

**STATE OF FLORIDA
FIRST DISTRICT COURT OF APPEAL**

Case No. 1D05-5079

Division of Administrative Hearings Case No. 05-1246RP

DAVID MCKALIP, M.D.,

Appellant,

v.

STATE OF FLORIDA,

AGENCY FOR HEALTH CARE

ADMINISTRATION,

Appellee.

**MOTION FOR LEAVE TO FILE AN *AMICUS CURIAE* BRIEF
OF THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS
IN SUPPORT OF PETITIONER DAVID MCKALIP, M.D.**

Pursuant to Florida Rules of Appellate Procedure 9.370 and 9.300, Movant Association of American Physicians and Surgeons, Inc. (the “Association”), by and through the undersigned counsel, requests leave to file an *amicus curiae* brief in support of Petitioner David McKalip, M.D. in the above-styled matter, and states:

1. Founded in 1943, the Association is a nationwide non-profit membership organization of thousands of physicians. Incorporated under the laws of Indiana, the Association is dedicated to ensuring the highest ethical standards in

the practice of medicine and expressing the views of private physicians in policy matters such as the appropriate implementation of infection control standards. Among its members are physicians who practice in Florida. They and the Association are deeply concerned by incremental regulatory intrusions into the professional practice of medicine that infringe and curtail the exercise of sound medical judgment. The Association has an immediate interest in protecting and preserving the ability of physicians to provide the best care possible for each individual patient according to the patient's circumstances and the physicians' medical judgment, training and experience, without restrictions inherent in monitoring practices oriented toward ensuring conformance with one-size-fits-all administrative requirements. The Association objects to direct and indirect attempts to constrain the care provided by the medical profession to patients, particularly when those patients wish to exercise their right to make an informed medical decision and to pay for the care recommended by their doctor.

2. The Courts of Florida have welcomed assistance and *amicus curiae* briefs by the Association in the past. For example, the Supreme Court of Florida granted a motion by the Association to file an *amicus curiae* brief in the high-profile case of *Limbaugh v. State of Florida*, 887 So.2d 387 (Fla. 4th DCA 2004), *rev den.*, 903 So.2d 189 (Fla. 2005) . There, as here, the Association brings the

views of an independent group of physicians to the litigation of medical issues, for the benefit of the courts.

3. In the tribunal below, Petitioner challenged Proposed Florida Administrative Code Rules 59B-15.001 through 59B-15.007 as an invalid exercise of delegated legislative authority. The focus of the challenge included the seemingly innocuous requirement that hospitals report Surgical Infection Prevention (“SIP”) measures, as follows:

- (2) Hospitals shall report the following measures for all eligible patients regardless of type of payer:
 - (a) Prophylactic antibiotics received within 1 hour prior to surgical incision;
 - (b) Prophylactic antibiotic selection for surgical patients;
 - (c) Prophylactic antibiotics discontinued within 24 hours after surgery end time.

Fla. Admin. Code R. 59B-15.004(2).

4. In the Division of Administrative Hearings’ Final Order, the Administrative Law Judge (“ALJ”) found that:

The Proposed Rules do not require Dr. McKalip to report the use of SIP measures; they require the hospitals in which he performs the procedures to report the SIP measures. The Proposed Rules do not require the hospitals to implement SIP measures, merely to report whether the SIP measures were implemented.

Final Order finding 9.

5. Based upon the foregoing finding, the ALJ concluded Dr. McKalip lacked standing to challenge the Proposed Rules. This conclusion failed to consider the practical circumstances, including the facts found later in Final Order paragraph 26 that some “scientific studies support the use of the SIP measures as a means of combating surgical infections” and that:

The Proposed Rules are supported by the Florida Hospital Association; Florida Medical Quality Assurance, Inc.; and CMS. The use of SIP measures is supported by many medical societies and organizations.

Final Order Finding 11.

6. The evidence obviously demonstrated, and the foregoing determinations of the ALJ reflect, that the specific SIP measures promulgated in Proposed Rule 59B-15.004(2) are elevated by the Rule to the status of a standard of medical care, compliance with which must be reported by hospitals. The fact that hospitals are adopting the SIP measures as a requirement is merely evidence of the fact the governing bodies of medical providers at these hospitals recognize that the standard of care is being established in the Rule. The effect of the Rule on the care provided by Dr. McKalip and other surgeons is for all practicality a direct one. Every physician and every hospital must be concerned that they meet the prevailing standard of care, even if it is a disputed standard and even if the standard is being established inappropriately in a reporting rule.

7. The Association seeks to file an *amicus curiae* brief here to ensure legal access for its physician members to challenge regulations that affect their practice of medicine. The ALJ erred below in denying the right of a physician to object to a regulation that directly requires scrutiny of the physician's conduct. The ALJ mistakenly held that because physicians were not the ones required to make the reports of their compliance with the SIP measures, they lack standing to object to the reports. The ALJ's ruling cannot withstand scrutiny and threatens to deprive all subjects of reporting requirements the legal standing necessary to challenge new regulatory requirements.

