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IN THE COURT OF APPEAL OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION THREE

CLIFFORD J. MERLO,

Plaintiff, Respondent,
and Cross-Appellant,

v.

CEDARS-SINAI MEDICAL CENTER,

Defendant, Appellant
and Cross-Respondent.

Appeal from the Superior Court for Los Angeles County,
Ernest George Williams, Judge

BRIEF OF AMICI CURIAE CALIFORNIA MEDICAL ASSOCIATION AND CALIFORNIA RADIOLOGICAL SOCIETY

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CLIFFORD J. MERLO, M.D.,

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vs.

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BRIEF OF *AMICI CURIAE*

CALIFORNIA MEDICAL ASSOCIATION AND

CALIFORNIA RADIOLOGICAL SOCIETY

INTEREST OF AMICI

The California Medical Association ("CMA") is a non-profit, incorporated professional association of approximately 33,000 physicians practicing in the State of California. CMA's membership includes most California physicians engaged in the private practice of medicine, in all specialties. CMA's primary purposes are "...to promote the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession." CMA and its members share the objective of promoting effective and efficient health care for the people of California.

The California Radiological Society ("CRS") is a non-profit, incorporated professional association of approximately 2,000 board-certified diagnostic radiologists and radiation oncologist physicians practicing in California. The CRS is a chapter of the American College of Radiology. The CRS's primary purposes are "...to advance the science of radiology, improve radiologic service to patients and the medical community, and study the economics of radiology; the encouragement of improved and continuing education for radiologists; and the establishment and maintenance of high medical and ethical standards in the practice of radiology."

Both CMA and CRS have members who benefit from the existence of exclusive contracts, and members (and their patients) who are harmed when these physicians lose or are unable to obtain medical staff privileges because an exclusive contract has been given to a competitor. Because our members are often on both sides of any particular exclusive contract dispute, we file this brief in a neutral position. Our purpose is to provide our collective expertise in order to assist this court in addressing an underlying issue of law presented by this case which, independent of the facts of the case or the effect upon these parties, has a far-reaching impact on hospitals, physicians, and medical staffs throughout California. This issue is:

"What is required for a lawful hospital quasi-legislative determination to close a department or service?"

For the reasons set forth below, we submit that, to be lawful, a hospital's quasi-legislative determination to close a department or service must be made (1) only in consideration of the quality-of-care impact of the proposed closure when less extreme measures will not suffice, and (2) only upon recommendation from the medical staff, following a notice and comment process, which provides an opportunity for all medical and hospital staff who might be impacted by the decision, to address the hospital's concerns and to raise their own concerns and suggestions regarding the proposal.

ARGUMENT

I. EXCLUSIVE CONTRACTS ARE JUSTIFIED ONLY IN THE INTERESTS OF QUALITY CARE, WHEN LESS EXTREME MEASURES WILL NOT SUFFICE.

A. The Decision to Close a Hospital Department or Service Has Profound Ramifications.

Contrary to what some hospitals would have the California courts believe, the decision to enter into an exclusive contract, thereby closing a hospital department or service, is far from a mere administrative detail of the hospital's day-to-day business management activities. Rather, evaluating the propriety of an exclusive contract requires a careful balancing of the impact the contract will have on a number of matters, including the quality of care, the accessibility of care, the maintenance of existing physician-patient relationships, and the property interest

of physicians in maintaining staff privileges at the hospital. Because of their potential for harm, exclusive contracts are justified only when they are necessary to safeguard quality of care and protect the interests of patients, and when less drastic alternatives will not suffice.

In most hospital departments, scheduling and quality assurance matters can be resolved effectively, indeed optimally, through the use of medical staff rules and regulations in an open staffing arrangement. This is evidenced by the fact that most hospital departments and services are operated on open staffing arrangements. For some hospital-based service departments (e.g., emergency, pathology, and radiology), however, many hospitals have switched to a closed staffing arrangement for legitimate quality justifications. Such justifications include, for example, coordination and training of staff, 24-hour availability of professional services and equipment, and facilitation of scheduling for patients' needs. *See generally,* Mateo-Woodburn v. Fresno Comm. Hosp. (1990) 221 Cal.App.3d 1169, 270 Cal.Rptr. 894.

Even where the resort to closed staffing through an exclusive contract is preferred, however, each such determination by each hospital must be closely scrutinized to ensure that it is justified under the specific circumstances presented. This is because each staff closure determination may have a number of adverse consequences. First, it may disrupt or destroy established physician-patient relationships. A physician who loses his or her privileges no longer can provide those services in that hospital. Thus, patients who are unwilling or unable to travel

to a hospital where their physician retains his or her privileges, will be forced to find another physician. The impact will be particularly severe when the hospital is the only one in the area, or when, due to the existence of various Medi-Cal, HMO or PPO contracts, it is the only hospital in the area in which the patient can afford to receive care.

