GOVERNMENT REGULATION AND OVERSIGHT OF MANAGED HEALTH CARE

FINDINGS AND RECOMMENDATIONS

I. FINDINGS

Health care services are not like other commodities or consumer goods. Health care has a special moral status and therefore a particular public interest. Most people consider it unacceptable for others to suffer, to be disabled, or to have shortened lives for lack of access to at least basic medical care. Thus, we have many public programs intended to respond to people's need for care. The markets for health services and health care are prone to fail for many reasons, such as the incentive effects of health insurance that undermine cost-consciousness, the very high cost and asymmetry of information between practitioner and patient, and the wide variations among people in medical risks that make pooling of risks difficult. Health care is often a matter of life and death or disability. Government action is needed to protect public safety. The cost of care is an important public policy problem because so much of it is paid for by the taxpayers.

Thus, there are many important roles for government in the financing and regulation of health care and health insurance, including consumer protection, improving the market for health coverage, and providing leadership by being a responsible purchaser of health care benefits. One of the roles of Government is to protect consumers by creating the conditions for markets to serve consumers well. These conditions include the rule of law (including laws against fraudulent or deceptive practices), securing property rights, defining liability, licensing facilities and professionals, contract enforcement, and anti-trust. The complexity of health insurance contracts makes necessary special rules to ensure there is a meeting of minds between buyers and sellers that lead to the reasonable expectations of reasonable persons being met. Another is maintenance of an acceptable level of quality. Ways the government can improve the market for health coverage include requiring or encouraging the pooling of risks, helping to create an information infrastructure, enabling comparative information, facilitating desirable structural change, considering anti-trust actions, and not creating barriers to market entry. Because of its size and authority, government's role as purchaser is also important.

The operations of health care service plans and other managed care organizations are controlled by many governmental and private entities. Health care service plans are regulated by the Department of Corporations (DOC), the lead agency for health plan regulation, under the Knox-Keene Act. The Department of Health Services (DHS) contracts with some plans to serve Medi-Cal beneficiaries. DHS's Audits and Investigations Division performs fiscal and medical audits of Medi-Cal managed care organizations. Its licensing and certification program licenses the facilities managed care uses. The Department of Industrial Relations (DIR) oversees managed care organizations offering managed care services for work-related injuries and illnesses. The Medical Board of California, under the Department of Consumer Affairs (DCA), licenses health professionals who work for managed care. The Managed Risk Medical Insurance Board (MRMIB) contracts with many managed care organizations involved in Access for Infants and Mothers, the Health Insurance Plan of California (HIPC), and the Major Risk Medical Insurance Program. The California Public Employees Retirement System (CalPERS), which is the single largest customer for many health service plans, purchases coverage for 1,000,000 California public employees, retirees and dependents. Health care service plans are also overseen by the Health Care Financing Administration (HCFA) for the federal Medicare program to the extent they serve Medicare beneficiaries and by the federal Office of Personnel Management (OPM) that purchases coverage for over nine million federal employees, retirees, and dependents.

These and other government agencies also regulate health professionals, facilities, and other health insurance arrangements. Under the present regulatory structure, however, there is no direct regulation of many medical groups/IPAs by a government agency. Rather, most medical groups/IPAs are regulated indirectly by the Knox-Keene plans with which they contract. In addition, in order for medical groups to accept fully capitated contracts, some of them have received limited licensure from the DOC, which requires meeting Knox-Keene standards.

The private sector supplements these state and federal regulatory functions through a variety of quality measurement and accreditation organizations, which assist and provide information to employers and consumers to evaluate their purchases. Their efforts, as well as their counterparts that are internal to managed care organizations,

are also intended to be used by providers, provider groups and plans to improve quality of care and service. In addition, large purchasers, including government, can use their substantial negotiating power to influence positively the health care system. Large purchasers could provide consumers with the ability to choose the best value plan for their needs, through appropriate information, incentives and choices.

II. IMPROVING THE REGULATORY PROCESS

The Task Force heard and received testimony that there is public dissatisfaction with the DOC as health care service plan regulator. The creation of this Task Force suggests that the Legislature, the Governor, and many citizens believe that there may be some deficiency in the structure or operations of the regulation of the managed care industry. Two hundred four pages of Knox Keene law have failed to satisfy the dissatisfied. This certainly calls into question whether two hundred more such pages would make things any better. We need to focus on ways to improve the existing regulatory process, including:

A. Adequate Attention

The DOC is the primary business regulator in California. As such, it regulates much more than health care service plans. Therefore, its leader does not focus 100% of his or her attention to health care service plans. Recently, DOC's head has been a securities lawyer. This made sense in 1976 when Knox-Keene was passed because health care service plans were few and small, not large enough to warrant their own department. Now, more than half of all Californians are enrolled in health care service plans and they are, or soon will be, the largest industry in the state. Given the size, the complexity, and the high degree of public interest, health care service plans ought to have their own regulatory agency, headed by a person who devotes his or her complete attention to the industry and who has had a substantial career in health services.

B. Appropriate Leadership

The ideal leader of the state's lead regulatory agency for health systems should have a deep understanding of health care and a well-founded strategic sense of how the industry should evolve. The leader should have the ability to prioritize law enforcement and to work on a pro-active basis with the industry, employers and consumer groups to define and solve broad system problems. The right person must understand medical quality management and how to create conditions that foster quality improvement. He or she must also understand sympathetically the culture and values of health care. This person should be qualified to make judgments as to whether proposed innovations are in the public interest, and if they are, to "fast track" their approval.

C. Compassionate Face

By fulfilling its legal obligation to enforce the law according to the Knox-Keene Act, the DOC often appears insensitive.[1] A letter stating that no violation of law has been found might be quite appropriate in a matter of securities law (a body of laws and rules with fairly clear lines in which the issue is whether or not someone played by the rules). In this case only money, not lives, is at stake. While compassion might not be something one expects from a government agency, the style of securities law enforcement seems inappropriate when one's life or health is involved.

For parents, for example, who have lost a child and want to know whether he/she received the standard of care (a subjective judgment), whether he/she was cared for by appropriately qualified practitioners, and, if not, what corrective action would be taken, an appropriate response would include: (1) reasons why the regulatory authority understands a plan to be or not to be in compliance with the law, (2) reference to contact with a qualified practitioner and the answers he or she provided to their questions, and (3) if their charges were correct, information about the corrective actions taken.

[1] While the Task Force did not attempt to discern whether a pattern of insensitivity by the DOC exists, it heard and received testimony from several unhappy citizens who feel they have experienced insensitive treatment.

D. Streamlining Regulation

The regulatory process is cumbersome and complex. The DOC and other regulatory agencies appear to have missed numerous opportunities for streamlining. Cooperation among public and private agencies performing similar regulatory functions could be improved.

A particular example is the regulation of medical groups, IPAs and other entities bearing risk in contracts with Knox-Keene plans. The solvency and the quality of these entities is a matter of legitimate public interest and concern. The average medical group contracts with 15 health plans. The medical groups understandably do not want to share financial information with the health plans with whom they are negotiating for payments, and they understandably do not want 15 financial audits per year. Moreover, they understandably feel overburdened by numerous quality audits that disrupt their work and add to their costs. To avoid such redundancy, The Medical Quality Commission and the Pacific Business Group on Health launched an effort to evaluate directly performance of physician groups. The Physician Value Check Survey measures clinical quality and member satisfaction. This private sector regulation should be embraced and not duplicated by the public sector.

E. Developing Capabilities to Meet the Challenges of Accelerating Industry Change

Despite the best efforts of the legislative process, it lacks clarity. While the intention of the DOC is to avoid inconsistency and resolve it when found, some apparent and actual inconsistencies inevitably exist. In regards to DOC-regulated health care service plans, some decisions seem inconsistent, subjective, arbitrary, or very different from those that have been imposed on other health care service plans. Plans have also experienced delays when they have submitted material modifications to their filings. Delays are costly to health care service plans and consumers because approval often would enable plans to provide a new product or a product to a new service area.

III. RECOMMENDATIONS

1. **Streamline Regulatory Oversight**

   (a) The Governor and the Legislature should create a new Office of Health System Oversight (OHSO) to regulate health care service plans, currently regulated by the DOC. The Office of Statewide Health Planning and Development should be immediately transferred to the new OHSO.

   (b) All entities that practice medicine, whether individuals or organizations, to the extent they can be shown to practice medicine, should be regulated for the care they provide and the impact of their medical decisions. To this end, the Governor and the Legislature should require OHSO to regulate directly medical groups/IPAs and any other entities practicing medicine that are currently not regulated directly by any government oversight agency.

   (c) Within two years, the Governor and the Legislature should consider folding into OSHO regulation of other health insurers providing insurance through indemnity, PPO and EPO products currently regulated by DOI, in order to assure, to the extent possible, that all health insurers compete on a level playing field. Subsequently, the Governor and the Legislature should examine the merits of folding into OHSO other regulatory functions.

2. **Provide Appropriate Leadership**

   (a) The head of OHSO should be (as described above) a person of stature in the health service industry who can command respect and exercise strategic leadership. The person should have a sympathetic understanding of the problems of patients and their families.

   (b) The head of OHSO should be appointed by the Governor to ensure accountability. OHSO should be headed by a single person to maximize clarity of policy direction.

3. **Streamline Regulation of Medical Groups/IPAs**

The State should give OHSO the authority to facilitate the existing oversight of medical groups, IPAs and other entities that enter into risk contracts with Knox-Keene plans, including solvency and quality audits (as described below), the credentialing process, monitoring of provider compensation arrangements and their disclosure, dispute resolution processes, and other areas if necessary. This oversight could be exercised in a way that would reduce cost for providers and health plans.

4. **Adopt Appropriate Principles for Regulation**

The following principles should guide regulation by the OHSO: (a) regulation should be as efficient and streamlined as possible, (b) regulation should be conducted in cooperation with other public and private bodies that also regulate or purchase from health care service plans and other health insurers to the maximum extent possible, and (c) regulation should recognize and expedite approval of beneficial innovations (i.e., those that consumers want, improve quality, or save costs without causing harm).

5. **Streamline Solvency Audits**

Currently, many health plans seek to audit provider organizations to seek to determine their financial status. This creates burdens for provider organizations that might contract with many different plans. It also creates difficulties because health plans may seek information that medical groups consider proprietary.

(a) In order to facilitate the development of this information in a less burdensome manner, a provider organization should be able to request that the state's HMO regulatory authority oversee one solvency audit on a periodic basis that would meet the requirements of all contracting health plans.

(b) The state's HMO regulatory authority should delegate the authority to audit provider organizations by subcontracting with independent, third-party organizations such as accounting firms. These organizations should meet standards established by the regulatory authority through a request for proposal process.

(c) Provider organizations that contract with multiple health plans and the health plans with which they contract should convene a working group to develop acceptable solvency standards. The solvency standards may vary by size and type of organization, amount of risk assumed, or other pertinent factors.

6. **Streamline Quality Audits**

In order to comply with Knox-Keene standards for health plan quality, health plans must audit the quality of the provider organizations with which it contracts.

(a) In order to facilitate the collection of information necessary to audit quality in an efficient manner, a provider organization should be able to request that the state's HMO regulatory authority oversee one quality audit on a periodic basis (e.g., annually) that would determine compliance with the quality standards of all contracting health plans. The regulatory authority would need to provide that the audits establish whether provider organizations treat different plan members differently.

(b) The state's HMO regulatory authority should delegate the authority to audit medical groups by subcontracting with independent, third-party organizations, such as CCHRI, NCQA and other quality measurement or accrediting organizations, that meet standards the state's HMO regulatory authority establishes through a request for proposal process.

(c) The cost of the single quality audit should be shared among all the health care service plans with which a provider organization contracts. This would save health care service plans and providers time and money.

7. **Eliminate Inter-departmental and Private Sector Redundancy**

Government departments, in addition to the state's HMO regulatory authority, that regulate health insurers which offer indemnity, PPO, and EPO products (e.g., DOI) or different populations (e.g., DHS, Division of

Workers' Compensation), should work with the state's HMO regulatory authority and private sector quality measurement and accreditation bodies to develop solvency and quality standards to ensure that they satisfy their respective requirements with regard to the scope of issues covered by the audit. Government departments should not duplicate audits conducted by independent third-party, approved auditors, but rather organizations that are certified by these audits should be deemed in compliance with similar contractual requirements. Health insurers offering indemnity, PPO, and EPO products should be subject to regulatory review by other departments only in those areas where the program differs from Knox-Keene Act requirements or exceeds those requirements.

