STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

FLORIDA MEDICAL ASSOCIATION,	)	
	)	
Petitioner,	)	
and	)	
	)	Case No. 06-2899RP
FLORIDA ACADEMY OF FAMILY PHYSICIANS, FLORIDA ACADEMY OF PAIN MEDICINE, THE FLORIDA ASSOCIATION OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE, FLORIDA CHAPTER OF THE AMERICAN COLLEGE OF CARDIOLOGY, FLORIDA CHAPTER OF THE AMERICAN COLLEGE OF PHYSICIANS, FLORIDA CHAPTER OF THE AMERICAN COLLEGE OF SURGEONS, FLORIDA GERIATRICS SOCIETY, FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION, FLORIDA PEDIATRIC SOCIETY, FLORIDA PSYCHIATRIC SOCIETY, FLORIDA PULMONARY SOCIETY, FLORIDA SOCIETY OF ADDICTION MEDICINE, FLORIDA SOCIETY OF ANESTHESIOLOGISTS, FLORIDA SOCIETY OF CLINICAL ONCOLOGY, FLORIDA SOCIETY OF DERMATOLOGIC SURGEONS, FLORIDA SOCIETY OF FACIAL PLASTIC AND RE-CONSTRUCTIVE SURGERY, FLORIDA SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS, FLORIDA SOCIETY OF NEUROLOGY, FLORIDA SOCIETY OF OTOLARYNGOLOGY HEAD AND NECK SURGERY, FLORIDA SOCIETY OF PATHOLOGISTS, AND THE FLORIDA SOCIETY OF PHYSICAL MEDICINE AND REHABILITATION,	)	
	)	
Intervenors,	)	
	)	
vs.	)	
	)	
DEPARTMENT OF HEALTH, BOARD OF PHARMACY,	)	
	)	
Respondent.	)	
_____	)	

FINAL ORDER

On September 15, 2006, a hearing was held in Tallahassee, Florida, pursuant to the authority granted in Sections 120.56, 120.569 and 120.57(1), Florida Statutes. The case was considered by Lisa Shearer Nelson, Administrative Law Judge.

APPEARANCES

For Petitioner: Francesca Plendl, Esquire
John M. Knight, Esquire
Florida Medical Association
123 South Adams Street
Tallahassee, Florida 32301

For Respondent: Reginald D. Dixon, Esquire
Assistant Attorney General
Office of the Attorney General
The Capitol, PL-01
Tallahassee, Florida 32399-1050

For Intervenors: Jeffrey M. Scott
123 South Adams Street
Tallahassee, Florida 32301

STATEMENT OF THE ISSUE

Whether proposed rule 64B16-27.830 of the Board of Pharmacy (Board) is an invalid exercise of delegated authority pursuant to Section 120.52(8), Florida Statutes?

PRELIMINARY STATEMENT

On August 14, 2006, the Florida Medical Association (FMA) filed a Petition to Determine the Invalidity of Proposed Rule, asserting that proposed rule 64B16-27.830 of the Florida Board of Pharmacy is an invalid exercise of delegated legislative authority. The FMA alleged that the Board has exceeded its grant of rulemaking authority; the proposed rule sections are arbitrary

and capricious; the proposed rule is not supported by competent, substantial evidence; and the Board's actions are not substantially justified, in that there is no reasonable basis in law or fact to support the promulgation of the proposed rule.

On August 16, 2006, Robert J. Cohen, Chief Judge of the Division of Administrative Hearings, determined that the petition challenging the proposed rule was in compliance with the requirements of Section 120.56(2), Florida Statutes, and assigned the case to Administrative Law Judge Lisa Shearer Nelson. On August 17, 2006, the matter was set for hearing September 15, 2006.

On August 24, 2006, Petitioner filed a Motion for Summary Final Order, alleging that the material facts were not in dispute. On August 29, 2006, a Petition to Intervene was filed on behalf of the Florida Academy of Family Physicians, Florida Academy of Pain Medicine, the Florida Association of Occupational and Environmental Medicine, Florida Chapter of the American College of Cardiology, Florida Chapter of the American College of Physicians, Florida Chapter of the American College of Surgeons, Florida Geriatrics Society, Florida Orthapaedic Society, Florida Osteopathic Medical Association, Florida Pediatric Society, Florida Psychiatric Society, Florida Pulmonary Society, Florida Society of Addiction Medicine, Florida Society of Anesthesiologists, Florida Society of Clinical Oncology, Florida Society of Dermatologic Surgeons, Florida Society of Facial Plastic and Reconstructive Surgery, Florida Society of

Interventional Pain Physicians, Florida Society of Nephrology, Florida Society of Neurology, Florida Society of Otolaryngology Head and Neck Surgery, Florida Society of Pathologists and the Florida Society of Physical Medicine and Rehabilitation. Respondent opposed both Motions. On August 31, 2006, an Order was entered denying the Motion for Summary Final Order and granting the Petition to Intervene, subject to proof of standing at final hearing.

The Board also moved to dismiss the Petition, asserting that the FMA did not have standing and that the Petition was not timely filed. After reviewing the response filed by Petitioner, the Motion was denied. With respect to the timeliness of the Petition, the undersigned advised the parties that the pleadings on file with the Division did not conclusively establish the timeline of activities contemplated by Sections 120.54 and 120.56, Florida Statutes, and that the Board was free to raise the issue of timeliness at the hearing.

