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. 31,690
[CONSOLIDATED with No. 31,690]

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

BRIEF IN CHIEF

Gary K. King
New Mexico Attorney General
Mary H. Smith
Assistant Attorney General
111 Lomas Blvd NW Ste 300
Albuquerque NM 87102
(505) 222-9000; FAX (505) 222-9006
msmith@nmag.gov

For New Mexico Board of Pharmacy

Daniel R. Rubin
Special Assistant Attorney General
New Mexico Medical Board
2055 S Pacheco, Bldg 400
Santa Fe NM 87505
(505) 476-7233; FAX (505) 476-7237
dan.rubin@state.nm.us

For New Mexico Medical Board

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STATEMENT REGARDING CITATION FORM

Appellee New Mexico Board of Chiropractic Examiners' August 30, 2011 rulemaking hearing record and transcript are marked and cited as "CHIRO," with any preceding zeroes omitted.

SUMMARY OF PROCEEDINGS

A. NATURE OF THE CASE

Appellants New Mexico Board of Pharmacy and New Mexico Medical Board challenge as contrary to law Appellee New Mexico Board of Chiropractic Examiners' adoption of an administrative rule amending a chiropractic formulary at 16.4.15.11 NMAC. This administrative rule was filed with the New Mexico State Records Center and Archives on October 14, 2011, with an effective date of November 14, 2011. Appellants no longer challenge the formulary-related education rule at 16.4.15.12 NMAC, as preserved in the Docketing Statement.

The Court has jurisdiction pursuant to NMSA 1978, Section 61-1-31(A) (any person affected by an administrative rule may appeal to the court of appeals for relief).

B. COURSE OF PROCEEDINGS

On July 29, 2011, Appellee issued formal notice to the public and interested parties of its August 30, 2011 rulemaking hearing at which it would, among other

things, consider amendments to its chiropractic formulary ("Formulary"), 16.4.15.11 NMAC, and adoption of a new rule establishing additional education requirements related to this Formulary, 16.4.15.12 NMAC. [CHIRO 1-2, 7-10]. Appellee made these proposed rules available to the public and to interested parties, including both Appellants. [CHIRO 33-37].

Appellee did not formally submit the proposed Formulary to either Appellant for their respective review and approval prior to the rulemaking hearing. However, both Appellants provided written comments and/or oral testimony regarding the Formulary at the August 30, 2011 rulemaking hearing. [CHIRO 42-46 (Medical Board letter); CHIRO 239-241 (Medical Board testimony); CHIRO 83-86 (Board of Pharmacy letter)].

Over the specific objections of both Appellants, Appellee adopted a Formulary on August 30, 2011. [CHIRO 406-431].

C. DISPOSITION BELOW

At a public meeting following the conclusion of its August 30, 2011 rulemaking hearing, Appellee New Mexico Board of Chiropractic Examiners: (1) amended its administrative rule, 16.4.15.11 NMAC, establishing a Formulary that includes minerals and a number of additional drugs to be administered by injection, and (2) adopted a new administrative rule prescribing additional

education to be approved by the Medical Board, 16.4.15.12 NMAC. [CHIRO 406-452].

On October 14, 2011, Appellee filed these two administrative rules with the State Records Center and Archives, with an effective date of November 14, 2011.

In accordance with Section 61-1-31(A) and within thirty days after Appellee's filing of its rules, Appellants timely appealed by filing their notice of appeal with the Court on November 3, 2011.

Appellee denied all Appellants' oral motions to stay 16.4.15.11 and 16.4.15.12 NMAC. Following a hearing on Appellant ICA's Motion for Stay, this Court granted a stay of Appellee's two administrative rules on February 27, 2012.

D. SUMMARY OF FACTS RELEVANT TO ISSUES PRESENTED FOR REVIEW

Appellee is statutorily charged with developing and approving an advanced practice chiropractic formulary that (1) includes all substances listed in Section 61-4-9.2(A), including "compounded preparations for topical and oral administration," and (2) includes "for injection the substances in [Section 61-4-9.2(A)]." NMSA 1978, Section 61-4-9.2(B) (2009). This statute further mandates that Appellee submit for approval by both Appellants — the Board of Pharmacy and the Medical Board — "[d]angerous drugs or controlled substances, drugs for

administration by injection and substances not listed in Subsection A" that will be included in this Formulary. Id.