8. **Meet the Challenges Presented by Accelerating Industry Change**

(a) The state's HMO regulatory authority should define and publish formal policies and procedures regarding filing formats, filing requirements, interpretive guidelines for plans and counsel regarding how requirements apply in critical areas, and an approval process that contains quality control and "consistency control" checks. With criteria set up front, healthcare service plans could plan effectively and modify applications to improve likelihood of approval. Furthermore, with standard decision criteria, the regulatory authority's regulators would become more efficient.

(b) The state's HMO regulatory authority should take steps to improve efficiency and consistency of its decisions. Steps may include: (a) expediting the hiring of additional staff provided for by the budget augmentation, (b) setting guidelines for and requiring counsel to participate in training about policies and interpretations, (c) setting standards for health care service plan documents, (d) consistently assigning counsel to the same plans unless and until concerns over a counsel's objectivity arise, and (e) reviewing workload allocations.

(c) The Governor and legislature should pass legislation that would allow health care service plans to consolidate minor amendments that occur during the year into one annual filing.

(d) The Governor or legislature should hire an independent organization to evaluate the use of the recent DOC budget augmentation to determine its impact on responsiveness and to assess the need for additional or reallocated funds, given proposed steps for streamlining.

(e) The state's HMO regulatory authority should allow health care service plans to consider material modifications approved, if not acted upon within 60 days. If the state's HMO regulatory authority requires changes to any aspect of the material modification after the 60-day period, the health care service plan should be required to make those changes prospectively, but should not be subjected to departmental disciplinary actions.

GOVERNMENT REGULATION AND OVERSIGHT OF MANAGED HEALTH CARE BACKGROUND PAPER

I. INTRODUCTION

Nationally, over one trillion dollars per year are spent in the United States on health care. As health care has become a larger proportion of the overall economy, more entrepreneurs have become involved in the industry, developing market innovations that often do not fit neatly into the categories of businesses and insurance coverages that have traditionally been regulated. In recent years, as managed care has obtained the dominant market position, health care financial intermediaries have become increasingly involved in managing not just the business end of health delivery, but the clinical end. In the current California health care market place, many different regulators are involved in a fragmented oversight structure.

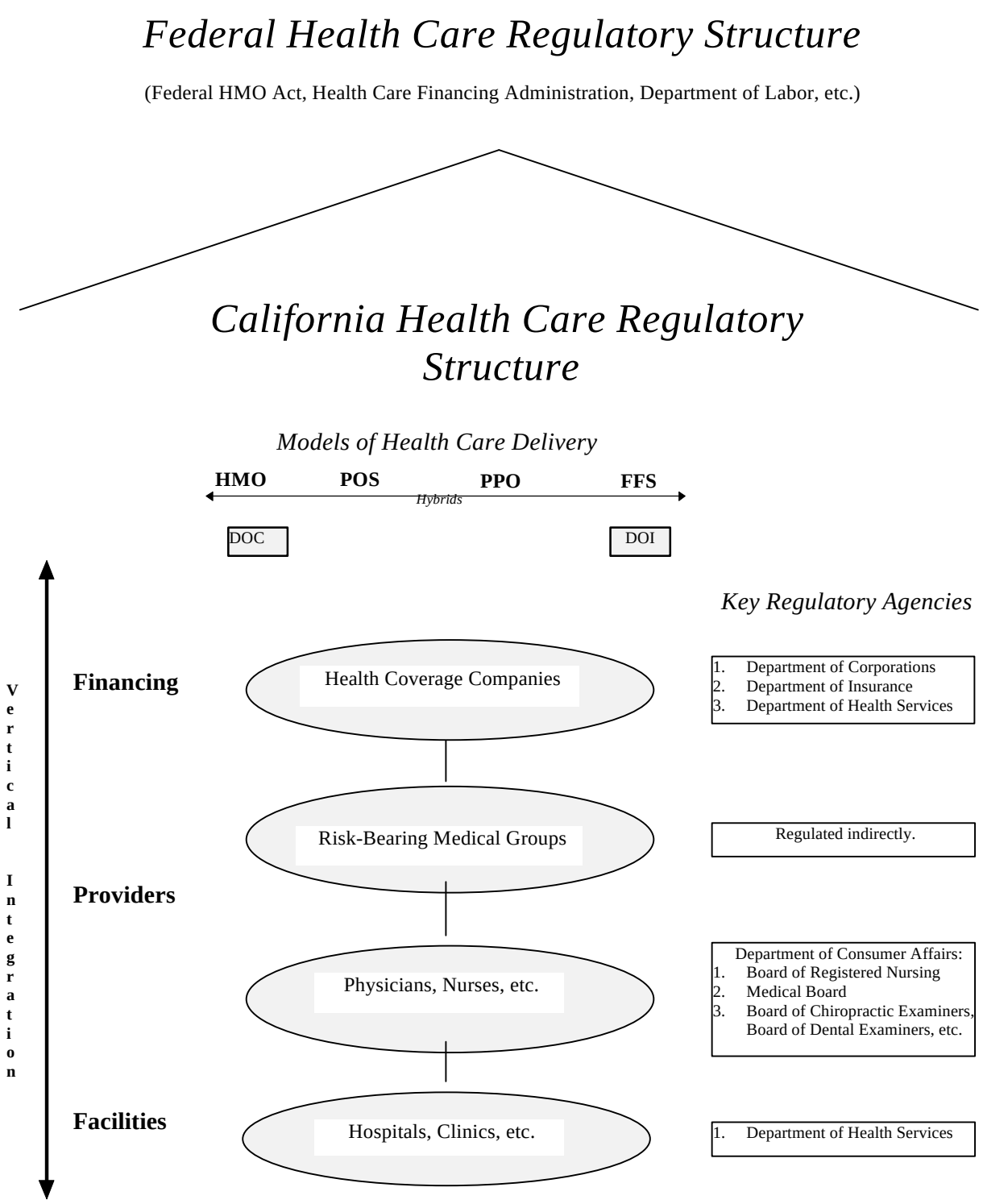
The state of California utilizes a regulatory structure designed in the 1970s, when managed care organizations were responsible for financing the health care of at most a few percent of Californians, to oversee a rapidly evolving industry that has grown manyfold. (Figure 1 places the regulatory structure in the context of the current marketplace.) One of the central charges of the Task Force is to review the organizational structure of state regulators and determine whether it needs updating. That is the purpose of this paper: to summarize the key players in state and federal regulation of managed care and their responsibilities; to identify design criteria for evaluating the current structure and (if necessary) redesigning a new one; and to recommend changes in state regulatory organization, if needed.

The authors conclude that the industry has evolved business forms well beyond the definitions that govern existing lines of jurisdiction, and some consolidation of jurisdiction among state regulators is necessary.

How this Paper is Organized

Section II summarizes the necessary roles for government. Section III summarizes the responsibilities of state and federal regulators. Section IV outlines the quasi-regulatory functions performed by private actors such as NCQA. Section V outlines the options available for reorganizing state regulatory organization, and Section VI presents our conclusions and recommendations.

Figure 1. Overview of Regulatory Structure



II. NECESSARY ROLE FOR GOVERNMENT

There are several areas in which government intervention is required, where purchasers, plans, and the industry can not or do not satisfy desired goals. Two of the essential roles of government include consumer protection and helping the market work well.

A. CONSUMER PROTECTION

One of the most fundamental tasks of government is to create the conditions for markets to serve consumers well. These conditions include the rule of law, including securing property rights and defining liability, licensing facilities and professionals, contract enforcement, anti-trust and a regulatory scheme that fits the needs of each market. Well-conceived rules can help markets work better and increase satisfaction all around. For example, the rule that permits airlines to overbook and then auction vouchers to induce volunteers to take later flights creates a "win-win" situation. Consumers' health and safety need special government protection because when consumers get sick, they are unable to "shop" for themselves as they would for other goods in other markets. Advocacy groups for the poor and disenfranchised are natural allies in the government's efforts to protect health care consumers; regulators should view them as such.

Government has been active in defining and securing patients' rights under health care coverage contracts, such as rights to free expression of medical judgments by doctors, to information about how plans operate, to timely payment for care for emergencies, and to confidentiality of personal medical records. In several of these areas, there is a need for careful balancing. For example, protection of confidentiality needs to be balanced against the legitimate and important needs for research on the relationship between treatments and outcomes to find out what medical treatments work best.

The California Legislature has instituted government regulation of health care coverage through two major bodies of law, which are enforced by two governmental Departments. The Insurance Code provides a regulatory framework for indemnity insurers and preferred provider organizations (PPOs), and is enforced by the Department of Insurance (DOI). The Knox-Keene Act, a portion of the Health and Safety Code, governs health care service plans and is enforced by the Department of Corporations (DOC). The Medical Practice Act governs individual medical licensure. These three bodies of law, which contain many similar provisions, provide consumer protections through financial standards, contractual requirements, quality assurance programs, required grievance and appeals processes, oversight of soliciting and marketing practices, and mandatory basic benefits.

The Knox-Keene Act, in particular, is an extensive document that contains specific requirements in numerous areas. For example, the Act requires health plans to file extensive documentation on their proposed health care delivery systems prior to licensure. Health plans must file copies of their contracts with network providers; maps illustrating where provider facilities and offices are located to ensure that licensed facilities and professionals are within 30 minutes or 15 miles of the enrollee's workplace or residence; documentation regarding the ratio of full-time equivalent physicians to anticipated enrollees; demonstrations that the number of specialists will be adequate to serve the expected population of enrollees; and descriptions of the plan's quality assurance program, grievance and appeals processes, and provisions for continuity of care as a patient moves through the health care delivery system. The licensing application also requires detailed financial information to ensure regulators that the health plan's management has realistic projections about costs and revenues and to ensure that the plan has enough reserves to cover all claims costs.

Once a health plan is licensed, the Knox-Keene Act requires the plan to submit quarterly and annual financial statements and to maintain a reserve, or tangible net equity, sufficient to cover outstanding claims. Plans also undergo regular financial audits, and may be placed under closer examination if their financial reports indicate problems.

The Knox-Keene Act contains more extensive requirements in the areas of consumer protection relating to patient care. The Act requires all health plans to have grievance and appeals processes that allow enrollees to submit

disputes to the plan and receive a timely response, including expedited review of grievances involving serious conditions. The Act also allows enrollees to seek assistance from the DOC if they are unsatisfied with the health plan's response. When a plan denies coverage for care, the Act requires that the plan must disclose to patients and providers the criteria or clinical basis for the decision upon request. The Act also contains an outside, independent review process for terminally ill patients who have been denied coverage for experimental treatments. Finally, the Act protects consumers by prohibiting unethical marketing and solicitation practices, such as using statements in advertising that are false, deceptive or misleading. All advertising and marketing materials must be submitted to the DOC for review prior to use.

1. Insurance Contracts

The complexity of health insurance contracts makes necessary special rules to ensure there is a meeting of minds between buyers and sellers - what is being sold is what is being delivered. There must be rules and processes that lead to the reasonable expectations of reasonable persons being met.

The Knox-Keene Act and its underlying regulations, which govern HMOs in California, sets comprehensive standards for the contracts between health plans and consumers. All contracts between plans and enrollees, plans and employers, and plans and providers must be filed with the DOC for review and approval, and must meet the statutory "fair and reasonable" requirement that is imposed. Specific requirements are spelled out. Health plans, for example, must cover all medically necessary basic health care services, which are defined to include physician care, hospital care, emergency care in and out of the network (in accordance with a "prudent layperson" standard), urgent care in and out of the network, home health care, diagnostic tests, laboratory tests, preventive care, physical therapy, speech therapy, and occupational therapy. In addition, there are statutory mandates regarding preventive care for children, reconstructive surgery and prosthetics for mastectomy patients, medical transportation, screening and diagnostic tests for cervical cancer and osteoporosis, and medically necessary surgery for temporal mandibular joint disorder. These benefits are not subject to negotiation between plans and employers; they must be provided in any benefit package. Plans are also required to *offer* employers coverage for services such as diabetes education, acupuncture, special footwear, substance abuse treatment, infertility coverage, and orthotics and prosthetics.

The Act sets out specific disclosure requirements pertaining to these benefit mandates, as well as other disclosures regarding exclusions, limitations and copayments, and physician payment arrangements. There are specific contractual requirements for plan contracts with small employers of fewer than 50 employees so that plans may not refuse them coverage nor refuse to renew existing coverage.