An exclusive contract may also reduce access to care generally. The contracting group may not be able to care for as many patients as were treated under the open-staffing arrangement. Moreover, the exclusive contract may affect patients differentially, depending upon whether the contract physicians treat the same mix of patients. For example, the granting of an exclusive contract may result in the loss of privileges for physicians who care for large numbers of Medi-Cal patients. If the contracting physicians are unable or unwilling to make the same commitment, it may be extremely difficult for these Medi-Cal patients to obtain inpatient care. Medi-Cal contracting hospitals often are far apart, and Medi-Cal patients frequently must rely on public transportation. Travel under these conditions is very hard, especially for single parents with small children.

The exclusive contract also will injure those physicians who are excluded. While the impact on each physician varies, depending on the facts, it can be devastating, particularly where no comparable hospital is available and the physician has an established practice gained after years of hard work and dedication. It is well settled under California law that, before an organization which affects important economic interests of its members (such as a hospital)

may exclude a member, the exclusion must be based on substantive rationality, following fair procedures. *See e.g.,* Anton v. Bd of Directors of San Antonio Community Hosp. (1977) 19 Cal.3d 802, 140 Cal.Rptr. 442; Ascherman v. St. Francis Memorial Hosp. (1975) 45 Cal.App.3d 509, 119 Cal.Rptr. 507; Miller v. Eisenhower Med. Ctr. (1980) 27 Cal.3d 614, 166 Cal.Rptr. 826; Volpicelli v. Jared Sydney Torrance Memorial Hosp. (1980) 109 Cal.App.3d 242, 167 Cal.Rptr. 610. Any physician who feels that he or she has been excluded unlawfully from hospital medical staff membership and/or clinical privileges may seek court review of this action on the grounds that such action was substantively or procedurally defective.

Although the courts have allowed for more limited review in cases involving exclusive contracts, they have done so only when the facts of the case demonstrate that the hospital has engaged in a valid, quasi-legislative process in support of its exclusive contracting decision. *See* Lewin v. St. Joseph Hospital of Orange, discussed below under Section II, and other cases cited therein. As is further discussed below, this process is designed to ensure that the contract is necessitated by quality-of-care reasons, thus justifying the burdens imposed upon excluded physicians and their patients. It is also designed to provide notice in advance of the closure to all who might be adversely affected by it so that they might have the opportunity to comment (e.g., by expressing quality-related concerns and/or by suggesting less drastic solutions).

B. Cost-Containment Pressures Must Not Be Allowed to Compromise Quality of Care.

In the hospital industry, providing high-quality health care should be good business. But high-quality health care can be expensive, and under capitation, prospective payment and other public- and private-sector cost-containment mechanisms, providing more health care may not necessarily mean more revenue to its providers. Restricting the membership of the medical staff to those practitioners whose patients and practices are profitable to the hospital may be seen by administration as a tempting, immediate solution to hospital financial concerns. This, however, could lead to improper "economic credentialing"[1] and exclusive contracts which may create conflicts with the medical staffs' responsibility to provide quality patient care.[2]

This need to prevent cost and profit motives from being paramount in determining how and whether patients receive needed care has been addressed on

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[1] Economic credentialing" may be described as "the use of economic criteria that do not relate to quality to determine a physician's qualifications for the granting or renewal of medical staff membership or privileges." *Joint Statement on Economic Credentialing and Exclusive Contracting* of the California Medical Association ("CMA") and the California Association of Hospitals and Health Systems ("CAHHS"), January 1992, p.2. "CMA and CAHHS believe that termination or granting of medical staff privileges based solely on economic criteria unrelated to clinical qualifications, professional responsibilities or quality of care is inappropriate, with the exception of statutory, regulatory, or judicial requirements, such as professional liability insurance, or other exceptions which are defined in the medical staff bylaws." *Id.* For the court's convenience, a copy of the *Joint Statement* is attached hereto as Appendix A.

[2] For example, in one recent Request For Proposal for the provision of emergency services via an exclusive contract, it was noted that the proposals would be evaluated on, among other criteria, each proposal's "Attempt to minimize or at least reduce level of laboratory and radiology services. Also include as project the clinical review of CT and ultrasound. Need to recognize that these are cost centers, not revenue generating areas." While the need to monitor costs in health care is beyond dispute, so too is the need to safeguard quality.

both state and federal levels. Congress, via Medicare, has recognized that cost-containment must be offset by quality assurance mechanisms to prevent fiscal considerations from corrupting or improperly influencing professional judgment.[3] In California, the Courts, the Legislature, and state agencies have all taken steps to assure quality protection. A summary of important California protections follows.

