Code section 1375.4 and any of these regulations is grounds for disciplinary action by the DMHC Director.

◆ ***Reaction to Draft Regulations***. At its first meeting on August 21, 2000, FSSB discussed DOC's draft regulations and the many written comments it had received thereon. FSSB also took considerable public comment on DOC's draft regulations. Many witnesses questioned the concept of the "external party" and the complete absence of any information in the draft regulations on the "external party" to whom much of what appears to be the Department's regulatory obligation is being transferred (for example, how the "external party" should be selected, by whom, how it should be staffed, its required qualifications, whether and how it will be overseen by DMHC, and how to insulate it from conflicts of interest).

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In addition, physician groups complained about the TNE/working capital levels and argued that most groups would not be able to meet those standards "at all times" (as is required by the statute) and that many small IPAs will not be able to meet those standards at all. Health plans were unhappy because the regulations are not specific in identifying the circumstances under which a CAP must be initiated and because they do not provide plans with unfettered access to the books of RBOs; the plans argued that because DMHC's periodic "public reports" on health plans are public information, financial information needed by plans to determine RBO solvency should also be public information (or at least available to plans). Plans also argued that the regulations are overbroad because they apply to "every contract" between a plan and an RBO, when some contracts do not shift all financial risk to an RBO. Con-

sumer groups noted that the draft regulations deal exclusively with financial indicators of fiscal solvency, and suggested that non-financial indicators be evaluated as well (for example, number of complaints and grievances filed due to delays in scheduling physician visits, delays in referrals to specialists, a decrease in the number of referrals to specialists, reductions in referrals outside the physician group, narrower or restricted criteria for second opinions, and a decrease in the number of treatments for which the RBO is at financial risk). The Board decided to split up into three subcommittees which could focus specifically on particular areas of the required regulations: (1) Definitions and Organization Criteria; (2) Risk-Sharing and Organization Information; and (3) Organization Evaluation, Corrective Action, and Plan Reporting.

Senator Jackie Speier, the author of SB 260, attended FSSB's September 2000 meeting to present her insights into the Board's role, the requirements of SB 260, and the draft regulations. She noted that while other bills in the 1999 managed care package had received more media attention, "in the grand scheme of things AB 78 and SB 260 are the most important in getting at the underlying problem, which is needed if this deeply troubled health care model is to survive." She explained that SB 260 was originally conceived as an "early warning system" to alert DMHC to medical groups that may be "in disorder." Senator Speier also said that, at one time, she was going to insert into the bill what FSSB is being asked to adopt in regulations—"but we were discouraged from doing so, because these standards will need to be reevaluated and changed from time to time." She stated that the bill was "hammered out over many months and was intended to be balanced—to give plans confidence that RBOs can provide services, and to give RBOs information and a promise that they will be paid on time."

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Also at the September 2000 meeting, three panels convened to provide FSSB members with feedback on DOC's draft regulations from three primary stakeholder groups: plans, providers, and patients. A panel of plan representatives testified first, and they stressed their need for access to detailed financial information (including cash flow information, which is not addressed in the draft regulations) and nonfinancial information which may be indicative of an impending solvency problem at an RBO throughout the term of the contract so as to be able to fulfill their statutory duties. Plan representatives also expressed confusion about the role and authority of the "external party." Senator Speier interjected her view of the legislative intent behind the inclusion of the "external party" in SB 260. According to the Senator, "the third party will evaluate proprietary information submitted by the RBO in order to evaluate the RBO's solvency. If the third party finds that the RBO is solvent, that determination will be reported to the plan and that is it. If the RBO meets the solvency standards, plans would not have access to the financial information submitted to the third party (outside quarterly statements, which are already public information)." The plan representatives argued that this process may not be adequate to allow them to fulfill their legal duties, and argued that their existing duty to monitor RBOs' solvency on an ongoing basis "should go away if we have an external party or evaluator upon whom we must rely for solvency information."

When asked why DMHC was not delegated the role of the "external party," Senator Speier stated: "At that time, we didn't know what the Department or its staffing would look like. If there is consensus that the Department can and should fill that role, that could be the subject of legislation next year." During subsequent testimony, representatives of consumer groups argued that DMHC should be properly resourced and authorized to perform the role of the external party, expressing strong support for the insertion of a government agency into the review process (instead of a private entity controlled by health plans that sets standards in private).

Over the course of the next several months, FSSB and its three subcommittees convened monthly meetings to work on the language of the proposed solvency regulations. At each monthly hearing, the Board accepted public comment on the emerging draft. By December 2000, the Board had decided to recommend that DMHC (or its designated agent) serve as the "external party" described in SB 260, and to amend the draft regulations accordingly. With input from representatives of plans, medical groups, and patient advocates, FSSB also debated numerous other issues, finalized the language of its financial solvency regulations at its meeting on January 9, 2001, and formally recommended them to DMHC Director Daniel Zingale. The Director approved them on January 29; BTH approved them on March 9; and the Office of Administrative Law (OAL) approved them as emergency regulations on March 22, 2001.

◆ ***The Emergency Regulations***. Following is a summary of DMHC's March 2001 emergency financial solvency regulations adopted pursuant to SB 260 (Speier):

• *Section 1300.75.4—Definitions*. Section 1300.75.4 defines several terms used in SB 260, including "external party," "organization," "risk arrangement," and "lawfully organized group of physicians." The term "external party" means DMHC "or its designated agent, which may be an outside entity or person contracted or appointed to fulfill the functions stated in these regulations." In response to public comment, FSSB also defined the term "risk arrangement" to include both "risk-sharing arrangements" and "risk-shifting arrangements"; in

limited areas, the regulations treat risk-sharing arrangements differently from risk-shifting arrangements.

• *Section 1300.75.4.1—Risk Arrangement Disclosure.* This section describes the detailed information that plans must provide RBOs (and the method and frequency in which that information must be disclosed) on enrollees who are being assigned to the RBO, to enable the RBO to evaluate the risks associated with delivering health care services to their assigned group of enrollees. The section also requires plans to disclose to RBOs the following information for each type of risk arrangement (Medicare+Choice, Medi-Cal, traditional commercial, point of service, small group, and individual plans) under the contract: (1) a matrix of responsibility for medical expenses which will be allocated to the RBO, facility, or plan under the risk arrangement; (2) projected utilization rates and unit costs for each major expense service group (inpatient, outpatient, primary care physician, specialist, pharmacy, home health, durable medical equipment, ambulance, and other), the source of the data, and the actuarial methods employed in determining the utilization rates and unit costs by benefit plan type for the type of risk arrangement; and (3) all factors used to adjust payments or risk-sharing targets, including but not limited to age, sex, localized geographic area, family size, experience rated, and benefit plan design, including copayment/deductible levels.

This section also requires plans to disclose to RBOs, on a quarterly basis beginning with the first quarter of 2001, a detailed description of each and every amount (including expenses and income) allocated to the RBO and to the plan under each and every risk-sharing arrangement. The regulation requires payment by plans on all risk arrangements (excluding capitation) within 180 days after the close of the RBO's contract year or the contract termination date (whichever occurs first). For risk-sharing arrangements, the regulation requires plans to disclose the amount of payment for each and every service to be provided under the contract, including any fee schedules or other factors or units used in determining the fees for each and every service; for risk-shifting arrangements, the plan must disclose, in the case of capitated payment, the amount to be paid per enrollee per month.

• *Section 1300.75.4.2—Organization Information.* This section describes the disclosure and performance requirements for RBOs (and eliminates the minimum $50,000 TNE requirement and the required working capital level of $25,000 in excess of current liabilities contained in DOC's draft regulations). For each quarter beginning on or after January 1, 2001, an RBO must submit to DMHC a quarterly report containing all of the following: (1) financial statements (including at least a balance sheet, an income statement, and a statement of cash flows) for the immediately preceding quarter prepared in accordance with GAAP; (2) a statement as to what percentage of claims have been reimbursed, contested, or denied during that quarter by the RBO within 45 working days, and in accordance with Health and Safety Code section 1371; if less than 95% of all claims have been reimbursed, contested, or denied on a timely basis, the statement shall be accompanied by a report describing the reason why the claims-paying process is not meeting the requirements of applicable law; (3) a statement as to whether or not the RBO has estimated and documented on a monthly basis IBNR claims, pursuant to section 1300.77.2, Title 16 of the CCR; if not, the RBO must submit a detailed report describing the nature of the deficiency, reasons for the deficiency, actions taken to correct any deficiency, and the results of that action; and (4) a statement as to whether or not the RBO has at all times maintained both a positive TNE and positive working capital; if not, the RBO must include a detailed report describing the nature of the deficiency, reasons for the deficiency, actions taken to correct any deficiency, and the results of that action. Section 1300.75.4.2 also requires a principal officer of the RBO to attach a written verification that the information described above and submitted to DMHC is true and correct.

Section 1300.75.4.2 also requires certified financial audits of RBOs on an annual basis. Subsection (b)(2) allows a one-time limited exception for small RBOs which served fewer than 10,000 lives on December 1, 2000. Under this one-time exception, a small RBO may submit reviewed financial statements prepared by a certified public accountant for the fiscal year starting in 2000; after that, all RBOs—regardless of size—must submit annual certified audits of their books.

Section 1300.75.4.2 also requires each RBO to submit detailed information to the Department on an annual basis, to enable DMHC to engage in meaningful review of an RBO's compliance with the four criteria in Health and Safety Code section 1375.4(b)(1)(A) (see above). At this point, the Department has opted not to implement the registration process for RBOs (which is authorized in SB 260), preferring instead to collect information. Finally, this regulation requires an RBO to notify DMHC within five business days of discovering that it "has experienced any event which materially alters its financial situation or threatens its solvency," and permits DMHC to make any examination of an RBO that it deems reasonable and necessary to implement and enforce the Health and Safety Code.

• *Section 1300.75.4.3—Plan Reporting.* This section requires plans to submit to DMHC quarterly reports including detailed information on all contracting RBOs. Additionally, plans must submit to DMHC, on an annual basis, a separate matrix for each product line (commercial, Medicare+Choice, and Medi-Cal) showing the allocation of risk among the plan, each RBO, and the facility by major expense category. This report must disclose, for each product line, the number of lives covered by each contracted RBO. The regulation also requires a plan to disclose whether it provides stop-loss insurance to the RBO and, if so, the nature of any and all stop-loss arrangements. Each such report or matrix must include a written verification that the report or matrix is true and correct to the best knowledge and belief of a principal officer of the plan. Finally, a plan is required to notify DMHC within

five business days of discovering that any of its RBOs experienced any event which materially alters the RBO's financial situation or threatens its solvency.

• *Section 1300.75.4.4—Confidentiality.* This section states that "the Director shall provide for the confidentiality of financial and other records to be produced, disclosed, or otherwise made available pursuant to Health and Safety Code section 1375.4, and to these solvency regulations, unless the Director determines otherwise." Despite DMHC's adoption of this emergency regulation, the confidentiality issue continues to be controversial, with HMOs and consumer groups arguing in favor of public access to RBO financial information and physician groups strongly opposed.

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• *Section 1300.75.4.5—Plan Compliance.* This section provides that any failure of a plan to comply with Health and Safety Code section 1375.4 and these solvency regulations shall constitute grounds for disciplinary action by DMHC.

• *Section 1300.75.4.6—Department Costs.* This section specifies that DMHC's costs in administering Health and Safety Code sections 1347.15 (which creates FSSB) and 1375.4 (which establishes solvency requirements for RBOs) shall be paid by health plans, except specialized health plans, pursuant to Health and Safety Code section 1356.