The Knox-Keene Act also protects consumers in ways that help expand access to health care coverage. For example, the Act prohibits the use of genetic information in underwriting so that individuals with genetic predispositions to certain diseases cannot be denied coverage simply because of that predisposition. The Act also prohibits plans from denying coverage or services to individuals who are blind, who are physically or mentally impaired, who have conditions related to diethylstilbestrol, or for reasons related to the race, color, national origin, ancestry, religion, sex , marital status, sexual orientation, or age of an individual.

Large purchasers such as PBGH, CalPERS, and the University of California have the resources to negotiate contracts that are satisfactory to their beneficiaries, but non-pooled small businesses and individuals do not. State regulators have stepped in and must step in to protect small purchasers. For example, the state Legislature passed legislation (AB 1672) creating a purchasing pool for small businesses that set rating limitations on small group premiums, required guaranteed issue and renewal, and allowed for the creation of two standardized benefit packages. By standardizing the benefit packages, small employers and their employees could better compare each plan. This legislation solved some of the difficulties small employers were facing in obtaining affordable coverage for their employees.

2. Quality Standards

In general, regulators and large purchasers should focus on managed care deliverables rather than the delivery process in order to preserve maximum opportunity for efficiency-improving innovation. However, broad standards

of operation are appropriate. Such a list would include standards for quality assurance and utilization management systems, rules to assure that medical decisions are made by qualified physicians, rules to assure no interference with doctor-patient communication about treatment options, and curbs on schemes that give doctors incentives to deny necessary treatment.

The Knox-Keene Act, for example, requires that every health care service plan have in place a quality assurance program that is designed to continuously review the quality of care provided, review problems and complaints, and design corrective action plans that prevent problems health plan-wide. In addition, health care service plans undergo a medical audit every three years to determine whether they are meeting the requirements of the law regarding quality assurance as well as access to care, continuity of care, and provision of benefits. These audits include examinations of patient records and documents from quality assurance committee meetings to ensure that problems have been corrected in a systematic way.

The Knox-Keene Act also prohibits any contractual requirements that would inhibit a provider from discussing treatment options with his or her patient and prohibits incentive arrangements that would induce the delay, denial, or reduction of medically necessary and appropriate care. State law also prohibits any termination or disciplinary action against a provider for advocating appropriate health care on behalf of a patient. The Knox-Keene Act and its underlying regulations require that medical decision-making be separated from fiscal and administrative functions so that these functions do not hinder the medical decision-making process. When a claim is denied for clinical reasons and appealed, for example, it must be reviewed by a licensed professional with competency in the clinical area in question. Individuals who are hired to review claims may not be compensated on the basis of the number of claims denied or the dollar amount of the claims involved. These provisions of the Act are designed to ban inappropriate financial incentives that may lead to inappropriate denials.

B. IMPROVING THE MARKET FOR HEALTH COVERAGE

1. Pooling of Risks

In a system that is based on voluntary insurance, with a large proportion made up of individuals and small groups, government action is needed to require or encourage the healthy to subsidize the sick. Three main ways this is done in our society are public programs supported by taxes such as Medicare and Medicaid; employment-based health insurance which is motivated by exclusion of employer paid health insurance from taxable incomes of employees; and state laws limiting the variation in small group premiums.

If everyone could obtain coverage through a large employer or purchasing group that organized and managed a choice of health coverage options for group members, the market would be likely to provide a satisfactory result. However, much of the population works for small employers or is self employed, unemployed, early retirees, part time workers, etc. and does not have access to purchasing groups. Purchasing groups are not currently growing and forming rapidly enough to provide access for everyone in the foreseeable future. State and private entities have attempted to form purchasing groups, but so far have experienced limited growth. In 1996, the California Legislature passed SB 1559 (Peace), which created a statutory framework for the creation of purchasing pools. At this writing, no entity has received licensure under this statute.

Because individuals and small groups of healthy people prefer not to subsidize the costs of individuals or small groups that include sick or high risk individuals, it is difficult to pool individuals and small groups on a purely voluntary basis. Where large purchasers or purchasing groups are not accessible, government can either encourage purchasing through pooled arrangements and the formation of new purchasing entities, e.g., through subsidies, or can act as purchaser or sponsor itself. To limit adverse selection, purchasing pools for individuals would also require specific public policy interventions to achieve market equilibrium, such as a mandate that individuals who purchase coverage do so for minimum periods or subsidies to encourage the healthy ones to buy it.

2. Creating an Information Infrastructure

Government leadership is likely to be required to create an information infrastructure for medical outcomes

research, quality oversight, and utilization management (i.e. electronic records, compatible interfaces so entities can communicate, standard definitions of data elements, and the like.) Government can exercise a convening function as well as exert leverage through its purchasing decisions. Private sector initiatives are already underway. However, due to its significant cost, this project may require government leadership and assistance for successful completion.

3. Enabling Comparative Information

Government action is likely to be needed to secure the timely production of accurate quality-related data and health plan performance data that consumers and purchasers need to make well-informed decisions. Though many California health plans and medical groups have cooperated voluntarily in the collection and reporting of the Health Plan/Employer Data Information Set (HEDIS) without government intervention, data needed for risk-adjusted medical outcomes studies, by hospitals, health plans, and providers in California is lagging behind other states.

Government might help to lead the whole health services industry in the development of uniform data standards for reporting about prices, performance, quality, and service and for comparative evaluation studies. Government should coordinate these efforts with and build on local private, national, and international efforts to set and promote data standards which are a prerequisite to generating adequate information on the basis of which to judge health plans and providers.

4. Facilitating Structural Change

Collective action may be required to enact basic structural reforms to address market failures such as the lack of choice among plans and the lack of competition among delivery systems. For example, in the early 1970s, the federal government saw that HMOs were a potentially desirable alternative to the dominant fee-for-service system, but that their establishment and growth were inhibited by lack of capital, and by state legislative barriers. So the government enacted legislation that defined HMOs, provided access to grants and loans, required most employers to offer them to employees as a choice, and overrode restrictive state laws. Thus government actions led to the transformation of the industry. Legislative changes have led to similar and fundamental changes in the electric power and telecommunications industries. Collective action in Minnesota by private employers and government as purchaser, have led to a partial replacement of the carrier-based HMO system with a system based on competing medical groups.

5. Considering Antitrust Actions

Where necessary, government must take anti-trust actions to prevent business combinations or actions that block competition. Existing antitrust law is designed to prevent this. When health plans merge, the Federal Trade Commission conducts a review under existing antitrust law and principles. In addition, the state Attorney General typically undertakes a review as well, using national standards and guidelines. There have been several large mergers among California HMOs recently which have received, and passed, anti-trust scrutiny. However, those conducting the analyses and making the decisions face a significant challenge to understand the implications of a market changing so rapidly. The consolidation of medical groups/IPAs and their collective bargaining-type activities also pose challenges for regulators in this area.

6. Not Creating Entry Barriers

It is important to be sure that government does not inadvertently create artificial barriers to market entry by new health plans. For instance, the time and cost for DOC approval of a new Knox-Keene license have been reported to be very substantial, and DOC's requirement for contiguous expansion makes growth more difficult for new health plans. These requirements lead some to seek less onerous regulation under the DOI. Ultimately, consumers pay for entry barriers through fewer choices and higher costs.

C. GOVERNMENT AS PURCHASER

Government is California's largest single health care purchaser. As such, its significant buying power has external effects on other purchasers, and therefore on the entire health system. These effects can be for good (e.g., holding vendor plans and providers to rigorous quality standards) or ill (e.g., cost-shifting public liabilities onto private payers). Pursuing self-interest can conflict with broader policy objectives.

III. STATE AND FEDERAL REGULATORY STRUCTURES FOR MANAGED HEALTH CARE

A. STATE GOVERNMENT

The following bullets lay out the general California oversight framework. We then describe each agency in detail. Refer to Figure 2 ("State Health Care Oversight Related to Managed Care") for an overview.

- Health coverage plans: Indemnity health plans, including their Preferred Provider Organization (PPO) products, are regulated by the Department of Insurance (1). Health maintenance organizations (HMOs) and point of service (POS) plans are under the purview of the Department of Corporations (2). The Department of Health Services regulates managed care organizations through its Medi-Cal managed care contracts (3).

- Facilities: The Department of Health Services licenses health care facilities and certifies them for Medi-Cal and Medicare payments (3).

- Providers: The Department of Consumer Affairs has numerous boards and commissions that regulate medical practitioners and their continuing medical education requirements (4). The Medical Board of California licenses and investigates complaints against physicians and the Board of Registered Nursing licenses and disciplines registered nurses.

- Workers' compensation: The Department of Industrial Relations certifies health care organizations that provide managed care to injured workers (5).

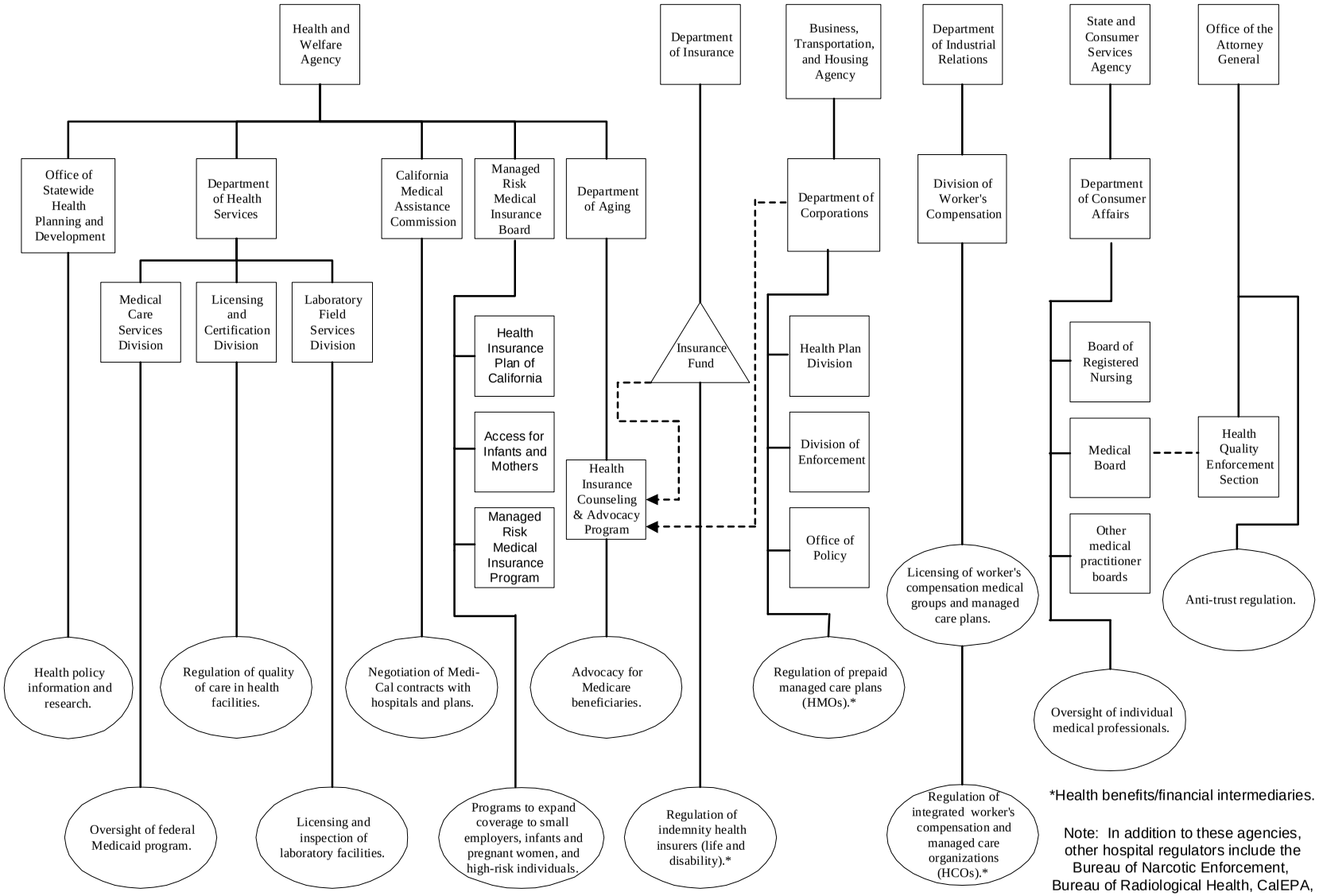
- Programs to expand access: The Managed Risk Medical Insurance Board operates three specialized programs: the Major Risk Medical Insurance Program, Access for Infants and Mothers Program, the new California Children's Health Plan, and the Health Insurance Plan of California, which is presently being outsourced to private contractors (6). The Department of Health Services oversees Medi-Cal, California's Medicaid program (3). The California Medical Assistance Commission negotiates Medi-Cal contracts with medical providers, including hospitals and managed care plans (7). The Department of Aging operates the Health Insurance Counseling and Advocacy Program (HICAP) to assist Medicare beneficiaries with their health care questions (8).