1. Corporate Practice of Medicine Bar.

The corporate practice of medicine bar is designed to protect the public from possible abuses stemming from commercial exploitation of the practice of medicine. As the Attorney General's Office correctly noted, the reasons underlying this proscription are two-fold:

> [F]irst, that the presence of a corporate entity is incongruous in the workings of a professional regulatory licensing scheme which is based on personal qualification, responsibility and sanction, and second, that the interposition of a lay commercial entity between the professional and his/her patients would give rise to divided loyalties on the part of the professional and would destroy the professional relationship into which it was cast. 65 Ops.Cal.Atty.Gen. 223, 225 (1982).

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[3] Medicare's cost-containment mechanisms, Diagnostic Related Groupings ("DRGs") and the prospective payment system, are intended to be balanced by the Peer Review Organizations ("PROs"), which have been charged with quality oversight of the care rendered to Medicare patients. Although controversial, the PROs are nonetheless the embodiment of the Congressional recognition that quality must be assured and monitored in the face of cost containment.

Indeed, as early as 1938, the California Supreme Court recognized the dangers inherent in a system which would allow control over medical professional judgment by a lay entity concerned primarily with business considerations. People v. Pacific Health Corp. (1938) 12 Cal.2d 156,158-159. This general prohibition against the corporate practice of medicine is now codified in Business & Professions Code §2400 (initially enacted in 1937 as Business & Professions Code §2008), a provision which denies corporations and other artificial legal entities professional rights, privileges or powers pursuant to California's Medical Practice Act. Business & Professions Code §§2000 et seq.

California's long-standing public policy against permitting laypersons to practice medicine or exercise undue control over medical decision-making is now reflected throughout the law governing the provision of health care. For example, the corporate practice bar's public policy concerns were expressly incorporated into the Moscone-Knox Professional Corporations Act (Corporations Code §§13400 et seq.). Specifically, that Act prohibits persons other than certain health professionals licensed under their respective licensing boards, from becoming shareholders or directors of corporations engaged in rendering medical services. Corporations Code §13401.5. Additionally, while the Knox-Keene Health Care Service Plan Act (Health & Safety Codes §§1340 et seq.) enables health care service plans to employ or contract with physicians, the Act contains specific provisions prohibiting such plans from taking any other action which directly or indirectly constitutes the practice of medicine. (*See e.g.,* Health & Safety Code

§1395(b).)[4] Recognizing that one of the purposes of the Knox-Keene Act was to help "assure the best possible health care for the public at the lowest cost," the Legislature expressly declared its intent to assure "the continued role of the professional as the determiner of the patient's health needs which fosters the traditional relationship of trust and confidence between the patient and the professional"and to assure "that subscribers and enrollees receive available and accessible health and medical services rendered in a manner providing continuity of care." Health & Safety Code §1342. Therefore, the law requires that all health care service plans be able to demonstrate to the Department of Corporations that "medical decisions are rendered by qualified medical providers **unhindered by fiscal and administrative management**." Health & Safety Code §1367(g), emphasis added. *See also* 10 C.C.R. §1300.67.3 (stating that the organization of a health care service plan must include "**separation of medical services from fiscal and administrative management sufficient to ensure the Commissioner that medical decisions will not be unduly influenced by fiscal and administrative management.**").

2. Common-Law Liability for Negligently Designed or Implemented Utilization Review Programs.

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4 Health care service plans typically consist of health maintenance organizations (HMOs), which are organizations that either directly furnish or assume responsibility for providing health services for their members, who pay a fixed pre-paid monthly or annual sum for coverage. In return for such a fee, the member is guaranteed a defined set of benefits, without regard to the type or frequency of services rendered.

Acknowledgment of the need to monitor and protect quality in the face of cost containment pressures has only increased over time. In 1986, and 1990, the California Courts of Appeal issued two opinions which, taken together, clearly provide for potential liability to utilization review plans, physicians, and any other involved parties for economically motivated prospective utilization decisions which adversely impact quality care (or for the failure to protest such decisions). Wickline v. California (1986) 192 Cal.App.3d 1630, 239 Cal.Rptr. 810; Wilson v. Blue Cross of Southern Cal. (1990) 222 Cal.App.3d 660, 271 Cal.Rptr. 876. Wickline makes clear that physicians must fight for their patients by protesting decisions made by laypersons which jeopardize proper medical care. Wilson extends this potential liability to all persons and entities involved in prospective review decisions. While the Wickline court expressly recognized that "cost consciousness has become a permanent feature of the health care system," it stressed that "**cost limitations not be permitted to corrupt medical judgment.**" *Ibid.* at 1647, emphasis added.

