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Primary Cardiology supplement starting on page 44-1.

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Physicians' Rights as Hospital Staff Members

Henry R. Fenton

Physicians may be denied appointment to the staff of a hospital or may find themselves threatened by removal or limitation of their staff privileges for reasons that have nothing to do with their competence. This article reviews the conditions under which physicians can or cannot be legally denied staff membership or reappointment, as well as the legal precedents for fair procedure if a hospital tries to remove a physician from its staff. All physicians should be aware of their rights in these areas to protect themselves from unjust denial of staff privileges, which could result in adverse career consequences.

It is important for physicians to be aware of their legal rights when they are being considered for staff membership in a public or private hospital, or when their membership is threatened by charges of misconduct or inadequate performance. Staff physicians are independent contractors, not employees, and their employment rights



are more limited than those of workers in the private and public sectors. They must therefore be more vigilant in exercising their rights to ensure protection

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against the arbitrary or unfair denial of staff privileges.

Some physicians may be under the impression that they have no reason to be concerned, or even informed, about their rights because revocation or denial of staff privileges is something that happens only to incompetent physicians. Or they may believe that denial or revocation of staff privileges, while somewhat inhibiting one's practice, does not pose a real threat to one's career. These views are incorrect.

First, a capable physician and skillful surgeon may be denied admission to the staff of a hospital or steps may be taken to remove him or her from the staff by competitors who will gain economically by such a move. Personality conflicts, strong disagreements with other staff members, or any number of other arbitrary reasons can be the basis of false accusations unrelated to the physician's ability to function effectively as a member of a hospital staff.

Second, denial of an application for staff privileges or removal from a hospital staff can have various adverse consequences. Because of the reporting requirement of Business and Professions Code S805, denial or revocation of staff membership can lead to a disciplinary proceeding before the Board of Medical Quality Assurance (BMQA). It can also lead to the denial of staff privileges at other hospitals.

Third, hospitals are far more disposed to take disciplinary action against staff physicians at the slightest indication of negligence, error, or omission as a result of a recent court decision¹ maintaining that a hospital

may be held liable for the negligent conduct of a staff physician if the physician was imprudently selected or retained.

Finally, recent changes in the law permitting the rapid growth of preferred provider organizations (PPOs) have been accompanied by a system of utilization review for the purpose of cutting medical costs. Decisions made by reviewers about the necessity of particular services—whether that review occurs before or after hospital admission—can lead to disagreements and, ultimately, to efforts to impose discipline on recalcitrant members of a hospital's staff.

The Right to Fair Treatment

A hospital's bylaws set forth the conditions under which physicians become members of the staff; they also regulate physicians' relationships with their colleagues on the staff and with other personnel in the hospital. Any action to discipline a staff member or to remove him or her from the staff must be pursuant to the hospital bylaws. In fact, Business & Professions Code S2282 prohibits physicians from practicing in private hospitals with five or more physicians without bylaws that require, at a minimum, that there be (1) a formal, self-governing medical staff, (2) review of all staff appointments at least biennially, (3) staff appointments only of physicians and surgeons competent in their respective fields and worthy in professional ethics, and (4) periodic peer review.

In addition to bylaw provisions, laws have evolved concerning physicians' rights to be appointed or retained on a hospital staff. Due to various court cases, it is now well established that justification must be given for rejection or removal from the staff of a public or private hospital. Some courts have required that the basis for removal be rational, not arbitrary, capricious, or

Termination of Residency

Residents are, in a sense, hybrids, being both employees and students. They are entitled to fundamental fairness, which means that, prior to dismissal, they are entitled to adequate notice of the charges against them, a meaningful opportunity to respond to the charges, and a hearing. The hospital need not, however, establish that the physician's inability to function in a residency training program adversely affected the quality of medical care in the hospital, as required for a denial of staff privileges.¹² Some lesser showing of cause, however, is necessary.

In termination of residency cases, the independent judgment rule must be adhered to when a public hospital is involved; the substantial evidence rule applies to private hospitals.

discriminatory.