8. In particular, the ALJ erred in denying standing to a physician because he is not personally burdened with the obligation to file a report under the new guidelines. The consistency of the physician's professional conduct with standards of care promulgated by the regulatory agencies is undeniably the subject of the report and physicians are affected by the comparison of their conduct with such regulatory standards. The Association seeks leave of this court to file an *amicus curiae* brief to support and explain its position that physicians should be found to have standing to challenge regulations, such as the subject regulations, that affect them in their practice of medicine.

9. The instant case is analogous to the circumstances addressed by the First District Court of Appeal in *Florida Board of Medicine v. Florida Academy of Cosmetic Surgery, Inc.*, 808 So.2d 243, at 251 (Fla. 1st DCA 2002), involving review of a final order in a rule challenge case. The Board of Medicine and the Florida Association of Anesthesiologists appealed the ALJ's determination that the Florida Association of Nurse Anesthetists and the Florida Nurse Association had standing to challenge a rule that would require anesthesiologist supervision of all administration of general anesthesia. The Court said:

The fact that the proposed rule would not directly regulate CRNA's [certified registered nurse anesthetists] is not fatal to a finding of standing. A challenger to a rule may be 'substantially affected' by a rule, and thus have standing to challenge it, even where the rule or promulgating statute does not regulate the challenger's profession per se. *Ward v. Bd. of Trs. of Internal Improvement Trust Fund*, 651 So.2d 1236, 1238 (Fla. 4th DCA 1995). For instance, we have held that a challenger can be substantially affected by a rule which has a collateral financial impact on the challenger's business. *See Televisual Communications, Inc. v. State Dep't of Labor & Employment Sec.*, 667 So.2d 372 (Fla. 1st DCA 1995)

See also, Ward v. Board of Trustees of the Intern. Improv. Trust Fund, 651 So.2d 1236 (Fla 4th DCA 1995); *Florida Med. Ass'n v. Department of Prof. Reg.*, 426 So.2d 1112, 1118 (Fla. 1st DCA 1983) (physician has standing to challenge rules premised on his "rights as a licensed physician, and his rights derived from

Chapter 458 to challenge interpretations of that chapter or other laws which would allow medical practices in derogation of the purpose and intent of those laws”).

10. It is essential that this Court consider the accompanying *amicus* brief so that it may be fully apprised of the effects of the SIP guidelines on the practice of medicine by physicians like Petitioner. Hospitals do not practice medicine; physicians do. Accordingly, physicians are the ones who must comply with the SIP guidelines when prescribing antibiotics. This severe infringement on a physician’s ability to practice medicine and prescribe the optimal treatments for a particular patient supports his standing to object to the monitoring. *See Ward*, 651 So.2d at 1237 (“[E]ven where a challenged rule or its promulgating statute does not regulate the challenger’s profession per se, for example, setting criteria to engage in that profession, but the rule has the effect of directly regulating professional conduct of persons within such occupation, such challenger has been found to be substantially affected.”) (citations omitted).

11. In its accompanying *amicus* brief, the Association gives several compelling examples of how the SIP guidelines will severely affect the practice of medicine in this State. Consider, for example, a patient who has a medical history of susceptibility to infections. A physician like Petitioner is often asked to perform a complex operation, such as vascular surgery, on such a patient. The physician often prescribes and the patient is often willing to pay the relatively modest cost

for the extra protection against infection afforded by extended prophylactic treatment by antibiotics. However, a physician like Petitioner would be reluctant, and rightly so, to raise a red flag with his hospital and the regulators by ordering antibiotics for longer than the recommended periods. The mandatory reporting and surveillance of the antibiotic treatment periods under the SIP guidelines coerce Petitioner into giving fewer antibiotics than the physician would recommend and the patient may need. This coercion may result in a higher chance of deadly infection, which may result in a needless fatality.

12. The issue the Association will argue to this Court is not whether extended antibiotic treatment for such a patient is desirable. That judgment should be properly left to the treating physician. Rather, the issue of greatest concern to the Association here is whether the Petitioner has standing to challenge a state-mandated monitoring requirement and its coercive effect with respect the physician's prescription of antibiotics. As explained by the accompanying brief, physicians must enjoy standing to challenge such measures and guidelines that so obviously affect them.

WHEREFORE, Movant Association of American Physicians and Surgeons, Inc., respectfully requests the Court enter an order granting Movant leave to file the attached proposed *amicus curiae* brief and accepting the attached brief as filed as of the date of such order.

Dated: March 24, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 24, 2006, the foregoing was sent via overnight

delivery to:

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief was prepared in Times New Roman, 14-point font, in compliance with Rule 9.210(a)(2) of the Florida Rules of Appellate Procedure.

By: _____
 John R. Thomas