IN THE COURT OF APPEALS OF THE STATE OF NEW MEXICO

NEW MEXICO BOARD OF PHARMACY
and NEW MEXICO MEDICAL BOARD,
Appellants,
v.
NEW MEXICO BOARD OF CHIROPRACTIC
EXAMINERS,
Appellee,

and

INTERNATIONAL CHIROPRACTORS
ASSOCIATION,
Appellant,
v.
NEW MEXICO BOARD OF CHIROPRACTIC
EXAMINERS,
Appellee.

No. 31,668
No. 31,690
[CONSOLIDATED
under Ct. App.
31,690

Oral Argument Requested

Direct Appeal from Rulemaking by
Appellee New Mexico Board of Chiropractic Examiners

BRIEF IN CHIEF OF APPELLANT, INTERNATIONAL CHIROPRACTORS ASSOCIATION

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TABLE OF CONTENTS

Table of Authorities ..... ii-iii

Statement of the Case 1

Argument 3

I. The Chiropractic Board's Adoption of Its 2011 Formulary Is Contrary to Statute 3

a. The Plain Language of the Chiropractic Physician Act Shows that Pharmacy and Medical Board Approvals Are Required 4

b. Other Related Statutes Show that Pharmacy and Medical Board Approvals Are Required 7

II. The Chiropractic Board's Adoption of Its 2011 Formulary Is in Violation of Its Own Rules 12

a. Chiropractic Board Rules Require Pharmacy and Medical Board Approval for Expansion of the Formulary 12

b. Chiropractic Board Rules Require Medical Board Approval for Training Programs to Certify Advanced Practice Chiropractic Physicians 14

c. The Training Prescribed by the Chiropractic Board Fails to Meet Statutory and Board Requirements 15

III. The Chiropractic Board Must Fulfill Its Statutory Mandate and Act to Protect the Health and Well-Being of the Citizens of the State 16

Conclusion 17

Statement Regarding Oral Argument 17

TABLE OF AUTHORITIES

Cases

Attorney General v. New Mexico Public Regulation Commission, 2011-NMSC-034 ..... 3, 4, 7-8

General Telephone Co. of the SW v. Corporation Commission, 98 N.M. 749, 652 P.2d 1200 (1982) 12

Jicarilla Apache Nation v. Rodarte, 2004–NMSC–035, 136 N.M. 630, 103 P.3d 554 (2004) 6-7

Morningstar Water Users Ass'n v. New Mexico Public Utility Commission, 120 N.M. 579, 904 P.2d 28 (1995) 4

Statutes

NMSA 1978 §26-1-2 ..... 8, 9, 10, 11

NMSA 1978 §§30-31-6 to 30-31-10 10

NMSA 1978 § 61-1-31(C) 3

NMSA 1978 § 61-4-1 4

NMSA 1978 § 61-4-2 ..... 4, 7

NMSA 1978 § 61-4-3.G 16

NMSA 1978 § 61-4-9.1(D) 14, 15

NMSA 1978 § 61-4-9.2 ..... 5, 6, 10, 11, 12

Regulations

16.4.15.7 NMAC 13, 14

16.4.15.8 NMAC 12, 13, 15

16.4.15.10 NMAC 14

16.4.15.11 NMAC 1, 2, 3,

16.4.15.12 NMAC 1, 2, 3, 15, 16

STATEMENT OF THE CASE

This is a consolidated appeal by Appellant International Chiropractors Associations ("ICA"), and Appellants New Mexico Board of Pharmacy ("Pharmacy Board") and New Mexico Medical Board ("Medical Board"), to set aside 16.4.15.11 and 16.4.15.12 NMAC, adopted by Appellee New Mexico Board of Chiropractic Examiner ("Chiropractic Board"). The issue before the Court is whether 16.4.15.11 and 16.4.15.12 were adopted contrary to law.