According to a decision by the California Supreme Court,^{2*} rejection of a physician from a hospital staff is prohibited unless it can be shown that a real and substantial danger exists for the patients treated by the physician in question—that is, it must be shown that these patients receive other than a high quality of medical care at the hospital if the physician is admitted to or retained on the staff.

The court upheld a hospital's refusal to reappoint a doctor to the medical staff because he failed to maintain malpractice insurance with a "recognized insurance company."

Other laws affecting conditions under which staff membership can or cannot be denied include the following:

- Hospital bylaws may include a requirement of malpractice insurance for membership on the staff. In one California case,³ the court upheld a hospital's refusal to reappoint a doctor to the medical staff because he failed to maintain malpractice insurance with a "recognized insurance company." The court held that any insurance requirement proposed by a hospital as a condition for membership on the staff was allowable, as long as it was not arbitrary, irrational, or discriminatory. In the case in question, the physician had obtained insurance for \$1 million per occurrence; however, the insurance carrier was based in Central America and was not admitted in California to conduct a malpractice insurance business. Thus, held the court, the hospital properly interpreted its own rule to require insurance in the minimum amount of \$500,000 with an insurance company admitted to transact insurance business in California.
- Hospitals cannot use overly vague bylaws to exclude a physician from staff membership because this might allow discriminatory or nonuniform application.

continued

*The references cited here pertain to California court decisions and statutes. Such rulings are analogous to other states' statutory provisions. Moreover, California has set precedents that traditionally guide and influence legal actions in other courts. Nonetheless, the law varies from state to state and should therefore be reviewed carefully.

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continued

- A physician cannot be excluded from the staff of a hospital on the basis of failure to include references from active members of the hospital staff. Such a rule, held one court of appeals,⁴ would pose too great a danger that necessary endorsements would be arbitrarily or discriminatorily withheld.
- A hospital cannot deny a physician the right to staff privileges because of past disciplinary action by the BMQA.⁵ If, however, the hospital bases its decision on the circumstances that led to the BMQA proceeding, and if those circumstances currently constitute a rational basis for denial of staff privileges, the exclusion might be upheld.

Medical Society Membership

Rules of fair procedure described in the text also apply to the denial of an application for medical society membership or removal from membership.⁸ The application may not be denied arbitrarily or capriciously, and a physician is entitled to timely and reasonably detailed charges outlining the basis of an expulsion or rejection. The physician is also entitled to a hearing where he or she must be given an opportunity to present a defense. The physician has a right to be judged by an impartial body and may *voir dire*, or examine, the members of the hearing panel for possible bias or prejudice. Additionally, cause for the expulsion or rejection must be established, and the basis for denial may not be arbitrary, capricious, or contrary to public policy. Any court review of the factual bases for the rejection will be on the basis of the substantial evidence rule described in the text.

- A physician cannot be denied staff membership exclusively on the basis that he or she has been denied privileges at some other hospital.⁵
- A physician cannot be denied staff membership on the basis of nonmembership in a medical society.
- A hospital cannot condition staff membership on a physician's participation or nonparticipation in a PPO.