At this writing, these emergency regulations are in effect for 120 days from March 22, 2001. On April 6, 2001, DMHC published notice of its intent to permanently adopt the emergency regulations. Written comments are due by May 22, 2001.

Advisory Committee on Managed Health Care

The 22-member Advisory Committee on Managed Health Care held its first meeting on October 24, 2000 in Sacramento. After hearing presentations by Assemblymember Martin Gallegos (past chair of the Assembly Health Committee and author of the bill that created the Department), DMHC Director Daniel Zingale, and other members of DMHC management, the Committee divided into three subcommittees that will provide input to the Department on major deliverables required by AB 78 (Gallegos) and other recent managed care legislation.

◆ ***Quality and Performance Measurement Subcommittee.*** This subcommittee has two major charges:

• *HMO Report Card.* The subcommittee is charged with developing recommendations for an annual HMO report card on the comparative performance of the managed care organizations overseen by the Department. The report card is to be produced by the Office of the Patient Advocate.

At its December 2000 meeting, the subcommittee noted that OPA's first report card is not due until the fall of 2001, and that it will focus on full-service health plans; members discussed whether subsequent report cards should also evaluate specialized plans, provider groups, and hospitals. DMHC staff announced that OPA was already in the process of developing the fall 2001 ("Year 1") report card, and that the subcommittee's recommendations would pertain to the "Year 2" report card due in the fall of 2002.

At its December 2000 and January 2001 meetings, subcommittee members reviewed HMO report cards already published by the Pacific Business Group on Health (PBGH), the California Public Employees Retirement System (CalPERS), the National Committee for Quality Assurance (NCQA), and the California HealthCare Foundation (CHCF), and received testimony from individuals representing those groups on the kinds of information considered in evaluating HMO performance. Several report cards and accreditation systems rely on so-called "HEDIS" and "CAHPS" measures: The Health Plan Employer Data and Information Set (HEDIS) evaluates a large number of clinical performance measures, and most quality reporting systems typically report on whether plans cover nine preventive measures (such as immunizations and cancer screening); the Consumer Assessment of Health Plans Study (CAHPS) is a member satisfaction instrument which measures satisfaction with getting needed care, getting care quickly, how well doctors communicate, the effectiveness of office staff and customer service, claims processing, and overall ratings of primary care doctors, specialists, and the health plan. Some witnesses urged DMHC to concentrate on use of these existing tools rather than "reinventing the wheel"; others noted that HEDIS, CAHPS, and other evaluation systems are not all-inclusive and do not always or consistently measure cost (including out-of-pocket cost to enrollees), complaint data, the cultural/linguistic capacities of plans, and plans' responsiveness to the needs of different populations (such as the Medi-Cal and Medicare populations). Several witnesses recommended that DMHC produce several report cards for different audiences (and in different languages and in a variety of formats); others urged DMHC to educate consumers on how to use already-existing report cards because the collection of new data is very disruptive to providers.

At its March 2001 meeting, the subcommittee heard a presentation by Judith Hibbard, Professor of Health Policy at the University of Oregon, an expert in how consumers use report card information and how to format a report card so it is more likely to be used in decisionmaking. DMHC staff informed the subcommittee that PBGH had been retained by the Department to produce the Year 1 report card. As to the Year 2 report card, the subcommittee voted to submit the following recommendations to DMHC: (1) consumers are the key audience of the report card, and a key purpose of the report card should be to assist consumers in health plan choice; (2) commercial and Medicare populations are separate audiences, and reporting for both audiences should be included in the report card; (3) Medi-Cal enrollees are a separate audi-

ence, and reporting for Medi-Cal enrollees should be included in the report card; (4) consumers are a regional audience, and the report card should report findings by region so that the most relevant information for consumers is conveyed and available; (5) purchasers of health care (*e.g.*, benefits managers at employers) are also a key audience of the report card, and DMHC/OPA should do outreach to purchasers so they are aware of the report card and can make report card information available to employees at the time of health plan choice and open enrollment; (6) even though they are not a primary audience, regulators should be encouraged to monitor report card results; (7) if and when the report card evaluates providers and/or hospitals, those entities will also be a key audience of the report card.

The subcommittee also agreed on a framework for reporting and choosing performance measures for inclusion in the Year 2 report card: (1) the report card should include credible, independent, validated, and standardized information; (2) the report card should build on existing tools, but some additional measures that are of value to the key audiences should be included in Year 2 and others should be considered for rollout in Year 3 and beyond; (3) the subcommittee could not agree on whether to include provider group information in the Year 2 report card; (4) although accreditation information might be useful to include in a report card, the subcommittee could not make a recommendation about the inclusion of accreditation information; (5) the question whether to include HEDIS and CAHPS measures in the Year 2 report card requires further consideration; (6) the Year 2 report card should not provide information on hospitals; (7) DMHC Help Center complaint and IMR data should be included in the report card; (8) the Year 2 report card should include additional comparative information (such as credentialing information, financial information such as market share and medical loss ratios, provider turnover rates, assessment of enrollees' linguistic needs, DMHC medical survey information, and enforcement actions and arbitration results against plans) to the extent feasible; and (9) the Year 2 report card need not include lengthy general information (because this type of information is already provided on DMHC's Web site).

• *Uniform Medical Quality Audit System.* The Quality and Performance Measurement Subcommittee will also produce recommendations on the development of a uniform medical quality audit system, as required by SB 2136 (Dunn) (Chapter 856, Statutes of 2000) (see 2000 LEGISLATION). Under SB 2136, the DMHC Director is required to release regulations regarding the standards for a uniform medical quality audit by January 1, 2002.

The subcommittee will develop a plan for completing the legislative report required by AB 78 (Gallegos) on the regulatory framework for entities within California's managed care industry.

At its March 2001 meeting, the subcommittee heard a presentation by DMHC counsel Tom Gilevich on pre-SB 2136 efforts to establish standards for a uniform medical quality audit system. In 1998, the legislature passed AB 1959 (Gallegos) (Chapter 658, Statutes of 1998), which added section 1380.1 to the Health and Safety Code. Section 1380.1 required the Department of Health Services (DHS) to convene a working group to develop standards for quality audits of providers that provide services to enrollees of health plans. In December 1999, the so-called "Section 1380.1 Working Group"—which included representatives of plans, consumer organizations, public and private purchasers of health care, and providers (including medical groups, independent practice associations, and health facilities)—produced a report entitled *Reducing Duplicative Provider Audits: A Strategic Blue Print for Action*, which included eleven recommendations toward reducing duplicative audits of providers by health plans. SB 2136 includes several of those recommendations, and now requires DMHC to propose regulatory standards for a uniform medical quality audit system "which shall include a single periodic medical quality audit." DMHC's regulations must identify: (1) standards that will serve as the basis of the single periodic medical quality audit; (2) standards that will not be covered by the single periodic medical quality audit and that may be audited directly by health plans; and (3) a list of private sector accreditation organizations, if any, that have or can develop systems comparable to the recommended system, and the capability and expertise to accredit, audit, or credential providers. SB 2136 also authorizes the DMHC Director to approve private sector accreditation organizations as qualified organizations to perform the periodic audit.

Gilevich proposed a workplan that includes the following steps: (1) identification of the problem by stakeholders, with attention paid to the work of the Section 1380.1 Working Group and the purpose of the regulations that the DMHC Director is required to adopt; (2) provision of a draft of the regulations to the subcommittee based on the information provided by stakeholders; and (3) submission of a work product to the full ACMHC by October 2001. The subcommittee approved the workplan.

◆ ***Regulatory Implementation and Structure Subcommittee.*** This subcommittee has two major charges:

• *Regulatory Consolidation Report.* First, the subcommittee will develop a plan for completing the legislative report required by AB 78 (Gallegos) on the regulatory framework for entities within California's managed care industry. Under Health and Safety Code section 1342.3, this report is required to consider "the feasibility and benefit of consolidating into DMHC the regulation of other health insurers providing insurance through indemnity, preferred provider organizations, and exclusive provider organization products, as well as through other managed care products regulated by the Department of Insurance." The report is due to the legislature on December 31, 2001.

At its November 29, 2000 meeting, the subcommittee—after accepting public comment—decided to limit the Decem-

ber 31, 2001 study to health insurance entities and products that are currently regulated by the Department of Insurance (DOI). However, the subcommittee committed to performing a broader study of other entities and health care programs (including programs under the jurisdiction of other agencies, such as Healthy Families and Medi-Cal) after concluding the December 2001 report. The subcommittee also agreed to recommend that DMHC retain an academician consultant to coordinate and assist in conducting the study and drafting the report, and decided to solicit testimony and input from health insurers and health plans, health care providers, health care purchasers, DOI, the National Association of Insurance Commissioners, and the National Association of Managed Care Regulators.

During its meetings in early 2001, the subcommittee further discussed and identified the precise issues to be addressed in the study, including the criteria that should guide any recommendation made (including impacts on consumer protection, complaint procedures and handling, revenue, administrative simplification, providers, plans, regulatory consistency, and protection against "forum shopping") and the options that should be considered (from the status quo to a complete merger of DOI-regulated health care entities and products into DMHC). The subcommittee also solicited expert testimony to educate itself on the various ways in which health care coverage is regulated in California.

At its February 2001 meeting, the subcommittee heard from panels representing insurers, plans, and consumers on the differences between DMHC regulation of managed care plans and DOI regulation of preferred provider organizations (PPOs). Insurance industry representatives predicted that if PPO regulation is transferred to DMHC, PPOs will try to convert to self-insured entities or sell off their PPO business, such that the PPO industry will diminish. Consumer group representatives argued that the same reasons that justified the transfer of managed care regulation from a generalist non-health-care-focused agency like DOC to a specialist health-care-focused agency like DMHC support the consolidation of the regulation of all health care insurance products under one regulator. *[16:2 CRLR 5–7; CRLR 22–26]*

At its April 2001 meeting, the subcommittee heard two panel presentations—one panel included DMHC and DOI representatives discussing the agencies' respective consumer complaint handling programs; the other concerned the regulatory oversight provided by each agency. During the complaint handling panel presentation, staff from both agencies noted that each receives calls for help that should be directed to the other. DMHC's consumer complaints relate solely to health care coverage and quality, while DOI's consumer complaints relate to any of 22 different lines of insurance regulated by that department. DMHC's hotline functions 24 hours a day, seven days a week, and its personnel include nurses and attorneys because they handle some cases in which health care services have not yet been provided and disputes over whether care should be provided. DOI's hotline functions only during weekdays. Its personnel include no clinical experts because they deal solely with coverage issues and not with quality of care issues; quality of care cases are referred to the Medical Board of California, which licenses physicians. The subcommittee also heard from Shelley Rouillard, program director of Health Rights Hotline (HRH), a joint program of the Center for Health Care Rights and Legal Services of Northern California, which serves all consumers in four counties in northern California. HRH's staff receive questions and complaints from consumers, advise people about their rights and teach them how to use the health care system, and may intervene on behalf of consumers with health plans when necessary. Rouillard related her experience that "there is particular confusion over which agency has jurisdiction over Blue Shield and Blue Cross PPOs. It is important that one agency oversee all health plan activities, to make it easier for consumers, and to see the big picture of health care."