On August 30, 2011, Appellee conducted a rulemaking hearing pursuant to the Uniform Licensing Act, NMSA 1978, Section 61-1-29, to consider amendments to its 2010 Formulary that included both substances specifically listed in Section 61-4-9.2(A) and certain other substances described in Section 61-4-9.2(B). 16.4.15.11 NMAC. [CHIRO 207-363]. Appellee also considered a new rule prescribing additional education to be approved by Appellant Medical Board for an advanced practice chiropractic physician wishing to prescribe and administer certain substances listed in the Formulary. 16.4.15.12 NMAC. [CHIRO 207-363].

At its August 30, 2011 meeting immediately following the rulemaking hearing, Appellee deleted from the proposed Formulary several substances that had not been approved by either Appellant, considered Appellants' stated objections to the proposed Formulary, and adopted the Formulary, 16.4.15.11 NMAC, as amended. [CHIRO 406-431]. Appellee then discussed the proposed additional education requirements, 16.4.15.12 NMAC, increased the required hours for IV therapy and prolotherapy programs, and adopted this rule as amended. [CHIRO 431-452]. The meeting minutes, transcribed by a court

reporter, reflect these discussions and amendments, and show Appellee's votes on the two amended rules. [CHIRO 406-456].

The current appeal involves Appellee's third approval of an advanced practice chiropractic Formulary. Appellee adopted a new administrative rule establishing a formulary with an effective date of September 11, 2009. [CHIRO 131-133, 164-183]. Appellant Board of Pharmacy appealed that rule adoption to this Court (No. 29,809); an Agreement to Voluntary Dismissal was filed on September 24, 2010. Appellee and the Board of Pharmacy then created a joint formulary committee, which has not met since the spring of 2010, to discuss the Formulary and, on October 19, 2009, the Board of Pharmacy approved a number of substances to be included and delineated their specific route of administration. [CHIRO 83-86]. A year later, despite objections from Appellants to including any "drugs for administration by injection" until those were approved by both Appellants, Appellee repealed and replaced the 2009 Formulary with a Formulary with an effective date of July 23, 2010. [CHIRO 125-130].

As with its 2009 and 2010 Formularies, this third time, Appellee adopted a Formulary to which both Appellants expressed their objections and opposition, most specifically the inclusion of all the proposed new "drugs for administration by injection" that have not been approved in advance by both Appellants.

[CHIRO 42-46, 83-86, 125-130].

Consolidated Appellant International Chiropractors Association ("ICA") filed its appeal of Appellee's rulemaking on November 14, 2011. This Court consolidated the ICA appeal with that of the Board of Pharmacy and the Medical Board on January 31, 2012.

On December 23, 2011, Appellee denied all Appellants' oral motions to stay 16.4.15.11 and 16.4.15.12 NMAC. However, following a hearing on Appellant ICA's Motion for Stay, this Court granted a stay of Appellee's two administrative rules on February 27, 2012.

All three Appellants and Appellee participated in mediation on February 27, 2012, but were unable to resolve the issues raised in this consolidated appeal.

INTRODUCTION TO ARGUMENT

Appellee acted contrary to its own law, the Chiropractic Physician Practice Act, NMSA 1978, Sections 61-4-1 through -17 (1968, as amended through 2009), when it adopted a Formulary that includes "[d]angerous drugs or controlled substances, drugs for administration by injection and substances not listed in [Section 61-4-9.2(A)]" without first submitting this proposed Formulary "to the board of pharmacy and the New Mexico medical board for approval." Section 61-4-9.2(B). Both Appellants submitted written comments and/or provided oral

testimony at Appellee's August 30, 2011 rulemaking hearing that clearly stated their specific objections to, and specifically disapproving, the proposed Formulary. Appellee nonetheless adopted a Formulary — without the statutorily-required Board of Pharmacy and Medical Board approval — that included a number of "dangerous drugs," "drugs for administration by injection" and "substances not listed in [Section 61-4-9.2(A)]." Consequently, Appellee's actions violate the plain language of Section 61-4-9.2(B), are thus contrary to law and must be reversed.

The Board of Pharmacy and Medical Board jointly assert the positions in both Point I and Point II below. To the extent that the arguments herein differ from the issues presented in the Docketing Statement, the Medical Board hereby disavows its endorsement of the latter. Consolidated Appellant International Chiropractors Association will file a separate brief in chief.