On September 7, 2006, a second Petition to Intervene was filed, this time on behalf of the Florida Society of Thoracic and Cardiovascular Surgeons, Inc., Florida Gastroenterologic Society, Inc., Florida Neurosurgical Society, Inc., and Florida Society of Plastic Surgeons, Inc. A third Motion to Intervene was filed September 13, 2006, on behalf of the Florida Society of Rheumatology, Florida Society of Dermatology and Dermatologic Surgery, Florida Thoracic Society, Florida Society of Opthalmology and the Florida Obstetric and Gynecologic Society.

Despite the limited time before hearing, the Petitions were served by regular mail and did not indicate whether counsel for the Board of Pharmacy objected to either petition.

The FMA also filed a Motion for Leave to File Amended Petition on September 13, 2006. The Amended Petition added as grounds for challenge that the Board had failed to follow the applicable rulemaking procedures set forth in Chapter 120, Florida Statutes. A Joint Pre-hearing Statement was submitted on behalf of Petitioner and Respondent[1/] in which the parties stipulated to several factual matters that have been incorporated into the Findings of Fact listed below.

The hearing was conducted as scheduled September 15, 2006, and at that time the Second and Third Petitions to Intervene were granted, subject to the same conditions imposed upon the first set of Intervenors in terms of proof. All of those seeking to intervene will be referred to collectively as Intervenors. The Board stipulated to the facts alleged by each of the Intervenors regarding their membership and purpose, but did not stipulate that those facts constituted a sufficient basis to establish standing. The Board agreed, however, that if it was determined that the FMA had standing to challenge the proposed rule, then the Intervenors also had standing. Petitioner's Motion for Leave to File Amended Petition was granted, and the Amended Petition was further amended at page 6 to correct the text of the quotation from Section 465.003(13), Florida Statutes.

At hearing, the FMA presented the testimony of Louis St. Petery, M.D., John O'Brien, R.Ph., Pharm.D., M.P.H., and Lisette Gonzalez-Mariner. Petitioner's Exhibits 1 through 4 were admitted into evidence. The Board called one witness, Rebecca Poston, R.Ph., and Respondent's Exhibit 1 was admitted. Joint Exhibit 1 was also admitted. No witnesses or exhibits were submitted on behalf of the Intervenors.

A hearing transcript was prepared and filed with the Division on September 29, 2006. Pursuant to agreement of the parties, they were granted until October 16, 2006, to file proposed final orders. All submissions were timely filed, and these submissions have been considered in the preparation of the final order.

FINDINGS OF FACT

1. Respondent, Board of Pharmacy is the state entity charged with regulating the practice of pharmacy in the State of Florida pursuant to Section 20.43 and Chapters 456 and 465, Florida Statutes.

2. Petitioner, the FMA, is organized and maintained for the benefit of the approximately 16,000 licensed Florida physicians who comprise its membership. One of the primary purposes of the FMA is to act on behalf of its members by representing their common interests before various governmental entities in the State of Florida, including the Department of Health and its Boards.

3. Intervenors comprise 33 medical societies representing physicians licensed pursuant to Chapters 458 and 459, Florida Statutes. The membership totals for each of the Intervenors is listed in Petitioner's Exhibit 1. A primary purpose of each of the Intervenors is to act on behalf of its membership by representing their common interests before the various governmental entities of the State of Florida, including the Department of Health and its Boards.

The Proposed Rule

4. The text of the proposed rule is as follows:

> 64B16-27.830 Standards of Practice - Drug Therapy Management.
> (1) through (3) No change
> (4) A pharmacist may dispense a drug pursuant to a prescription where the practitioner indicates on the prescription "formulary compliance approval" either in the practitioner's own handwriting or preprinted with a box where the practitioner indicates approval by checking the box when:
> (a) The pharmacist receives a formulary change as a consequence of the patient's third party plan or Medicaid.
> (b) The product that the third party formulary designates as its preferred product is a therapeutic equivalent for the prescribed product. A therapeutic equivalent is a product that is in the same therapeutic class as the prescribed drug.
> (c) The pharmacist, within 24 hours of the formulary compliance substitution, shall provide to the practitioner either in writing or by facsimile a statement indicating that the pharmacist engaged in formulary compliance and the therapeutic equivalent that the pharmacist dispensed.
> (d) The pharmacist has complied with the requirements of Rule 64B16-27.530 with regard to the notification to the patient.
> The pharmacist may make adjustments in the quantity and directions to provide for an

equivalent dose of the preferred formulary therapeutic alternative.
(5)~~(4)~~ No change.
Specific authority 465.005, 465.0155 F.S.
Law implemented 465.003(13), 465.0155, 465.022(1)(b) F.S.

5. Section 465.005, Florida Statutes, listed as specific authority, provides the Board's general rulemaking authority.

6. Section 465.0155, Florida Statutes, listed as both specific authority and law implemented, directs the Board to adopt by rule standards of practice relating to the practice of pharmacy.

7. Section 465.003(13), Florida Statutes, listed as law implemented, defines the practice of pharmacy.

8. Section 465.022(1)(b), Florida Statutes, listed as law implemented, provides:

> (1) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter. Such rules shall include, but shall not be limited to, rules relating to:
> . . . .
> (b) Minimum standards for the physical facilities of pharmacies.