During the regulatory oversight panel discussion, a DMHC representative noted that the Knox-Keene Act requires the Department to conduct detailed "medical surveys" of health plans every three years (with follow-up surveys within 18 months), and authorizes DMHC to conduct non-routine surveys as often as necessary. The surveys assess utilization management (including procedures for pre-authorization and review of medical necessity and continuity of care), quality management (including a review of the results of plan actions to improve health care services), access and availability (including a review of the plan's provider network by type, number of providers, availability, and timeliness of services), and grievance system procedures (including whether the plan acts promptly to investigate and resolve grievances). Following the survey, DMHC releases a preliminary report, and the plan has 45 days to comment on that report. DMHC reviews the plan's response and then issues a final public report which identifies deficiencies and the plan's progress in making corrections. DMHC also conducts financial examinations of health plans every five years. DOI conducts "market conduct surveys" (which are similar procedurally to DMHC's "medical surveys" but look only at rating/underwriting and claims practices) and financial examinations of its insurance company licensees. DOI tries to conduct market conduct surveys once every three to five years, but is not sufficiently staffed to meet that goal; thus, most exams are targeted exams based on high rates of complaints regarding claims settlement practices, delays, or underwriting issues. Between January 1999 and December 2000, DOI conducted only 30 market conduct exams of life and disability insurance carriers where health claims were part of the examination.

• *Grievance System/IMR Regulations.* The Regulatory Implementation and Structure Subcommittee will also assist in the development of regulations to implement recent legislation related to health plan grievance systems and DMHC's new Independent Medical Review (IMR) system. Effective January 1, 2000, SB 189 (Schiff) (Chapter 542, Statutes of 1999) shortened the period of time from 60 to 30 days in

which health plans and the Department have to review and resolve enrollee grievances; allows an enrollee to seek DMHC's review of unresolved grievances after 30 days; and requires plans to act on emergency grievances within three days of receipt of the grievance by the plan (instead of the prior five days). SB 189 was joined to AB 55 (Migden) (Chapter 533, Statutes of 1999), which established—effective January 1, 2001—a system for the independent review by medical professionals of a plan's decision to deny, modify, or delay a health care service because the plan determines that the service is not medically necessary. Pursuant to AB 55, plans must now include in every plan contract a provision allowing enrollees to seek an IMR whenever a health care decision is based on a finding that the service is not medically necessary; AB 55 also specifies that the IMR may be expedited if there is a serious threat to the health of the enrollee. *[17:1 CRLR 13]*

Thus, DMHC must establish a process for initial screening of all grievances to determine if an issue of medical necessity is involved, and has the final authority to determine if a grievance meets the definition of "medical necessity" for the purpose of IMR, or whether the grievance should go through the grievance process as modified by SB 189. At its November and December 2000 meetings, and further at its February and April 2001 meetings, the subcommittee reviewed a preliminary draft of regulations to implement SB 189 and AB 55, and took public comment thereon. DMHC was not able to adopt these regulations in time for the January 1, 2001 commencement of the IMR system; until it does, the DMHC Director will make IMR decisions public through the issuance of an order. At this writing, the subcommittee has not yet recommended, and the Department has not yet formally published, its grievance system/IMR regulations.

The subcommittee is charged with reviewing and providing input to the Department on its $2 million targeted consumer education program to inform health plan enrollees of the Department's existence and purpose.

◆ ***Health Care Education and Access Subcommittee.*** This subcommittee also has two primary charges:

• *Consumer Education Program.* The subcommittee is charged with reviewing and providing input to the Department on its $2 million targeted consumer education program to inform health plan enrollees of the Department's existence and purpose. At its December 2000 meeting, the subcommittee was addressed by Steven Fisher, DMHC's Deputy Director for Communications and Planning, who reported on the Department's HMO Help Center, which is available via a toll-free number to consumers 24 hours a day, 365 days a year in over 150 languages, and is staffed by 100 consumer rights experts. According to Fisher, "the Department's challenge is to determine how to let consumers know about the HMO Help Center." Patient Advocate Angela Mora also addressed the subcommittee, and suggested ways to maximize use of the funds by preparing public service announcements and distributing fact sheets and brochures. Subcommittee members had additional suggestions, including visible publication of the Help Center's toll-free number on all DMHC publications, and posting of Help Center information on prescription bottles, in open enrollment benefit packages, and on prescribers' prescription pads. Audience members suggested advertising through Spanish language radio stations, community-based newsletters, celebrities and sports figures, medical television shows, provider organizations, and health plans, and other advertising targeted at consumers who may not have access to the Internet (such as senior citizens, Healthy Family recipients, and low-income populations).

At the subcommittee's February 2001 meeting, DMHC staff noted that the Help Center had started a pilot program whereby a consumer who contacts the Help Center with a complaint about an HMO is instantly connected with the HMO via a three-way conference call, in which the consumer, the HMO, and the Department attempt to resolve the problem immediately. The pilot program had worked successfully with Pacificare and was being expanded to Kaiser Foundation Health Plan. The pilot was already resulting in a decline in the number of pending complaints because the Help Center can achieve quick problem resolution over the phone. Subcommittee members also reviewed and approved Patient Advocate Angela Mora's proposed breakdown of the $2 million allocated for consumer education.

At the subcommittee's March 2001 meeting, DMHC staff reported that no formal complaints over 30 days old were pending at the HMO Help Center (whereas 69% of the complaints pending at the Help Center in January 2000 were over 30 days old). Staff also provided subcommittee members with a copy of DMHC's new brochure, *Your HMO Rights and Responsibilities*, which will be translated into languages other than English, turned into placards for posting in physicians' offices, and distributed to pharmacies and to legislators' district offices. Staff also noted that DMHC is attempting to provide employers and their human resources departments with information on the brochure, because consumers with an HMO problem most often contact their human resources office before contacting their HMO or DMHC.

The Health Care Education and Access Subcommittee is also charged with studying issues related to prevention—health care approaches that will prevent expensive and debilitating health care problems.

• *Prevention.* The Health Care Education and Access Subcommittee is also charged with studying issues related to prevention—health care approaches that will prevent expensive and debilitating health care problems. The subcommittee is to develop a framework for a report regarding the state of

prevention in California, including consumer access to prevention services. The prevention report should explain the history of prevention, identify approaches that work, describe the distribution system, and provide incentives to promote involvement by plans and providers in prevention approaches. DMHC's position is that prevention is the key to better quality health care and to ensuring there is more money in the health care system.

At its December 2000 meeting, the subcommittee reviewed an article on New Jersey's prevention initiative. At its February and March 2001 meetings, the subcommittee invited several experts to make presentations on prevention. In February, Sara McMenamin, MPH, Director of Research at UC Berkeley's Center for Health and Public Policy Studies, noted that although many HMOs offer coverage for preventive services (such as pap smears, childhood immunizations, and well-baby check-ups), most charge a copayment for them. Further, her research has indicated a trend in HMOs increasing coverage for some health promotion programs (such as smoking cessation and physical fitness programs) while they drop coverage for other such programs (such as substance abuse, sexually transmitted disease, childhood injury, and HIV/AIDS prevention programs). According to McMenamin, a very low level of members report they have participated in a health improvement program through their health plan, and very few plans offer financial incentives to providers to improve performance on HEDIS preventive measures (see above). The subcommittee also heard from Margaret Taylor, MFT, who directs the San Mateo County Health Services Agency, regarding the Health Plan of San Mateo's preventive care initiatives. Every patient must have a history and physical within one year of enrollment, and the physician must develop a health plan for that patient. San Mateo's plan also includes a comprehensive perinatal program which involves incentives to physicians to get more services to their patients, targeted health promotion interventions aimed at diabetes and obesity in children, a smoking cessation program for pregnant women, and health screenings for the elderly.

At its March 2001 meeting, the subcommittee heard a panel presentation entitled *A National Perspective on Improving the Provision of Preventive Services*. The subcommittee was introduced to the Guide to Clinical Preventive Services (Second Edition), which contains the recommendations on clinical preventive services of the U.S. Preventive Services Task Force, which was convened in 1984 to evaluate the benefits based on science for each of the individual clinical preventive services based on age, gender, and risk. The end result was the basis of clinical guidelines, which are used by private accreditation agencies to rate health plans. Additionally, a representative of Partnership for Prevention noted that PFP studied 30 clinical preventive services and identified several that provide a good value at low cost: tobacco cessation, adolescent counseling, adult vision screening, chlamydia screening for young females, colorectal cancer screening for persons over 50, adult alcoholism screen, and senior pneumococcal vaccinations. Finally, the subcommittee was introduced to the Guide to Community Preventive Services, a major prevention initiative funded by the federal government and led by the Task Force on Community Preventive Services, which summarizes what is known about the effectiveness and cost-effectiveness of population-based interventions designed to promote health and prevent disease, injury, disability, and premature death as well as exposure to environmental hazards. The Community Guide is a complement to the Clinical Guide, and looks outside the health and medical care system to identify evidence-based prevention strategies that can assist managed care organizations in disease prevention and health promotion.

DMHC Rulemaking

The following is an update on recent DMHC/DOC rulemaking proceedings, some of which are described in more detail in Volume 17, No. 1 (Winter 2000) of the *California Regulatory Law Reporter*:

◆ ***Transfer of DMHC's Regulations***. On November 14, 2000, DMHC asked OAL to transfer DOC's managed care regulations from Title 10 of the CCR into Title 28 of the CCR. This regulatory action, which has no substantive effect, simply reflects the July 1, 2000 removal of responsibility for the regulation of the managed health care industry from DOC to DMHC. DMHC's regulations were moved to Title 28 effective January 20, 2001.

◆ ***Hospice Care***. AB 892 (Alquist) (Chapter 528, Statutes of 1999) added section 1368.2 to the Health and Safety Code. Section 1368.2 requires all health plan contracts, except for specialized plan contracts, to include hospice care as a basic health care service on and after January 1, 2002. The bill further requires the adoption of regulations before January 1, 2001 to implement section 1368.2. *[17:1 CRLR 16]*

On May 12, 2000, DOC published notice of its intent to amend section 1300.67 and adopt new section 1300.68.2, Title 10 of the CCR, to implement AB 892 (Alquist). The amendment to section 1300.67 adds hospice care to the list of basic health services that must be covered by health plans. As proposed, new section 1300.68.2 would define the terms "bereavement services," "hospice service," "home health aide services," "homemaker services," "interdisciplinary team," "medical direction," "plan of care," "skilled nursing services," "social service/counseling services," "terminal disease or illness," and "volunteer services." "Hospice service" is defined as a specialized form of interdisciplinary health care that is designed to provide palliative care; alleviate the physical, emotional, social, and spiritual discomforts of an enrollee who is experiencing the last phases of life due to the existence of a terminal disease; and provide supportive care to the primary care giver and the family of the hospice patient which meets all of the following criteria: (1) considers the enrollee and the enrollee's family as the unit of care; (2) utilizes an interdisciplinary team to assess the physical, medical, psy-

chological, social, and spiritual needs of the enrollee and the enrollee's family; (3) requires the interdisciplinary team to develop an overall plan of care and to provide coordinated care emphasizing supportive services such as home care, pain control, and other services intended to ensure both continuity and appropriateness of care for enrollees who cannot be cared for at home; (4) provides for the palliative medical treatment of pain and other symptoms associated with the terminal disease, but does not provide for efforts to cure the disease; (5) provides for bereavement services following death, to assist the enrollee's family with their social and emotional needs; (6) actively utilizes volunteers in the delivery of hospice services; and (7) to the extent appropriate based on the medical needs of the enrollee, provides services in the enrollee's home or primary place of residence.