The newly adopted 16.4.15.11 NMAC (CHIRO0035-0036) expands the chiropractic formulary to include certain dangerous drugs and drugs to be administered by injection. NMSA 1978, § 61-4-9.2 (B) expressly provides that "[d]angerous drugs or controlled substances, drugs for administration by injection and substances not listed in Subsection A... *shall be submitted to the board of pharmacy and the New Mexico medical board for approval*" (emphasis added). The Chiropractic Board adopted 16.4.15.11 without approval from the Pharmacy Board and Medical Board.

The newly adopted 16.4.15.12 NMAC (CHIRO0036-0037) prescribes training to certify advanced practice doctors of chiropractic. 16.4.15.7(D) NMAC expressly provides that "[a]ny educational institution allowed to provide clinical and didactic programs credited toward advanced practice certification must have *concurrent approval* from the New Mexico medical board and the New Mexico

board of chiropractic examiners" (emphasis added). The Chiropractic Board adopted 16.4.15.12 without approval from the Medical Board.

To be effective September 11, 2009, the Chiropractic Board had adopted a rule establishing an advanced practice chiropractic formulary. On September 9, 2009, the Pharmacy Board appealed the 2009 formulary rule in this Court. On September 24, 2009, the Pharmacy Board withdrew its appeal after a series of meetings of a joint committee composed of representatives of the Pharmacy Board and the Chiropractic Board, with participation by the Medical Board. The Chiropractic Board repealed and replaced the 2009 formulary with a new formulary of substances approved by the Pharmacy Board, to be effective July 23, 2010. On June 14, 2010, the Chiropractic Board once again voted to include in the formulary certain drugs to be administered by injection that the Pharmacy Board had not approved (CHIRO0126-0130). At its rule hearing on August 30, 2011, the Chiropractic Board adopted 16.4.15.11 to include in the chiropractic formulary those dangerous drugs and drugs to be administered by injection, and 16.4.15.12 NMAC to prescribe training requirements for advanced practice chiropractic physicians, notwithstanding express objections from ICA (CHIRO0066-0072) and the Medical Board (CHIRO0042-0046).

On November 3, 2011, the Medical Board and the Pharmacy Board filed an appeal (No. 31,668) in this Court. On December 12, 2011, ICA filed its own

appeal (No. 31,690) in this Court. At its December 13, 2011 board meeting, the Chiropractic Board denied an oral motion for stay presented on behalf of ICA, the Pharmacy Board, and the Medical Board. This Court subsequently granted ICA's motion for stay and motion to consolidate.

On February 27, 2012, ICA, the Pharmacy Board, and the Medical Board attended mediation with the Chiropractic Board. The mediation reached an impasse.

ARGUMENT

The Court should set aside 16.4.15.11 NMAC and 16.4.15.12 NMAC on the basis that both rules were adopted contrary to law and to the Chiropractic Board's own rules. This Court must set aside an administrative rule if it is: (1) arbitrary, capricious, or an abuse of discretion; (2) contrary to law; or (3) against the clear weight of substantial evidence in the record. NMSA 1978 § 61-1-31(C).

Standard of Review: This appeal involves statutory construction – a question of law, which is reviewed de novo. *Attorney General v. New Mexico Public Regulation Commission,* 2011-NMSC-034 at ¶¶ 9, 10.

Preservation of Issue: The issues were preserved by Appellants' timely filing of their respective Notices of Appeal.

I. The Chiropractic Board's Adoption of Its 2011 Formulary Is Contrary to Statute

The Chiropractic Board's authority to act is defined by, and therefore limited

to, the statutory authority expressly granted to it by the New Mexico legislature. *Morningstar Water Users Ass'n v. New Mexico Public Utility Comm'n*, 120 N.M. 579, 583, 904 P.2d 28, 32 (1995), (*citing*, *New Mexico Elec. Serv. Co. v. New Mexico Pub. Serv. Comm'n*, 81 N.M. 683, 684-85, 472 P.2d 648, 649-50 (1970)).

a. The Plain Language of the Chiropractic Physician Act Shows that Pharmacy and Medical Board Approvals Are Required

The guiding principle in interpreting statutes is to determine and give effect to legislative intent, looking first to the plain language of the statute, giving the words their ordinary meaning unless the Legislature indicates a different one was intended. *Attorney General v. New Mexico Public Regulation Commission,* 2011-NMSC-034 at ¶ 10. Here, two key provisions of the Chiropractic Physician Practice Act, NMSA 1978 § 61-4-1 *et seq*. (the "Act") plainly describe the authority of the Chiropractic Board and identify the activities authorized for the practice of certified advanced practice chiropractic physicians ("CAPCP")[1].

