

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

AMERICAN BOARD OF CHELATION)
THERAPY,)
)
Petitioner,)
)
vs.) Case No. 96-4963RX
)
BOARD OF MEDICINE,)
)
Respondent.)
_____)

FINAL ORDER

Pursuant to notice, an administrative hearing was held before William A. Buzzett, an Administrative Law Judge with the Division of Administrative Hearings, on November 15, 1996, in Tallahassee, Leon County, Florida.

APPEARANCES

For Petitioner: Gregory D. Seeley, Esquire
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For Respondent: Allen R. Grossman, Esquire
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STATEMENT OF ISSUES

Whether Respondent's Rule 59R-11.001, Florida Administrative Code, is an invalid exercise of delegated legislative authority.

PRELIMINARY STATEMENT

This cause arose on July 17, 1995, when Petitioner, the American Board of Chelation Therapy (ABCT) submitted its petition to the Florida Board of Medicine (Board of Medicine) to be

certified as a "Recognizing Agency" within the requirements of Rule 59R-11.001, Florida's Advertising Rule. In October 1995, the Board of Medicine considered the issue and referred the Petition to its Rules Committee. In March 1996, the Rules Committee recommended that the petition be denied. On April 15, 1996, the Board of Medicine issued an order denying the petition, citing that ABCT failed to establish compliance with the requirements for approval as set forth in Rule 59R-11.001(2)(f), Florida Administrative Code.

On May 17, 1996, ABCT filed a Petition for formal hearing. This cause was later assigned to the undersigned administrative law judge for adjudication. An initial order was issued on July 12, 1996, and the parties filed a Joint Response to the order within the 10-day deadline. Subsequently, a Motion for Continuance of the Hearing was filed and granted. ABCT then filed a Petition Seeking Administrative Determination of the Validity of Rule 59R-11.001(2)(f), Florida Administrative Code, as an invalid exercise of delegated legislative authority. On October 21, 1996, the undersigned issued an Order of Consolidation, and the matter was set for hearing on November 15, 1996, in Tallahassee, Florida.

At the hearing, ABCT designated Dr. Arthur Koch as its representative. The Board of Medicine designated Dr. Marm Harris, the Executive Director of the Board of Medicine, as its representative. ABCT called two witnesses: Dr. Arthur Koch and Dr. Marm Harris and submitted three exhibits.¹ The Board of Medicine cross-examined Dr. Koch, produced one witness, Dr. Marm

Harris, and offered four exhibits that were admitted without objection.²

The parties elected to transcribe the proceedings. At the hearing, the parties requested the right to file proposed findings of fact and conclusions of law in the form of Proposed Final Orders. The parties, however, waived the statutory time requirement for rule challenges by requesting that such proposals be filed on January 31, 1997. The proposed final orders were received, reviewed, and considered by the undersigned.

FINDINGS OF FACT

1. Chelation therapy is the introduction of a man-made amino acid into a patient's vein. It has been approved by the U.S. Food and Drug Administration and is used for the treatment of heavy metal toxicity and the removal of lead.

2. American Board of Chelation Therapy (ABCT) is an autonomous organization that provides education and certification to any physician who wishes to become knowledgeable in Chelation therapy. ABCT was established in 1982 for the purpose of establishing the criteria necessary for certification in the area of Chelation therapy.

3. The Board of Medicine is a statutory entity, established by Chapter 458, Florida Statutes, as the primary regulatory authority for the practice of allopathic medicine in the State of Florida.

4. Pursuant to section 458.301, Florida Statutes, the legislature recognizes that the practice of medicine is potentially dangerous to the public if conducted by unsafe and

incompetent practitioners. The section further provides that the primary legislative purpose in enacting the medical practices act is to "ensure that every physician practicing in this state meets minimum requirements for safe practice."

5. In keeping with the legislative mandate to ensure that purpose of the medical practices act, the legislature created the Board of Medicine and authorized the Board to create administrative rules for the purpose of implementing chapter 458.

6. Rule 59R-11.001, Florida Administrative Code, is the advertising rule of the Board of Medicine.³ The rule codifies provisions of section 458.331(1)(d), Florida Statutes, and provides criteria for identifying false, deceptive, or misleading advertising.