Section 1300.68.2 requires plans to contract with hospices that are either licensed by the state Department of Health Services or certified in accordance with federal Medicare conditions of participation; all contracts between plans and hospices must be in accordance with all federal and state licensure requirements. The section sets forth the hospice services that plans must provide at a minimum: interdisciplinary team care with development and maintenance of an appropriate plan of care; skilled nursing services, home health aide services, and homemaker services under the supervision of a qualified registered nurse; social services/counseling services provided by a qualified social worker; medical direction, with the plan's medical director responsible for meeting the general medical needs of the enrollee to the extent that these needs are not met by the attending physician; volunteer services; short-term inpatient care arrangements; pharmaceuticals, medical equipment, and supplies that are reasonable and necessary for the palliation and management of the terminal illness and related conditions; and certain rehabilitative therapies including physical therapy, occupational therapy, and speech-language pathology for purposes of symptom control or to enable the enrollee to maintain activities of daily living and basic functional skills. These services must be available on a 24-hour basis, and may be provided in the home or a facility. Finally, every plan must include notice and evidence of the hospice coverage in its disclosure form.

DOC held no public hearing on its proposal, but accepted written comments until June 30, 2000. Thereafter, DMHC slightly revised the proposed regulations based on the comments received, and released the modified version for an additional 15-day comment period on December 21, 2000. Subsequently, DMHC approved the proposed regulations and forwarded them to OAL, where they are pending approval at this writing.

◆ ***Outpatient Prescription Drug Benefits.*** Effective November 3, 2000, DMHC adopted new section 1300.67.24, Title 10 of the CCR, on an emergency basis. Section 1300.67.24 expressly states that every health plan that provides prescription drugs shall provide coverage for all medically necessary outpatient prescription drugs. Consistent with the Knox-Keene Act, plans may require prior authorization for coverage of these drugs; they may establish copayments or deductibles for these drugs; and they may establish preferred drug lists and formularies relating to prescription drug benefits. However, DMHC's intent in adopting section 1300.67.24 is to notify plans that they must also provide any other prescription drug to the extent that it is medically necessary for a particular enrollee.

On November 24, 2000, the Department published notice of its intent to permanently adopt section 1300.67.24. Following a public hearing on January 19, 2001 in Sacramento, DMHC adopted the proposed section. OAL approved it on April 16, 2001 and it became effective that day.

◆ ***Enrollee Grievance Process.*** Prior to 1999, the Knox-Keene Act required all health plans to establish and maintain a grievance process approved by the Department under which enrollees and subscribers may submit grievances to the plan; after completing or participating in a plan's grievance process for at least 60 days, an enrollee or subscriber may submit the grievance or complaint to the Department for review. SB 189 (Schiff) (Chapter 542, Statutes of 1999) modifies this system to require plans to complete the grievance process in 30 days (rather than 60 days), and in three days (instead of five days) in cases involving an imminent and serious threat to the health of the patient—after which time period the patient may submit the grievance to DMHC; and directs DMHC to investigate and take enforcement action against plans regarding grievances that involve plan noncompliance with the law. *[17:1 CRLR 13]*

On May 30, 2000, DOC amended section 1300.68 and adopted new section 1300.68.01, Title 10 of the CCR, on an emergency basis to conform its regulations to the requirements of SB 189 (Schiff). DOC's amendments to section 1300.68 establish definitions for terms used in the statute and regulations (including "grievance," "complaint," and "resolved") and require plans to establish (in writing) grievance systems that receive, handle, and resolve grievances within 30 calendar days of receipt. The section includes minimum required features for all plan grievance systems, including a new requirement mandating plan retention of grievances, responses, and all medical records, documents, evidence of coverage, and other relevant information for five years. The amendments also set forth the process for the Department's review of a plan's response to a grievance at the request of an enrollee, and set forth the information that must be submitted by the plan to the Department. DOC also amended section 1300.68(d), which describes the form on which plans, on a quarterly basis, must report to the Department all grievances that are pending and unresolved for 30 days or more. Under DOC's amendments, the quarterly report need not include information on grievances filed and/or processed outside the plan's grievance system in other grievance resolution procedures, such as arbitration, voluntary mediation, the Center for Dispute Resolution (an independent review organization), the Department of Social Services, or DOC.

New section 1300.68.01 establishes requirements for a plan's expedited review of grievances in cases involving imminent and serious threat to the health of the enrollee. The new section requires plans to consider an enrollee's medical condition when determining its response time, and requires plans to furnish the Department with contact information for a primary contact person and at least two back-up contact persons who will handle urgent and emergency contacts by the Department regarding urgent grievances.

On June 23, 2000, DOC published notice of its intent to permanently adopt its emergency amendments to section 1300.68 and new section 1300.68.01. However, DOC never finished that rulemaking process because managed care regulation was transferred to DMHC effective July 1, 2000. On August 14, 2000, DMHC repealed DOC's emergency regulations (which were still in effect) and adopted its own emergency amendments to section 1300.68 and new section 1300.68.01. DMHC's emergency regulations are similar to DOC's regulations, except that DMHC amended section 1300.68 to delete the definitions adopted by DOC, restructure the order of the provision, and expand the kinds of non-plan grievances that need not be included on the quarterly report form to include the Medi-Cal Fair Hearing Process. Additionally, DMHC amended section 1300.68.01(b) to specifically require plans to establish a system that provides for receipt of Department contacts regarding urgent grievances 24 hours per day, seven days per week.

DMHC's emergency regulations went into effect on August 14, 2000. Thereafter, on September 1, 2000, DMHC published notice of its intent to permanently adopt its emergency changes to sections 1300.68 and 1300.68.1; after a 45-day comment period, the Department adopted the proposed changes and forwarded them to OAL, which approved them on January 10, 2001.

◆ ***Medical Care Following Stabilization of Emergency Medical Condition***. In June 1999, DOC amended section 1300.71.4, Title 10 of the CCR, on an emergency basis. Section 1300.71.4 sets forth emergency medical condition and post-stabilization responsibilities of health plans for medically necessary health care services. The amendments, which clarify that a health plan is responsible for post-stabilization emergency care regardless of whether the services are administered by a contracting or non-contracting provider, are required under AB 682 (Morrow) (Chapter 1015, Statutes of 1998). *[17:1 CRLR 12]* In July 1999, the Department published notice of its intent to permanently adopt the amendments to section 1300.71.4. DOC held no public hearing on its proposal, but accepted written comments until August 27. Thereafter, then-Acting DOC Commissioner William Kenefick approved the proposal; OAL approved the amendments on November 8, 1999.

OAL Invalidates DOC's Assessment Calculation

In February 1999, Healthdent of California Inc. filed a petition with OAL challenging as "underground rulemaking" the method utilized by the Department of Corporations for calculating the number of enrollees in health plans for the purpose of assessing annual fees. Under the Knox-Keene Act, each licensee plan must pay an annual fee to its regulator—which, at that time, was the Department of Corporations. The purpose of the fee is to reimburse the Department for the costs associated with administering the Knox-Keene Act. The amount of the fee is assessed based on the number of enrollees in the plan.

Healthdent arranges for its subscribers to receive dental care through contracts with other dental providers, and it also operates its own dental care facilities. At its facilities, Healthdent provides services to its own subscribers as well as to subscribers of other health plans. In determining Healthdent's annual assessment, the Commissioner counted not only Healthdent's own subscribers, but also "enrollees obtained through contracts with other plans."

In *OAL Determination No. 5, Docket No. 99-007* (February 24, 2000), OAL first noted that under Corporations Code section 25614, Administrative Procedure Act (APA) rulemaking requirements are applicable to the Department. Next, OAL found that "the requirement for paying an annual assessment or fee applies generally to member of a 'class, kind or order.' That class would encompass all Knox-Keene health care service plans licensed by the Commissioner....Therefore, the Commissioner's method of determining the amount of annual fees to be paid by health care service plans is a standard of general application," such that APA rulemaking requirements apply.

The Department asserted that "there is no rule because whatever assessment is made is the consequence or result of transactions occurring between various health care plans." OAL disagreed, stating: "Of regulatory necessity, the Commissioner must determine who is an 'enrollee' for purposes of assessing these fees....The Commissioner has done this....The rule essentially states that 'enrollees' in health care service plans may be 'acquired' through subcontracts with other plans. That is the 'regulation' which interprets, implements or makes specific the term 'enrollees' as it is used in the statute."

Next, OAL addressed the question of whether the Department's interpretation of the statutory requirement was the only legally tenable one. "If a rule simply applies an existing constitutional, statutory or regulatory requirement that has only one legally tenable 'interpretation,' that rule is not quasi-legislative in nature—no new 'law' is created." By claiming that "the procedure followed by the Commissioner to calculate the annual assessment for Healthdent is a direct application of Health and Safety Code section 1356(b)," the Department invoked this issue.

OAL pointed out that the Department's claim that it was merely following the statutory mandate by "counting all the enrollees in every plan" amounted to a circular argument "be-

cause the term 'enrollees' means anyone so labeled by the Department." OAL looked to Health and Safety Code section 1345(c), which defines "enrollee" as a "person who is enrolled in a plan *and* who is a recipient of services from *the* plan" (emphasis added by OAL). "The Department's 'only tenable' interpretation appears to ignore or even obliterate the separate elements necessary for enrollment found in the statute. In doing this, the Department introduces the concept of acquiring enrollees through subcontracts." Finding that the Department's interpretation was not the only tenable one, and perhaps not even the most reasonable one under the existing statutory and regulatory scheme, OAL concluded that the Commissioner's method of calculation of the number of enrollees amounted to an underground regulation that is invalid unless adopted according to APA rulemaking requirements.

2000 LEGISLATION

AB 2903 (Committee on Health), as amended August 29, 2000, is a technical clean-up bill to the Assembly's managed care reform bills of 1999. This bill renames the Department of Managed Care (as it was called in AB 78) to "Department of Managed Health Care" and replaces incorrect references to DOC with references to DMHC; clarifies that DMHC employees are not prohibited from being plan enrollees; and clarifies the DMHC Director's authority to halt a health plan's act or practice that is unsafe and injurious to an enrollee. This bill also permits the Department of Insurance to contract with DMHC to administer independent medical reviews; clarifies that a "disputed health care service" under the Independent Medical Review System does not include services provided by a specialized health care service plan, or an individual dental-only or vision-only health insurance policy; and deletes inadvertent language that contradicts comparable Insurance Code provisions relative to contraceptive coverage. AB 2903 was signed by the Governor on September 28, 2000 (Chapter 857, Statutes of 2000).

SB 2094 (Committee on Insurance), as amended August 28, 2000, is a technical clean-up bill to the Senate's managed care reform bills of 1999, including SB 19 (Figueroa) (Chapter 536, Statutes of 1999), which regulates the disclosure of medical information; SB 260 (Speier) (Chapter 529, Statutes of 1999), which creates FSSB and requires regulation of RBOs; SB 59 (Perata) (Chapter 539, Statutes of 1999), which sets forth requirements for health plans engaging in utilization review; and SB 189 (Schiff) (Chapter 542, Statutes of 1999), which expedites health plans' internal grievance processes. SB 2094 was signed by the Governor on September 30, 2000 (Chapter 1067, Statutes of 2000).

SB 2136 (Dunn), as amended August 29, 2000, makes findings that multiple required medical quality audits of health care providers—as many as 25 for some physician offices—increase costs for health care providers and health plans, and thus ultimately increase costs for the purchaser and the consumer and result in the direction of limited health care resources to administrative costs instead of to patient care; and that streamlining the multiple medical quality audits required by health plans and insurers is vital to increasing the resources directed to patient care. In an attempt to avoid duplicative medical quality audits of health care providers, SB 2136 requires ACMHC to recommend to the DMHC Director standards for a uniform medical quality audit system which shall include a single periodic medical quality audit. In developing the standards, ACMHC must seek input from a broad and balanced range of interested parties. The bill further requires the DMHC Director to publish proposed regulations for the system on or before January 1, 2002. ACMHC must also include standards that will not be covered by the single audit but that may be audited directly by the health plan, and a list of private sector accreditation organizations that have or can develop systems comparable to the recommended system (see MAJOR PROJECTS). SB 2136 was signed by the Governor on September 28, 2000 (Chapter 856, Statutes of 2000).