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[1] The term "certified advanced practice chiropractic physician" means "a chiropractic physician who has been included in the advanced practice chiropractic certification registry." NMSA 1978 § 61-4-2.B.

The term "advance practice chiropractic certification registry" means "a compendium kept by the board that meets and maintains the board's established credentials for certified advanced practice chiropractic physicians." NMSA 1978 § 61-4-2.A. The credentials or qualifications necessary for listing in the registry are subject to review and update by the Chiropractic Board.

The first is NMSA 1978 §61-4-9.2.A, which provides that a CAPCP may prescribe, administer and dispense a number of substances specifically listed in this provision. Although substances are specifically identified and listed in this statutory provision, the term "substances" is not a statutorily defined term in either the Act or other statutes providing authority for the Pharmacy or Medical Boards.

The second key provision is NMSA 1978 §61-4-9.2.B. Three sentences in this provision provide different authority to the Chiropractic Board:

1. The Chiropractic Board shall develop and approve a formulary that includes all substances listed in Subsection A, including compounded preparations for topical and oral administration. This provision prescribes that the formulary developed by the Chiropractic Board must contain the specific substances listed in §61-4-9.2.A.

2. The Chiropractic Board shall develop and approve a formulary for injection that includes the substances in subsection "A" that are within the scope of practice of the CAPCP. This provision prescribes that the formulary for injection of substances listed in subsection "A," as well as any other substances identified for injection, must be within the properly authorized scope of chiropractic practice of a CAPCP.

3. To the extent the formulary contains (i) dangerous drugs or controlled substances, (ii) drugs[2] for administration by injection, and (iii) substances not listed in subsection A, the proposed formulary *shall be* submitted to the Pharmacy and Medical Boards for approval. This provision prescribes that to the extent the chiropractic formulary contains any "substances" that also constitute a "dangerous drug," or are a "controlled substance," or are a "drug" for administration by injection, or includes "substances" not already listed in §61-4-9.2.A, the formulary must be submitted to the Pharmacy and Medical Boards for their approval.

The key to the grant of authority under this statute is that while the Chiropractic Board is authorized to develop a formulary for injection of the "substances" listed in subsection A, if such "substances," by their nature or their manner of administration, are also dangerous drugs, controlled substances, or drugs for administration by injection, or not already listed in subsection A, a formulary that includes these "substances" must be approved by the Pharmacy and Medical Boards.

There is no conflict between the second and third sentences of this section of the statute. The legislature is presumed to know specific provisions it was enacting and courts must interpret each provision of the statute in manner that gives meaning to each provision. *See Jicarilla Apache Nation v. Rodarte*, 2004–NMSC–

[2] Underlined terms are defined in other statutes.

035, ¶ 15, 136 N.M. 630, 103 P.3d 554. Therefore, these two sentences must be read in the manner that the statutorily defined terms of "dangerous drugs," "controlled substances," and "drugs" for administration by injection are subsets of the broader, undefined term of "substances."

Furthermore, the Act's definition of "chiropractic" supports Appellant's position that the Chiropractic Board may not unilaterally expand the formulary to include dangerous drugs, controlled substances, or drugs for administration by injection. Although the Act defines "Chiropractic" to include, but is not limited to, administering a drug by injection by a CAPCP, the term "Chiropractic" excludes the prescription or use of controlled or dangerous drugs. *See* NMSA 1978 §61-4-2.C.