- Legal issues: The Office of the Attorney General provides legal assistance to various health care services oversight agencies and monitors antitrust matters such as mergers and acquisitions (9).

- Data and policy: The Office of Statewide Health Planning and Development collects and tracks data to support improvement in California's health care delivery system (10).

- Employee benefits: The California Public Employees' Retirement System provides health benefits to one million people (11).

Figure 4 summarizes current state jurisdiction over different segments of the industry by regulatory function and broad public policy goal.



*Health benefits/financial intermediaries.

Note: In addition to these agencies, other hospital regulators include the Bureau of Narcotic Enforcement, Bureau of Radiological Health, CalEPA, CalOSHA, Office of Emergency Services, and State Board of Equalization.

Figure 2. State Health Care Oversight Related to Managed Care

Figure 4: CALIFORNIA'S MANAGED HEALTH INDUSTRY:
CURRENT STATE REGULATORY OVERSIGHT JURISDICTION

Industry Segment	Financial Intermediaries		Providers		Facilities		
I. REGULATORY FUNCTION	**INDEMNITY INSURANCE**	**PREPAID HEALTH PLANS**	**INDIVIDUAL CLINICIANS Health Aides & Technicians**	**MEDICAL GROUPS**	**HOSPITALS**	**LONG TERM & NURSING FACILITIES**	**SHORT TERM OUTPATIENT CLINICS**
A. Licensure	DOI	DOC	DCA Health Boards DHS Soc. Services	DOC (if bear risk) DIR (workers' comp.) Health Board	DHS	DHS	DHS DCA Health Boards
B. Monitoring/ Auditing	DOI	DOC DHS (Medi-Cal)	-	DOC (if bear risk) DIR (workers' comp.)	DHS	DHS	DHS DCA Health Boards
C. Operational Modifications	DOI	DOC	-	-	DHS	DHS	DHS
D. Complaints	DOI	DOC DHS	DCA Health Boards	DCA Health Boards	DHS	DHS	DHS DCA Health Boards
E. Enforcement	DOI Attorney General	DOC DHS (Medi-Cal)	DCA Health Boards Attorney General	Market (through plans)	DHS	DHS	DHS DCA Health Boards
II. PUBLIC POLICY GOALS							
A. Financial Solvency	DOI	DOC	-	DOC (if bear risk)	DHS CMAC	-	-
B. Quality of Care		DOC DHS (Medi-Cal)	DCA Health Boards	Medical Board (indirectly) Market (through purchasers)	DHS	DHS	DHS
C. Due Process	DOI	DOC DHS (Medi-Cal)	DHS (Medi-Cal)	DHS (Medi-Cal)	DHS	DHS	DHS
D. Access	Market	DOC DHS (Medi-Cal) Market	DHS Market	DHS Market	DHS Market	DHS Market	DHS Market
E. Affordability	Market	DHS (Medi-Cal) Market	Market	Market	Market	Market	Market

KEY

DOC: Department of Corporations.
DOI: Department of Insurance.
DCA Health Boards: Boards under the Department of Consumers Affairs that license and regulate health professionals.
DHS: Department of Health Services
Market: Private Marketplace
DIR: Department of Industrial Relations
CMAC: California Medical Assistance Commission

Many new managed care organizations that are not risk-bearing have virtually no state oversight currently.
Clinics - If business is licensed under the private physician's license, regulation is by Medical Board based primarily on complaints; if licensed by DHS as a clinic, regulation includes periodic audits as well.

1. Department of Insurance[2]

The Department of Insurance (DOI) is an independent department headed by an elected Insurance Commissioner. DOI regulates the indemnity insurance industry to protect policyholders. To accomplish this, DOI conducts field examinations, maintains solvency surveillance, reviews policy forms, and investigates consumer complaints.

DOI licenses approximately 1,300 California insurance companies that collect $63 billion in annual premiums. Approximately 600 of these companies specialize in writing life and/or accident and health policies.[3] In addition, DOI collects annual taxes from the indemnity insurance industry.

The Insurance Code empowers the Commissioner to hold hearings and to enjoin an insurer from doing business within the state. However, the Commissioner may not force an insurer to pay a claim; that power is reserved for the courts.[4]

For fiscal year 1996/97, DOI anticipates receiving approximately $129 million from its Insurance Fund to support 1,050 positions. The Department funds its regulatory activities almost exclusively from fees and assessments collected from insurance companies, agents, and brokers.

2. Department of Corporations[5]

The Department of Corporations (DOC) is part of the Business, Transportation, and Housing Agency. The Commissioner of Corporations is appointed by the Governor to oversee and administer the duties of the department.

The Commissioner of Corporations is the sole administrator and enforcer of the Knox-Keene Health Care Service Plan Act of 1975 (Act), which governs health care service plans and specialized health plan contracts. A health care service plan (plan) is defined as an entity "who undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to 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."[6] The Act proscribes an extensive licensing process and a continuing compliance system of periodic examinations, reports, and medical surveys.

The Health Plan Division, with support from the Division of Enforcement and Office of Policy, carries out these responsibilities. Currently the DOC licenses and monitors 53 full-service health care service plans and 62 specialized health plans enrolling approximately 17 million Californians.

The Knox-Keene Act requires DOC to ensure that health plans demonstrate financial solvency, quality of care, accessibility of services, continuity of care, contracting requirements, and consumer grievance processes. The Act grants DOC the authority to issue administrative cease and desist orders, institute civil injunctive actions, seek appointments of receiver, seize businesses, freeze enrollments, and issue civil penalties. Moreover, a willful violation of the Knox-Keene Act is a misdemeanor.

The Health Plan Division is financed by the plans through administrative assessments, annual regulatory fees based on the number of plan enrollees, and penalty assessments. The state's 1997/98 budget includes a $6.1 million augmentation for DOC's Health Plan Division, a 74% increase over the previous year. The funds will be generated

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[2] Insurance Code Section 10110 *et seq.*; Title 10, Cal. Code of Regs., Section 2249 *et seq.*

[3] California Regulatory Law Reporter, Vol. 15, No. 4 (Fall 1995) p. 218

[4] California Regulatory Law Reporter, Vol. 15, No. 1 (Winter 1995) p. 110.

[5] Knox-Keene Health Care Service Plan Act of 1975; Health & Safety Code, Section 1340 *et seq.*; 10 Cal. Code of Regs., Section 1300 *et seq.* Existing law requires the Commissioner of Corporations to consult with the Insurance Commissioner to maximize consistency between health care service plan and indemnity insurer regulations. (H&S §1342.5)

[6] Knox-Keene Health Care Service Plan Act of 1975 Section 1345(f)

through increased assessment fees on the plans.

3. Department of Health Services

The Department of Health Services (DHS) is part of the Health & Welfare Agency. The Governor appoints the Director of Health Services.

a. *Involvement with Managed Care*[7]

In an effort to promote Medi-Cal beneficiaries' access to high quality care while controlling costs, DHS is transitioning approximately 3.2 million (60%) of its 5.4 million Medi-Cal recipients into managed care plans.

DHS currently oversees three Medi-Cal managed care models: Geographic Managed Care (GMC), County Organized Health Systems (COHS), and the Two-Plan model. The California Medical Assistance Commission within the Health and Welfare Agency negotiates GMC and COHS contracts. Under the Two-Plan model, DHS contracts with one commercial plan and one locally organized plan in each participating county.

DHS's Audits and Investigations Division performs fiscal and medical audits of Medi-Cal managed care organizations. Noncompliance issues are forwarded to DHS's Managed Care Division for action. DHS has the authority to freeze plan enrollments, terminate contracts, and impose civil penalties.

To meet federal requirements, DHS's 1997-98 budget includes $3 million for the External Quality Review Organization (EQRO) program, in which a private contractor conducts independent quality reviews.

The state and federal government jointly fund Medi-Cal. Expenses, including administration and payments, are generally split evenly between the two agencies.

Federal regulations establish standards for the state programs. Variations from these standards require a waiver from the Health Care Financing Administration (HCFA), a division of the federal Department of Health and Human Services.

b. *Licensing and Certification*[8]

The Licensing and Certification (L&C) program licenses 30 different types of health care facilities and providers under state law. In addition, L&C certifies facilities and providers for Medicare and Medicaid. This program regulates the quality of care in over 6,000 public and private health facilities, clinics, and agencies throughout the state.

DHS enforcement depends on whether state or federal law has been violated and the type of facility involved. Under state law, DHS can impose citations and fines on long term care facilities. For all other types of facilities, the Department is limited to providing "statements of deficiency" or revoking licenses. When enforcing federal standards, DHS can impose civil penalties and appoint facility caretakers.

L&C is funded by the state general fund, licensing fees, penalty assessments, and the federal government.

4. Department of Industrial Relations

The Department of Industrial Relations (DIR) is a Cabinet-level agency with a Governor-appointed Director.

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[7] Welfare & Institutions Code, Section 14000 *et seq.*, Section 14200 *et seq.*, Section 14450 *et seq.*; 22 Cal. Code of Regs., Section 50000 *et seq.*, Section 53000 *et seq.*, Section 53200 *et seq.*

[8] Health & Safety Code, Section 1200 *et seq.* (clinics), Section 1250 *et seq.* (health facilities); Title 22, Cal. Code of Regs., Section 70001 *et seq.*

DIR oversees all workers' compensation programs. Existing law establishes employer liability for job-related injuries. To address high costs, managed care was considered in the Workers' Compensation Reform package.[9] Under this legislation, DIR certifies health care organizations (HCOs) that provide managed care to injured workers and operates a pilot program for providing comprehensive health care services.

a. *Involvement with Managed Care*[10]

DIR's Division of Workers' Compensation (DWC) certifies and monitors workers' compensation Health Care Organizations (HCOs). HCOs offer managed care services for work-related injuries and illnesses. To be certified, these provider organizations must demonstrate financial stability. Three types of organizations are eligible to apply for HCO certification: DOI-licensed disability insurers, DOC-licensed health plans, and DWC-licensed Workers' Compensation Health Care Provider Organizations (WCHCPOs). As of August 1997, DWC has certified 10 HCOs, covering 35,000 workers. Three of these HCOs are disability insurers, two are HMOs, and the remaining five are WCHCPOs.[11]

DOI- or DOC-licensed HCOs are subject to those licensing authorities. In addition, DWC requires three-year certification, monitoring, and on-site audits for all HCOs.

b. *24 Hour Pilot Program*[12]

DWC also oversees a "24-Hour" pilot project to evaluate "integrated health delivery systems." These systems provide both workers' compensation and non-occupational medical care. The 24-Hour pilots and HCO requirements are similar in many respects, although the HCOs are subject to far more complex administrative requirements. Four pilot projects, with approximately 6,000 enrollees, are operating in four counties.[13] A privately-funded evaluation will examine administrative efficiencies, cost control potential, and service capabilities.[14]

5. <u>Department of Consumer Affairs</u>

The Department of Consumer Affairs (DCA) is part of the State and Consumer Services Agency and is the umbrella agency for a number of independent boards and commissions that oversee specific professions. The major health-related boards are the Medical Board of California and the Board of Registered Nursing. Additional boards regulate other medical practitioners, including acupuncturists, dentists, optometrists, pharmacists, physical therapists, physician assistants, podiatrists, psychologists, respiratory therapists, speech pathologists, vocational nurses, and psychiatric technicians. The Governor appoints DCA's Director.

a. *Medical Board of California*

The Medical Board of California (MBC) consists of twelve physicians and seven public members appointed to four-year terms. The Governor appoints all members except two public members appointed by the Speaker of the Assembly and the Senate Rules Committee. All members are subject to Senate confirmation.

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[9] Dr. Linda Rudolph, *Managed Care in California's Workers' Compensation System: A Survey of Current Practices* (February 1996), Department of Industrial Relations, Division of Workers' Compensation.

[10] Workers' Compensation Health Care Provider Organization Act of 1993, Labor Code Section 5150 *et seq.*; 10 Cal. Code of Regs., Section 1959 *et seq.*

[11] Telephone conversation with Marissa Pereira, DWC.