AB 1455 (Scott), as amended August 30, 2000, and **SB 1177 (Perata)**, as amended August 31, 2000, are identical bills that prohibit health plans from engaging in "unfair payment patterns" resulting in payment delays, reduced payments, denials of complete and accurate claims, or failure to pay interest due; authorize providers to report such misconduct to DMHC; and authorize the Director to investigate such complaints and to impose sanctions where the Director finds an "unfair payment pattern" to have occurred. If a plan engages in unfair payment patterns, DMHC is authorized to impose monetary penalties, order the plan to pay claims in an accelerated manner for three years, and collect its costs incurred for investigative and enforcement expenses. These bills additionally increase the interest rate on uncontested provider claims that are not paid by a plan within a prescribed time period to 15% per annum, and impose a $10 charge on a plan that fails to automatically include this interest amount in its payment to a provider.

AB 1455 and SB 1177 revise the dispute resolution process for medical service payment claims between medical providers and health plans.

The bills also prohibit plans from denying a claim based on lack of authorization if four requirements are met: (1) the service was medically necessary; (2) the service related to previously authorized services; (3) the service was provided after business hours; and (4) the plan does not have an after-hours authorization process.

AB 1455 and SB 1177 also revise the dispute resolution process for medical service payment claims between medical providers and health plans. The bills require health plan contracts with medical providers to include a fast, fair, and cost-effective dispute resolution mechanism; require this

mechanism to be accessible to non-contracting medical providers for billing disputes; and require health plans to annually submit a dispute resolution report to DMHC. On or before July 1, 2001, DMHC must adopt regulations that ensure that plans have adopted a dispute resolution mechanism pursuant to this bill; those regulations must define the term "complete and accurate claim." By December 30, 2001, DMHC must file a report with the legislature and Governor setting forth its recommendations for any additional statutory requirements relating to plan and provider dispute resolution mechanisms. The report must also include information regarding DMHC's development of the definition of "unjust pattern" (as used in these bills), a description of the process used and a list of the parties involved in the Department's development of this definition, and recommendations for statutory adoption. DMHC must also make information regarding actions taken on payment practices available upon public request and on its Web site; provide a toll-free telephone and email service by which medical providers and health plans may report possible unfair payment patterns; and report to the legislature the process by which it responds to these patterns. The Governor signed AB 1455 (Chapter 827, Statutes of 2000) and SB 1177 (Chapter 825, Statutes of 2000) on September 28, 2000.

AB 1751 (Kuehl), as amended May 26, 2000, the "Patient's Right to Trial Act," would have prohibited health plans and disability insurers from including a provision in their contracts that requires enrollees or policyholders to submit to binding arbitration to resolve disputes arising under the contract or policy; and provided that any pre-dispute binding arbitration clause inserted into a health plan contract or disability insurance policy is void and unenforceable. The bill's author, Assembly Judiciary Committee Chair Sheila James Kuehl, whose effort was supported strongly by consumer groups, said AB 1751 was necessary to further the purpose of SB 21 (Figueroa) (Chapter 536, Statutes of 1999), which permits health plan enrollees and subscribers to sue their plans for negligence under certain circumstances (including a requirement that they suffer "substantial harm"); the author and patient groups insisted that the routine tendency of HMOs to insert non-negotiable binding arbitration clauses in their contracts nullifies the potential impact of SB 21. *[17:1 CRLR 8, 14]* Although HMOs defend arbitration as a quick and inexpensive way to resolve disputes, consumer groups insist the private arbitration systems used by HMOs are unfair to consumers, shrouded in secrecy, and take too long when a patient's life may be at stake. Up against heavy opposition by HMOs and "tort reformers," Assemblymember Kuehl was forced to shelve AB 1751 in June 2000.

AB 2039 (Kuehl), as amended May 3, 2000, was carried by Assemblymember Kuehl at the request of the Governor when he signed SB 21 (Figueroa) in 1999, which permits enrollees to sue their health plan for negligence under certain circumstances. SB 21 generally provides that a person may not maintain a cause of action again a health plan unless he/she has exhausted the Department's Independent Medical Review remedy. However, that general rule is subject to several exceptions. Specifically, a patient who has suffered "substantial harm," including "significant financial loss," need not participate in IMR if his/her substantial harm, including significant financial loss, either "occurred prior to completion of the applicable review" or "will imminently occur prior to completion of the applicable review." AB 2039 would have precluded an injured patient who suffers significant out-of-pocket losses from proceeding to court without completing IMR, except in the narrow instance when a judge finds, as a matter of law, that exhaustion by the patient of the applicable independent review system would be futile under the circumstances. Consumer groups argued that the bill would have gutted one of the most hard-fought HMO reforms of 1999. On May 10, 2000, the Assembly Judiciary Committee rejected AB 2039 on a 3–8 bipartisan vote.

SB 1746 (Figueroa), as amended August 24, 2000, requires a health plan to notify enrollees thirty days prior to terminating a contractual arrangement with a medical group, IPA, or primary care provider. This requirement applies unless the contract has been terminated because the provider has endangered the health and safety of patients, committed criminal or fraudulent acts, or engaged in grossly unprofessional conduct. If an enrollee has not been given the requisite thirty-day notice where required, the enrollee may self-refer within the plan for up to sixty days or until a new provider is chosen or assigned, whichever occurs first. The bill also requires a plan that relies on providers to have a process in place to ensure that patients who do not have a provider have access to medical care, including access to specialists. SB 1746 was signed by the Governor on September 28, 2000 (Chapter 849, Statutes of 2000).

SB 1471 (Schiff), as amended August 28, 2000, prohibits a health plan, insurer, medical group, or IPA lien for reimbursement of health care service costs from exceeding the amount actually paid for those services. This provision does not apply to a lien made against a workers' compensation claim, against a third party for Medi-Cal benefits, and for hospital services, as specified. SB 1471 comes in response to several class action lawsuits filed by enrollees against HMOs challenging the HMOs' practice of filing and then suing to enforce liens against moneys recovered by these enrollees from third-party tortfeasors. Rather than seeking the actual costs paid, the HMOs file liens for the "listed" or "reasonable" rates for medical services rendered; these "reasonable" rates sometimes exceed the actual cost to the plan and, when recovered from an enrollee, result in a windfall for the HMO. A 1999 *Los Angeles Times* article highlighted the windfall gained by HMOs filing and enforcing liens in excess of the actual payments they made to treating medical providers, resulting in an estimated $765.7 million received in 1998. SB 1471 was signed by the Governor on September 28, 2000 (Chapter 848, Statutes of 2000).

SB 168 (Speier), as amended August 30, 2000, prohibits a risk-based contract between a health plan and a physician or physician group from including, as a condition of accepting the contract, a provision requiring the physician or group to assume the financial risk of incurring the costs of required childhood immunizations. This bill also provides that a physician or physician group shall not be required to assume financial risk for immunizations that are not a part of the current contract, and requires plans to reimburse physicians or physician groups for such immunizations, until the contract is renegotiated. Health plans are also prohibited from including the acquisition costs associated with required childhood immunizations in the capitation rate of a physician who is individually capitated. SB 168 was signed by the Governor on September 28, 2000 (Chapter 845, Statutes of 2000).

SB 1764 (Chesbro) requires the Legislative Analyst to review data and research relating to the cost-effectiveness of substance abuse treatment services in health plans and disability insurance policies.

AB 2168 (Gallegos), as amended August 22, 2000, clarifies existing law to ensure that health plans establish and implement procedures by which enrollees with HIV or AIDS may receive a referral to a specialist or specialty care center that has expertise in treating HIV or AIDS. This provision sunsets on January 1, 2004, or upon the adoption of an accreditation or designation by a state or federal agency or by a national organization of AIDS or HIV specialists, whichever comes first. AB 2168 was signed by the Governor on September 12, 2000 (Chapter 426, Statutes of 2000).

SB 2046 (Speier), as amended August 18, 2000, prohibits health plan contracts and disability insurance contracts from excluding coverage for a drug prescribed for a chronic and seriously debilitating condition, including "off label drugs" (drugs prescribed for a use that does not appear on the drug's labeling that has been specifically approved by the U.S. Food and Drug Administration) that are on the plan's formulary; the bill further requires plans health plans to maintain an expeditious process by which prescribing providers may obtain authorization for medically necessary nonformulary drugs to treat chronic and seriously debilitating conditions.

SB 2046 expands legislation enacted in 1992—AB 1985 (Speier) (Chapter 1268, Statutes of 1992)—which provides patients facing life-threatening conditions with access to off label drugs. Supporters argued that patients with disabling or chronic conditions—such as those who suffer from cancer, HIV infection or AIDS, sickle cell anemia, multiple sclerosis, cystic fibrosis, and cerebral palsy—require complex care involving multiple providers and highly specialized services, supplies, and equipment. In treating these patients, physicians have no choice but to turn to innovative uses of FDA-approved drugs because there may be no therapeutic alternatives. Such off-label uses may save, prolong, and/or improve the lives of these patients by making it possible for them to sustain independent functioning. SB 2046 was signed by the Governor on September 28, 2000 (Chapter 852, Statutes of 2000).

SB 1764 (Chesbro), as amended May 26, 2000, requires the Legislative Analyst to review data and research relating to the cost-effectiveness of substance abuse treatment services in health plans and disability insurance policies. This bill also requires the Legislative Analyst to survey a sample of health plans, review information on entities that provide alcohol and drug treatment services, and report findings to the legislature. SB 1764 was signed by the Governor on September 1, 2000 (Chapter 305, Statutes of 2000).

SB 1839 (Speier), as amended August 28, 2000, would have required health plans and disability insurers to cover routine patient care costs associated with Phase II and III clinical trials for life-threatening prostate cancer, if the clinical trial is provided in California and the patient's physician certifies that it is likely to be more beneficial than any available standard treatment. On September 30, 2000, the Governor vetoed SB 1839, stating: "I believe that health plans should cover the cost of routine patient care for enrollees participating in clinical trials—in fact, it should not even be controversial....However, under this bill, thousands of Californians suffering from breast cancer and other cancers would continue to be denied coverage. I favor a more comprehensive approach, one which would cover other cancer trials in addition to prostate....I intend to sponsor this legislation for introduction on the first day of the next legislative session, and I will be requesting swift passage" (see 2001 LEGISLATION for description of SB 37 (Speier)).

AB 525 (Kuehl and Thomson), as amended August 14, 2000, requires health plans, disability insurers, and Medi-Cal managed care plans to provide specific information and disclosures to consumers in order to assist them in obtaining access to needed reproductive health services. The potential enrollee must be informed that some hospitals and other providers do not provide family planning, contraceptive service, sterilization, infertility treatments, or abortion, even though the services may be covered under the plan contract. AB 525 was signed by the Governor on September 7, 2000 (Chapter 347, Statutes of 2000).

AB 726 (Gallegos), as amended January 27, 2000, would have required that all monies resulting from conversion of a nonprofit health care service plan to a for-profit plan be directed to the fund of the Major Risk Medical Insurance Program (MRMIP), a state-sponsored health insurance risk pool that provides health care coverage to certain persons with preexisting conditions who are unable to obtain or afford health care coverage. The purpose of this bill was to help uninsured individuals to gain access to health insurance coverage by assisting the overburdened and underfunded MRMIP. On September 28, 2000, the Governor vetoed AB 726, noting that "the bill is inconsistent with the direction I provided in the 2000–01 Budget Act." The Governor stated that it is inappropriate to direct to one program all of the potential funding generated by nonprofit plan conversion—which funding

is currently provided to multiple programs serving a range of health care needs. He further stated that "a large, one-time infusion of funds to this program, which is currently funded from tobacco taxes, would not be particularly useful in resolving any ongoing funding needs for this program."