3. Statutes Requiring Utilization Reviewers to be Qualified.

In 1994, the health care service plan statutes were amended to require expressly that appeals of contested claims must be reviewed by licensed health care providers who are competent to evaluate the specific clinical issues. "Competent to evaluate the specific clinical issues" is defined to mean that "the reviewer has education, training, and relevant expertise that is pertinent for evaluating the specific clinical issues that serve as the basis of the contested

claim." Health & Safety Code §1370.2. This section goes on to provide that "the requirements of this section shall also apply to claims that are contested on the basis of a clinical issue, the necessity for treatment, or the type of treatment proposed or utilized."

4. Business & Professions Codes §§510 and 2056.

In 1993, the Legislature enacted Business & Professions Code §2056, designed to prevent retaliation by managed care plans against physicians who have advocated for their patients' health care needs. (Stats. 1993, ch. 947; stats 1994, ch. 1119.) Specifically, this section provides that:

> "the application and rendering by any person of a decision to terminate an employment or other contractual relationship with, or otherwise penalize a physician and surgeon, principally for advocating for medically appropriate health care consistent with that degree of learning and skill ordinarily possessed by reputable physicians practicing according to the applicable legal standard of care violates the public policy of this state." (*Id.* at (c).)

In 1994, the Legislature extended this protection to all health care practitioners. (Business & Professions Code §510, Stats. 1994, ch. 1119.)

These developments underscore the public's recognition of increasing cost-containment pressures in the health care delivery marketplace and the need to take affirmative steps to preserve quality. As exclusive contracting decisions have numerous quality-of-care implications, it is imperative that the Courts recognize

and preserve mechanisms designed to protect quality in the exclusive contract decision-making process.

EXCLUSIVE CONTRACTS ARE JUSTIFIED ONLY UPON RECOMMENDATION FROM THE MEDICAL STAFF, FOLLOWING AN APPROPRIATE NOTICE-AND-COMMENT PROCESS.

For a hospital to make a proper quasi-legislative decision, it is essential that it engage in a rigorous fact-finding process to ensure that all relevant considerations, most importantly those related to quality concerns, are revealed and are thoroughly addressed prior to making its decision. At the very least, this process requires consultation with and a thorough review by the medical staff, so that the medical staff may make a reasoned recommendation regarding all quality-of-care ramifications. Indeed, the importance of medical staff involvement is amply demonstrated by the facts of prior California cases which found exclusive contracts to be justified. *See, e.g.,* Mateo-Woodburn v. Fresno Comm. Hosp. (1990), 221 Cal.App.3d 1169, 270 Cal.Rptr. 894 (initial recommendation for closed staff made by medical staff, investigatory task force established, notice-and-comment hearing held at which 15 medical staff members provided comment); Lewin v. St. Joseph Hospital of Orange (1978) 82 Cal.App.3d 368, 146 Cal.Rptr. 892 (medical staff recommended continued closure of department at time of physician application for privileges, medical staff conducted two notice-

and-comment hearings to determine need for continued closure, and recommended continued closure); Redding v. St. Francis Med. Ctr. (1989) 208 Cal.App.3d 98, 255 Cal.Rptr. 806 (proposal to close department was openly discussed for two years in light of quality concerns and physicians to be directly affected were offered the contract); Centano v. Roseville Comm. Hosp. (1979) 107 Cal.App.3d 62, 167 Cal.Rptr. 183 (terms of the exclusive contract previously held by plaintiff's group required that hospital consult with medical staff executive committee prior to terminating agreement, decision to enter into exclusive contract made only after a number of meetings with interested persons, including affected medical staff members).

A. Medical Staff's Role in Quasi-Legislative Determination.

In order to understand what is at issue in this matter, the role of the medical staff in the hospital must be understood. In this regard, it must be emphasized that physicians do not work in isolation. They must work cooperatively when performing their duties, both in the performance of quality assurance activities and in the rendering of medical care and treatment to individual patients. *See generally,* Miller v. Eisenhower Medical Center (1980) 27 Cal. 3d 614, 166 Cal. Rptr. 826 (physicians must work cooperatively with members of the medical staff to ensure quality patient care). For their own protection, as well as that of their patients, physicians must perform these activities diligently. For example, physicians performing necessary cooperative activities such as providing consultations or coverage, or referring to specialists

for services such as performance of radiological testing and evaluation, may face increased potential liability if another physician with whom they must work is professionally unqualified. To facilitate these relationships, while protecting quality, the laws of California, like those of all states, require the physicians who practice at the hospital to organize themselves into a collective entity, generally legally separate from the hospital, that is the medical staff.