ARGUMENT

Standard of Review

This Court reviews Appellee's rulemaking to determine if it is (1) arbitrary, capricious or an abuse of discretion; (2) contrary to law; or (3) against the clear weight of substantial evidence of the record. See § 61-1-31(C) (1981).

This case necessarily implicates this Court's review of the statute governing

adoption of a Formulary, and the "meaning of language used in [this] statute is a question of law that [this Court] review[s] de novo." New Mexico Real Estate Comm'n v. Barger, No. 31,262, slip op. at 4, ¶ 7, (N.M. Ct. App. July 2, 2012), citing Bishop v. Evangelical Good Samaritan Soc'y, 2009-NMSC-036, ¶ 8, 146 N.M. 473, 212 P.3d 361.

I. THE FORMULARY ADOPTED BY APPELLEE IS CONTRARY TO LAW, SPECIFICALLY SECTION 61-4-9.2(B), BECAUSE APPELLEE FAILED TO OBTAIN BOTH APPELLANTS' PRIOR APPROVAL OF ALL DRUGS INCLUDED IN THAT FORMULARY

The issue in this appeal is the legality of the Formulary promulgated by Appellee at 16.4.15.11 NMAC, and whether Appellee has adopted its 2011 Formulary in accordance with both the Chiropractic Physician Practice Act and its related administrative rules. As a preliminary matter, the parties agree that such a Formulary is defined as "those substances that have been approved for use by the chiropractor registered in advanced practice by [Appellee] and as by statute with consensus between [both Appellants]." 16.4.15.7(E) NMAC (emphasis added). Despite the words in Appellee's own administrative rule, the parties dispute whether the Formulary requires such consensus "by statute," i.e. Section 61-4-9.2(B) (2008, as amended through 2009).

Providing additional insight, another of Appellee's administrative rules

states that an advanced practice chiropractor 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.

16.4.15.8(A) NMAC (emphasis added). This rule then states that "All 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." 16.4.15.8(H) (emphasis added).

Section 61-4-9.2, entitled "Certified advanced practice chiropractic physician authority defined," dictates when Appellee must obtain such consensus with both Appellants. It states as follows:

> A. A certified advanced practice chiropractic physician may prescribe, administer and dispense herbal medicines, homeopathic medicines, over-the-counter drugs, vitamins, minerals, enzymes, glandular products, protomorphogens, live cell products, gerovital, amino acids, dietary supplements, foods for special dietary use, bioidentical hormones, sterile water, sterile saline, sarapin or its generic, caffeine, procaine, oxygen, epinephrine and vapocoolants.
>
> B. A formulary that includes all substances listed in Subsection A of this section, including compounded preparations for topical and oral administration, shall be developed and approved by the board. A formulary for injection that includes the substances in Subsection A of this section that are within the scope of practice of the certified advanced practice chiropractic physician shall be developed and approved by the board. Dangerous drugs or controlled substances, drugs for administration by injection and substances not listed in Subsection A of this section shall be submitted to the board

of pharmacy and the New Mexico medical board for approval.

Section 61-4-9.2.

The two paragraphs of this section need to be read together. Subsection A grants chiropractic physicians professional discretion to "prescribe, administer and dispense" certain substances, subject to regulatory oversight solely by Appellee. Subsection B then explicitly states what is implicit in Subsection A, namely, that a formulary for substances not listed in Subsection A is subject to the approval of both Appellants. More specifically, Subsection B specifically identifies those substances that require such approval as "[d]angerous drugs or controlled substances, drugs for administration by injection and substances not listed in Subsection A." Section 61-4-9.2(B). As discussed below, these substances in Subsection B are substances that require a prescription for their use.

A. Any Chiropractic Formulary That Includes a Dangerous Drug or Controlled Substance, a Drug for Administration by Injection, or Any Substance Not Listed in Section 61-4-9.2(A) Must Be Approved by Both Appellants

Appellants believe that Appellee has not acted in accordance with its laws and administrative rules, and thus argue that Appellee has instead acted contrary to law. As discussed below, interpreting the statutory framework that parses the respective jurisdictions of Appellee and each Appellant to approve a Formulary

requires this Court to read, with each other, both subsections of Section 61-4-9.2, Section 61-4-2, Section 61-4-9.1, and the New Mexico Drug, Device and Cosmetic Act, NMSA 1978, Sections 26-1-1 through -26 (1967, as amended through 2011). See Town & Country Food Stores, Inc. v. New Mexico Regulation and Licensing Dept., 2012-NMCA-046, ¶ 9, __ N.M. __, 277 P.3d 490 (the court ascertains legislative intent "by reading all of the provisions of a statute together, along with other statutes in pari materia").