SB 195 (Chesbro), as amended August 7, 2000, alters the number of geographic areas that a small health plan can use to determine its premium rates under the Small Employer Group Health Coverage Reform Act of 1992 (SGRA) enacted in AB 1672 (Margolin) (Chapter 1128, Statutes of 1992). *[12:4 CRLR 149]* SGRA was designed to ensure that small businesses could gain access to affordable health care coverage, and to prevent discriminatory underwriting practices that would exclude or price small employers out of the health care coverage market. SGRA established limits on the variability of health plan and insurer premiums for small employee groups. Health plans may charge 90–110% of a standard rate in a geographic region. This bill provides small health plans that do not operate statewide with more flexibility in establishing rates for the small employer (2 to 50 employees) market. SGRA specifies a formula for determining the number of geographic regions a small health plan may use in setting small employer health care rates. When that formula results in only one allowable region, this bill permits a small plan that operates in more than one county to have two geographic regions, as long as no county is divided into more than one region. SB 195 was signed by the Governor on September 8, 2000 (Chapter 389, Statutes of 2000).

SB 265 (Speier), as amended August 30, 2000, revises California law to conform to the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and requires health plans and disability insurers to issue HIPAA coverage to federally eligible individuals at certain premium rates beginning July 1, 2000. This bill defines a "federally eligible individual" as an individual who (a) has had 18 or more months of prior group coverage; (b) is not otherwise eligible for health coverage; (c) was not terminated from his/her most recent health coverage plan due to nonpayment of premiums or fraud; and (d) has exhausted any Consolidated Omnibus Budget Reconciliation Act (COBRA) or Cal-COBRA continuation coverage. AB 265 was signed by the Governor on September 28, 2000 (Chapter 810, Statutes of 2000).

SB 764 (Speier), as amended August 18, 2000, brings California into conformance with federal law governing Medicare supplemental insurance (also known as "Medigap insurance"). In recent legislation, Congress mandated that each state bring its Medigap legislation into conformance with the revised standards set forth in a model regulation established by the National Association of Insurance Commissioners in April 1998. The deadline for state compliance was April 24, 1999. SB 764 was signed by the Governor on September 25, 2000 (Chapter 706, Statutes of 2000).

SB 1903 (Speier), as amended August 29, 2000, applies provisions of the existing Confidentiality of Medical Information Act (CMIA), which generally prohibit health care providers and contractors from sharing or selling a patient's medical information, to corporations and their subsidiaries and affiliates; and specifies that any person or entity seeking an individual's medical information, other than those specifically authorized to do so pursuant to the CMIA, must obtain valid authorization for release of the information. SB 1903 was signed by the Governor on September 30, 2000 (Chapter 1066, Statutes of 2000).

The following bills reported in Volume 17, No. 1 (Winter 2000) died in committee or otherwise failed to be enacted during 2000: **AB 138 (Gallegos)**, which would have allocated funds for an independent health care ombudsprogram; **AB 368 (Kuehl)**, which would have required health plans covering prosthetic aids or visual aids to provide such coverage for individuals with low vision; **AB 735 (Knox)**, relating to penalties for late payment by health plans; **AB 888 (Wayne)**, requiring health plans to report a calculation of their actual or expected loss ratios; **AB 1283 (Baugh)**, relating to independent review of plans' health coverage decisions; **AB 1285 (Baugh)**, which would have enacted various provisions applicable to health plans; **SB 7 (Figueroa)** and **SB 18 (Figueroa)**, which, like the successful SB 59 (Perata) in 1999, would have required persons making medical necessity or appropriateness decisions to be appropriately licensed; **SB 217 (Baca)**, which would have required plans to annually survey the satisfaction of their subscribers and enrollees; **SB 254 (Speier)**, relating to health plan grievance procedures; **SB 292 (Figueroa)**, relating to second opinions; **SB 337 (Figueroa)**, prohibiting a health plan with more than 25,000 enrollees from expending or allocating more than 15% of its gross revenues as administrative costs; **SB 420 (Figueroa)**, which was similar to the successful AB 78 (Gallegos) in 1999; and **SB 422 (Figueroa)**, requiring denials or modifications of prior authorizations to be communicated to enrollees in writing.

The following bills reported in Volume 17, No. 1 (Winter 2000) were subsequently amended and are no longer relevant to the regulation of managed care: **AB 1124 (Havice)**, **AB 1621 (Thomson)**, and **SB 362 (Alpert)**.

2001 LEGISLATION

SB 458 (Escutia), as amended April 17, 2001, is essentially a reintroduction of AB 1751 (Kuehl), which failed in 2000 (see above). SB 458 would amend Civil Code 3428, the "right to sue" provision added by SB 21 (Figueroa) in 1999, to provide that a health plan is liable "in a court of law" when it fails to comply with its duty to exercise ordinary care in arranging for the provision of medically appropriate health care services to its enrollees and its subscribers, and that failure results in the denial, delay, or modification of the health care service, and the enrollee or subscriber suffers substantial harm. According to the author, this bill is necessary to clarify that the new statutory right to sue health plans in SB 21 is not compromised by pre-dispute mandatory arbitration clauses in health plans' contracts. *[S. Jud]*

SB 37 (Speier), as amended April 16, 2001, is Senator Speier's response to the Governor's 2000 veto of SB 1839 (Speier) (see above). SB 37 would require health plans and certain disability insurers to cover the cost of health care services related to a cancer patient's enrollment in a cancer clinical trial, if the patient's physician has recommended participation in the trial. However, plans and insurers would not be responsible for costs related to a drug or device not approved by the FDA, management of the trial, the enrollee's travel and nonclinical expenses, or items and services provided free to the enrollee by the research sponsors. *[S. Appr]*

SB 686 (Ortiz), as amended April 17, 2001, would change the way DMHC calculates administrative assessments on health plans. Specifically, this bill would require full-service health plans to pay $12,500 plus 80 cents per enrollee per year; specialized health plans would pay $7,500 plus 30 cents per enrollee per year. *[S. Appr]*

SB 492 (Scott), as amended April 16, 2001, would add a dentist to the ACMHC (thus increasing the membership of ACMHC from 22 to 23 members) and specify that the additional member shall be a dentist in active practice, with five years of experience in providing services to enrollees of a dental service plan, and shall be appointed by the Governor. The bill would also amend SB 2136 Dunn, enacted in 2000 (see above), to provide DMHC with a six-month extension of the deadline for publishing proposed uniform medical quality audit regulations; under SB 492, DMHC must publish those regulations by July 1, 2002. *[S. Appr]*

SB 103 (Speier), as amended April 4, 2001, is intended to address the abrupt "doctor switching" that occurs when health plans cut off medical groups due to contractual disputes and providers are thus terminated. If a patient's physician is no longer an authorized provider, the patient must switch physicians. If the patient wants to keep that physician as his/her provider, the patient typically must wait until the next "open enrollment period" before he/she can switch plans (thus necessitating a switch to a new physician in the meantime). According to the author, this imposed "doctor switching" is not fair to patients or doctors and corrupts the patient-doctor relationship that is critical to the quality of care. SB 103 would require health plans and disability insurers to provide continuity of care from a terminated provider to an enrollee or insured for any condition, and extend that period of coverage until the commencement date of the enrollee's next open enrollment period. The bill would delete the conditions described under existing law that excuse the plan or insurer from providing continuity of care coverage, and instead require a contract between a provider and a plan or insurer to specify reimbursement rates payable in those circumstances. *[S. Appr]*

SB 801 (Speier), as amended April 23, 2001, would require the DMHC Director to assist in non-binding negotiations between a health care provider and a health plan when a new contract cannot be reached and negotiations have been in progress for at least 30 days, or notices have been sent to enrollees informing them of the contract termination. *[S. Appr]*

AB 1600 (Keeley), as amended April 30, 2001, would authorize health care providers on a class basis and health plans to negotiate any contract term or condition and upon an impasse, as defined, to submit the dispute to mediation and, if unsuccessful, to refer the matter to arbitration. Sponsored by CMA, the bill would also require the Department to adopt regulations prior to July 1, 2002, pertaining to these mediation and arbitration processes. CMA and numerous other health care provider trade associations argue that AB 1600 will allow providers to obtain contracts that are fair, reasonable, and sufficient to assure patient access; opponents—led by the HMOs and the California Chamber of Commerce—argue that this bill will have the effect of granting health care providers immunity from federal antitrust laws by permitting them to collude in negotiating managed care contracts. *[A. Health]*

CMA and numerous other health care provider trade associations argue that AB 1600 will allow providers to obtain contracts that are fair, reasonable, and sufficient to assure patient access; opponents—led by the HMOs and the California Chamber of Commerce—argue that this bill will have the effect of granting health care providers immunity from federal antitrust laws by permitting them to collude in negotiating managed care contracts.

SB 1092 (Sher), as amended April 17, 2001, would make changes in the grievance system required at each plan by the Knox-Keene Act. This bill would define "grievance" to include any written or oral expression of dissatisfaction, and any dispute, request for reconsideration, or appeal made by a subscriber or enrollee or by his/her representative to a plan or to an entity to which a plan has delegated authority to resolve grievances on behalf of the plan. The bill also defines the term "complaint" and distinguishes between a "grievance" and a "complaint." SB 1092 would also require plans to maintain a written or electronic log of all complaints. This log shall contain the date of the call, the name of the complainant, the member identification number, the nature of the complaint, the nature of the resolution, and the identification of the plan representative who took the call and resolved the complaint. This complaint log shall be reviewed by the plan officer responsible for the grievance process. *[S. Appr]*

AB 142 (Richman), as amended March 29, 2001, would prohibit—effective July 1, 2002—a contract between a physician or physician group and a health plan from requiring the physician or physician group to be at financial risk for the following medical services when covered under the contract: chemotherapeutic medications and adjunct pharmaceutical therapies; drugs, medication, or blood products for hemophiliacs; medications related to transplants; injectable medication costing more than $500 per patient per calendar year; vaccines; and self-injectable medications. The bill would also define "financial risk" to include capitation payments, case

rates, risk pools, and other reimbursement methods other than a fee-for-service rate structure. *[A. Appr]*

SB 599 (Chesbro), as amended April 25, 2001, would require health plans, disability insurers, and self-insured employee welfare benefit plans to provide coverage for the treatment of substance abuse disorders on the same basis as they provide coverage for any other medical condition. Additionally, this measure would require plans and insurers to reimburse providers of these services, and prohibit plans that contract directly with such providers from delegating risk to them, unless certain requirements are met. *[A. Appr]*

SB 1219 (Romero, Kuehl), as amended April 16, 2001, would require health plans and disability insurers to offer coverage for an annual liquid based cervical cancer screening test as approved by the FDA. *[S. Appr]*

AB 207 (Matthews), as amended April 17, 2001, would require certain health plans and disability insurers that offer coverage for prescription drug benefits and that issue identification cards to enrollees and insureds to issue a card containing uniform information necessary to process claims for prescription drug benefits. *[A. Appr]*

AB 937 (Koretz), as introduced February 23, 2001, would require every health plan covering hospital, medical, or surgical expenses to develop and file with DMHC a plan establishing risk-adjusted, capitated rates for the reimbursement of providers for the treatment of enrollees infected with HIV. This bill would also require DMHC to develop risk-adjusted, capitated rates for treatment of Medi-Cal recipients infected with HIV. *[A. Health]*