In doing so, the California Legislature recognized that, in order to ensure quality patient care, professional services in the hospital must be regularly monitored and evaluated. A comprehensive quality assurance process is critical to the resolution of problems as well as the identification and opportunity to improve patient care. Protocols and procedures must be continuously analyzed and revised to reflect new information and technologies. The clinical performance of physicians and other health care providers must be repeatedly assessed so that substandard performance and impaired or incompetent individuals may be identified before patients are seriously injured. To be effective, this monitoring function must be performed by individuals who have both the expertise necessary to conduct these quality assurance activities and the ability to implement any indicated changes. An effective medical staff quality assessment/improvement and peer review system provides the optimal solution. Medical staffs, comprised of physicians and certain other health professionals, have both the necessary expertise and familiarity with the health care facility and the physicians and other health care providers involved to conduct effective quality assessment and peer

review. It should be noted that members of the medical staff, whether officers or not, generally are not paid for these activities. This factor is of particular importance given current concerns over the escalating cost of health care.

1. The Medical Staff's Overall Responsibility for the Quality of Care Rendered in the Hospital.

Under California law, it is not disputed that the medical staff has overall responsibility for the quality of care rendered in the hospital, although the hospital board has oversight authority. *See* Business & Professions Code §2400 (corporate practice bar), Business & Professions Code §§2282, 2283 (requiring all hospitals to have an organized medical staff, which is self-governing with respect to the professional work performed), Health & Safety Code §1250(a) (defining "general acute care hospital" as one which has an "organized medical staff"), Health & Safety Code §32128 (requiring district hospitals to have self-governing medical staffs), 22 C.C.R. §§70701, 70703 (requiring the hospital to have a self-governing, organized medical staff "responsible to the governing body for the adequacy and quality of the medical care rendered to patients in the hospital"). The public policy principles reflected in these requirements are also present in the standards established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the private association which accredits hospitals nationwide (*see, e.g.,* JCAHO Standard MS.1, requiring a single organized medical staff with overall responsibility for the quality of professional services rendered by individuals having clinical privileges and other standards included in the Medical Staff

Chapter of the JCAHO's 1995 Accreditation Manual for Hospitals).[5] Both California law and JCAHO Standards require that medical staffs perform numerous detailed quality assurance-related activities.

2. The Medical Staff's Responsibility for Patient Care Services and Decisions.

First and foremost, each physician member of the medical staff is responsible for overseeing the general medical condition of every patient that the physician admits to the hospital. This is not only a moral and ethical obligation, it is required by legal standards. *See e.g.,* 22 California Code of Regulations Section 70703(a) (physicians and other medical staff members responsible for adequacy and quality of medical care rendered to patients in hospital). Additionally, because medicine is a continually evolving science, physicians must be continually aware of, employ, and strive to improve the developing medical procedures and technology. Patients expect, and the law requires, such ongoing activity. See Cobbs v. Grant (1972) 8 Cal.3d 229, 104 Cal. Rptr. 505. See also the American Medical Association Principles of Medical Ethics V (which provides:

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[5] This court may take judicial notice of the JCAHO's standards pursuant to Evidence Code Section 452 (h). *See* Anton v. San Antonio Community Hospital, (1977) 19 Cal. 3d 802, 819; 140 Cal. Rptr. 442. Moreover, it should be noted that institutions accredited as hospitals by the JCAHO are generally deemed to meet all of the Medicare conditions of participation. See 42 U.S.C. Section 1395bb(a)(1); 42 CFR Section 488.5. See also Health and Safety Code Section 1282 (authorizing quality of care inspections of hospitals by the JCAHO).

"A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.")

Physicians' responsibilities, however, are not limited to the "diagnosis" and "treatment" of their patients. As a part of the physician/patient relationship, physicians have a number of duties to their patients, separate and apart from their responsibility to conform to the standard of care involving clinical determinations. These include, for example, the duty to advocate for their patients' needs (*see* Wickline and Wilson, *supra*) and the duty to participate in hospital deliberations which may impact the quality of care provided. (*See e.g.,* 1995 JCAHO Standard MS.3.3.8 requiring "medical staff representation and participation in any hospital deliberation affecting the discharge of medical staff responsibilities.") As the JCAHO standard recognizes, many decisions of a hospital board will have patient care ramifications. *See also* Marik v. Superior Court (1987) 191 Cal.App.3d 1136, 236 Cal.Rptr. 751, in which the court recognized that it is difficult in the health care arena to isolate "purely business" decisions from those affecting the quality of care. Notably, in holding that the provisional director of a medical corporation was required to be either a physician or another qualified licensed person, the Marik court recognized the interrelated nature of these concerns:

> "...in the case of a professional medical corporation, the directors may be called upon to render decisions which are purely "business" in nature, purely "medical" in nature, or a combination of both. [Footnote: For

example, the prospective purchase of a piece of radiological equipment could be impacted by business considerations (costs, gross billings to be generated, space, and employee needs), medical considerations (type of equipment needed, scope of practice, skill levels required by operators of the equipment, medical ethics), or by an amalgam of factors emanating from both business and medical areas. The interfacing of these variables may also require medical training, experience, and judgment."] *Id.* at 1140.

Thus, to the extent that a hospital is considering a business issue that has a medical component, such as the decision to enter into an exclusive contract, it is essential that the licensed professionals comprising the medical staff take part in the decision-making process.

3. Medical Staff's Responsibility for Credentialing.

In addition to the responsibilities of medical staff members to provide medical care to patients and to speak out on quality issues, medical staff members are also responsible for credentialing, that is, assuring the initial and ongoing competence of every physician, dentist, podiatrist, and in some cases clinical psychologist who practices in the hospital. *See, generally,* Unterthiner v. Desert Hospital District (1983) 33 Cal. 3d 285, 188 Cal. Rptr. 590.

The Department of Health Services has emphasized the importance of the medical staff's expertise in the credentialing area. Thus, DHS specifically requires hospital boards to have the medical staff establish peer review and credentialing procedures. 22 C.C.R. section 70701(a)(7). It is the medical staff which must develop, adopt and enforce "formal procedures for the evaluation of staff applications and credentials, appointments, reappointments, assignment of clinical privileges, appeal mechanisms and such other subjects or conditions which the medical staff and governing body deem appropriate". 22 C.C.R. section 70703(b). Moreover, these procedures must be:

> [d]esigned to ensure the achievement and maintenance of high standards of professional ethical practices including provision that all members of the medical staff be required to demonstrate their ability to perform surgical and/or other procedures competently and to the satisfaction of an appropriate committee or committees of the staff, at the time of original application for appointment to the staff and at least every two years thereafter. 22 C.C.R. §70701(a)(7).

4. Medical Staff's Responsibility for Patient Care Review.

Perhaps most important is the medical staff's responsibility for assuring the ongoing quality of patient care throughout the hospital. Indeed, hospital licensing regulations specifically require that the medical staff maintain one or more committees formally organized to monitor the care and treatment rendered to hospital patients. 22 C.C.R. §70703(d). For example, pursuant to the law, the medical staff is obligated to perform the following patient care review functions on a regular basis:

1. Medical records review: the evaluation of medical records for their timely completion and adequate reflection of the patient's condition and treatment which is necessary to ensure that others will be able to assume the patient's care if required. 22 C.C.R. §§70703(d), 70749 and 70751.

2. Surgery review: the evaluation of surgeries performed to determine whether the surgery was both indicated and properly executed. 22 C.C.R. §§70703(d) and 70223, (b) and (h).

3. Utilization review: the evaluation of the allocation of the hospital's health care resources to monitor and address overutilization, underutilization and inefficient scheduling. 22 C.C.R. §70703(d).

4. Infection control and antibiotic usage review: the evaluation of the clinical use of antibiotics and the ongoing prevention, surveillance, and control of infections from whatever source, throughout the hospital. 22 C.C.R. §70703(d) and 70739.

5. Pharmacy and therapeutics review: the evaluation of pharmacy and therapeutics practice and the development of a drug formulary and policy relating to the safe handling, distribution, and administration of drugs. 22 C.C.R. §70703(d) and 70263.

6. Interdisciplinary practice committee: the development of written "standardized procedures" and supervision requirements which permit nurses and physicians' assistants to perform extended functions in the hospital. Business and Professions Code §2725, 22 C.C.R. §§70706 et seq.

7. Clinical laboratories/radiology/anesthesiology review: the evaluation of, and the development of procedures governing clinical laboratory, radiology and anesthesiology practice. 22 C.C.R. §§70233, 70243, and 70253.

8. Disaster planning: the development of a written disaster and mass casualty program. 22 C.C.R. §70741.

9. Hospital safety planning: the development of a written program to deal with internal disasters such as fires. 22 C.C.R. §§70743, 70745 and 70746.