7. In particular, the rule governs advertising on physician letterhead and limits the use of the term "specialist" unless the specialty is recognized by (1) a specialty board of the American Board of Medical Specialties (ABMS) or (2) a board that meets the requirements of Rule 59R-11.001, Florida Administrative Code. For those specialties recognized by organizations that do not meet the requirements of the rule, the physicians may still advertise their specialty so long as they provide a disclaimer. By rule the disclaimer must state the following "The Specialty recognition identified herein has been received from a private organization not affiliated with or recognized by the Florida Board of Medicine."

8. ABMS is generally recognized in the United States as the agency that approves allopathic medical specialty boards and the

Board of Medicine has historically relied upon ABMS and its standards and, as reflected in the current rule, continues to rely on ABMS and its standards for approving recognizing agencies.

9. On July 17, 1995, the Petitioner, ABCT submitted an application to Florida Board of Medicine for the purpose of being certified as a "recognizing agency" pursuant to rule 59R-11.001.

10. ABCT is not a specialty board of the ABMS.

11. Because ABCT is not a member board of the ABMS, the Board of Medicine looked to the requirements of rule 59R-11.001(2)(f) to determine whether ABCT met the criteria enunciated in the rule and whether it is therefore a "recognizing agency" capable of bestowing specialty status on a physician.

12. Rule 59R-11.001(2)(f), Florida Administrative Code, provides that non-ABMS Boards may seek recognition as "recognizing agencies" if they meet the following criteria:

1. The recognizing agency must be an independent body that certifies members as having advanced qualifications in a particular allopathic medical specialty through peer review demonstrations of competence in the specialty being recognized.

2. Specialty recognition must require completion of an allopathic medical residency program approved by either the Accreditation Council of Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada that includes substantial and identifiable training in the allopathic specialty being recognized.

3. Specialty recognition must require successful completion of a comprehensive examination administered by the recognizing agency pursuant to written procedures that

ensure adequate security and appropriate grading standards.

4. The recognizing agency, if it is not an ABMS board, must require as part of its certification requirement that each member receiving certification be currently certified by a specialty board of the ABMS.

5. The recognizing agency must have been determined by the Internal Revenue Service of the United States to be a legitimate not for profit entity pursuant to Section 501 (c) of the Internal Revenue Code.

6. The recognizing agency must have full time administrative staff, housed in dedicated office space which is appropriate for the agency's program and sufficient for responding to consumer or regulatory inquiries.

7. The recognizing agency must have written by-laws, and a code of ethics to guide the practice of its members and an internal review and control process including budgetary practices, to ensure effective utilization of resources. However, a physician may indicate the service offered and may state that practice is limited to one or more types of services when this is in fact the case;

13. On April 15, 1996, the Board of Medicine issued an order denying the ABCT's application for specialty status. As basis for the denial, the order stated that the application of the ABCT failed to establish compliance with the requirements for approval as set forth in Rule 59R-11.001(2)(f), Florida Administrative Code.

14. Specifically, the order stated:

The requirements for diplomat status in ABCT do not require advanced qualifications in a particular allopathic medicine specialty; specialty recognition given by ABCT does not require completion of an allopathic medical residency program approved by the ACGME or

the Royal College of Physicians and Surgeons of Canada that include substantial and identifiable training in the allopathic specialty being recognized; specialty recognition provided by the ABCT does not require successful completion of a comprehensive examination pursuant to written procedures that ensure adequate security and appropriate grading standards in that ABCT requires only a score of 60% to pass the examination, the examination consists of true false questions and answers, and the examination is not a medically comprehensive examination; ABCT is not an ABMS board and does not require that each member it certifies be currently certified by an ABMS board; and ABCT has not provided evidence that it is a legitimate not-for-profit entity pursuant to Section 501(c) of the Internal Revenue Code as determined by the Internal Revenue Service.

15. Each of the requirements of rule 59R-11.001(2)(f) were addressed at the administrative hearing.

16. With regard to criteria (1) of rule 59R-11.001(2)(f), advanced qualifications in a particular allopathic medical specialty through peer review, the ABCT does not require an advanced qualification in a particular allopathic medical specialty. Furthermore, ABCT admitted that it does not meet the requirement of rule 59R-11.001(2)(f)(1).