[12] Labor Code Section 4612; 8 Cal. Code of Regs., 10175 *et seq.*

[13] Dr. Linda Rudolph, *loc. cit.*, p. 2,

[14] Ibid., p. 2.

The MBC is financed by annual physician licensing fees and administrative fees on physicians in violation of the Medical Practice Act. The State Auditor has criticized the MBC for their failure to pursue collection of fines.[15]

The Board is divided into two separate Divisions: the Division of Licensing (DOL) and the Division of Medical Quality (DMQ).

i. Physician Licensing and Oversight[16]

The Division of Licensing (DOL), composed of four physicians and three public members, is responsible for ensuring that all California-licensed physicians have adequate medical education and training. DOL issues licenses and certificates, administers the continuous medical education program, and administers examinations for some license applicants. The Board's Committee on Affiliated Healing Arts Professions and the DOL also regulate dispensing opticians, lay midwives, research psychoanalysts, and medical assistants.

The DMQ, composed of eight physicians and four public members, reviews medical practice quality. The DMQ receives, evaluates, and investigates complaints of physician misconduct and negligence and files charges as appropriate. Following an administrative hearing, the DMQ takes final disciplinary action to revoke, suspend, or restrict the physician's license.

ii. Outpatient Clinic Accreditation

The DOL accredits medical offices, including mobile vans, where outpatient surgery is performed. Depending on the type of licensing, DHS might also license the entity. This accreditation is mandatory.

The Medical Board can terminate approval and bring an injunction for violations. Willful violations are a misdemeanor and can be fined $1,000 per day.

b. *Board of Registered Nursing*[17]

The nine-member Board of Registered Nursing (BRN) consists of three public members, three RNs actively engaged in patient care, one licensed RN administrator, one nurse educator, and one licensed physician. The Governor appoints one public member and all licensed members. The Senate Rules Committee and the Assembly Speaker appoint two public members. All members serve four-year terms.

The BRN licenses RNs, establishes accreditation requirements for California nursing schools, and reviews nursing school curricula. In addition, the BRN certifies nurse-midwives (CNM), nurse practitioners (NP), and nurse anesthetists (CRNA).

The BRN has enforcement powers comparable to the MBC.

6. Managed Risk Medical Insurance Board (MRMIB)[18]

MRMIB is housed within the Health & Welfare Agency and consists of seven members. Two ex-officio, non-voting members represent the Secretary of the Business, Transportation, and Housing Agency and the Secretary of the Health & Welfare Agency. Of the five voting members, three are appointed by the Governor, one is appointed by the Senate Committee on Rules, and one is appointed by the Speaker of the Assembly.

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[15] California Regulatory Law Reporter, Vol. 15, No. 4 (Fall 1995), p. 86.

[16] Medical Practice Act, Business and Professions Code, Section 2000 *et seq.*; 16 Cal. Code of Regs., 1300 *et seq.*

[17] Nursing Practice Act, Business & Professions Code, Section 2700 *et seq.*; Title 16, California Code of Regulations, Section 1400 *et seq.*

[18] All information from the Governor's proposed 97/98 budget, p. HW 77 to 78.

MRMIB administers programs that extend private health coverage to certain uninsured groups (as described below). In addition, the Board develops policy and recommendations on providing health insurance to over six million uninsured Californians.

MRMIB manages the Major Risk Medical Insurance Program (MRMIP), Access for Infants and Mothers (AIM) Program, and the Health Insurance Plan of California (HIPC).

a. *Major Risk Medical Insurance Program (MRMIP)*[19]

This program provides health coverage to Californians who are unable to secure adequate coverage for themselves and their dependents because insurers consider them to be "medically uninsurable," i.e., at high risk of needing costly medical care. Subscribers can choose among three PPOs and four HMOs. The program has the capacity to enroll 19,500 individuals.

b. *Access for Infants and Mothers (AIM) Program*[20]

AIM provides comprehensive subsidized coverage through nine managed care plans to pregnant women and their infants. Women whose family income is between 200 and 300 percent of the Federal Poverty Level (FPL) are eligible for the program. (Those with incomes below 200 percent of FPL are eligible for Medi-Cal.)

c. *The Health Insurance Plan of California (HIPC)*[21]

The HIPC program makes health insurance more affordable for small employers (two to 50 employees) by establishing a statewide purchasing pool. Under the HIPC, MRMIB contracts with 25 health plans and seven dental plans.

7. <u>California Medical Assistance Commission (CMAC)</u>[22]

CMAC is an independent commission within the Health & Welfare Agency. The Governor appoints three voting members, and the Speaker of the Assembly and the Senate Rules Committee each appoint two voting members. The Directors of DHS and the Department of Finance serve as ex-officio members. All members serve staggered four-year terms.

The Commission negotiates contract rates, terms, and conditions with hospitals and the plans participating in the GMC and COHS Medi-Cal managed care programs. CMAC's objective is to promote efficiency and cost-effectiveness.

8. <u>Department of Aging</u>

The Department of Aging operates the Health Insurance Counseling and Advocacy Program (HICAP). HICAP's staff assist Medicare beneficiaries.

HICAP receives a portion of the state Insurance Fund. The Department of Aging can also assess a fee against Medicare HMOs to fund HICAP.[23]

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[19] Insurance Code, Section 12700; Title 10, Cal. Code of Regs., Section 2698 *et seq.*

[20] Insurance Code Section 12695 *et seq.*; Title 10 Cal. Code of Regs., Section 2699.100 *et seq.*

[21] Insurance Code Section 10730 *et seq.*; Title 10 Cal. Code of Regs., Section 2699.6000 *et seq.*

[22] Welfare and Institutions Code, Section 14167 *et seq.*; 22 Cal. Code of Regs., Section 100531 *et seq.*

[23] Chapter 797, Statutes of 1996 (SB 1482, Mello).

9. Attorney General

The Office of the Attorney General (AG) within the Department of Justice provides legal support and advice to DCA's professional boards. The Health Quality Enforcement Section provides 50 specialized attorneys statewide to represent the medical board in administrative hearings. The Licensing Division represents the Nursing and Dental Boards.

The AG has general authority over antitrust matters and must give prior approval for acquisitions of non-profit health facilities (e.g., hospital) by for-profit corporations. Pending legislation (SB 330, Rosenthal) would require both AG and DOC prior approval for all health plan mergers.

10. Office of Statewide Health Planning and Development[24]

The Office of Statewide Health Planning and Development (OSHPD), under the Health & Welfare Agency, provides data that assists health care systems and regulators plan for California's needs and recognize deficiencies. OSHPD collects financial, utilization, and outcome data from health care providers and facilities, researches health care needs and outcomes, and establishes hospital outcomes measures.[25] OSHPD edits this data, and then produces aggregated reports by region. Much of the data are available on the Internet. OSHPD programs include Health Policy and Analysis, Demonstration Projects, Health Professions Development, Facilities Development, Cal-Mortgage Loan Insurance, and Health Facilities Data.

11. California Public Employees' Retirement System (CalPERS)[26]

CalPERS provides pension and welfare benefits to over 1,000 public sector employers, including the State of California. CalPERS' Health Plan Administration Division administers the Health Benefits Program through health plan contracts. The one million-member system is the second largest purchasing pool in the country, after the federal employees' system.

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[24] Health & Safety Code, § 436.10, 437-443, 446-446.8; Welfare & Institutions Code, § 57551 (Health Policy and Analysis)

[25] OSHPD web page, www.ospd.cahwnet.gov)

[26] Gov. Code Section 22751*et seq.;* 2 Cal. Code of Regs., 599.500*et seq.*

B. FEDERAL GOVERNMENT

The following bullets lay out the general federal oversight framework. We then describe each agency in detail. Refer to Figure 3 ("Federal Health Care Oversight Related to Managed Care") for an overview.

- Health plans: The federal government does not directly regulate health insurance indemnity plans. The Health Care Financing Administration qualifies health maintenance organizations and monitors Medicare and Medicaid managed care plans (1). The Department of Labor regulates employee benefit plans (4).

- Facilities: The Health Care Financing Administration sets standards for facilities receiving Medicare and Medicaid reimbursement (1).

- Government purchasing The Office of Personnel Management oversees plan eligibility standards for federal employees, the largest single purchasing pool in the nation (5). The Department of Veterans Affairs operates one of the largest health care facilities networks in the nation (6). The Department of Defense administers the Civilian Health and Medical Program of the Uniformed Services (7).

- Legal issues: The Office of the Inspector General provides legal assistance to the Department of Health and Human Services (3). The Department of Justice oversees antitrust matters (8).

- Data and policy: The Agency for Health Care Policy and Research conducts and supports research, guideline development, and data collection (2).

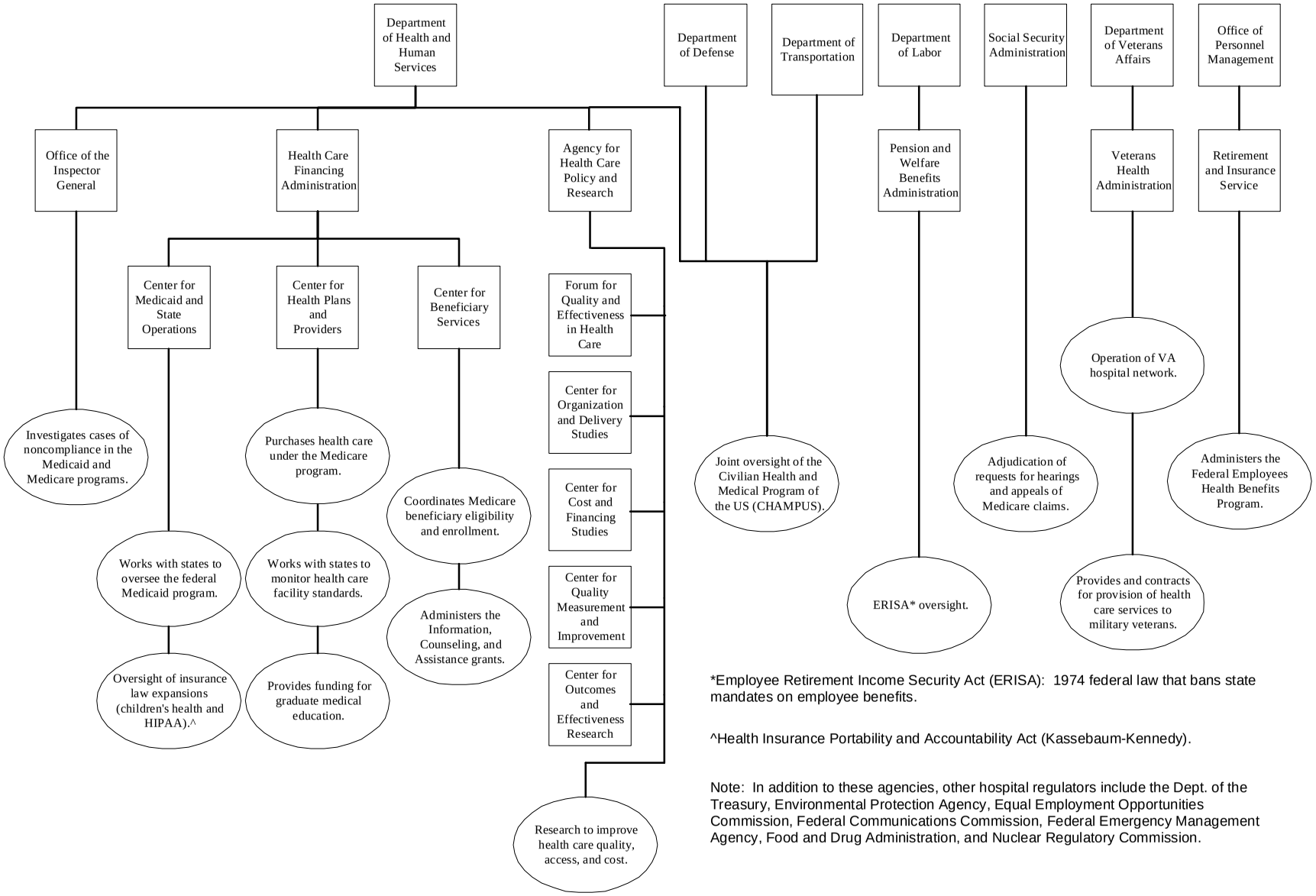

Figure 3. Federal Health Care Oversight Related to Managed Care

1. Health Care Financing Administration

The Health Care Financing Administration (HCFA) of the Department of Health and Human Services administers Medicare and Medicaid (as well as other federal health insurance expansion efforts), which benefit over 72 million Americans. HCFA regulates health care facilities and HMOs receiving Medicare and Medicaid payments. DHS is its California sister agency responsible for state-level implementation and oversight.

a. *Medicare*[27]

In fiscal year 1996, Medicare provided coverage for over 38 million beneficiaries at an estimated cost of $196.6 billion. The beneficiaries included approximately 33 million elderly, five million disabled, and 270,000 end-stage kidney disease patients. HCFA's Center for Health Plans and Providers purchases health care for Medicare. Medicare HMOs must meet the applicable standards of the Federal Health Maintenance Organization Act of 1973.[28]

HCFA can suspend, modify, terminate, or fine noncomplying plans. Examples of prohibited conduct include: failure to provide services, collecting excess premiums, and refusing to enroll eligible individuals. HCFA often refers noncompliance cases to the Office of the Inspector General.