10. Continuing education: the development of and participation in a mandatory, ongoing program of continuing education addressing the problems discovered during the foregoing patient care review activities. 22 C.C.R. §70703(g).

Given that medical staff members engage in the above-mentioned quality-related activities on an ongoing basis—often, for example, via participation on two or more medical staff committees simultaneously, as well as via participation at regularly scheduled section and department meetings—they are uniquely situated and qualified to assess a proposal to close a hospital department or service with respect to its potential impact on the quality of care rendered throughout the hospital. However, to ensure that all medical staff members who may be affected by the decision are included in the assessment process, it is important that the hospital and medical staff provide formal notice of the intended closure and the opportunity for a thorough discussion and comment process.

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B. Notice and Comment Process.

1. Examination and Documentation of Problems, Objectives and Potential Alternatives.

Any proposal to close a hospital department or service should result only from a careful consideration of the concerns giving rise to the proposal, along with alternatives which may resolve the concerns through less drastic means. Ideally, the medical staff and hospital should work together on development of the initial proposal. Regardless of who begins the process, however, the medical staff may wish to appoint a committee for the purpose of conducting a thorough investigation of the matter, soliciting views from the broad spectrum of medical staff members, hospital employees and administration, and others as appropriate. The benefits and detriments of department/service closure and each alternative should be documented and carefully weighed. Patient care justifications which appear merely to disguise anticompetitive motives or preferential treatment should be rejected. The final proposal should be documented, detailing its underlying rationale, consideration of alternatives and reasons why each alternative was rejected, if applicable.

Generally, such closures are appropriate only where:

- a failure to provide full coverage of a needed service cannot be remedied by less extreme measures, such as mandated call schedules; or
- irreconcilable differences within an existing department/service adversely affecting quality of care have not been resolved by less extreme measures; or
- demonstrable efficiencies would result, producing significant improvement in the ability of the medical staff to dispense quality care, which have not been accomplished through less extreme measures.[6]

2. 2. Notice of Proposed Action.

Once a proposal has been drafted, notice of the proposal should be given to all interested parties. Such persons would typically include, for example, any

[6] Ideally, this process should be described in the medical staff bylaws, the key organizational document of the staff which sets forth its structure and the rights and responsibilities of its members vis-a-vis the staff as a collective and the hospital. In California, as in most states, the bylaws must be developed initially by the medical staff and approved by the hospital board. (22 C.C.R. §70701(a)(8).) For this reason, it is widely held that the medical staff bylaws form a binding contract between the hospital and the medical staff. *See, e.g.*, Westlake Comm. Hosp. v. Sup. Ct. (1976) 17 Cal.3d 465 (implicitly recognizing contractual nature of medical staff bylaws, yet rejecting enforceability of specific bylaw provision on the grounds that contractual provisions which attempt to exempt a person from responsibility for his or her own wrongdoing are against public policy); Lawler v. Eugene Wuesthoff Memorial Hosp. Ass'n, 497 So. 2d 1261, 1264 (Fla. 5th DCA 1986) ("majority view is that a Hospital's By-laws, when approved and adopted by the governing board, become a binding and enforceable contract"); Palm Beach-Martin City Medical Center, Inc. v. Panaro, 431 So. 2d 1023, 1024 (Fla. 4th DCA 1983) (bylaws are enforceable contract between physician and hospital); *see also* Pariser v. Christian Health Care Sys., Inc., 816 F.2d 1248, 1251 (8th Cir. 1987) (under Illinois law, hospital's bylaws are an enforceable part of contract between hospital and physician with privileges, and court will annul revocation of privileges not accomplished in accordance with bylaws); Posner v. The Lankenau Hosp., 645 F. Supp. 1102, 1106 (E.D. Pa. 1986) (under Pennsylvania law, hospital bylaws constitute contract between physician and hospital); Gianetti v. Norwalk Hosp., 557 A.2d 1249, 1255 (Conn. 1989) (hospital bylaws are enforceable part of contract between physician and hospital).

current medical staff member whose privileges or membership may be directly affected by the decision (i.e., medical staff members with clinical privileges in the department or service under consideration for closure) and any medical staff member whose patients may be referred to the department or service under consideration for closure or who, of necessity, will rely upon that department or service for medical care. The latter would include, for example, all surgeons in the department of surgery when the department considered for closure is the department of anesthesiology. This is because, of necessity, surgeons rely upon anesthesiologists of their choice to provide this vital service to their patients. It would also include all departments of the hospital, arguably, when the department or service under consideration for closure is pathology, radiology, or emergency services. This is because all departments and services of the hospital typically, on a 24-hour basis, rely upon these departments to provide prompt testing and evaluative reports, as well as to render any necessary emergency care. It is essential that the staff members who refer to these departments have confidence that the care provided meets or exceeds medical staff standards in order to ensure that their patients will receive quality care. Often, such services provide crucial information in urgent situations. Moreover, each physician's own treatment plan, in part, is based upon testing results and other services typically provided by these departments. Thus, it is vital that all such medical staff members be fully apprised of any exclusive contract proposal and have the opportunity to present their concerns.