17. Criteria (2) of rule 59R-11.001(2)(f) provides that the specialty recognition must require completion of an allopathic medical residency program approved by either the Accreditation Council of Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada.

18. The ACGME is generally recognized as the organization that sets criteria for graduate medical education in the United States. The Board of Medicine has incorporated that recognition

in the rule by requiring that the advanced education component of the rule be ACGME approved.

19. The Royal College of Physicians and Surgeons of Canada is ACGME's counterpart in Canada.

20. With regard to criteria (2) of rule 59R-11.001(2)(f), ABCT does not require completion of an allopathic residency program approved by either the ACGME or the Royal College of Physicians and Surgeons of Canada. In fact, ABCT has no requirement for a residency program. ABCT reasoned that there is no need for a residency program for Chelation therapists because Chelation therapy does not require overnight hospital stay. The only requirement remotely relating to residency is an ABCT requirement that applicants for diplomat status administer a minimum of 1000 Chelation treatments. There is no requirement that these treatments be supervised and no requirement for verification that the minimum number of treatments were administered.

21. With regard to criteria (3) of rule 59R-11.001(2)(f), requiring successful completion of a comprehensive examination, ABCT does not require all applicants for diplomat status to complete a written examination in order to obtain certification.

Specifically, some candidates are grandfathered in without being required to complete the written examination.

22. For those applicants that are required to submit to an examination, Dr. Arthur L. Koch testified that the examination is composed of approximately sixty percent true/false questions. In addition, Dr. Koch testified that another ten percent of the test

is not medically oriented but rather addresses the history and politics of Chelation therapy in the United States.

23. At the hearing, ABCT submitted its Spring 1994 examination as an exhibit. That examination contained a majority true/false questions and a few multiple choice questions.

24. To pass the ABCT diplomat examination, the candidate is required to achieve a score of 62.5 percent. In contrast, the Board of Medicine generally requires a passing score of at least 75%.

25. The Board of Medicine expressed concern about the low passing score accepted by ABCT on its certification examination.

The Board of Medicine also expressed concern over the large number of true/false questions used in the example examination submitted by ABCT. Uncontroverted testimony was presented at the hearing to support a finding that an examination consisting of a majority of true/false questions is not a viable method of testing knowledge.

26. With regard to criteria (4) of rule 59R-11.001(2)(f), requiring members of non-ABMS boards to also be certified by a specialty board of the ABMS, the ABCT does not require that each physician seeking diplomat status be currently certified by an ABMS specialty board. Furthermore, ABCT admitted that it does not meet the requirement of rule 59R-11.001(2)(f)(4).

27. With regard to criteria (5) of rule 59R-11.001(2)(f), that the recognizing agency must be a legitimate not for profit entity under the Internal Revenue Code, evidence was presented to verify that ABCT is a non-profit, tax-exempt organization.

28. With regard to criteria (6) of rule 59R-11.001(2)(f), requiring the recognizing agency to have full-time administrative staff sufficient to respond to consumer or regulatory inquiries, no evidence was presented at the hearing relating to this criteria.

29. With regard to criteria (7) of rule 59R-11.001(2)(f), requiring the recognizing agency to have written by-laws and a code of ethics to guide the practice of its members, ABCT submitted its Constitution and Bylaws as adopted in March of 1982 and subsequently amended. The Constitution and bylaws, however, did not include a written code of ethics and therefore did not fully comply with the requirements of the rule.

CONCLUSIONS OF LAW

30. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. Section 120.57(1), Florida Statutes. The parties were duly noticed of the formal hearing.

31. ABCT initiated these proceedings under section 120.57(1), Florida Statutes, requesting a formal hearing to review a preliminary order of the Board of Medicine that provided the Board of Medicine's intent to deny ABCT's application for approval as a "recognizing agency" pursuant to Rule 59R-11.001, Florida Administrative Code. (Case No. 96-3173).

32. Subsequently, ABCT filed a petition pursuant to section 120.56, Florida Statutes, to determine the invalidity of rule 59R-11.001(2)(f). (Case No. 96-4963RX).

33. While Case No. 96-4963RX and Case No. 96-3173 were consolidated for the purposes of the hearing, a separate recommended order determining that the Respondent properly denied the Petitioner's request to be a "recognizing agency" was rendered in Case No. 96-3173.