The Rulemaking Process

9. On October 22, 2004, in Volume 30, Number 43, Florida Administrative Weekly, the Board published its Notice of Development of Proposed Rule 64B16-27.830, entitled "Standards of Practice - Drug Therapy Management."

10. On October 29, 2004, the FMA requested a rule workshop.

11. On November, 19, 2004, in Volume 30, Number 47, Florida Administrative Weekly, the Board published a notice of a rule

workshop on the proposed rule to be held December 7, 2004, in Jacksonville, Florida.

12. On December 7, 2004, the Board held a rule workshop on the proposed rule.

13. On December 17, 2004, in Volume 30, Number 51, Florida Administrative Weekly, the Board published a notice of withdrawal of the proposed rule.

14. On April 29, 2005, in Volume 31, Number 17, Florida Administrative Weekly, the Board published the same rule language again, this time as a proposed rule.

15. On April 29, 2005, the FMA requested a rule hearing.

16. On May 12, 2005, Suzanne G. Printy, Chief Attorney for the Joint Administrative Procedures Committee (JAPC), sent to Ann Cocheu, Assistant Attorney General for the Board of Pharmacy, a letter indicating that she had "completed a review" of the rule and questioning the Board's authority to promulgate the rule.

17. On May 20, 2005, in Volume 31, Number 20, Florida Administrative Weekly, the Board published a notice of a rule hearing on the proposed rule to be held June 14, 2005, in Tampa, Florida.

18. On June 14, 2005, the rule hearing was held before the Board. At that time, several individuals spoke in opposition to the proposed rule. The Board voted to conduct a further public meeting with respect to the proposed language.

19. On July 14, 2005, F. Scott Boyd, Executive Director and General Counsel for JAPC sent to Ann Cocheu a letter advising her

of the deadlines applicable to the rulemaking process.

Specifically, Mr. Boyd's letter stated:

> According to our records, the above-styled rule was noticed in the Florida Administrative Weekly on April 29, 2005.
>
> Paragraph 120.54(3)(e), F.S., requires that rules be filed for adoption not more than 90 days from the date of the original notice unless specified circumstances prevail. The 90-day period for filing the rule expires on July 28, 2005.
>
> If you intend to adopt the rule, we remind you that paragraph 120.54(3)(d), F.S., requires that if the rule has not been changed since the rule was filed with the Committee, or if the rule contains only technical changes, you must file a notice to that effect with this Committee at least 7 days prior to filing the rule for adoption. If any change has been made in the rule, other than a technical change, you must publish a notice, and file a copy with the committee, at least 21 days prior to filing the rule for adoption.
>
> If the rule is not filed within 90 days, and if an exception is not applicable, you must notice withdrawal of the rule. Any further action to adopt the rule must comply with the rulemaking procedures of § 120.54, F.S. Please advise us of any exceptions which apply to the rule so that we may keep our records current.

20. On July 21, 2005, a paralegal from the Office of the Attorney General wrote to Suzanne Printy at JAPC and requested to "toll" the proposed rule. The July 21, 2005, letter advised that the Board had scheduled a review of the rule at a committee meeting to be held on August 15, 2005. While the July 21, 2005, letter refers to a copy of the meeting notice for August 15, 2006, no notice for the meeting is included in the record.

21. At no time did JAPC notify the Board that an objection to the proposed rule was being considered.

22. On August 15, 2005, the Board's Rules Committee met again to review the proposed rule. Minutes from the committee meeting reflect that the Rules Committee reviewed letters from the Florida Medical Association and the Chair of the Osteopathic Board of Medicine in opposition to the rule. These written materials, however, are not included in Respondent's Exhibit 1, which purports to be the Board's entire record with respect to the rulemaking proceedings for amendments to Rule 64B16-27.830. The Executive Director of the Board acknowledged receiving letters from Laurie Davies, M.D., Chair of the Board of Medicine and from the Coalition to Protect Health Care Access, representing several patient advocacy organizations expressing opposition to the proposed rule. These documents, likewise, are not in the Board's rulemaking record.

23. The minutes of the August 15, 2005, meeting indicate that the Committee voted to hold the rule until statutory authority was obtained to enact it. Ms. Poston, the Board's Executive Director, was to send a letter to the Attorney General's office asking for a formal opinion regarding the Board's statutory authority.

24. There is no indication in the record of any activity with respect to the proposed rule from August 15, 2005, until April 26, 2006, when Suzanne Printy wrote to Reginald Dixon,

Assistant Attorney General, regarding its status. Her letter states in part:

> On July 21, 2005, the Office of the Attorney General, Administrative Law Bureau, notified this office that the board was tolling the 90 day time limit for adoption of those amendments in order to accommodate review of the amendments by this Committee. That original 90 day time limit would have expired on July 28, 2005.
>
> As of this date, we have not received any proposed revisions or notices of change in response to my concerns. Please be aware that if I have not received a notice of change or a notice of additional public hearing on the amendments within the next two weeks, I will have to conclude that my review of the rule is complete. The tolling of the adoption will then come to an end, and the board will have 7 days within which to change, adopt or withdraw the amendments.

25. On May 19, 2006, in Volume 32, Number 20, Florida Administrative Weekly, the Board noticed an additional public meeting on the proposed rule to be held June 6, 2006, in Fort Lauderdale. A copy of the notice was provided to Suzanne Printy on May 11, 2006, one day after the two-week period set out in her letter of April 26, 2006, expired.