Medicare HMOs operating in California are also subject to regulation by the Department of Corporations. "Medi-Gap" insurance (supplemental insurance for fee-for-service Medicare beneficiaries) is subject to state regulation by the Department of Insurance. Health insurance counseling is available to Medicare recipients through the Department of Aging.

b. *Medicaid*[29]

HCFA's Center for Medicaid and State Operations works with states to oversee the Medicaid program and other federal insurance expansion efforts, such as the Health Insurance Portability and Accountability Act (HIPAA/Kassebaum-Kennedy) and the children's health insurance expansion project. Unlike Medicare, Medicaid is administered by the states, with matching funds from the federal government. Federal law mandates coverage of basic health care services for categories of low-income people. States have the option of covering other needy people and providing medical services not mandated by federal law. The Medicaid program covered nearly 37 million people in fiscal year 1996 at an estimated cost of $163 billion, including $92 billion in federal funds.

Approximately 13 million Medicaid beneficiaries in 41 states are covered by managed care organizations. States have been required to obtain a waiver from HCFA before implementing Medicaid managed care programs. California has obtained both available waivers: Section 1915(b) "freedom of choice" waivers that allow restrictions on provider networks and Section 1115 research and demonstration waivers.

Medicaid- and Medicare-serving HMOs that fail to meet federal standards can be fined up to $100,000 per determination of noncompliance, plus double the excess amount overpaid, and $15,000 for each recipient not enrolled because of the HMO's acts. In addition, the federal government can withhold matching payments to the state for individuals enrolled after a determination of HMO noncompliance.[30]

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[27] Health Insurance for the Aged and Disabled; Social Security Act, Title XVIII; 42 USC § 1395 *et seq.*; 42 CFR 405 *et seq.*

[28] 42 USC § 300e *et seq.;* 42 CFR § 417 *et seq.* Any HMO may seek qualification; compliance is mandatory only for Medicare HMOs. Almost half of all HMOs are not federally qualified.

[29] Grants to States for Medical Assistance; Social Security Act, Title XIX; 42 USC § 1396 *et seq.*; 42 CFR 430 *et seq.*

[30] 42 USC § 1396(m)(5)(A) and (B).

c. *Facilities*[31]

Health care facilities - including laboratories, nursing homes, hospitals, home health agencies, ambulatory surgical centers, and hospices - must be certified as a condition of Medicare and Medicaid reimbursement. This function is typically handled by state agencies through interagency agreements. HCFA trains the state surveyors to enforce the federal quality standards.

Noncompliance can result in nonpayment, disqualification from Medicare and Medicaid, and civil penalties. For long-term nursing homes, the state agency or HCFA can appoint a temporary manager.

The Licensing and Certification Program of the State Department of Health Services enforces federal health facility standards.

2. Agency for Health Care Policy and Research[32]

The Agency for Health Care Policy and Research (AHCPR) is the lead agency for research about the quality of health care, reducing its cost, and broadening access to essential services. AHCPR's programs include the following:

- The Office of the Forum for Quality and Effectiveness in Health Care directs the Evidence-Based Practice Program which develops evidence reports and technology assessments, houses the on-line National Guideline Clearinghouse, and evaluates efforts to translate evidence-based research into clinical practice. They have published science-based guidelines on such high-cost conditions as low back pain, asthma, and pain management.

- The Center for Organization and Delivery Studies conducts studies of the structure, financing, organization, behavior, and performance of the health care system and providers within it.

- The Center for Cost and Financing Studies conducts and supports studies of health care cost and financing.

- The Center for Quality Measurement and Improvement conducts and supports research on measuring and improving the quality of health care.

The Office of Statewide Health Planning and Development and the Department of Health Services carry out similar functions at the state level.

3. Office of the Inspector General[33]

The Office of the Inspector General (OIG) audits, evaluates, and conducts criminal and civil investigations for HCFA. The OIG can impose civil penalties of up to $100,000 per determination of wrongdoing and can terminate providers from Medicare and Medicaid.

4. Department of Labor

The US Department of Labor (DOL), through its Pension and Welfare Benefits Administration (PWBA), oversees the Employee Retirement Income Security Act of 1974 (ERISA)[34].

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[31] 42 CFR § 482 (hospitals); 42 CFR § 483 (long term care facilities); 42 CFR § 484 (home health agencies); 42 CFR § 485 (specialized providers).

[32] 42 USC § 299 *et seq.*

[33] Titles XVIII and XIX of the Social Security Act; 42 CFR 1003 *et seq.*

ERISA sets uniform standards for employee benefits. It applies to any "employee welfare benefit plan which is established or maintained by an employer or by an employee organization (e.g., a labor union) for the purpose of providing...through the purchase of insurance or otherwise...medical, surgical or hospital care or benefits.[35]"

ERISA plans, also known as self-insured plans, are preempted from state regulation. By some estimates, at least 40% of insured Americans, including 70% of managed care recipients, are enrolled in ERISA plans.[36]

While ERISA may offer some advantages, enrollees in ERISA plans are not protected by state regulations. ERISA allows multi-state employers to design consistent benefit programs across state lines without regard to individual state benefits requirements. ERISA plans are less costly due to their exemption from state financial requirements, fees, taxes, and benefit mandates. These state requirements, however, establish more substantial financial and quality standards. The ERISA preemption creates an unlevel playing field for Californians in ERISA plans versus state-regulated plans.

5. Office of Personnel Management[37]

The U.S. Office of Personnel Management (formerly the Civil Service Commission) oversees health benefits for over nine million non-military federal employees and their dependents. The Federal Employees Health Benefits Program is the largest beneficiary pool in the U.S. Three basic types of plans are available: managed fee-for-service, HMOs, and point-of-service plans.

6. Department of Veterans Affairs[38]

The Veterans Health Administration provides hospital, nursing home, outpatient medical care, and dental care to eligible veterans. It operates 173 medical centers, 376 outpatient clinics, and 131 nursing home care units. It also provides for similar care in non-VA inpatient and outpatient settings.

7. Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS)[39]

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[34] 29 USC § 1001 *et seq.*; 29 CFR § 2509 *et seq.*

[35] 29 USC § 1002(1).

[36] Kalmeyer, Steve (The Council on State Governments), "ERISA and State Health Reform", p. 1-2.

[37] Federal Employees Health Benefits Act, 5 USC 8901 et seq.; CFR 890 *et seq.*

[38] 38 USC 1701 *et seq.;* 38 CFR 17 *et seq.*

[39] 10 USC 1071 *et seq.;* 32 CFR 199 *et seq.*

OCHAMPUS, under the authority of the Assistant Secretary of Defense for Health Affairs, administers health and medical programs for retirees, and dependents of active duty, retired, and deceased Uniformed Services members. OCHAMPUS contracts for health benefits, and provides utilization review, peer review, and quality assurance. This program includes regional managed care for military treatment facilities and civilian sources.

8. The Department of Justice

The Department of Justice and the Federal Trade Commission review mergers, acquisitions, and contracts for antitrust violations. The Office of the Attorney General under the state Department of Justice performs similar functions. Health care fraud has now been elevated to one of the top two areas of investigation within the Federal Bureau of Investigations.

IV. PRIVATE REGULATORY STRUCTURES FOR MANAGED HEALTH CARE

D. QUALITY MEASUREMENT AND ACCREDITATION ORGANIZATIONS

With the growth of managed care, employers and consumer groups wanted more information to evaluate their purchases and improve quality. As a result, several groups have developed quality measures. Two types of quality measures are available: *process* measures such as childhood inoculation and adult mammography rates and risk-adjusted *outcomes* measures for particular diseases.

There are three major obstacles to developing quality measures. Each is addressed in other Task Force recommendations. First, to allow valid comparisons, all measures must use standard definitions and methods. There is wide disagreement about what those standards should be. Second, outcomes data must be risk-adjusted to compensate for patient differences. Risk adjustment is still an inexact science. Third, data collection is expensive. Few organizations have the information infrastructure to collect quality data automatically; therefore, paperwork and cost are prohibitive. Despite calls to create information infrastructure for decision-making at both the state and federal level, little progress has been made.

Quality measurement has evolved into accreditation programs. Large purchasers and consumer groups have demanded accreditation to guarantee minimum quality. Typically, accreditation involves scheduled on-site audits and the provision of limited quality measures.

Several private and joint public/private groups are addressing quality measures and accreditation needs. Many are financed in such a way that conflicts of interest are not insignificant problems.

1. National Committee of Quality Assurance (NCQA)

NCQA's board of directors includes employers, consumers, labor, health plans, quality experts, government regulators, and physicians.NCQA accredits various health care organizations and has established quality measurement standards. NCQA has accredited managed care organizations (MCOs) since 1991.[40] In 1997, NCQA will begin accrediting managed behavioral healthcare organizations (MBHO). Also this year, NCQA is rolling out an accreditation program for medical groups and Independent Physician Associations (IPAs). Beginning in 1999, NCQA will concurrently assess an MCO's medical and behavioral health programs and award a single decision.

Managed Care. A team of physicians and managed care experts performs on- and off-site evaluations of the health plan's quality improvement, utilization management, provider credentials, preventive health programs, members' rights and responsibilities, and medical records. A national oversight committee of physicians analyzes the findings and assigns an accreditation level: full accreditation for 3 years (to date 40% of reviewed plans), one year accreditation (37%), provisional accreditation for 1 year (11%), or denial (11%). Health plans can request a review of the initial decision; 1% of plans are currently listed as under review. Accreditation status reports are available on NCQA's web page.

Medical Groups and IPAs. NCQA recently created a Physician Organization Certification (POC) program, based on a subset of the MCO Accreditation Standards.[41] The same categories are reviewed. NCQA will initially offer one year certification; subsequent certifications may be up to 3 years. This certificate will replace duplicative inspections for NCQA's MCO accreditations; however, MCOs will remain responsible for quality of the medical groups.

Health Plan Employer Data and Information Set (HEDIS)NCQA developed HEDIS to measure health plan quality for purchasers and consumers.[42] HEDIS measures effectiveness of care, accessibility of care, satisfaction with care, health plan stability, use of services, and cost of care. In the future, NCQA will license auditors to conduct HEDIS

[40] NCQA web page, www.ncqa.org.
[41] NCQA Press Release, "NCQA releases draft standards for new Physician Organization Certification Program," May 7, 1997.
[42] National Committee for Quality Assurance, web page, www.ncqa.org.

audits. NCQA's Quality Compass, a national database, includes comparative HEDIS scores and accreditation data from 250 health plans. HEDIS is criticized for focusing on utilization management and preventive care process measures rather than chronic or acute disease outcomes measures.[43,44]

2. Joint Commission for the Accreditation of Healthcare Organizations (JCAHO)

JCAHO accredits hospitals, health plans, medical groups, home care agencies, long term care facilities, behavioral health organizations, laboratories, and outpatient services. JCAHO's on-site audits focus on member rights and education, organization leadership, human resources, information management, and performance improvement. JCAHO requires detailed process standards for accreditation.

In February 1997, JCAHO launched ORYX, which integrates performance measures into the accreditation process of all organizations. Under the ORYX program, JCAHO created a list of 60 acceptable performance measurement systems. By December 31, 1997, organizations must choose and begin to phase in their measurement system(s) and measurements. Integrated delivery systems and health plans will be required to collect at least 10 measures from up to five approved measurement systems. Initial data must be sent to JCAHO by the end of first quarter 1999. JCAHO will use the data to review performance between on-site audits.

3. Foundation for Accountability (FAcct)

FAcct promotes shifting from process measures to outcomes measures. To date, they have developed for use by other organizations patient satisfaction, disease prevention, and outcomes measures for diabetes, breast cancer, and major depression. Large employers, consumer groups, and government sponsor FAcct.