The operation of Section 61-4-9.2 relies upon the definitions of "dangerous drug," "controlled substance," and "drug" found in the New Mexico Drug, Device and Cosmetic Act. This statute defines a "drug" in relevant part as an article:

> (1) recognized in an official compendium;
> (2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans ..., and the biological products applicable to humans ...;
> (3) other than food, that affect the structure or any function of the human body...; and
> (4) intended for use as a component of Paragraph (1), (2) or (3) of this subsection....

Section 26-1-2(E).

"Controlled substance" is defined as a "drug, substance or immediate precursor enumerated in Schedules I through V of the Controlled Substances Act." Section 26-1-2(D).

Quite simply, a "dangerous drug" is one that requires a valid prescription. "Dangerous drug" is statutorily defined as:

> ... 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 and hence for which adequate directions for use cannot be prepared ....

Section 26-1-2(F) (emphasis added).

A Board of Pharmacy administrative rule further clarifies that a "dangerous drug" is one that "shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe such drug." 16.19.17.7(B)(2) NMAC (emphasis added). Drugs that are administered via injection into the human body are classified by law as "dangerous drugs" because these injectable drugs require a prescription. See § 26-1-2(F) (dangerous drug defined).

From these statutory definitions, "drugs" include both "dangerous drugs" and "drugs for administration by injection." Section 61-4-9.2(B) expressly excludes these two subsets of drugs from being added to the Formulary solely at Appellee's discretion, and in fact mandates that any such "dangerous drugs" and "drugs for administration by injection" be approved by both Appellants prior to their adoption into a Formulary. Certain substances listed in Section 61-4-9.2(A)

and 16.4.15.11 NMAC are classified by state and federal law, and state administrative rules, as "dangerous drugs."

Both Appellants hold a particular knowledge of and expertise in pharmacology, the "science of drugs including their origin, composition, pharmacokinetics, therapeutic use, and toxicology." Merriam-Webster.com. Because of this specialized knowledge of drugs in general, and their effects and dangers in particular, it is critical that both Appellants review and approve any dangerous drugs that Appellee wishes to include in its chiropractic Formulary. The "consensus" of Appellee and both Appellants before adding substances to the Formulary, as specifically mandated by Appellee's own rule, 16.4.15.8 NMAC, is intended to protect the public health, safety and welfare. To argue that consensus and approval is unnecessary is absurd, disregards the public's health, safety and welfare, and is contrary to law. See § 61-4-9.2(B).

In sum, both Appellants must approve in advance of its adoption by Appellee any chiropractic Formulary that intends to include "dangerous drugs," "controlled substances" or "drugs for administration by injection."

B. The Formulary Improperly Included "Drugs for Administration by Injection" Without Obtaining Prior Approval by Both Appellants Because Such Drugs Are Statutorily Defined as "Dangerous Drugs"

Appellant Board of Pharmacy is committed to ensuring the safe and effective prescribing and administering of dangerous drugs. The Pharmacy Act affirms as its purpose "to promote, preserve and protect the public health, safety and welfare by and through ... the regulation and control of ... materials as may be used in the diagnosis, treatment and prevention of injury, illness or disease of a patient or other person." Section 61-11-1.1(B) (1997). Appellant Medical Board is similarly committed to public safety. The Medical Practice Act states its "interest of the public health, safety and welfare and [protecting] the public from the improper ... and unlawful practice of medicine." Section 61-6-1(B) (1989, as amended through 2003). Appellants and the public they are charged with protecting are adversely affected because not all of the "dangerous drugs" on the Formulary have been approved by the Board of Pharmacy and the Medical Board. [CHIRO 42-46, 83-86]. In the absence of Appellants' approval, the inclusion of dangerous drugs in the Formulary is contrary to Section 61-4-9.2(B).

Much of the Formulary's adverse effect on Appellants and the public is focused on serious concerns about the intended route of administration of certain "dangerous drugs" and, particularly, "drugs for administration by injection." In fact, both Appellants informed Appellee in advance of the August 30, 2011 rulemaking that certain Formulary categories and Formulary items were <u>not</u>

approved by Appellants. [CHIRO 42-46 (Medical Board August 12, 2011 letter disapproving 16.4.15.11 NMAC); 83-86 (Board of Pharmacy June 2, 2011 letter identifying new and old Formulary items not yet approved)].