Therefore, the plain statutory language indicates that the legislature intended Pharmacy and Medical Board approval for any (i) dangerous drugs or controlled substances, (ii) drugs for administration by injection, and (iii) substances not listed in Subsection A that the Chiropractic Board places in its formulary.

b. Other Related Statutes Show that Pharmacy and Medical Board Approvals Are Required

When construing statutes related to the same subject matter, statutes must be read together with other statutes *in pari materia* under the presumption that the Legislature acted with full knowledge of relevant existing statutes. *Attorney General v. New Mexico Public Regulation Commission,* 2011-NMSC-034 at ¶ 10.

Statutory definitions in Act utilize and rely upon the defined terms of other statutory provisions, especially those related to authority of the New Mexico Pharmacy and Medical Boards. One must read and interpret specific terms of Act given meaning of defined terms from other pertinent statutory provisions. *See id.*

The Drug, Device and Cosmetic Act ("DDCA"), NMSA 1978 §26-1-2.E, provides the definition for the term "drug," which includes articles that:

1. Are recognized in an official compendium.
2. Are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, and the biological products applicable to humans regulated under federal law.
3. Affect the structure of any function of the human body, other than food.
4. Are intended for use as a component of paragraphs (1), (2) or (3) of this subsection, but does not include devices or their component parts or accessories.

NMSA 1978 §26-1-2.F defines "dangerous drugs" to mean a drug, other than a controlled substance enumerated in Schedule I of the Controlled Substances Act, that because of a potentiality for harmful effect or *the method of its use* or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug. A drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer

or prescribe the drug if it:

1. Is a habit forming drug and contains any quantity of a narcotic or hypnotic substance or a chemical derivative of such substance that has been found under the federal act and the Pharmacy Board to be habit forming;
2. Because of its toxicity or other potential for harmful effect or *the method if its use* or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioners licensed by law to administer or prescribe the drug;
3. Is limited by an approved application by Section 505 of the Federal Food Drug & Cosmetic Act;
4. Bears the legend: "Caution: federal law prohibits dispensing without prescription;"
5. [Restriction dealing with drugs used by veterinarians]; or
6. Bears the legend: "RX only."

NMSA 1978 §26-1-2.I defines "prescription" as an order given individually for the person for whom prescribed, either directly from a licensed practitioner or the practitioner's agent to the pharmacist, or by means of written order signed by the prescriber, and bearing the name and quantity of the drug prescribed, directions for use and the date of issue, among other things.

NMSA 1978 §26-1-2.J defines "practitioner" to include a CAPCP, pharmacist, pharmacist clinician, [among others] licensed or certified to prescribe and administer drugs that are subject to the DDCA.

NMSA 1978 §26-1-2.L defines "official compendium" to mean the official U.S. pharmacopoeia national formulary or the official homeopathic pharmacopoeia of the U.S. or any supplement to either of them.

NMSA 1978 §26-1-2.D defines "controlled substance" as a drug, "substance" or immediate precursor enumerated in Scheduled I through V of the Controlled Substances Act [NMSA 1978 §§30-31-6 to 30-31-10], ("CSA").

In examining the plain language of the statutes, the Court must conclude the following:

1. Unless approved by the Pharmacy and Medical Boards, "substances" listed in §61-4-9.2.A are "substances" only as long as they are not injected, and can be prescribed and administered by CAPCPs for topical or oral administration only.

2. "Substances" listed in §61-4-9.2.A become a "drug" under §26-1-2.E when they are used to cure, mitigate, treat or prevent a disease, or affect the structure or any function of the human body, or are intended as a component of any "drug" prescribed by an CAPCP, medical doctor or other licensed "practitioner."

3. "Substances" listed in §61-4-9.2.A that are intended to be injected become a "dangerous drug" under §26-1-2.F because injection of these

"substances" creates the potentiality for harmful effects because the method of use, i.e., administration by injection, is not safe except under the supervision of a CAPCP licensed to direct the use of such "drug."

Different methods of injection require approval by the Medical Board, depending upon the injection method to be used. Levels of potential harm to the patient vary depending upon the method of injection used.

No formulary providing for the injection of any "drug," including "substances" listed in §62-4-9.2.A, is authorized unless approved by the Medical Board, and only after a CAPCP receives training/education program approved by the Medical Board.