26. Nothing in the Notice of Public Hearing for the June 6, 2006, public hearing gives any indication that this will be the final public hearing related to proposed amendments to Rule 64B16-27.830.

27. On May 22, 2006, Suzanne Printy acknowledged receipt of the Notice of Public Hearing published May 19, 2006. In a letter addressed to Reginald Dixon, she stated:

> Please be advised that at the conclusion of the hearing, presumably June 6, 2006, the Board of Pharmacy will have 45 days from the conclusion of the hearing, or until July 21, 2006, within which to either publish a notice of change, publish another notice of public hearing, or to adopt the rules.

28. On June 6, 2006, the rule hearing was held. The Board did not publish a notice of change, publish another notice of public hearing or adopt the proposed rule by July 21, 2006. Nor did the Board publish any notice that would indicate the June 6, 2006, hearing was intended to be the last public hearing on the proposed rule. However, Rebecca Poston, Executive Director for the Board of Pharmacy, testified that the Board voted to "move forward" with the rule.

29. On July 20, 2006, Reginald Dixon advised Suzanne Printy of the Board's consideration of JAPC's concerns regarding the proposed amendments to Rule 64B16-27.830, and stated that the Board believed the amendment to the rule was authorized by the 1999 change to Section 465.003(15), adding "other pharmaceutical services" to the definition of the practice of the profession of pharmacy. Mr. Dixon stated that "The Board believes that this explanation addresses JAPC's concerns regarding the 64B16-27.830(4), F.A.C., and has voted to go forward with the promulgation of the rule."

30. On August 11, 2006, Ms. Printy again wrote to Mr. Dixon, reiterating JAPC's concerns about the rule:

> This rule authorizes pharmacists to dispense drugs from the same therapeutic class as the prescribed drug, pursuant to a prescription

> where the practitioner authorizes on the prescription "formulary compliance approval." Please explain whether a "therapeutic equivalent" of a prescribed drug which is in the same "therapeutic class" constitutes a generic equivalent. If a "therapeutic equivalent" of a prescribed medication does not constitute a general generic equivalent, please explain why changing the practitioner's prescription does not violate the following prohibition in s. 465.003(13), F.S.:
>
> However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law.

31. On August 14, 2006, the FMA filed its petition to challenge the proposed rule.

32. On August 30, 2006, Mr. Dixon wrote to Ms. Printy advising that a "therapeutic equivalent" is not a "generic" equivalent." He advised that the Board was relying on the "other pharmaceutical services" portion of Section 465.003(13) as authority for the proposed rule.

The Contents of the Rule

33. There is no generally accepted definition of "therapeutic equivalent" or "therapeutic class." The proposed rule simply states: "The product that the third party formulary designates as its preferred product is a therapeutic equivalent for the prescribed product. A therapeutic equivalent is a product that is in the same therapeutic class as the prescribed drug."

34. The Board of Pharmacy did not conduct any research or determine whether any studies existed that examined the safety, benefits or detriments of following the course of conduct permitted by the proposed rule. Likewise, no studies were conducted regarding the definition of "therapeutic equivalent."

35. A "generically equivalent drug product" is defined by statute as "a drug product with the same active ingredient, finished dosage form, and strength." § 465.025, Fla. Stat.

36. Section 465.025(6) allows the Boards of Pharmacy and Medicine to establish a formulary of generic drug type and brand name products which the boards determine "demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication." No pharmacist may substitute a generically equivalent drug product for a prescribed name brand product, if the brand name drug or generic drug is included in the formulary established by the Boards of Medicine and Pharmacy. § 465.025(6)(b), Fla. Stat. Thus, there are instances where even drugs having the same active ingredient, finished dosage form, and strength cannot be substituted for a brand name drug prescribed by a health care practitioner.

37. According to John O'Brien, The United States Food and Drug Administration defines "therapeutic equivalent" to mean drugs that contain the same active ingredients and route of administration and strength; and they are assigned by the FDA the same therapeutic equivalence codes starting with the letter "A."

There is no indication on the record presented that the Board's definition of therapeutic equivalent, i.e., a product in the same therapeutic class, is tied to or consistent with the Food and Drug Administration's use of that term.

38. Formularies differ based upon the third party entity developing the formulary. As a consequence, a drug may be designated as part of different therapeutic classes, depending on the persons making up the formulary. For example, the drug Digoxin is listed on the Capital Health Plan formulary as an anti-eurhythmic, while it is listed under Blue Cross Blue Shield's formulary as a cardiac glycoside. The drug can be used for both purposes.

39. Similarly, drugs with different side effects and contra-indications may be listed under the same class under a particular formulary. There is a group of blood pressure drugs known as angiotensin receptor blockers (ARBs). These drugs have a low side effect profile. There is another group of blood pressure medications called ACE inhibitors. These drugs have a higher side effect profile than ARBs. Under Florida's Medicaid formulary, ACE inhibitors and ARBs are both in the hypotensive category of drugs, as are beta blockers. Some studies suggest that beta-blockers may either mask the symptoms of or cause diabetes. Likewise, beta blockers should not be taken by patients who have asthma. It is possible, should the proposed rule be adopted, that a physician would prescribe a drug with the chemical make-up of an ARB and check the formulary compliance box

thinking only another ARB could be substituted. Florida's Medicaid formulary, however, would allow a pharmacist to substitute either an ACE inhibitor or a beta-blocker for the originally prescribed ARB. This substitution could have significant negative effects on patient care.

