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.

INITIAL BRIEF OF *AMICUS CURIAE* ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS [FILED WITH MOTION FOR LEAVE OF COURT]

JOHN R. THOMAS, ESQUIRE
THOMAS & ASSOCIATES, P.A.
Florida Bar No. 0868043
233 Third Street North, Suite 101
St. Petersburg, Florida 33701
Telephone No.: (727) 550-9072
Telefacsimile No: (727) 550-9073
Counsel for *Amicus Curiae* Association of
American Physicians and Surgeons

TABLE OF CONTENTS

Page

TABLE OF CITATIONS

CONCISE STATEMENT OF IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of American Physicians and Surgeons, Inc. (the "Association"), by and through the undersigned counsel, respectfully submits this *amicus curiae* brief in support of Petitioner David McKalip, pursuant to Florida Rule of Appellate Procedure 9.370. 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.

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.

SUMMARY OF THE ARGUMENT

This Court should reverse the decision below, and confirm that a physician has standing to challenge a regulation establishing reporting and monitoring that affect his practice of medicine.

Professionals retain standing to challenge regulations that affect their livelihood and professional obligations. The administrative law judge (ALJ) erred below in denying the right of a physician to object to a regulation that directly scrutinizes the physician's conduct. The ALJ mistakenly held that because physicians were not the ones required to make the reports, they therefore lack standing to object to the reports. However, the subject of a monitoring program has as much right to challenge it as those required to file the paperwork. The ALJ's ruling cannot withstand scrutiny and threatens to deprive all subjects of reporting requirements the legal standing necessary to challenge the new requirements.

For reasons further explained below, the Association respectfully requests this Court to reverse the decision below.

ARGUMENT

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).

Subsection 120.56(2)(a), Florida Statutes, provides:

> (a) Any substantially affected person may seek an administrative determination of the invalidity of an proposed rule by filing a petition seeking such a determination with the [Division of Administrative Hearings].

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.

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.

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 receiving tacit agency approval and are therefore being elevated by the Rule to the status of an agency 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 clear 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.

The consistency of the physician's professional conduct with standards of care promulgated by the regulatory agencies is undeniably the subject of the Rule's reporting requirement and physicians are affected by the comparison of their conduct with such regulatory standards. Physicians, like other licensed workers, have standing to challenge regulations that affect them in the performance of their duties. *See 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"). *Cf.*, *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 74 U.S.L.W. 4159 (Mar. 6, 2006) (holding unanimously that an association of law school faculties and others had standing to challenged a condition placed on federal funding of universities). The SIP measures unquestionably can affect how a physician practices medicine, and Petitioner therefore has standing to challenge them.

As a practical matter, 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).

The proposed reporting rule under challenge is analogous to Florida Rule of Professional Conduct 4-6.1 which requires lawyers and law firms operating under an approved plan to report whether the lawyers have meet the standard of 20 hours of pro bono legal service to the poor or a $350 donation to a legal aid organization per year. Though the standards in this analogous ethics rule are aspirational rather than mandatory, no attorney or law firm would prefer to voluntarily reveal a failure to meet even this aspirational ethical standard and it cannot be gainsaid that the reporting requirement acts coercively to ensure attorneys meet the aspirational standard. The SIP measures of Proposed Rule 59B-15.004(2) more directly affect a physician's conduct than this ethics rule affects lawyers because failure to

prescribe antibiotics consistently with the SIP measures would be viewed as a failure to meet the standard of care established by the agency charged with regulation of the field, not just an ethical failure. Furthermore, attorneys themselves, not only their firms, would have standing to challenge the ethics rule if it did not expressly state that "failure to fulfill one's responsibility" under the rule "will not subject a lawyer to discipline."

Consider, as another 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 patient would often be willing to pay the modest additional cost for the extra protection against infection afforded by extended prophylactic treatment by antibiotics. However, Petitioner would be reluctant (and in some cases prohibited) to *raise a red flag* with his hospital and the regulators by ordering antibiotic administration for longer than the recommended periods. The new reporting and surveillance of the antibiotic treatment periods under the SIP guidelines coerce Petitioner to adhere to the SIP limitations by giving fewer antibiotic doses than the physician would recommend and the patient may need. The consequence of such truncated antibiotic administration is a higher chance of deadly infection, which may result in a needless fatality.

The issue presented 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 here is whether the Petitioner has standing to challenge a state-mandated monitoring requirement that tacitly establishes a standard of care and is imbued with coercive effect with respect to the prescription of antibiotics. Physicians must enjoy standing to challenge such measures and guidelines that so obviously affect them.

The Florida Constitution reinforces the need for judicial review of the type of monitoring regulation at issue here. Article I, Section 23 of the Florida Constitution, entitled "Right to Privacy," mandates that "[e]very natural person has the right to be let alone and free from government intrusion into the person's private life except as otherwise provided herein. …." Similarly, the Oath of Hippocrates taken by most physicians states that "[a]ll that may come to my knowledge in the exercise of my profession or outside of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and never reveal." http://www.aapsonline.org/ethics/oaths.htm. There would be no doubt that a physician and patient had standing to challenge a monitoring regulation governing *individualized* medical records, even though the physician or patient is not required to do the reporting. The Constitution does not base its guarantee of rights on who is doing the reporting. Where, as here, reporting affects

the right of patients "to be let alone and free from government intrusion," the patients and their physicians must have standing to challenge the regulation. *Cf., State v. North Fl. Women's Health*, 852 So.2d 254, 259 (Fla. 1st DCA 2001)("Physicians especially have been granted standing to invoke the rights of privacy of half of their patients").

CONCLUSION

For the foregoing reasons, this Court should reverse the decision below and confirm that Petitioner has alleged and proved standing.

Dated: March 24, 2006

Respectfully submitted,

_____

JOHN R. THOMAS, ESQUIRE
THOMAS & ASSOCIATES, P.A.
Florida Bar No. 0868043
233 Third Street North, Suite 101
St. Petersburg, Florida 33701
Telephone No.: (727) 550-9072
Telefacsimile No: (727) 550-9073
Counsel for *Amicus Curiae* The Association of American Physicians & Surgeons, Inc.

CERTIFICATE OF SERVICE

I certify that on March __, 2006, the foregoing was sent via overnight delivery to:

Garnett Chrisenhall
General Counsel
2727 Mahan Drive, MS #3
Tallahassee, FL 32399-1050
Counsel for Respondent

David McKalip, M.D., P.A.
Neurological Surgery
1201 5th Ave. N., Suite 210
St. Petersburg, FL 33705
Petitioner, pro se

By:_____
John R. Thomas

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