4. "Dangerous drugs" shall be dispensed, under §26-1-2.F, *only upon the "prescription"* of a CAPCP licensed to administer or prescribe the "drug" if the method of its use, i.e., injection of the "drug," is not safe except under the supervision of an CAPCP licensed to administer or prescribe the "drug."

In effect, any "drug" requiring a "prescription" is subject to the review of the Pharmacy and Medical Boards and must be approved by them. This then necessarily means any educational/training requirements for a CAPCP to administer such "prescription drugs" must be approved by the Medical Board.

5. The Chiropractic Board's adoption of 2011 chiropractic formulary is contrary to law because absent formal and express approval by the Pharmacy and

Medical Boards, including approval of the training and education requirements for CAPCPs to administer drugs by injection or other dangerous drugs, any chiropractic formulary adopted by the Chiropractic Board and issued to CAPCPs for their use in New Mexico that contains "substances" that are also a "dangerous drug," or a "controlled substance," or a "drug" for administration by injection, or "substances" not already listed in §61-4-9.2.A, is unlawful.

II. The Chiropractic Board's Adoption of Its 2011 Formulary Was in Violation of Its Own Rules

The Chiropractic Board must follow its statutory mandate and its own rules when acting in its capacity as a rulemaking body in developing and adopting a chiropractic formulary. *General Telephone Co. of SW*, 98 N.M. 749, 755, 652 P.2d 1200, 1206 (1982), (administrative agency is bound by and limited to its existing rules and regulations and proper application of the law).

a. Chiropractic Board Rules Require Pharmacy and Medical Board Approval for Expansion of the Formulary

The Chiropractic Board's own rules specify that all amendments to the formulary shall be made *following consensus* of Medical and Pharmacy Boards and the Chiropractic Board.

Specifically, 16.4.15.8(H) NMAC expressly provides in part that "[a]ll amendments to the formulary shall be made following *consensus* of the NM board of medicine, NM pharmacy board and the NM board of chiropractic examiners"

(emphasis added). 16.4.15.8(A) NMAC provides in part that an advanced practice chiropractic physician is "allowed prescription authority that is limited to the current formulary as agreed on by the New Mexico board of chiropractic examiners *and as by statute, by the New Mexico board of pharmacy and the New Mexico medical board*" (emphasis added).

Furthermore, 16.4.15.7(E) NMAC defines "chiropractic formulary" as "those substances that have been approved for use by the chiropractor registered in advanced practice by the chiropractic board *and as by statute with consensus between the New Mexico medical board and New Mexico board of pharmacy*" (emphasis added).

Read individually and read together, 16.4.15.7(E) and 16.4.15.8(A), (H) all provide that any expansion of the chiropractic formulary must be made by consensus of all three boards.

Here, the Chiropractic Board adopted the formulary notwithstanding express opposition by the Medical Board and Pharmacy Board. The Pharmacy Board, in a June 2, 2011 letter to the Chiropractic Board (CHIRO0083-0086), identified specific substances under the Medical Board's jurisdiction in the expanded formulary that had not been approved by the Medical Board, and stated that the Pharmacy Board would therefore withhold its approval. Furthermore, the Medical Board, in an August 12, 2011 letter to the Chiropractic Board (CHIRO000042-

0046), stated that it had voted unanimously not to approve the proposed formulary changes. The reasons cited by the Medical Board include the following: certain new drugs in the formulary have been disapproved by the Pharmacy Board; and certain drugs in the formulary to be administered by injection have been disapproved by the Pharmacy Board, and several are not within the scope of chiropractic practice (CHIRO0042).

b. Chiropractic Board Rules Require Medical Board Approval for Training Programs to Certify Advanced Practice Chiropractic Physicians

The Chiropractic Board's own regulations require the Medical Board to approve the institutions of higher learning to provide the additional training necessary under the new formulary. *See* §61-4-9.1(D) and 16.4.15.10(c) NMAC.

Specifically, 16.4.15.7(D) NMAC expressly provides that "[a]ny educational institution allowed to provide clinical and didactic programs credited toward advanced practice certification must have *concurrent approval* from the New Mexico medical board and the New Mexico board of chiropractic examiners" (emphasis added).