The Right to Fair Procedure

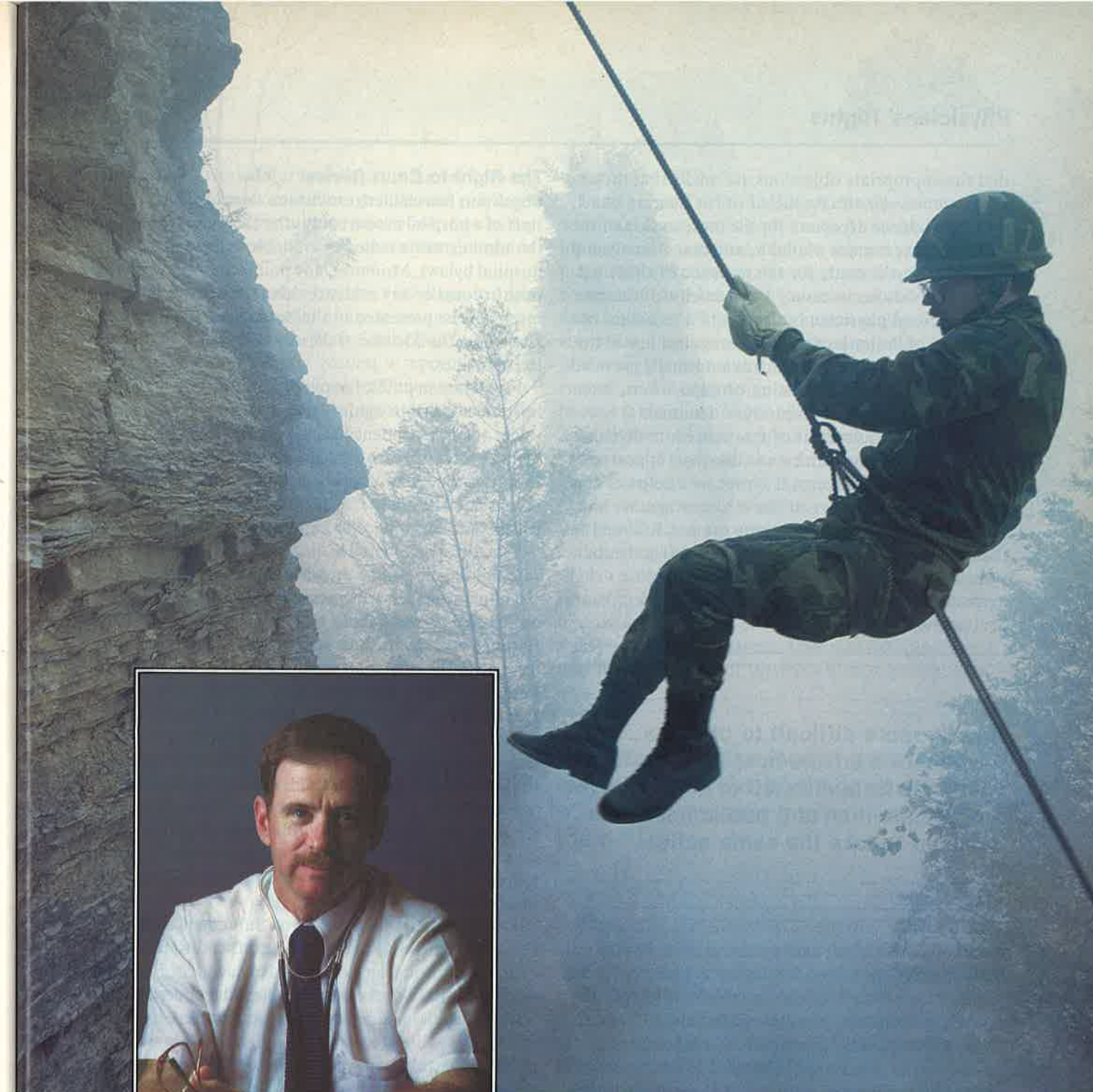
With some important exceptions, which will be noted, the procedural requirements that apply to staff application or revocation are the same for public and private hospitals.

The courts have held that physicians who are rejected for admission to the hospital staff, or who are removed from the staff for a reason related to their performance or qualifications as a physician or surgeon, are entitled to have the decision made against them in accordance with a fair procedure.⁶ The basic components of that fair procedure are the following:

- The physician is entitled to adequate notice of the charges that are the basis for rejection or removal. The notice must be provided sufficiently in advance of the hearing so that a defense may be prepared. The charges must be sufficiently specific that the physician can understand what he or she is being accused of. Moreover, the charges must make it clear that removal from the staff is being contemplated.
- In the case of staff removal, the physician is entitled to present his or her defense at a hearing prior to the effective date of removal.⁷
- At the hearing, physicians must be given an opportunity to confront and cross-examine the witnesses testifying against them and to present witnesses and evidence in their defense. In the case of a private hospital, however, neither hospital nor the accused physician has subpoena power. Nonetheless, "fundamental fairness" requires that witnesses against the physician be made available by the hospital and that the evidence relied on also be made available.⁸ Public hospitals, on the other hand, have subpoena power in such cases, and physicians must be careful to request that their witnesses be subpoenaed.
- The accused physician is entitled to an impartial hearing panel. Therefore, he or she is entitled to a "*voir dire*"—that is, a preliminary examination—of the members of the hearing panel or the appeals panel to ensure that the panel is impartial.⁸ Thus, if a business competitor of the accused or someone else who has a direct pecuniary interest in the outcome of the proceeding is on the panel, the accused can challenge the panel member on that basis. Fair procedure also requires that any physician who participated in the investigation of the charges as a member of the investigatory committee cannot sit as a member of the hearing committee or the review committee.⁹