40. The proposed rule also removes any requirement the pharmacist currently has to speak to the prescribing physician before substituting a drug on the compliance formulary for the drug specified by the physician. Instead, the pharmacist need only notify the physician, in writing or by facsimile, within 24 hours after the substitution, that the pharmacist has engaged in formulary compliance and what "therapeutic equivalent" has been dispensed to the patient.

41. While pharmacies keep records regarding drugs already prescribed to patients, those records are limited to those medications dispensed by that pharmacy. They would not necessarily have access to patient records indicating problems with another drug. By the time the physician knows of a substitution made by a pharmacist, the patient may have already received, and used, a medication that is not consistent with that person's particular needs.

CONCLUSIONS OF LAW

42. The Division of Administrative Hearings has jurisdiction over the subject matter and the parties to this action in accordance with Sections 120.569 and 120.57(1), Florida Statutes.

43. The Amended Petition challenging the proposed rule states with particularity the objections to the proposed rule, the reasons why Petitioner believes the proposed rule to be an invalid exercise of legislative authority and why Petitioner believes that the Board failed to comply with the rulemaking requirements of Section 120.54, Florida Statutes.

44. Petitioner challenges the proposed rule in accordance with the definition of "invalid exercise of delegated legislative authority" in Section 120.52(8)(b), Florida Statutes (2006), which states:

> (8) "Invalid exercise of delegated legislative authority" means action which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:
>
> (a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;
>
> (b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;
>
> (c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation which is required by s. 120.54(3)(a)1.;
>
> (d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;
>
> (e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational; or

> (f) The rule imposes regulatory costs on the regulated person, county or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory directives.
>
> A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious and is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of any agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the same statute.

45. In a proceeding to challenge a proposed rule, the petitioner has the burden of going forward. The agency then has the burden to prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority as to the objection raised. § 120.56(2), Fla. Stat.; St. Johns River Water Management District v. Consolidated-Tomoka Land Co., 717 So. 2d 72 (Fla. 1st DCA 1998). The proposed rule is not presumed to be valid or invalid. § 120.56(2)(c), Fla. Stat.

Whether the Petition Was Timely Filed

46. Section 120.56(2)(a), Florida Statutes, provides the time frame for challenging a proposed rule:

> (a) Any substantially affected person may seek an administrative determination of the validity of any proposed rule by filing a petition seeking such a determination with the division within 21 days after the date of publication of the notice required by s. 120.54(3)(a), within 10 days after the final public hearing is held on the proposed rule as provided by s. 120.54(3)(c), within 20 days after the preparation of a statement of estimated regulatory costs required pursuant to s. 120.541, if applicable, or within 20 days after the date of publication of the notice required by s. 120.54(3)(d). . . .

47. There is no dispute that the FMA did not file its challenge within 21 days after the publication of the proposed rule, within 20 days after a statement of estimated regulatory costs (as none was prepared), or within 20 days of a notice of change (as none was ever filed).

48. The issue then becomes whether FMA filed its challenge within 10 days "after the final public hearing is held in the proposed rule." The record indicates that a public hearing was held June 6, 2006, and the FMA did not file its petition until August 14, 2006, over two months later. If the June 6, 2006, public hearing was the "final public hearing," then FMA's petition is untimely. If it is not the final public hearing, then FMA's petition is within the time limits allowed by Section 120.56.

49. In order to determine whether the June 6, 2006, public hearing was the "final public hearing," one must consider the notices provided by the Board, any vote taken at the Board's hearings, and the actions of the Board and its staff subsequent

to June 6, 2006. First, nothing in the notices regarding the public hearing indicates that the Board considered the June 6, 2006, hearing to be the final opportunity for public input on the proposed rule. Second, the vote taken by the Rules Committee was to "go forward" with the rule. This vote provides no real guidance, as "going forward" with the rule does not indicate whether the Board intended to direct staff to file the proposed rule for adoption or simply to proceed with the rulemaking process.

50. Finally, if the Board intended to direct the rule to be filed, its direction was not followed. If the June 6, 2006, public hearing was intended to be the "last public hearing," the deadline for filing the rule was July 21, 2006. See § 120.54(3)(e)2., Fla. Stat. The Board did not file the rule by that date and had not filed the rule by the time FMA filed its petition in this proceeding. In light of the Board's failure to file the rule within the statutory time frame, it must be concluded that the June 6, 2006, public hearing was not intended to be the "last public hearing" on the proposed rule. Under this circumstance, the FMA's petition was timely filed.

51. The FMA has also argued that the doctrine of equitable tolling would apply to in order to allow the late filing of its petition, citing Machules v. Department of Administration, 523 So. 2d 1132, 1134 (Fla. 1988). The doctrine of equitable tolling generally applies when a person has been misled or lulled into action, or has in some extraordinary way been prevented from

asserting his rights, or has timely asserted his rights but in the wrong forum.

52. The FMA was never prevented from asserting its rights. Neither did it assert its rights in the wrong forum. It relies on that part of the doctrine that excuses those who have been "lulled into inaction," claiming that it was the FMA's belief that due to the extremely long amount of time (13 months) that passed between the last advertisement of the rule and the final public hearing, the Respondent would be required to readvertise the proposed rule. Once it discovered that JAPC was not going to require the proposed rule to be readvertised, it filed the instant proceeding.