34. Section 120.56(1), Florida Statutes, provides affected persons may seek an administrative determination of the invalidity of a rule on the ground that the rule is an invalid exercise of delegated legislative authority.

35. ABCT's petition challenging the validity of rule 59R-11.001(2)(f) asserts that: (1) the rule violates the Sherman Anti-trust Act, (2) the rule is an improper delegation of legislative authority, (3) the rule violates the Fourteenth Amendment, and (4) the rule violates the First Amendment. The scope of this order, however, is limited to the "improper delegation" allegations as authorized in section 120.56(1), Florida Statutes. See Cook v. Florida Parole and Probation Commission, 415 So.2d 845 (Fla. 1st DCA 1982); Metropolitan Dade County v. Department of Commerce, 365 So.2d 432 (Fla. 3d DCA 1978).

36. Section 120.52(8) defines "an invalid exercise of delegated legislative authority" as an action which goes beyond the powers, functions, and duties delegated by the legislature. A proposed or existing rule is an invalid exercise of delegated authority if any one or more of the following apply:

(b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(7);

(c) The rule enlarges, modifies, or contravenes the specific provisions of the law implemented, citation to which is required by s. 120.54(7);

(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.

37. The challenger's burden to demonstrate an invalid exercise of delegated legislative authority is "is a stringent one indeed." Agrico Chemical Co. v. State Dept. of Env'tl. Regulation, 365 So.2d 759 (1st DCA 1978), cert. denied, 376 So.2d 74 (Fla. 1979).

38. Specifically, ABCT bears the burden of demonstrating that (1) the agency adopting the rule has exceeded its authority; (2) the requirements of the rule are not appropriate to the ends specified in the legislative act; (3) the requirements contained in the rule are not reasonably related to the purpose of the enabling legislation but are arbitrary and capricious, or (4) the rule is otherwise an invalid exercise of delegated legislative authority within the meaning of section 120.58(8), Florida Statutes. Cortes v. State Board of Regents, 655 So.2d 132 (Fla. 1st DCA 1995), citing, Department of Administration, Div. Of Retirement v. Albanese, 445 So.2d 639 (Fla. 1st DCA 1984).

39. The legislature may authorize administrative agencies to interpret, but never alter, statutes. The precise rule of decision for determining whether an administrative rule crosses the line dividing statutory implementation from statutory abrogation is not always clear. Cortes, 655 So.2d at 136.

40. While executive branch agencies cannot usurp legislative prerogatives, "rule making authority may be implied to the extent necessary to properly implement a statute governing the agency's statutory duties and responsibilities."

41. Section 458.309, Florida Statutes, explicitly conveys on the Board of Medicine rulemaking authority and provides that "[t]he board is authorized to make such rules not inconsistent with law as may be necessary to carry out the duties and authority conferred upon the board by this chapter and as may be necessary to protect the health, safety, and welfare of the public."

42. The health, safety, and welfare of the public is the underlying purpose of the Medical Practice Act as codified in Chapter 458, Florida Statutes. Section 458.301 specifically provides that:

[t]he Legislature recognizes that the practice of medicine is potentially dangerous to the public if conducted by unsafe and incompetent practitioners. The Legislature finds further that it is difficult for the public to make an informed choice when selecting a physician and the consequences of a wrong decision could seriously harm the public health and safety. The primary legislative purpose in enacting this chapter is to ensure that every physician practicing in this state meets minimum requirements for safe practice.

43. Pursuant to section 458.309, the Board of Medicine promulgated Rule 59R-11.001, Florida Administrative Code, regulating the advertising practices of physicians. The purpose of the rule is to permit the dissemination of information

regarding the practice of medicine and where and by whom medical services may be obtained.

44. The challenged rule appears to directly support the legislative purpose of making it easier for the "public to make an informed choice when selecting a physician." The qualifications and certification requirements go directly to the heart of protecting the public and providing information for an important decision. Pursuant to the legislative intent, the rule attempts to provide the public with information regarding a physician's advanced training so that such qualifications can be considered prior to making a choice of a physician.