To date, the California courts have rejected the argument that physicians are entitled in all cases to be represented by an attorney. Generally, unless the hospital is represented by an attorney or unless the bylaws provide for the right to be represented by an attorney at the hearing, the accused physician may not be represented by counsel at either the initial hearing or the appeals hearing.

Although accused physicians may, if permissible under the bylaws, represent themselves at the hearing or be represented by another member of the staff, they would be well advised to retain competent counsel to assist in the preparation of their defense, even if they are not allowed to be represented by an attorney in the hearing. A qualified attorney will ensure that the correct procedural points are raised, that the correct questions are asked on direct examination and cross-examination,



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Physicians' Rights

that the appropriate objections are made, that the appropriate *voir dire* is conducted of the hearing panel, that the evidence necessary for the presentation of the accused's case is made available, and that a timely and proper request is made for the presence of those witnesses who may be necessary to the defense of the case.

- The accused physician is also entitled to obtain fair disclosure of the basis of the charges against him or her. Although formal disclosure such as is normally provided in the court system (consisting of depositions, interrogatories, and notices to produce documents) is unavailable, the requirement of fair procedure demands that the accused physician have an adequate opportunity to respond to the charges and to prepare a defense. This contemplates disclosure of the evidence against him.
- Formal court rules of evidence are not followed in these cases. If the case is ultimately appealed in the court system, however, it is required that any finding made against the physician be supported by competent, non-hearsay evidence.

If is far more difficult to obtain a reversal of a private hospital's decision to remove from the staff or not reappoint a physician than of a public hospital's decision to take the same action.

- Although the courts have upheld bylaws, placing the burden of going forward with the evidence and the burden of proof on the physician, they have so held only on the basis that the hospital was required to make a "substantial showing" in support of its recommendation of removal or nonreappointment.¹⁰ If the bylaws do not assign the burden of proof, it is generally on the hospital.
- Hospital bylaws generally provide for review of a decision by the governing body of the hospital or an appeals committee. Although it is required by the Joint Commission on Accreditation of Hospitals, it is not necessarily required as a matter of fair procedure.
- The physician is entitled to a written decision from the hospital including the bases for the decision.⁶
- The physician is entitled to a complete record of the proceedings, whether that record is transcribed by a court reporter, tape recorder, or some other form, so that he or she can obtain review of the decision in the courts.⁶

The Right to Court Review

Physicians can challenge exclusion or removal from the staff of a hospital in court only after they have exhausted the administrative remedies available to them under the hospital bylaws. Moreover, any points that they wish to raise in court or any evidence that they want to present must first be presented in the hearings at the hospital level under the doctrine of the exhaustion of administrative remedies.

Physicians in public hospitals are entitled to have the hospital's decision against them reviewed by a judge under the independent judgment rule. However, their counterparts who are denied staff privileges in private hospitals may obtain review in court, but the court is required to sustain the decision of the hospital if there is substantial evidence to support that decision.

The difference between the independent judgment rule and the substantial evidence rule is very significant. Under the independent judgment rule the court is required to determine independently whether or not the findings made by the hospital in support of its decision to remove the physician from the staff are supported by the evidence. If not, the staff removal may be set aside. In contrast, when the court applies the substantial evidence rule, it must view the evidence presented in the hearing at the hospital level in a light most favorable to the hospital's findings, and it must interpret the evidence, if it can do so, to support those findings. Thus, it is far more difficult to obtain a reversal of a private hospital's decision to remove from the staff or not reappoint a physician, than a public hospital's decision to take the same action.