53. Under a normal rulemaking schedule, the Board would have been required to withdraw the rule or adopt it by July 2005. Clearly, it did neither. Whether the Board was justified in its inaction is discussed below. However, given that it did not and has not followed the required rulemaking schedule, the FMA was justified in believing that the Board was not finished with its rulemaking efforts. However, its petition is timely because there was nothing to indicate that the June 6, 2006, meeting was the final public hearing as opposed to one in a series of hearings. There is no reason to apply the doctrine of equitable tolling because the time frame for challenging the proposed rule had not yet run.

Whether FMA and The Intervenors Have Standing To Challenge The Proposed Rule

54. The Board has asserted that the FMA and the Intervenors do not have standing to challenge the validity of the proposed rule. The Board has agreed that should the FMA be found to have standing, then the Intervenors also have standing.

55. Standing to challenge a proposed rule is governed by Section 120.56(1)(a), Florida Statutes, which provides that "[a]ny person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority."

56. The Florida Supreme Court considered the issue of standing for associations in Florida Home Builders Association v. Department of Labor and Employment Security, 412 So. 2d 351 (Fla. 1982), when some or all of the association's members, as opposed to the association itself, is substantially affected by a proposed rule. The Court concluded that to meet the requirements of Section 120.56(1), Florida Statutes, an association must demonstrate that:

> substantial number of its members, although not necessarily a majority, are substantially affected by the proposed rule. Further, the subject matter of the rule must be within the association's general scope of interest and activity, and the relief requested must be of the type appropriate for a trade association to receive on behalf of its members.

412 So. 2d at 353-54. The Court reiterated this standard in NAACP, Inc. v. Florida Board of Regents, 863 So. 2d 294 (Fla.

2003), and stated that an association need not show an immediate and actual harm to demonstrate standing: rather, the required showing is that there would be a substantial effect of the rule change on a substantial number of the association's members.

57. In Florida Medical Association v. Department of Health, Board of Nursing, DOAH Case No. 99-5337RP (Final Order 2000), the FMA and several of the Intervenors now before the Division challenged a proposed rule of the Board of Nursing which would have allowed advanced registered nurse practitioners to prescribe controlled substances. The reasoning used to determine that the FMA and Intervenors had standing in that case is equally applicable here:

> 25. [B]oth Sections 464.003(3)(c) and 464.012(3), Florida Statutes (1999), recognize the role which physicians licensed in accordance with Chapters 458 and 459, Florida Statutes, play in the supervision of ARNPs in the framework of standing protocols where drugs are prescribed by the ARNPs. Unlike the optometrists in Board of Optometry [v. Society of Opthalmology, 538 So.2d 878 (Fla. 1st DCA 1989)], supra, ARNPs do not have exclusive authority in providing health care in the process of prescribing medications. The proposed rule contemplates a role by physicians which is both real and immediate. Physicians are affected by the proposed rule. That affect is substantial. The opportunity to participate or to decline participation with ARNPs in practices for prescribing controlled substances does not alter the fact that those physicians who would participate are substantially affected by the rule. For them the consequences of the proposed rule are not a matter of speculation or conjecture. By comparison to the physicians involved in ophthalmologic medicine described in Board of Optometry, supra, the physicians contemplated by the

> proposed rule have a vital role to play in the process wherein ARNPs are allowed to prescribe medications. . . .

58. Likewise, Section 465.003(13), along with other provisions in Chapter 465 recognize the role physicians play in the prescribing of medications. Proposed rule 64B16-27.830(4) contemplates a role by physicians that is real and immediate, and the affect on physicians is substantial. Moreover, regardless of whether an individual physician opts to decline default to the formulary medications as contemplated by the proposed rule, there is a very real possibility that patients for whom a physician prescribes medication will seek refills through a doctor on call and end up with a medication that does not comport with the original prescribing physician's intent for the care and wellbeing of that patient. Under these circumstances, both the FMA and the Intervenors have standing to challenge the proposed rule.

Whether The Board Complied With The Technical Requirements Of Section 120.54

59. The FMA asserts that the Board has not complied with the technical requirements of Section 120.54, Florida Statutes, in its effort to adopt the proposed rule. In its Amended Petition, the FMA asserts:

> 13. . . . In this case, the Proposed Rule was published in the Florida Administrative Weekly pursuant to 120.54(3)(e)2, Florida Statutes, on April 29, 2005. The 90-day period for filing the Proposed Rule for adoption ended on July 28, 2005. On May 20, 2005, the Board published a notice of a public hearing on the Proposed Rule in the

> Florida Administrative Weekly to be held June 14, 2005 in Tampa, Florida. As such, the period during which the Proposed Rule was required to be filed for adoption was extended to 45 days after adjournment of the final hearing on the rule, or until July 29, 2005. As of this date, this petition [sic] has not been filed for adoption. The Board, therefore, failed to file the Proposed Rule in accordance with the requirements of Section 120.54(3)(e), Florida Statutes, and must withdraw the proposed rule.
>
> Even assuming, for the sake of argument, that the public hearing held on June 6, 2006 served to extend the time for filing the Proposed Rule, the Board failed to file the Proposed Rule by the time required by Section 120.54(3)(e), Florida Statutes. The time for filing a proposed rule is extended only if the notice of a public hearing is published prior to the expiration of the time to file the rule for adoption. In this case, arguably, the time for filing the Proposed Rule for adoption expired in July 29, 2005. In order to avail itself of a further extension, the Board would have been required to file a notice of an additional public hearing on the Proposed Rule prior to July 29, 2005. The Board, therefore, failed to file the Proposed Rule in accordance with the requirements of Section 120.54(3)(e), Florida Statutes, and must withdraw the Rule.