Other people who should be provided with notice of the intent to close and an opportunity for comment are all hospital personnel who are either employed in or have professional relationships with the department or service under consideration for closure. Typically, for example, this would include nursing and technical support personnel. Finally, to the extent practicable, it may be advisable also to notify interested members of the lay community. The notice should fully apprise the interested parties of the proposal and invite the submission of comments and objections.

3. 3. Quasi-legislative Hearing.

Opportunity should be given for interested parties to present comments and objections to the medical staff's executive committee orally and in writing. A hearing should be held with adequate advance notice to allow open discussion of the issues. A detailed record of the hearing should be kept and made available to the medical staff executive committee and hospital administration for their further consideration. If the committee concludes that the proposal must be substantially revised based on the input received, a second hearing on the revised proposal may be advisable.

4. 4. Final Vote and Report.

The medical staff's final report should address all issues and objections raised by the proposal, including all matters raised at the hearing. A final draft of the proposal should be attached. When the medical staff is satisfied with the proposal, it should be sent to the hospital's board of directors/trustees. The board

should review the proposal and the supporting record. It may approve the medical staff's recommendation or may send the matter back for further consideration of specific issues. If the matter is remanded, the medical staff should ask the Board to state the reasons for its concern in writing. Conflicts between the medical staff and the board which are not resolved in this process may be referred to a joint conference committee comprised of equal numbers of members of the board of trustees and medical staff.

Such notice and comment procedure provides a fair opportunity for all affected parties to participate in the decision-making process and tends to avoid challenges to the final determination on the ground that it was arbitrary or capricious, such as a decision made for economic reasons, without consideration of a potentially adverse impact on quality.

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CONCLUSION

A hospital's decision to close a department or service via an exclusive contract with one or more providers is a major health care delivery determination having profound consequences. While such a decision may be justified when it is in the best interest of patient care and less extreme measures will not suffice, it also presents a potential for abuse (e.g. when it is primarily motivated for cost

reasons and could diminish the quality of care rendered to patients). Because of this potential for abuse, it is imperative that such determinations be made only upon recommendation from the medical staff, following notice of the proposal and an opportunity for comment by all who will be affected.

Indeed, in recognition of the importance of exclusive contracts in today's era of cost- containment, the California Medical Association and the California Association of Hospitals and Health Systems have recognized the need for hospital and medical staff collaboration "on any matter that may affect quality or availability of medical care at the hospital."[7] With respect to exclusive contracts, the CMA-CAHHS Joint Statement provides as follows:

> "In any exclusive contract, hospital governing bodies must meet certain legal criteria. Governing bodies' decisions must be fair, not unreasonable or arbitrary, assure quality and be justifiable in the exercise of their fiduciary responsibility.
>
> "Exclusive contracting is a mechanism which may be used to assure: continuity of care, enhanced access to care, quality, cost effectiveness, efficient uses of hospital equipment, and proper management of hospital professional and technical employees. **While the final decision relative to entering into, renewing, terminating and the terms in an exclusive**

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[7] *Joint Statement on Economic Credentialing and Exclusive Contracting* of the California Medical Association and the California Association of Hospitals and Health Systems (January 1992), *supra* note 1, at 2.

contract is the responsibility of the governing body and the physicians involved in the contract, there should be a defined process in the medical staff bylaws for the medical staff to make recommendations to the governing body. Exclusive contracts should not be used as a vehicle to preempt medical staff peer review. Closing departments through exclusive contracts should be considered only after other alternatives have been explored and recommendations of the medical staff have been carefully considered. The governing body should advise the medical staff of its decision, and reasons therefore if the decision is different from the recommendations of the medical staff."

(Id. at 3, emphasis added.)

For the foregoing reasons, we urge this court to acknowledge that, to be lawful, a hospital's quasi-legislative determination to close a department or service must be made (1) only

in consideration of the quality-of-care impact of the proposed closure when less extreme measures

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will not suffice, and (2) only upon recommendation from the medical staff, following a notice and comment process, which provides a full and fair opportunity for all persons who might be affected by the decision to express their concerns and suggestions.

DATE: August 28, 1995

Respectfully submitted,

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APPENDIX A