4. The Medical Quality Commission (TMQC)

TMQC's board consists of health plans, providers, purchasers, and consumers. Since 1990, TMQC has accredited medical groups and IPAs based on 14 review areas. Approximately 50% pass with complete, 3 year accreditation; 25% receive provisional accreditation and must improve by the 6-month re-inspection; 25% are not accredited but are re-surveyed after 6 months; and 3% fail completely. Currently, 22 medical groups are accredited in California, covering 2 million capitated lives. 1.8 million of these are commercial; 175,000 Medicare; and 25,000 Medicaid. In the future, TMQC will release the names of groups that fail the accreditation process and the results of the audits.

TMQC and PBGH are conducting a study of quality outcomes by following 55,000 HMO and 4,000 PPO/FFS enrollees for 2 years. They are measuring patient satisfaction, change in health status, and receipt of services for hypertension, high cholesterol, and prevention. At the end of this period, the results will be compared between HMO and PPO/FFS enrollees. In addition, the results will be correlated with medical group attributes, such as clinical guidelines, disease management, amount of capitation, years experience with capitation, and governance structure.

5. California Cooperative Healthcare Reporting Initiative (CCHRI)

CCHRI is a joint effort by California health plans, medical groups, and employers to produce comparable quality data for use by clinicians, purchasers, and consumers. An independent research firm gathers HEDIS and patient satisfaction data on preventive care from 24 health plans (95% of commercial HMO membership). The data are then reviewed and used to score plans as above average, average, or below average.

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[43] Philip T, "Health-care report cards don't measure up, critics say," *Sacramento Bee*, May 20, 1997.

[44] Blumenthal D, Epstein AM, "Part 6: The Role of Physicians in the Future of Quality Management," *The New England Journal of Medicine*, Volume 335, Number 17, pp. 1328-31.

6. Consumers Union

This organization is a good example of private sector involvement in efforts to improve the managed care marketplace. Consumers Union, the publisher of *Consumer Reports*, analyzed 1994 HEDIS data. Based on this analysis, they produced a preventive-care index that implies the best plans provide the most preventive care.[45] In addition, they produced a utilization measure for three commonly overused procedures: gall-bladder removal, prostate surgery, and hysterectomy. According to the article, high utilization plans are suspect for unnecessary procedures, while low utilization plans are suspect for inadequate care. Consumers Union reviewed nine California plans; one provided data too late, three plans refused to send their data, and one plan supplied inconsistent preventive care data. Consumers Union then made suggestions to improve HEDIS related to inconsistencies in how data is measured and collected, the lack of risk-adjustment, and the lack of outcomes measurements. In addition, Consumers Union surveys their 4.5 million subscribers in HMOs and PPOs for customer satisfaction and makes that information available to the public to enhance decision-making.[46]

7. Individual Health Plans

Health plans and medical groups use customer satisfaction surveys for internal and external purposes. Internally, surveys support strategic planning, marketing, quality improvement, provider profiling, and provider payments. In 1995, over 95% of HMOs and about 55% of PPOs reported using consumer surveys to monitor care patterns.[47] Externally, many employers are requiring customer satisfaction data at the plan level. Like other quality measures, employers and consumers want standard satisfaction measures that help them compare different health plans. The U.S. Agency for Health Care Policy and Research (AHCPR) has developed prototype satisfaction surveys. This prototype is modular, with different sections for different types of organizations.

B. PURCHASERS

Large purchasers can use their negotiating power to influence the health care system. They enable their consumers to choose the best value plan for their needs by establishing three important market-enhancing conditions:

- Choice. Consumers choosing among multiple plans tend to be more satisfied with their coverage, as they can make appropriate selections based on their needs, preferences, and established relationships with providers familiar with their case history.

- Standards. Consumers must be able to make valid comparisons among multiple plans. Large purchasers can negotiate prices on standardized benefits packages with several health plans, enabling consumers to compare products more easily. Large purchasers can also require standardized information about covered benefits and quality of care for consumers to compare as they make their decisions.

- Financial Incentives. Consumers must be able to share in the cost savings of lower-premium plans. Employers that pay all or most of plan premiums give HMOs an incentive to shadow-price the more expensive plans. This policy undermines purchasing power.

Given potential customers with a wide choice of plans, the ability to compare them, and a financial incentive to seek value for money, health plans competing for business have good reason to provide high quality care at low rates. Some large California purchasers (including government purchasers) are working to create these conditions for consumers, but as of this date, they are not available to the general population.

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[45] Consumers Union of U.S., Inc., "How Good Is Your Health Plan? Part One of a Two-part Report," *Consumer Reports*, August 1996.
[46] Consumers Union of U.S., Inc., "How Good Is Your Health Plan? Part One of a Two-part Report," Op Cit.
[47] Gold M, Wooldridge J, "Surveying Consumer Satisfaction to Assess Managed-Care Quality: Current Practice," *Health Care Financing Review*, Volume 16, Number 4, Summer 1995, pp. 155-73.

1. Pacific Business Group on Health (PBGH)

PBGH is an association of 32 public and private employers covering 2.5 million lives.[48] It includes such employers as Bank of America, Safeway, and Pacific Telesis. Seventeen of PBGH's employers participated in the 1996 health plan negotiations, representing $400 million in premiums. Most PBGH employers require, or will soon require, employees to pay the difference in premiums for more expensive plans. PBGH contracts require health plans to meet performance standards on quality of care, customer service, and data provision. In 1996, each health plan put 2% of premium at risk for all performance standards, weighted according to each health plan's relative weaknesses.

PBGH designed a web page to help consumers compare health plans and hospitals. For health plans, PBGH lists CCHRI's HEDIS scores, PBGH's customer satisfaction measures, Medicare HMO disenrollment rates, and NCQA accreditation status. PBGH annually measures customer satisfaction with each of 16 plans and with each type of plan (HMO, POS, and PPO/FFS). In analyzing hospital performance, PBGH publishes data on cesarean section births and on transplant outcomes.

2. Health Insurance Plan of California (HIPC)

The HIPC offers a choice of 25 health plans to nearly 7,000 small businesses (2 to 50 employees) throughout the state. Before the HIPC, small-firm employees seldom had a choice of plans. Participating employers are required to contribute at least 50% of the low-priced premium. To make the HIPC attractive to firms with younger, typically healthy employees, the HIPC offers rates by age category and family size. In addition, the HIPC adjusts health plan payments based on average risk profile of enrollees, using diagnostic information. This risk adjustment ensures that health plans that attract higher risk populations will be compensated for their additional costs. The HIPC provides health plan quality and access information to enrollees.

3. California Public Employees' Retirement System (CalPERS)

CalPERS purchases health care benefits for people working in over 1000 participating public agencies. The State is the largest participating employer, representing almost 640,000 (67%) of CalPERS' enrollees. Prior to 1992, the State paid 100% of individual premiums, up to the average of the four costliest plans. By shielding individuals from information related to price and from exposure to cost differences, this formula arguably denied low-premium health plans a marketplace reward for reducing premiums, thus contributing to inflation. In response to the 1992 fiscal crisis, the State froze its maximum contribution at the 1991-92 level. This change put employees at risk for future premium increases above that price freeze. In 1995, however, 19 of 24 health plans' individual premiums were below the defined maximum state benefit contribution level and thus were completely paid by the State. This contribution policy undermines CalPERS' negotiating power in that their price position is known prior to negotiations. CalPERS is the second largest beneficiary pool in the nation. Despite its vast size, it was only able to negotiate a 1.1% decrease in average premiums for the 1994-95 contract period.

4. Other Purchasers

Two California universities have increased their purchasing power by altering their contribution policies. They offer an example for other employers, though their size may limit their effect on the health care system.

[48] PBGH web page, www.healthscope.org.

Stanford University offers employees a choice among four HMOs. One HMO includes a full-provider-choice point of service (POS) option that covers out-of-network care, after a deductible and increased cost-sharing. Since 1992, Stanford has required employees to pay the full difference in premium for the most expensive plan. As the policy successfully reversed premium growth, Stanford increased employer contributions to share the savings with employees.

The University of California (UC) used to pay the full premium, up to the average of the four costliest plans. In 1993, UC established a contribution set at 100% of the lowest-priced plan serving all campuses.

V. STREAMLINING REGULATION

A. REGULATORY PROCESSES

In many areas, managed care regulation is inefficient or duplicative. In order to obtain a license from the Department of Corporations (DOC) to operate as a Knox-Keene regulated health care service plan, an entity must file numerous documents detailing its administrative framework, financial standing and capitalization, premium, revenue, cost and utilization projections, health care delivery network, contracts with providers, benefit disclosure documents, marketing materials, documentation pertaining to the quality assurance program and utilization review processes, and contractual documents with employers and individual members. Whenever any of this information materially changes, the health care service plan must file an amendment to these documents.

This regulation consumes a significant amount of time and resources of both DOC and the health care service plans it regulates. The regulatory processes are complex and often the relevant law and regulations are subject to various interpretations, which can lead to inconsistencies. Some of the regulatory processes are duplicated by other federal and state government entities, purchasers, and other private bodes that regulate health care service plans.[49] In contrast, medical groups/IPAs are not directly regulated. Indirect regulation of provider groups through up to a dozen or more contracting health care service plans results in duplication of regulatory oversight.

B. REGULATORY REDUNDANCY

Currently, some companies offer more than one plan model type: health maintenance organization (HMO), point-of-service (POS), preferred provider organization (PPO), traditional, unmanaged, fee-for-service indemnity, Blue Cross, and Blue Shield plans ("indemnity"), and exclusive provider organization (EPO); and many serve a variety of markets: commercial, Medi-Cal, Medicare, HIPC, workers compensation. As a result of serving multiple markets, multiple state and federal regulatory bodies (i.e., California Department of Health Services (DHS), DOC, California Division of Workers' Compensation, and the federal Health Care Financing Administration (HCFA)) and private bodies (e.g., California Cooperative Healthcare Reporting Initiative (CCHRI), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the National Committee for Quality Assurance (NCQA)) perform quality and financial audits of health care service plans, often requiring much of the same information in different formats or focused on different populations. In addition, the California Department of Insurance (DOI) conducts financial audits of indemnity (excluding Blue Cross and Blue Shield plans), PPO, and EPO plan insurers, even though the products they offer are similar in many respects to HMOs. Currently, these bodies operate independently of others and do not accept licensure by another agency. However, DOC coordinates quite closely with HCFA regarding Medicare related matters, and with DHS regarding prepaid Medi-Cal matters. HCFA requires DOC licensure of HMOs for Medicare Risk products (although not for provider service organizations (PSOs)), and DHS requires DOC licensure of health care service plans (although some demonstration projects and plans are exempted) that wish to contract as a prepaid health plan with DHS for Medi-Cal.

1. Medical Groups and Other Providers

Unlike much of the rest of the nation, large medical groups in California often assume financial risk from HMOs and responsibility for caring for the population of patients they serve. In doing so, the medical groups also undertake most of the utilization and quality management responsibility. Under current law, however, the contracting HMOs remain accountable to the regulatory authority for the quality and financial solvency of their affiliated medical groups, many of which contract with most of the health care service plans and health insurers offered in their area.

The government does not directly regulate medical groups that similarly assume financial risk from HMOs despite their direct involvement in patient care. Private sector accreditation requirements also hold HMOs accountable for the care provided by their contracting providers. To satisfy regulatory and private sector accreditation requirements,

[49] See for example, American Association of Health Plans, "HMO Quality and Access Standards: Federal Standards, State Guidelines, and Private Accreditation Requirements", 1997.

HMOs, or the regulatory or accreditation agencies, perform multiple audits (e.g., medical quality and solvency) of the medical groups and other providers with which the HMOs contract. Not only does this duplicative process require every HMO to pay for the accreditation or audit of the same providers, but it also often requires providers to submit to and bear the expense of multiple audits by the same regulatory or accrediting bodies. In addition, medical groups and other providers understandably resist providing information that they consider proprietary to the HMOs with which they negotiate payment rates. In contrast, the HCFA delegates Medicare hospital inspections, thereby avoiding redundancy.

2. Ongoing Streamlining Efforts

Private sector purchasers, health care service plans, health insurers, and medical groups in California have recognized the special structure into which the market has developed and the resultant need to reach through HMOs to medical groups for much of the quality and other information that is relevant to consumers. As a result, in 1996 The Medical Quality Commission and the Pacific Business Group on Health launched an effort to evaluate directly performance of physician groups. Their Physician Value Check Survey measures clinical quality and member satisfaction. (See Attachment I: Quality Measurement and Accreditation for additional information). In a similar effort, the non-profit NCQA has created a medical group certification. Contracting health plans need not inspect certified medical groups for NCQA accreditation.