AB 938 (Cohn), as amended April 19, 2001, would require health plans to provide to enrollees, upon request, a list of specified contracting health care providers within the enrollee's or prospective enrollee's general geographic area, including their medical education, board certification, and subspecialty training. The bill would also require health plans to permit enrollees to request this information through the plan's toll-free telephone number. AB 938 would also require plans to include on their required disclosure form any limitations on the patient's choice of a nonphysician health care provider, and information on general authorization requirements for referral by a primary care physician to a nonphysician health care practitioner. *[A. Appr]*

SB 117 (Speier), as amended April 3, 2001, would prohibit a health plan from assigning the responsibility for payment of claims for emergency services and care to any contracting medical provider, unless the contracting provider is able to demonstrate to DMHC an ability to pay contracting and noncontracting providers of emergency services and care in compliance with the law. *[S. Appr]*

AB 1282 (Cardoza), as introduced February 23, 2001, would prohibit a health plan from excluding an enrollee or potential enrollee solely on the grounds that the enrollee or potential enrollee does not reside within a particular region of the state. *[A. Health]*

AB 1311 (Goldberg), as amended April 24, 2001, would require health care providers to provide a copy, at no charge, of all or any portion of the patient's records to the patient or the patient's representative, upon proof that the record is needed to support a claim or appeal regarding eligibility for a public benefit program. *[A. Appr]*

AB 1503 (Nation), as amended April 19, 2001, would require specialized health plans offering professional mental health services to permit a new enrollee to complete a course of mental health treatment when the enrollee was involuntarily required to change health plans by his/her employer or sponsor. *[A. Health]*

AB 532 (Cogdill), as amended April 18, 2001, would require the Legislative Analyst to study the operation of health plans in rural areas of this state and to report to the legislature and to DMHC on or before July 1, 2002, regarding the reasons plans have discontinued operating in those areas and incentives for plans to resume operating there. *[A. Floor]*

LITIGATION

The federal courts have recently issued a potpourri of opinions in cases interpreting the impact of the federal Employee Retirement Income Security Act (ERISA) on the liability of managed care plans for the health care provided by them and the physicians with whom they contract. ERISA was originally enacted to protect private-sector employees from fraud by pension plan managers, but has been interpreted by the federal courts to preempt state law and state remedies governing private "employee benefit plans," including employer-subsidized health care coverage provided through managed care organizations. In the absence of Congressional action to amend ERISA to close this loophole, various states have enacted laws permitting state court lawsuits under certain circumstances (see below). While challenges to those state laws were pending, California enacted SB 21 (Figueroa) in 1999, which permits privately-employed California enrollees to sue their managed care organizations under certain circumstances under state law in state courts. SB 21 attempts to skirt ERISA by characterizing managed care as "the business of insurance," to which ERISA does not apply.

The federal courts have recently issued a potpourri of opinions in cases interpreting the impact of the federal Employee Retirement Income Security Act (ERISA) on the liability of managed care plans for the health care provided by them and the physicians with whom they contract.

In ***Pegram v. Herdrich***, plaintiff Herdrich—who was injured because her HMO required her to wait eight days before undergoing an appendectomy, during which time her appendix burst—sued her physician and HMO for medical malpractice under Illinois law and won $35,000. She also sued them under ERISA, claiming that the HMO's bonus system (which provided physicians with incentives to deny, limit, or

delay treatment) violated their fiduciary duties to their enrollees under ERISA. The district court held that the actions of the physician and HMO were not undertaken as ERISA fiduciaries; a divided Seventh Circuit reversed. Although the majority did not hold that the mere existence of incentives automatically gives rise to a breach of fiduciary duty, it stated that "incentives can rise to the level of a breach where, as pleaded here, the fiduciary trust between plan participants and plan fiduciaries no longer exists (*i.e.*, where physicians delay providing necessary treatment to, or withhold administering proper care to, plan beneficiaries for the sole purpose of increasing their bonuses)," and remanded the matter to the district court to determine whether the defendants had breached their fiduciary duty and, if so, whether the breach caused injuries to Herdrich. *[17:1 CRLR 18–19]*

In its June 12, 2000 decision at 530 U.S. 211 (2000), a unanimous U.S. Supreme Court narrowly framed the issue as "whether treatment decisions made by a health maintenance organization, acting through its physician employees, are fiduciary acts within the meaning of [ERISA]....We hold that they are not." After a brief discussion of the history and nature of managed health care, the Court concluded that all health plans must limit their costs by "rationing care" and inducing their employee physicians to also ration care. The Court rejected the notion that courts are in the best position to draw a line between acceptable and unacceptable incentives. Because profit incentives to ration care affect "mixed decisions" (that is, decisions that bear simultaneously on eligibility decisions of the health plan and treatment decisions of the physician), acceptance of plaintiff's fiduciary duty claim would eliminate all for-profit health plans and possibly all health plans. The Court found nothing to indicate that Congress intended to eliminate health plans when it enacted ERISA. Even a more limited case-by-case approach (such as that suggested by the Seventh Circuit) would be met in every case with the defense that the physician acted for good medical reasons, not bad financial ones, and would therefore simply parallel a medical malpractice claim rather than a breach of fiduciary duty under ERISA. The Court found that no purpose would be served in "opening the federal courthouse doors for a fiduciary malpractice claim...."

On June 19, 2000, the U.S. Supreme Court denied a petition for a writ of certiorari in ***In Re U.S. Healthcare, Inc.***, 193 F.3d 151 (1999), in which the Third Circuit held that while ERISA may preempt state law claims alleging denial of benefits, it was never intended to exempt HMOs from malpractice suits alleging quality of care violations. *[17:1 CRLR 19]*

On June 20, 2000, the U.S. Fifth Circuit Court of Appeals upheld a significant part of Texas' Health Care Liability Act in ***Corporate Health Insurance Inc. v. Texas Department of Insurance***, 215 F.3d 526 (2000). Enacted in 1997, the Texas statute allows an individual to sue a health insurance carrier, HMO, or other managed care entity for damages proximately caused by the entity's failure to exercise ordinary care when making a health care treatment decision. In addition, the law provides that these entities may be held liable for substandard health care treatment decisions made by their employees, agents, or representatives. When the liability provision was challenged by HMOs as being preempted by ERISA's general preemption clause, the district court found no preemption and upheld it. *[17:1 CRLR 19–20]*

In its June 2000 decision, the Fifth Circuit affirmed. In a decision similar to the Third Circuit's ruling in *In Re U.S. Healthcare* (see above), the court found that the Texas statute "does not encompass claims based on a managed care entity's denial of coverage for a medical service recommended by the treating physician....Rather, the Act would allow suit for claims that a treating physician was negligent in delivering medical services, and it imposes vicarious liability on managed care entities for that negligence." The court held that the Texas statute reflects "the regulatory reach of states exercising their traditional police powers in regulating the quality of health care. A suit for medical malpractice against a doctor is not preempted by ERISA simply because those services were arranged for by an HMO and paid for by an ERISA plan. Likewise, the vicarious liability of the entities for whom the doctor acted as an agent is rooted in general principles of state agency law. Seen in this light, the Act simply codifies Texas's already-existing standards regarding medical care. These standards are at the heart of Texas's regulatory power."

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The Texas statute also established an independent review process for adverse benefit determinations, and requires an insured or enrollee to submit his/her claim for review by an independent review organization (IRO) if such review is requested by the managed care entity. On this issue, the district court found ERISA preemption, ruling that the Act's IRO provision and other provisions "that address specific responsibilities of an HMO and further explain and define the procedure for independent review of an adverse benefit determination by an IRO" are preempted by ERISA because they "mandate employee benefit structures or their administration." The Fifth Circuit affirmed in part and reversed in part. To the extent that the statute allows independent review of quality of care claims for which patients may bring suit under the liability provision, there is no ERISA preemption. For other claims, however, the court held that the statute establishes a quasi-administrative procedure for the review of a denial of benefits and binds the ERISA plan to the decision of the IRO. "This scheme creates an alternative mechanism through which

plan members may seek benefits due them under the terms of the plan—the identical relief offered under section 1132(a)(1)(B) of ERISA. As such, the independent review provisions conflict with ERISA's exclusive remedy" and are thus preempted.

On October 19, 2000 in ***Moran v. Rush Prudential***, 230 F.3d 959 (2000), however, the Seventh Circuit Court of Appeals, by a 5--4 decision, held that a provision of the Illinois HMO Act requiring health plans to submit to an independent review when there is disagreement over whether a course of treatment is medically necessary between a patient's primary care physician and an HMO is not preempted by ERISA.

In this case, Debra Moran's primary care physician recommended a specific surgery for her, but Rush Prudential (Rush), her ERISA-governed health care plan, denied coverage for that surgery. Instead, Rush offered to pay for a less expensive surgery performed by a Rush-affiliated doctor. At her own expense, Moran underwent the $95,000 surgery proposed by her physician and later sought reimbursement in state court under the Illinois HMO Act. The state court eventually ordered Rush to submit to an independent physician review; that physician found that the recommended surgery was medically necessary (although he would have used a less intrusive and less time-consuming technique). Rush again denied her claim, and she refiled her action for reimbursement in state court. Rush removed the action to federal district court on ERISA preemption grounds. Rush argued that Moran's claim for reimbursement was a claim for benefits that is completely preempted because it falls within section 502(a)(1)(B) of ERISA's civil enforcement provision. The district court agreed and granted summary judgment to Rush.

The Seventh Circuit reversed. Although it found that the independent review provision falls within the broad scope of ERISA's preemption clause, it also found that—because it "regulates insurance," a regulatory power within the control of the states—the provision is "saved" from preemption by ERISA's "saving clause." On this point, the Seventh Circuit parted company with the Fifth Circuit in the Texas case (see above), thus setting up an inter-circuit split which will undoubtedly lead to review by the U.S. Supreme Court.

California courts have also issued their fair share of cases affecting regulation of the managed care industry. In a 4–3 decision in ***Potvin v. Metropolitan Life Insurance***, 22 Cal. 4th 1060 (May 8, 2000), the California Supreme Court held that, under certain circumstances, a physician is entitled to the common law right to fair procedure before he may be removed from an insurer's preferred provider list—and despite an at-will termination clause in the underlying contract.

In 1992, MetLife terminated physician-plaintiff Potvin's preferred provider status. At first, MetLife declined to give a reason for the termination. After further requests, Potvin was told that he did not meet MetLife's standard for malpractice history. At the time, MetLife would not include or retain on its preferred provider lists any physician who had more than two malpractice lawsuits, or who had paid an aggregate sum of $50,000 in judgment or settlement of such actions; Potvin's patients had sued him four times, resulting in one $713,000 settlement. Potvin sued MetLife for violating his right to fair procedure and for "devastating his practice" because no other managed care plans would retain him and physician groups "dependent on credentialing by MetLife" ceased referring patients to him. The superior court granted MetLife's motion for summary judgment but the Second District Court of Appeal reversed, holding that MetLife should have given Potvin notice of the grounds for its action and a reasonable opportunity to be heard. *[17:1 CRLR 21; 16:2 CRLR 13; 16:1 CRLR 33]*

The Supreme Court affirmed the appellate court's reversal of the trial court's grant of summary judgment to MetLife, but disagreed with the appellate court's holding that insurers and health plans must necessarily comply with the common law right of fair procedure. Writing for the majority, Justice Kennard stated that "when the right to fair procedure applies, the decision making must be both substantively rational and procedurally fair." Here, Kennard found that the right to fair procedure applies under *James v. Marinship Corp.*, 25 Cal. 2d 721 (1944); *Pinsker v. Pacific Coast Society of Orthodontists*, 12 Cal. 3d 541 (1974); and *Ezekial v. Winkley*, 20 Cal. 3d 267 (1977). In these cases, the decisions of private organizations to exclude or expel a member affected the public interest because the organization exercised a virtual monopoly over the supply of labor in that field (a labor union, associations of orthodontists, and a hospital offering a surgical residency program, respectively). As a result, each organization was subject to the common law right to fair procedure. From this precedent, Kennard concluded that an insurer wishing to remove a doctor from its preferred provider list must comply with the right to fair procedure only "when the insurer possesses power so substantial that the removal significantly impairs the ability of an ordinary, competent physician to practice medicine or a medical specialty in a particular geographic area, thereby affecting an important, substantial economic interest." The court found that if participation in a health plan is a practical necessity for physicians and if removing physicians from preferred provider networks that have a virtual monopoly on managed care significantly impairs those physicians' practice of medicine, then removal must be substantially rational and procedurally fair. Finally, the court clarified that a "without cause" termination clause in an employment contract is unenforceable if it limits an existing right to fair procedure under the common law.