45. Petitioners urge that the instant rule violates law in that it prohibits the dissemination of truthful information regarding lawful activity. The evidence at the hearing, coupled with a clear reading of the rule in question, however, reveals that ABCT's concerns are misplaced. The rule does not contain a prohibition against a physician who is a member of a non-ABMS Board as long as the recognizing agency (non-ABMS Board) meets the established criteria.

46. Petitioners complained that the Board of Medicine's reliance on ABMS and its standards is inappropriate. This assertion is not supported by the record. The Board of Medicine has, by its rule, defined what constitutes false, deceptive, or misleading advertisement. In fact, the record is clear that ABMS is generally recognized in the United States as the entity that approves allopathic specialty boards. The Petitioner provided no evidence to support a finding that the Board of Medicine's

reliance on ABMS is misplaced or that ABMS is not qualified to approve specialty boards. The Board's reliance on ABMS is consistent with the legislative intent enunciated in section 458.301, Florida Statutes.

47. Petitioners complained regarding the requirement that specialty recognition must require completion of an allopathic medical residency program approved by either the Accreditation Council of Graduate Medical Examiners (ACGME) or the Royal College of Physicians of Canada. ABCT presented no evidence that the Board of Medicine's reliance on the ACGME or the Royal College of Physicians of Canada was misplaced. In contrast, the Board provided overwhelming support that the ACGME and the Royal College of Physicians of Canada are the organizations that set criteria for graduate medical education in the United States.

48. Petitioners complained that the rule is vague because it fails to establish standards for agency decisions and because it vests unbridled discretion in the agency. To the contrary, the specific portion of the rules under challenge are specific rather than vague. The rule clearly defines as misleading advertising that states or implies that the physician has received specialty recognition unless (1) such physician has received recognition from the ABMS or a recognizing agency approved by the Board of Medicine or (2) includes a specific disclaimer that the specialty is not recognized by the Board of Medicine. It appears that no discretion is left to the Board of Medicine which is not clearly defined in the rule.

49. Petitioners complained that the challenged rule is

invalid because it is arbitrary and capricious. It is well established that a rule is arbitrary only if it is not supported by fact or logic, and capricious only if it is enacted without thought or reason. Conversely, if an administrative decision is justifiable under any analysis that a reasonable person would use to reach a decision of similar importance, it is neither arbitrary nor capricious. Dravo Basic Chemicals Co. v. State, 602 So.2d 632 (Fla. 2d DCA 1992). In the instant case, the Board of Medicine enacted rules pursuant to statute for the purpose of protecting the health, safety, and welfare of the public. The Board of Medicine also recognized that while an allopathic physician's accurate representation of specialty recognition may be neither false nor deceptive, it may be misleading in that such representation carries with it the additional weight of advanced qualification and achievement. If such recognition is from an agency, the standards of which do not meet those of the Board of Medicine, and they are offered to the public without a disclaimer, it is reasonable to believe that the public may be misled. Therefore, the Board's rule is supported by logic and fact and based on Dravo, is proper and appropriate.

50. In summary, based on the tests enunciated above, the Petitioner failed to meet its burden to demonstrate an invalid exercise of legislative authority within the meaning of section 120.52(8), Florida Statutes.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that the Petition to declare Rule 59R-11.001(2)(f), Florida Administrative Code, invalid is hereby denied.

DONE and ENTERED this 5th day of June, 1997, at Tallahassee, Florida.

WILLIAM A. BUZZETT
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 5th day of June, 1997.

ENDNOTES

¹ Petition to be certified by the Florida Board of Medicine as a recognizing Agency; American Board of Chelation Written Exam for Spring 1994; and IRS letter dated January 10, 1985, regarding tax exemption status.

² ABMS handbook; Copy of Rule 59R-11; Copy of Final Order in Feldman v. Board of Medicine; and Copy of Order of Intent to Deny.

³ Prior to its amendment in 1995, this rule had been challenged based, in part, on the rule's reliance and recognition of the ABMS and its standard. The challenge was resolved in favor of the rules validity finding that the reliance and recognition of the ABMS was consistent with the legislative intent to protect the public. (See Feldman v. Board of Medicine, 16 FALR 2272 (1994)).

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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 one copy of a notice of appeal with the Clerk of the Division of Administrative Hearings and a second 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.