NMSA 1978, § 61-4-9.1(D) expressly provides that an advanced practice chiropractic physician must have "completed a minimum of ninety clinical and didactic contact course hours … from an institution of higher education approved by the board [of chiropractic examiners] *and the New Mexico medical board*"

(emphasis added).

Furthermore, 16.4.15.8(B)(2) NMAC provides that chiropractic physicians applying for registry must submit to the Chiropractic Board "documentation that the chiropractic physician has successfully completed 90 clinical and didactic hours of education provided by an institution *approved by the New Mexico medical board* and the New Mexico board of chiropractic examiners" (emphasis added).

Here, the Chiropractic Board adopted 16.4.15.12 notwithstanding the Medical Board's express objection. In its August 12, 2011 letter to the Chiropractic Board, the Medical Board stated that "[t]he hours of training specified in 16.4.15.12 do not appear to the Medical Board to be sufficient... Therefore, the Medical Board will continue to disapprove all injectables until adequate training is proposed and agreed to by the NMMB..." (CHIRO0043).

c. The Training Prescribed by the Chiropractic Board Fails to Meet Statutory and Board Requirements

Furthermore, the training prescribed in 16.4.15.12 falls short of the ninety clinical and didactic hours required by NMSA § 61-4-9.1(D) and 16.4.15.8(B)(2) NMAC. The newly adopted 16.4.15.12(B) allows advanced practice chiropractic physicians to administer vitamins and/or minerals by IV administration after completion of only ten hours of training in IV therapy. 16.4.15.12(C) allows advanced practice chiropractic physicians to administer certain substances by injection after completion of only twenty-five hours in the relevant training.

16.4.15.12(D) allows advanced practice chiropractic physicians to administer EDTA by injection after completion of only ten hours of training in IV therapy and fifteen hours of training in chelation therapy.

III. The Chiropractic Board Must Fulfill Its Statutory Mandate and Act To Protect the Health and Well-Being of the Citizens of the State

The primary purpose sought by ICA's appeal is to ensure the Chiropractic Board fulfills its statutory obligation to act for the purpose of protecting the health and well-being of the citizens of this State. The Chiropractic Board fulfills this obligation when it acts pursuant to and consistent with statutory provisions and its duly adopted rules and regulations. NMSA 1978 § 61-4-3.G provides that the Chiropractic Board must establish regulations and mandatory continuing education requirements for chiropractic physicians and CAPCPs for the purpose of protecting the health and well-being of the citizens of the Sate and for maintaining and continuing informed professional knowledge and awareness of licensed chiropractic physicians and CAPCPs.

The Pharmacy and Medical Boards must also follow their own rules for review and approval of the revisions to the formulary as proposed by the Chiropractic Board, and each Board must formally act to approve the amended chiropractic formulary and the Medical Board must approved the education and training programs, as well as the institutions of higher learning at which such training must occur. Absent each Board formally acting to approve the

chiropractic formulary in a manner prescribed by statute and pursuant to their own rules, the 2011 chiropractic formulary and any subsequently proposed chiropractic formulary will be unlawful.

Chiropractic Board's adoption of its 2011 chiropractic formulary in violation of law and its own rules and regulations resulted in unnecessary risk to health and safety of patients of chiropractic physicians and CAPCPs in this State.

CONCLUSION

For the foregoing reasons, ICA respectfully requests that the Court set aside16.4.15.11 and 16.4.15.12 NMAC.

STATEMENT REGARDING ORAL ARGUMENT

Appellant requests oral argument. Oral argument would be helpful to resolution of issues because it may assist the Court in understanding the facts, analyzing the authorities, and evaluating the arguments of the parties.

Dated: July 19, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and accurate copy of the foregoing BRIEF IN CHIEF OF APPELLANT, INTERNATIONAL CHIROPRACTORS ASSOCIATION was served via first class mail, on the 19th day of July, 2012, upon Counsel for Appellee at the following address:

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