The three-member dissent led by Justice Janice Rogers Brown charged that the majority has, in effect, declared "that it is the public policy of this state that physicians are entitled to a minimum income and, therefore, if removal of a physician from an insurer's preferred provider list would reduce the physician's income below that guaranteed minimum, the physician is entitled to a hearing and to the judicial review that would inevitably follow upon an adverse decision. What is the majority's authority for declaring this public policy, for

singling out physicians for such special treatment?" The dissent also opined that the majority's decision is unclear and unworkable, "in the sense that decisions under it will be unpredictable. As a consequence, insurers will be forced to forego cost-cutting measures like MetLife's malpractice policy, or be prepared to grant hearings to all physicians terminated under such policies." Additionally, insurers will be unable to predict with confidence whether their decisions will invoke the common law right to fair procedure—"in theory, a physician in Riverside might be entitled to a hearing before being terminated by a given insurer, while a physician in Fremont might not be...." Finally, the dissent argued that Dr. Potvin had signed a contract with an at-will termination clause, and that such clause should be enforced.

On December 2, 1999, the California Supreme Court issued a 4–3 decision in ***Broughton v. Cigna Healthplans***, 21 Cal. 4th 1066. *[17:1 CRLR 20–21; 16:2 CRLR 12–13]* The majority held that a deceptive practices claim against an HMO for injunctive relief under the Consumer Legal Remedies Act (CLRA), Civil Code section 1750 *et seq.*, may not be decided by arbitrators regardless of the existence of a binding arbitration clause in the plan's contract, on grounds that "the injunction plaintiffs seek in the present case is...beyond the arbitrator's power to grant. The CLRA plaintiff in this case is functioning as a private attorney general, enjoining future deceptive practices on behalf of the general public. We hold that under such circumstances arbitration is not a suitable forum, and the Legislature did not intend this type of injunctive relief to be arbitrated." However, an injured plaintiff who advances a claim for damages under the same statute is bound by the arbitration clause.

On December 1, 1999, the California Supreme Court granted review of the Fourth District Court of Appeal's decision in ***McCall v. Pacificare of California, Inc.***, 74 Cal.App. 4th 257 (1999), on the issue of whether state law claims against an HMO arising out of a refusal by the plan to provide services under a Medicare-subsidized plan fall within the exclusive review provisions of the Medicare Act requiring exhaustion of administrative remedies. *[17:1 CRLR 20]* At this writing, the court has not yet issued its decision.

With varying degrees of success, physicians and the medical profession are increasingly turning to the courts to challenge HMO practices that adversely affect them.

With varying degrees of success, physicians and the medical profession are increasingly turning to the courts to challenge HMO practices that adversely affect them. In July 1999 in ***California Medical Association v. Aetna U.S. Healthcare, et al.***, No. 732614, CMA sued eight HMOs in San Diego County Superior Court over their refusal to pay its physician members for services rendered to patients of HMOs contracting with now-bankrupt FPA Medical Management. In part, CMA alleged that the HMOs violated Health and Safety Code section 1371, a provision requiring health plans to pay uncontested claims within 30 working days after receipt, and which states (in part) that "the obligation of the plan to comply with this section shall not be deemed to be waived when the plan requires its medical groups, independent practice associations, or other contracting entities to pay claims for covered services." CMA interprets this provision to require health plans to pay providers directly when RBOs do not *[17:1 CRLR 20]*, and argues that the HMOs are in a better position to monitor the financial solvency of RBOs than are individual physicians. The HMOs demurred, arguing that they had already paid FPA via capitation and that no law—including section 1371—requires them to pay twice.

In January 2000, the superior court sustained the HMOs' demurrer on CMA's section 1371 claims without leave to amend, ruling that section 1371 does not create the duty alleged by CMA. In so ruling, the court relied on a December 29, 1998 DOC decision denying CMA's petition for rulemaking. CMA had asked DOC to adopt a regulation making plans the primary obligors for payment of claims notwithstanding contractual provisions to the contrary. DOC declined to adopt such a rule, finding that section 1371 "does not create liability for the payment of claims that a plan is otherwise not responsible for paying" or "override all contractual agreements as to liability for payment that providers have entered into with other entities." *[16:1 CRLR 29]* The court held that DOC's decision interpreting section 1371 "is entitled to great weight and this court finds the DOC's interpretation is supported by the plain language of the statute." CMA has appealed the superior court's decision to the Fourth District Court of Appeal, where the case is pending at this writing.

Meanwhile, CMA launched a broader attack on the managed care system in federal court. On May 25, 2000, the trade association filed ***CMA v. Blue Cross of California, Inc., et al.***, No. CV1894 in U.S. District Court for the Northern District of California. In this class action against three major HMOs brought under several state and federal laws (including ERISA and the federal Racketeer Influenced and Corrupt Organization (RICO) Act), CMA alleges that the health plans have conspired to keep capitation rates low, fraudulently and intentionally deny or delay payments to physicians, and improperly interfere with the physician-patient relationship. CMA seeks an injunction to halt these practices.

CMA's action coincided with the filing of numerous other federal court class actions by other physician organizations claiming to represent every doctor who has signed a contract with an HMO in the past ten years, and with the filing of about a dozen federal class actions by attorneys representing 32 million HMO enrollees across the nation. In July 2000, the Judicial Panel on Multidistrict Litigation ordered 18 of these cases consolidated for pretrial purposes before U.S. District Court Judge Federico A. Moreno in the Southern District of Florida. ***In Re Managed Care Litigation***, MDL

No. 1334, has been divided into two cases: "the provider track" (the cases filed by physicians), and "the subscriber track" (the cases filed by patients).

On March 2, 2001, Judge Moreno ruled on the defendants' motion to dismiss the providers' matter, in which defendants relied heavily on the U.S. Supreme Court's decision in *Pegram v. Herdrich* (see above). Judge Moreno chided the HMOs for reading *Pegram* "as if it were a talisman before which all of Plaintiffs' claims should fail. Yet the Court in *Pegram* did not fashion an all-encompassing cloak of immunity for the health care industry. Instead, partly out of a concern that granting the remedy sought by the Plaintiff in *Pegram* would result in 'nothing less than elimination of the for-profit HMO,'...the Court reached its narrow holding....Furthermore, *Pegram* concerned an ERISA claim brought by a patient with a significantly different factual situation. The Plaintiffs here seek relief under a number of state and federal statutes....Consequently, *Pegram* does not act as a bar to these claims."

However, the court dismissed with prejudice plaintiffs' federal prompt payment cause of action, finding that no such claim exists under federal Medicare laws. Finding that plaintiffs failed to plead the RICO and state prompt payment claims properly, the court dismissed those claims with leave to file an amended complaint. On March 26, 2001, plaintiffs filed a new complaint with amended RICO allegations, contending the HMOs "have undertaken a common scheme to systematically deny, delay and diminish payments to health care providers" in violation of the federal RICO laws. Plaintiffs allege that they have information in their possession that the insurers have used "cost-based criteria to approve or deny claims" for payment and had offered cash incentives to claims reviewers who would deny or limit tests and treatments ordered by doctors. Plaintiffs further contend that the HMOs developed the criteria with an actuarial firm and a consulting firm, and used software that changed standard codes describing treatments to reduce payments.

In the "subscriber track" cases, plaintiffs allege that they were misled by the HMOs and have paid for more expensive plans than those they received, in violation of ERISA and RICO. The subscribers also claim that the defendants make coverage decisions based on cost rather than on medical necessity, and challenge the HMOs' practice of paying physicians bonuses and incentives to deny treatment. The subscribers seek money damages as well as injunctive relief to stop the defendants from engaging in deceptive practices.

The next phase in these matters will be plaintiffs' motions for class certification. At this writing, a hearing to consider certification of the physician class is scheduled for July 2001.

In May 2000, just before the transfer of managed care regulation to DMHC, DOC filed an accusation (***In Re Kaiser Foundation Health Plan, Inc. (Utterback)***), issued a cease and desist order, and levied a $1 million fine against Kaiser Foundation Health Plan, Inc., the state's largest HMO, stemming from its treatment of 74-year-old Margaret Utterback, a 50-year member of Kaiser who died in 1996.

According to the accusation, on January 26, 1996, Mrs. Utterback began experiencing back and abdominal pain during the early morning, and began telephoning her Kaiser primary care physician at 8:30 a.m. After several calls and repeated requests to see a physician, Mrs. Utterback was scheduled for a 4:15 p.m. appointment. Although she arrived at the clinic two hours before her scheduled appointed and asked three times to see a physician, Mrs. Utterback was not seen until 4:30 p.m. Upon examination, the physician immediately diagnosed Mrs. Utterback with a dissecting abdominal aortic aneurysm which—if it ruptures—can cause deadly blood loss. The physician, however, did not start an IV or administer oxygen or pain medication; according to DOC, he had his staff arrange for transport to the emergency room (and failed to communicate the seriousness of Mrs. Utterback's diagnosis to the transport vehicle staff). One hour after being diagnosed, and minutes after arriving at the emergency room, the aneurysm ruptured; Mrs. Utterback died two days later.

In its accusation, the Department charged Kaiser with violations of its duties under Health and Safety Code sections 1367(e) (failure to ensure that all medical services are readily available to all enrollees), 1367(d) (failure to provide continuity of care and ready referral of patients), 1345(b)(5) (failure to provide preventive services), 1345(b)(6) (failure to provide emergency services), 1367(g) (failure to have the organizational and administrative capacity to provide services to subscribers and enrollees, including the maintenance of medical records), and 1368.01 (failure to promptly resolve a grievance). DOC issued an order requiring Kaiser to cease and desist from (1) failing to ensure that subscribers and enrollees receive available and accessible health and medical services rendered in a manner providing continuity of care; (2) failing to provide basic health care services, including preventive and emergency services; and (3) failing to demonstrate that the plan has the organizational and administrative capacity to provide services to enrollees, including the maintenance and ready availability of medical records. Kaiser is appealing both the enforcement action and the fine.

FUTURE MEETINGS

ACMHC—2001: July 10 in San Francisco, October 10 in Glendale, December 5 in Sacramento. ***2002***: April 4 in Sacramento, June 19 in Sacramento, September 3 in Los Angeles, November 7 in Los Angeles.

FSSB—2001: May 22 in Sacramento, June 19 in Glendale, July 24 in Sacramento, August 21 in Sacramento, October 16 in Glendale, November 13 in Sacramento, December 11 in Glendale. ***2002***: January 29 in Sacramento, February 28 in Glendale, March 19 in Sacramento, April 23 in Burbank, June 18 in Burbank, July 30 in Sacramento, December 10 in Burbank.