In a recent case, the California Supreme Court held that physicians who are denied admission to the staff of a public hospital are not entitled to have a court review of the hospital's decision under the independent judgment rule and that the substantial evidence rule applies. Although the court held that the physician's interest in obtaining staff privileges was fundamental and conceivably crucial to his livelihood, the applicant, held the court, did not have a vested right to those privileges. Hence, he was entitled only to have the court review the denial of privileges under the substantial evidence rule.

The Consequences of Denial or Restriction of Staff Privileges

Physicians who face denial or restriction of staff privileges must bear in mind that their immediate situation may affect their right to practice medicine and their chances of obtaining staff privileges at other hospitals. As mentioned above, California Business and Professions Code S805 requires hospitals to report to the BMQA when any physician, psychologist, podiatrist,

or dentist "is denied staff privileges, removed from the medical staff of such institution, or if his staff privileges are restricted for a cumulative total of 45 days in any calendar year for any medical disciplinary cause or reason."

The threat posed to the physician's privileges in other hospitals for the remainder of his or her career derives from Business and Professions Code S805.5. This requires that every hospital request a report from the BMQA before appointing a new staff member to determine whether any report on the physician has ever been made by a hospital under S805.

Resignation in the face of threatened disciplinary action or after a suspension will not necessarily prevent a report to the BMQA. In fact, S805 states that if removal from the staff or restriction of staff privileges is by resignation as a result of a bargain in lieu of medical disciplinary action, the hospital is required to report this to the BMQA. Under S805.5, this report will subsequently be made available to all other hospitals where the physician may apply for staff privileges or for a renewal of staff privileges.

Therefore, any physician who faces restriction or denial of staff privileges must act quickly not only to resolve the immediate situation, but to avoid, if possible, a report to the BMQA. Although it may be possible to resolve a situation where suspension, restriction, or removal is threatened or has occurred, action must be taken as soon as possible and the advice of a competent attorney in this area should be obtained. In many cases, the physician may decide to vigorously contest the attempt to restrict or deny staff privileges. This decision must be made before staff privileges are restricted for a total of 45 days in any calendar year to avoid a report to the BMQA.

Finally, it is important to understand how seriously hospitals take the reporting requirement. Section 805 provides that failure to make a report pursuant to this section is a misdemeanor. But more importantly, based on a 1982 court decision,¹ some hospitals maintain that any failure to comply strictly with S805 of the Business and Professions Code would increase their potential liability for any future acts of malpractice by physicians whose staff privileges were previously denied or restricted.

Looking Ahead: The Effect of PPOs

As more hospitals contract with PPOs and more physicians participate as providers in such organizations through economic necessity, conflicts may arise between the independent physician, exercising professional responsibility to his or her patients, and the economic self-interest of the insurance company or other entity that

operates the PPO.

In a case in California,¹³ a patient was admitted to a hospital for an aortic graft insert. Although the treating physician requested an eight-day extension of the patient's hospitalization after the operation, a Medi-Cal consultant for the state of California authorized only four extra days. The patient subsequently developed complications that resulted in the amputation of a portion of his leg. A lawsuit against the state of California ensued, and a judgment was rendered in favor of the patient in the sum of \$500,000. However, the Court of Appeals reversed the judgment against the state of California on the basis that the treating physician was ultimately responsible for discharging the patient.

The nature of utilization review presents the danger that similar disagreements may result between the PPO and the provider physician about whether or not a particular procedure or course of treatment is medically necessary. Physicians have an obligation to their patients to provide whatever treatment they deem necessary in their professional judgment. They may not compromise that judgment, even if the PPO disagrees with them.

Resignation in the face of threatened disciplinary action or after a suspension will not necessarily prevent a report to the BMQA.