60. In response, the Board argues that the deadline for filing the proposed rule for adoption was tolled and continues to be tolled pursuant to Section 120.54(3)(e)6., Florida Statutes. Relevant portions of Section 120.54(3)(e) state:

> 3. At the time a rule is filed, the agency shall certify that the time limitations prescribed by this paragraph have been complied with, that all statutory rulemaking requirements have been met, and that there is no administrative determination pending on the rule.

> 4. At the time a rule is filed, the committee shall certify whether the agency has responded in writing to all material and timely written comments or written inquiries made on behalf of the committee. The department shall reject any rule not filed with the prescribed time limits; that does not satisfy all statutory rulemaking requirements; upon which an agency has not responded in writing to all material and timely written inquiries or written comments; upon which an administrative determination is pending; or which does not include a statement of estimated regulatory costs, if required.
>
> 5. If a rule has not been adopted within the time limits imposed by this paragraph or has not been adopted in compliance with all statutory rulemaking requirements, the agency proposing the rule shall withdraw the rule and give notice of its action in the next available issue of the Florida Administrative Weekly.
>
> 6. The proposed rule shall be adopted on being filed with the Department of State and become effective 20 days after being filed, on a later date specified in the rule, or on a date required by statute. . . . If the committee notifies an agency that an objection to a rule is being considered, the agency may postpone the adoption of the rule to accommodate review of the rule by the committee. When an agency postpones adoption of a rule to accommodate review by the committee, the 90-day period for filing the rule is tolled until the committee notifies the agency that it has completed its review of the rule.

61. The request for "tolling" referred to in paragraph 20, however, is not sufficient to invoke the provisions of Section 120.54(e)(e)6. Tolling is only available in order to accommodate review of a proposed rule by the JAPC upon notice that an objection to a rule is being considered. It is not available to

accommodate additional review by the agency proposing the rule. While the Board received comments or written inquiries from JAPC staff, as envisioned by Section 120.54(3)(e)4., there is no indication that it received notice that JAPC was considering an objection to the rule. To the contrary, correspondence from JAPC's general counsel a week before the request to invoke the tolling provision simply reminded the Board of the deadlines for filing. No such reminder would have been applicable if JAPC was considering an objection.

62. It appears that JAPC's staff may have treated the proposed rule as if it were tolled, as is evident from Ms. Printy's letters of April 26, 2006, and May 22, 2006. However, there is simply no authority for doing so. In any event, it is clear that JAPC's position was that, as of May 22, 2006, the proposed rule was no longer tolled and that the Board had until July 21, 2006, to either publish a notice of change, publish another notice of public hearing, or to adopt the rule. The Board did none of these things.

63. Failure to follow the applicable rulemaking procedures or requirements set forth in Chapter 120 is presumed to be material. An agency may rebut this presumption by showing that the substantial interests of the petitioner and the fairness of the proceedings have not been impaired. § 120.56(1)(c), Fla. Stat.; Osterback v. Ogwunobi, 873 So. 2d 437, 442 (Fla. 3d DCA 2004).

64. Respondent argues that it conducted multiple hearings regarding the proposed rule amendments and that Petitioner and Intervenors availed themselves of the opportunity to participate in those hearings. It also notes that Petitioner has had the opportunity to challenge the rule via Section 120.56, Florida Statutes (although it has also argued that the rule challenge should be dismissed as untimely). Under these circumstances, the Board asserts that the asserted failure to abide by the 90-day time frame has not affected the substantial interests of Petitioner or Intervenors or the fairness of the proceedings.

65. Under the unique circumstances presented here, it cannot be said that the failure to abide by the statutory timeframe has affected the fairness of the proceedings. Because of the Board's decision to hold multiple public hearings and failure to notify the public when those public hearings would come to an end, Petitioner continued to have a window of opportunity to seek invalidation of the proposed rule. Neither Petitioner nor the Intervenors were deprived of the ability to voice their concerns regarding the proposed rule, either through the public hearings or through this proceeding.

66. However, the Board cannot overcome the presumption that the failure to meet statutory requirements is material in this case. Subsections 120.54(3)(e) 3. and 4., require the agency to certify that the time limitations in the statute have been met and that the agency has responded to all material and timely written comments or inquiries made on behalf of JAPC. In this

case, no such certification can be made. Moreover, Subsection 120.54(3)(e)5. mandates that if a rule has not been adopted within the statutorily imposed time limits and or has not been adopted in compliance with all rulemaking requirements, the agency proposing the rule shall withdraw the rule. To allow the proposed rule to be adopted in light of this mandate is simply not permitted. Therefore, it is found that the Board has failed to follow applicable rulemaking procedures in violation of Section 120.52(8)(a), Florida Statutes.

Whether The Proposed Rule Exceeds The Board's Grant Of Rulemaking Authority

66. Section 120.52(8)(b), Florida Statutes, provides that a proposed or existing rule is an invalid exercise of legislative authority if the agency has exceeded its grant of rulemaking authority.