C. ACCELERATING INDUSTRY CHANGE CREATES CHALLENGES FOR DOC

Notwithstanding the best efforts of the legislative process, some of the drafting in the Knox-Keene Act, as in other laws, lacks specificity and precision, frequently resulting in inconsistency, especially when compounded by lack of resources for administering the law.

The general provisions of the Knox-Keene Act have enabled the DOC to be responsive to plan requests to interpret statutory provisions which clearly apply to new or innovative products or activities. If the basic provisions of the Knox-Keene Act had been highly prescriptive, or if the DOC had refused to be flexible, insisting on new legislation or rule making before considering new products or proposals from plans, the market may have been frustrated and enrollment in managed care in California may have been stunted.

The DOC's policy and practice is to avoid inconsistency to the maximum extent possible under the circumstances, and to resolve inconsistencies when found. However, apparent and actual inconsistencies inevitably exist. Many (but by no means all) of the inconsistencies which have been alleged over the years, upon investigation, have been found not to be inconsistencies, but consistent applications of a statutory provision to two different factual situations.

The DOC adapts certain provisions for certain circumstances. For example, in rural areas it may be difficult for health care service plans to contract with sufficient primary care providers and hospitals to satisfy the 30 minute/15 mile accessibility guideline presumed by the Knox-Keene Act.[50] In this instance, the DOC has shown flexibility by allowing health care service plans to provide other evidence of reasonable accessibility. In other instances, no guidelines exist, and to DOC-regulated health care service plans, DOC decisions seem inconsistent, subjective, and arbitrary, or very different from those that have been imposed on other health care service plans.[51] In such an unpredictable regulatory environment, regular business planning becomes difficult, often resulting in unnecessarily higher costs which are ultimately born by consumers. However, while the lack of specific, detailed, rigidly prescribed requirements creates a somewhat unpredictable regulatory environment, it is also a more flexible one. This flexible environment, however, should be better managed to avoid inconsistent decisions.

The DOC is required under Section 1352 of the Health and Safety Code to respond to plans regarding material modifications within 20 business days "or such additional time as the plan may specify." Despite this requirement, with the increasing pace and volume of change in the health care industry the DOC has not been able to

[50] Knox-Keene Act, Rule 1300.51(H).
[51] California of Health Plans, "Streamlining the Health Plan Regulatory Process", October 15, 1997.

consistently respond within this time period. The DOC's response may be a deficiency letter indicating missing information, unclear provisions, and/or noncompliance, allowing the plan to submit information resolving the problems. The total time from date of submission to date of approval may take up to six months or more, depending on the health care service plan's priorities and ability to demonstrate compliance and the plan's and the DOC's workloads. Delays are costly to health care service plans and consumers because approval often would enable plans to provide a new product or a product to a new service area.

Delays may be the result of under-staffing, in which case the recent $6 million DOC budget augmentation may remedy this situation. Delays may also be the result of many factors including lack of experience of newly hired counsel assigned to review plan filings, or shifting filings from one counsel to another. Counsel who are inexperienced or unfamiliar with other filings by the plan may raise previously resolved and thus often unnecessary objections to items, which requires time and explanation and increases the total time and cost for approval, particularly if the filing must be appealed to a supervisor.

VI. OPTIONS FOR REORGANIZATION

A. Criteria for Appraising Options

The yardsticks against which any organizational option—including the status quo—should be measured include:

(a) Fairness—different health system actors should be held to equivalent high standards, regardless of how they organize themselves, and like regulated entities should be charged roughly the same amount.

(b) Capability (Expertise)—the regulatory authority must be at least as technically sophisticated as the industry and be staffed sufficiently to keep pace with this rapidly evolving industry that directly effects the health and productivity of the population.

(c) Accountability—individual complaint cases must be disposed in the light of day, where aggrieved parties can know who made the decision, and their reasons. By the same token, state policymakers (the Governor and the Legislatures) are entitled to appointed regulatory personnel who will faithfully implement the policy that elected leaders set.

(d) Efficiency—regulation should rely on, and not interfere with, the disciplining force of market competition (which can encourage improvements in quality, access, and cost), unless the market fails to achieve particular public purposes. Where market failures exist, public policy must recognize, compensate for and/or address the failures to enable appropriate cost, quality, and access for consumers.

(e) Strict enforcement—the regulated community must trust that the regulator is ensuring that the health care industry meets high quality standards and that low performers are consistently culled from the pool of choices available to consumers.

(f) Systems approach—the regulator's jurisdiction should be broad enough to encompass all important segments of the health industry whose behavior might be affected by regulatory decisions; and the regulator's leadership and staff should have a broad vision of the desirable evolution of the entire industry.

(g) Adaptability—the regulator must be able to encourage, and assuredly not retard, desirable evolution in this fast-changing industry.

(h) Low net fiscal cost—any change in organization will have transition costs. Either those costs should be kept quite low, or there should be subsequent savings that defray most of them.

The debate over regulatory organization in 1996 and early 1997 centered on whether responsibility for regulatory oversight of Knox-Keene plans should remain at the Department of Corporations or be shifted to another state organization. Among those alternatives to the status quo that were cited were the Department of Consumer Affairs, the Insurance Commissioner, or the Health and Welfare Agency.

The authors wish to point out that Task Force recommendations on regulatory organization will be most thoughtful if they include not only who should be the regulator, but also what segments of the industry they should regulate, and how. The three elements are interdependent and cannot be intelligently treated in isolation. Components of "how" are addressed in a number of Task Force papers. Therefore, here we will offer recommendations only about "who". First, however, some observations about "what" should be regulated.

The health care industry is evolving quickly, with substantial consolidations occurring both vertically and horizontally. The regulatory architecture must be modernized to keep pace. There are substantial advantages to consolidating regulation of different segments of the industry in the same organization, where those segments are emerging as partial substitutes. For example, as health plans shift more financial risk onto medical groups, those groups will begin to act increasingly as substitutes for the plans. Whatever argument compels regulation of health plans should apply to pseudo-plans, such as risk-bearing medical groups, as well.

B. What Should be Regulated?

If the jurisdiction of a regulator should extend beyond traditional prepaid health plans, how far should it go? It

could include the following, in order of priority:

(a) Medical groups, for the reason cited above. One approach would be to broaden the issuance of limited Knox-Keene licenses. However, an alternative approach is to hold health plans accountable for the errors of their vendors, including medical groups, and make the plans responsible for policing their suppliers. That is DOC's approach today; however, it can be strengthened and streamlined, as recommended in Section V above.

(b) Indemnity health insurance, including PPOs and EPOs, because it is a substitute for prepaid health plans (albeit with a shrinking share of the market).

(c) Individual health professionals' licensure, which primarily emphasizes basic competence, not other criteria such as financial solvency.

(d) Health facilities (hospitals, outpatient clinics, or nursing homes).

Collectively, this group encompasses the jurisdictions of portions of the Departments of Corporations, Consumer Affairs, Health Services, and the Insurance Commissioner.

Recommendation #1: The Task Force recommends that regulation of Knox-Keene plans be consolidated with elements (a) and (b) from the list in the previous paragraph. In addition, the Office of Statewide Health Planning and Development (OSHPD), which has many synergies with oversight of these other components, should be consolidated into this function. Furthermore, the consolidation of the regulation of indemnity insurance with prepaid plans should be implemented over one year.

C. Who Should be the Regulator?

Fundamentally there are three classes of options:

(a) Status quo: make no organizational changes, but reduce friction and duplication among regulators.

(b) Move regulation of Knox-Keene plans, and other segments of the health system as desired, to a different, existing organization. (Or the reverse: move non-Knox-Keene responsibilities out of DOC and focus it exclusively on health system regulation).

(c) Create a new organization.

Recommendation #2: The Task Force recommends that a new freestanding office with a leader appointed by the Governor, but outside of the agency structure (like the Office of Administrative Law or the Office of Emergency Services) be created.Our working title for this organization is Office of Health Systems Oversight (OHSO).

This approach is fundamentally a compromise, because each of its alternatives has substantial disadvantages. If consolidation is limited to health insurance and other industry segments are omitted (as we recommend), then an alternative and possibly more descriptive title would be "Office of Health Systems and Insurance Oversight (OHSIO)". However, OHSO will be the title used in this paper.

There are two alternatives to a new stand-alone organization that are not recommended but that each have merit:

(a) Retaining Knox-Keene responsibility at the Department of Corporations (with increased resources devoted to quality of care oversight), but shifting securities functions to another department, most likely the Department of Financial Institutions. This is probably the best alternative to a brand-new OHSO.

(b) Consolidating Knox-Keene and indemnity responsibility in the elected Insurance Commissioner. While this approach nominally makes regulation more directly accountable to the voters, many have argued that the accountability is more theoretical than real. Commissioners need to raise campaign contributions from the regulated industry, which can present conflicts. For similar reasons the California Constitutional Revision Commission in 1995 recommended that such regulation be the responsibility of a gubernatorially appointed official, not an elected one.

Two other options were viewed less favorably: shifting health plan regulation to (c) the Department of Consumer Affairs (DCA); or (d) the Department of Health Services (DHS). DCA includes 14 boards that certify health professionals. DHS would face a conflict: the same organization should not both regulate plans and be one of their largest customers.

OHSO should be charged with regulation not only of health plans, but of other segments of the health care/finance industry which bear risk, as outlined in section B above. Beyond the specific regulatory functions that it would inherit from current organizations, OHSO's leader(s) would be expected to exercise leadership in advocating and helping implement broad health system reforms. Therefore that leadership should have experience in, and a vision for, the desired direction for the evolution of the health care marketplace (and government's role in affecting that evolution).

Guiding principles of OHSO's operation should include:

(a) Regulatory processes should be as efficient and streamlined as possible.

(b) Regulation should be conducted in cooperation with other public and private bodies that also regulate health care service plans and health insurers.

(c) Regulation should recognize and expedite beneficial innovations (i.e., those that consumers want, improve quality, or save costs without causing harm).

A design detail of OHSO pertains to the organization of its leadership. There are two main questions:

(a) Should the office's leader(s) be a single individual, like most departments in state government today, or a board/commission of several people?

(b) If a board, should the appointing authority be mixed between the Governor and the Legislature?

Individual leadership offers the greatest accountability to the appointing authority—there is no question about who is responsible for decisions—but the least transparency. A board gains transparency by sacrificing individual accountability—especially if appointments are mixed.

Recommendation #3: The Task Force recommends that OHSO be led by a director, but that he or she should be advised by a high-level advisory board, wholly appointed by the Governor (but subject to Senate confirmation).

The Task Force does not have an opinion about whether the board's workload would require a full-time commitment; if not (now or in the future), one approach recommended by a Task Force ex-officio member would be to make the board chair a full-time position and the remainder part-time slots.

VII. CONCLUSION

The Task Force believes that what is needed is oversight realignment into a single oversight organization (for instance an Office of Health Systems Oversight that reports to the Governor) that oversees clinical quality and financial viability for every health care company involved in the insurance and delivery functions. The consolidated oversight organization should have jurisdiction regardless of what the entity calls itself (HMO, PPO, POS, Indemnity FFS, PSO, Medical Group, etc.).

There are at present several pressures that can be combined to create positive synergies. These include: new federal legislation allowing new market forms (e.g. MSAs and PSOs); the market development of hybrid models that no longer fit neatly into current regulatory oversight structures; and growing public concerns about quality. There is, therefore, at present, an unusual opportunity for transitioning to an integrated and sophisticated oversight structure to keep up with this rapidly changing, dynamic marketplace.

Inherent in our recommendations is the belief that the past dichotomy between "business" regulation (which has been emphasized) and "quality" regulation (which has not) no longer is strictly necessary or desirable.

Summary of Task Force recommendations:

(1) California should consolidate the oversight of health plans with any other segments of the industry that bear risk.

(2) That organization (called OHSO in this paper as a working title) should be devoted exclusively to health systems oversight, led by officials experienced in the industry.

(3) OHSO's leadership should be appointed solely by the Governor (subject to Senate confirmation), to preserve upward accountability. To preserve downward accountability, it may need to have a board or commission to formally advise the director.

Transferring and consolidating the components should be done in a phased manner, to allow time for the inevitable teething problems. However, the first organizational moves should occur in 1998, ideally by July 1. The Governor and Legislature should review this new organization annually, with an eye to incorporating additional state organizations as they deem appropriate.