When such disagreements occur, they may result in steps to remove the physician from the PPO. At the same time, or shortly thereafter, the hospital may take steps to dismiss the physician from its staff. Although to date there are no published decisions concerning these issues, some possible defenses for physicians confronted with such cases are the following:

- First, and perhaps foremost, is the protection provided by California Health and Safety Code S1322, which prohibits conditioning hospital staff membership on participation in a PPO or exclusive provider organization. To the extent that removal from the staff is based on the events that resulted in dismissal from the PPO, physicians may well be able to rely on this code in their defense.
- Another basis for a defense in such cases may be Business and Professions Code S2400, which prohibits the corporate practice of law. If it can be shown that the attempted removal is a result of a disagreement between the PPO and a physician about whether or not certain

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE: TIMENTIN® is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below:

Bacterial Septicemia: including bacteremia, caused by β -lactamase producing strains of *Klebsiella* spp., *E. coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* (and other *Pseudomonas* species).

Lower Respiratory Infections: caused by β -lactamase producing strains of *Staphylococcus aureus*, *Hemophilus influenzae* and *Klebsiella* spp.

Bone and Joint Infections: caused by β -lactamase producing strains of *Staphylococcus aureus*.

Skin and Skin Structure Infections: caused by β -lactamase producing strains of *Staphylococcus aureus*, *Klebsiella* spp., and *E. coli*.

Urinary Tract Infections (complicated and uncomplicated): caused by β -lactamase producing strains of *E. coli*, *Klebsiella* spp., *Pseudomonas aeruginosa* (and other *Pseudomonas* species), *Citrobacter* spp., *Enterobacter cloacae*, *Serratia marcescens*, and *Staphylococcus aureus*. While TIMENTIN is indicated only for the conditions listed above, infections caused by ticarcillin susceptible organisms are also amenable to TIMENTIN treatment due to its ticarcillin content. Therefore, mixed infections caused by ticarcillin susceptible organisms and β -lactamase producing organisms susceptible to TIMENTIN should not require the addition of another antibiotic.

Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing infection and to determine their susceptibility to TIMENTIN. Because of its broad spectrum of bactericidal activity against Gram-positive and Gram-negative bacteria, TIMENTIN is particularly useful for the treatment of mixed infections and for presumptive therapy prior to the identification of the causative organisms. TIMENTIN has been shown to be effective as single drug therapy in the treatment of some serious infections where normally combination antibiotic therapy might be employed. Therapy with TIMENTIN may be initiated before results of such tests are known when there is reason to believe the infection may involve any of the β -lactamase producing organisms listed above; however, once these results become available, appropriate therapy should be continued.

CONTRAINDICATIONS: TIMENTIN is contraindicated in patients with a history of hypersensitivity reactions to any of the penicillins.

WARNINGS: SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTOID) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY AND/OR A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH TIMENTIN, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS, OR OTHER DRUGS. IF AN ALLERGIC REACTION OCCURS, TIMENTIN SHOULD BE DISCONTINUED AND THE APPROPRIATE THERAPY INSTITUTED. SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE, OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE PROVIDED AS INDICATED.

PRECAUTIONS: While TIMENTIN possesses the characteristic low toxicity of the penicillin group of antibiotics, organ system functions should be assessed periodically during therapy.

Bleeding manifestations have occurred in some patients receiving β -lactam antibiotics. These reactions have been associated with abnormalities of coagulation tests such as clotting time, platelet aggregation and prothrombin time and are more likely to occur in patients with renal impairment. If bleeding manifestations appear, TIMENTIN treatment should be discontinued and appropriate therapy instituted.

TIMENTIN has only rarely been reported to cause hypokalemia. Periodic monitoring of serum potassium may be advisable in patients receiving prolonged therapy.

Pregnancy (Category B): Reproduction studies have been performed in rats given doses up to 1050 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to TIMENTIN. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

DOSAGE AND ADMINISTRATION: TIMENTIN should be administered by intravenous infusion (30 min.). Usual recommended dose for systemic and urinary tract infections for average (60 kg) adults is 3.1 Gm TIMENTIN (3.1 Gm vial containing 3 Gm ticarcillin and 100 mg clavulanic acid) given every 4 to 6 hours. In urinary tract infections, a dosage of 3.2 Gm TIMENTIN (3.2 Gm vial containing 3 Gm ticarcillin and 200 mg clavulanic acid) given every 8 hours is adequate. Please see official package insert for details on dosages for other patients, including those with renal insufficiency, and directions for use.