67. The Board relied on Sections 465.005 and 465.0155, Florida Statutes, as its statutory authority for adopting the proposed rule amendments. Section 465.005, Florida Statutes, sets forth the Board's general grant of rulemaking authority, which, by definition, is not enough to support adoption. See § 120.52(8), Fla. Stat.

68. Section 465.0065, which the Board listed as both specific authority and the law implemented, provides:

> Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies when enforcing or implementing any authority

> granted by any applicable statute, rule, or regulation, whether federal or state.

In order for a rule to be within the scope of this grant of authority, it must be "consistent with the provisions of this act." Moreover, inasmuch as the grant of rulemaking authority directs the Board to establish standards of practice relating to the practice of pharmacy, such rules must conform to the definition of the practice of pharmacy provided by the Legislature. In this case, the proposed rule is not consistent with the legislative definition.

69. The Board asserts that the definition of the practice of pharmacy was amended in 1999 to include "other pharmaceutical services," and that the proposed rule amendment fits within those services. The 1999 amendment, however, must be read as a whole. It provided:

> (13)~~(12)~~ "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; ~~and~~ consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the

> patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" ~~The phrase~~ also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any breach of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients.

§ 118, Ch. 99-397, Laws of Fla.

70. Substituting one drug for another is not monitoring or reviewing a patient's drug therapy; is not assisting the patient in managing drug therapy; and is not communicating with the patient's health care provider. Likewise, making adjustments in the quantity and directions originally prescribed is not monitoring or reviewing a patient's drug therapy; is not assisting a patient in managing drug therapy; and is not communicating with a health care provider. Even if the actions permitted by the proposed rule could be characterized as assisting the patient in managing his or her drug therapy, it runs afoul of the specific prohibition in the definition of the practice of pharmacy contained in Section 465.005(13), as amended in Chapter 99-397. The same amendment that includes "other pharmaceutical services" expressly limits the definition of the practice of pharmacy to prohibit any alteration of a prescriber's

directions. Given this express limitation by the Legislature, the Board's proposed rule exceeds the Board's grant of rulemaking authority.

Whether The Proposed Rule Is Arbitrary And Capricious

71. Section 120.52(8)(e), Florida Statutes, provides that a rule is arbitrary if it is not supported by logic or the necessary facts, and a rule is capricious if it is adopted without thought or reason or is irrational. Compare Agrico Chemical Co. v. Department of Environmental Regulation, 365 So. 2d 759 (Fla. 1st DCA 1979).

72. The proposed rule at issue is arbitrary and capricious in that the Board neither conducted nor reviewed any studies or treatises and received no evidence to support the definition of therapeutic equivalent in the proposed rule, and likewise reviewed no studies as to the safety or benefits/detriments of having a pharmacist substitute a drug for one prescribed by the physician. In addition, the proposed rule is arbitrary in that it provides no definition for the term "therapeutic class."

73. Moreover, the proposed rule places the pharmacists' choices for substitution not in the hands of the Legislature, or a regulatory board or group of boards, as is the case for generic drugs pursuant to Section 465.025 or for pharmacists' order and dispensing of certain drugs pursuant to 465.186, Florida Statutes. It places the development of formularies, at least in part, in the hands of third party providers who have no

obligation to subject their choices to the rigors of rulemaking or public debate.

74. Petitioner has also alleged that the proposed rule is not supported by competent, substantial evidence. In 2003, the Legislature amended Section 120.52(8), so as to eliminate the former subsection (f) and, in the same chapter law, amended to clarify that hearings held with respect to challenges to an existing or proposed agency rule "shall be de novo in nature" and that the "standard of proof shall be the preponderance of the evidence." §§ 1, 3, Ch. 2003-94, Laws of Fla. See Department of Health v. Merritt, 919 So. 2d 561 (Fla. 1st DCA 2006). Inasmuch as the legislature has deleted this ground as a basis for challenge pursuant to Section 120.52(8), the undersigned has not addressed this issue.

75. Finally, Petitioner has requested attorney's fees and costs pursuant to Section 120.595(2), Florida Statutes, which provides:

> If the court or administrative law judge declares a proposed rule or portion of a proposed rule invalid pursuant to s. 120.56(2), a judgment or order shall be rendered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that its actions were substantially justified or special circumstances exist which would make the award unjust.

76. Petitioner is entitled to an award of reasonable fees and costs "unless the agency demonstrates that its actions were substantially justified or special circumstances exists which would make the award unjust." If the parties are unable to agree

upon the amount of reasonable costs and fees, or if the Board disputes Petitioner's legal entitlement based upon the statutory defenses of "substantial justification" and/or special circumstances," then Petitioner shall file a motion seeking an award of fees and costs (with supporting documentation), and an evidentiary hearing will be held.

Upon consideration of the facts found and conclusions of law reached, it is

ORDERED:

1. Proposed rule 64B16-27.830(4) is an invalid exercise of delegated legislative authority.

2. Jurisdiction is retained for the limited purpose of considering Petitioner's motion for an award of reasonable attorney's fees and costs pursuant to Section 120.595(2), Florida Statutes, if filed.

DONE AND ORDERED this 1st day of November, 2006, in Tallahassee, Leon County, Florida.

S

LISA SHEARER NELSON
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Filed with the Clerk of the
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this 1st day of November, 2006.

ENDNOTE

[1/] There is no indication that counsel for the Intervenors participated in the preparation of the Joint Pre-Hearing Statement.

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original notice of appeal with the Clerk of the Division of Administrative Hearings and a copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.