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1. Data on file, Medical Department, Beecham Laboratories. 7548/E-BS

2. In retrospective reviews of (1) 228 pneumonia patients enrolled in comparative studies; and (2) 181 patients with lower respiratory tract infections enrolled in multicenter TIMENTIN clinical trial protocols, who would appear to be candidates for DRG 79 (respiratory infection + inflammation, age > 69, and/or C.C.).

*Due to susceptible organisms. *In vitro* activity does not necessarily imply *in vivo* efficacy.

†Clinical response defined as cured or improved. Clinical cure defined as complete resolution of all presenting signs and symptoms by the end of therapy; improvement defined as substantial diminution in the severity of presenting signs and symptoms. Bacteriologic response defined as elimination of initial pathogen during therapy and for the duration of follow-up or unavailability of culture material.

ON ADMISSION

Based on the *in vitro* synergism between TIMENTIN and aminoglycosides against certain strains of *Pseudomonas aeruginosa*, combined therapy has been successful, especially in patients with impaired host defenses. Both drugs should be used in full therapeutic doses. As soon as results of culture and susceptibility tests become available, antimicrobial therapy should be adjusted as indicated.

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treatment was medically necessary, it may be argued that PPOs do not have a right to make medical judgments.

- The law clearly provides that in public and private hospitals the staff of the hospital must exist separately from the hospital, must be formally organized with appropriate officers and bylaws, and must be self-governing. To the extent that PPOs attempt to dictate to physicians on the staffs of hospitals what treatment should be provided or the manner in which treatment should be provided, they interfere with the independence of the medical staff and violate these provisions.

- Physicians facing removal in such cases can argue that they exercised their professional responsibility to ensure that their patients received a high quality of medical care at the hospital. The courts have held that a physician is entitled to retain staff membership unless it can be shown that retention may present a danger that patients treated by the physician would receive other than a high quality of medical care. Physicians threatened with removal from the staff can rely on these cases in their defense.

- Physicians who are excluded from a PPO may, in some instances, be able to cite a cause of action under the anti-trust laws. This can only be determined on a case-by-case basis, depending on the size and nature of the PPO and the contractual arrangements among the PPO, the hospital, other hospitals, and the provider physicians.

Conclusion

The right of physicians to be members of hospital staffs is integral to their right to practice medicine. For this reason, it is essential that all physicians have at least a rudimentary understanding of the nature of their rights for fair treatment and fair procedure when applying for staff membership or when faced with the threat of removal from a hospital staff. □

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Diabetes Update

Topical Hyperbaric Oxygen for Treatment of Foot Ulcers

Henry Ginsberg, MD

Primary Cardiology explores issues in diabetes, with emphasis on cardiovascular complications. A physician from the Columbia University College of Physicians and Surgeons has reviewed the current literature in diabetes and has selected the following article for evaluation.

—The Editors

■ The management of diabetic foot ulcers has concerned internists and vascular surgeons for some time. These seemingly small, benign lesions often develop into chronic, debilitating problems, and too often result in the loss of a toe or foot. Since diabetic ulcers occur more frequently in patients with peripheral neuropathy and vascular insufficiency, their response to the usual treatment modalities—antibiotics, dressings, and rest—are suboptimal. Poor diabetic control, with associated reductions in white blood cell function, may further complicate the situation.

These difficulties have led investigators to attempt novel approaches to treatment, including the local application of hyperbaric oxygen to the ulcer

lesions. The rationale for such an approach is not without merit when one considers how frequently anaerobic pathogens are found in necrotic and gangrenous diabetic foot ulcers, and the well-known association between peripheral vascular disease and development of these ulcers. Several uncontrolled trials of hyperbaric treatment, along with standard modalities, have yielded results demonstrating efficacy. The lack of randomization or other controls in these trials however, has left unanswered the basic question concerning the role of local hyperbaric oxygen therapy in the treatment of diabetic foot ulcers.

In this report by Leslie and associates, 28 diabetic patients with clearly demarcated but nongangrenous, nonnecrotic foot ulcers were randomized into two groups: the first group received local hyperbaric therapy and other standard modalities, and the second received only the standard modalities, ie,

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