The 2011 Formulary that is the subject of this appeal newly includes:

(1) lidocaine as a "substance by injection" [16.4.15.11(F)(8) NMAC] — the Board of Pharmacy believes that IV administration (due to risk of respiratory arrest and cardiac toxicity) and intra-articular injection (due to risk of chondrolysis with continuous intra-articular infusions and lack of FDA approval for this route of administration) should not be permitted;

(2) vitamins as "substances by injection" [16.4.15.11(F)(9)(a)-(g) NMAC] — both the Board of Pharmacy and the Medical Board believe that injectable vitamins can be toxic when administered in the wrong dose and wrong route. [CHIRO 42-46; 83-86]. In addition, Appellants believe that parenteral (by injection) vitamin therapy is unnecessary unless the patient cannot take oral vitamins or has documented malabsorption. [Id.];

(3) methycobalamin (vitamin B12) as a "substance by injection" by intramuscular means [16.4.15.11(F)(9)(f) NMAC] — the Board of Pharmacy believes that this route of administration is not available by the manufacturer;

(4) phenol as a "substance by injection" [16.4.15.11(F)(11) NMAC] — can

be toxic, has never been approved by Appellants, and the Board of Pharmacy believes its route of administration should be specifically delineated;

(5) dextrose as a "substance by injection" [16.4.15.11(F)(10) NMAC] — can be hazardous to human health (Institute for Safe Medication Practices (ISMP) identifies dextrose as a high alert medication because of the high risk of significant patient harm when used in error);

(6) glucosamine as a "substance by injection" (with additional medical board approved education) [16.4.15.11(F)(14) NMAC] — the Medical Board has stated that glucosamine is not FDA-approved for use in humans, and the Board of Pharmacy does not believe this substance is available as an injectable product; and

(7) collagenase, glycerin, platelet rich plasma, sodium morrhaute, sodium hyaluronate as "substances by injection" (all with additional medical board approved education, except for platelet rich plasma) [16.4.15.11(F)(13), (15)-(18) NMAC] — the Board of Pharmacy believes these substances are used for prolotherapy, which involves injection into tendons and ligaments, but is unaware of any studies demonstrating that the benefits of this therapy outweigh the potential risks.

The Formulary authorizes use of these drugs by injection. As such, they require a prescription and are thus considered "dangerous drugs." Section 26-1-

2(F); 16.19.17.7(B)(2) NMAC. [CHIRO 45]. The definition of a "dangerous drug" makes clear that the "method of its use" may make a drug dangerous when it otherwise is not, and avers that this method of use is potentially "not safe except under the supervision of a practitioner licensed by law to direct the use of such drug." Section 26-1-2(F). Section 61-4-9.2(A) includes vitamins, a drug listed in the Formulary at 16.4.15.11(F) NMAC. To the extent this drug is not injected, it can be purchased without a prescription, and it falls within the ambit of Subsection A. However, as proposed in the Formulary, it must be approved by Appellants because vitamins in injectable form can only be obtained with a prescription. The plain language of Section 61-4-9.2(B) mandates that all of the dangerous drugs listed in the Formulary, 16.4.15.11 NMAC, must have the approval of both Appellants.

Appellant Medical Board specifically objected to the use by injection of any of the drugs listed in Appellee's proposed Formulary. [CHIRO 42-46]. In its August 12, 2011 letter opposing the Formulary, it indicated its specific concerns with respect to many of these drugs, and stated its general objection to "all injectables" proposed in the Formulary, [CHIRO 42-46], and stated that it would approve "none" of the proposed injectables. [CHIRO 44]. The Medical Board also informed Appellee that the proposed Formulary did not include their

previously agreed upon language requiring the patient to be adequately pre-screened for existing problems and contraindications, and recommending coordination with the patient's allopathic or osteopathic physician. [CHIRO 42-43]. The Medical Board noted further that the proposed hours of additional education specified in 16.4.15.12 NMAC did not appear to be sufficient. [CHIRO 43].

Similarly, Appellant Board of Pharmacy has not approved the administration of these dangerous drugs by injection, and notified Appellee by its June 2, 2011 letter of its objection to the proposed Formulary. [CHIRO 83-86]. The Board of Pharmacy noted that the joint formulary committee had not met in the past year. [CHIRO 83]. Furthermore, because neither Appellee nor the Board of Pharmacy had considered or agreed to any changes to the Board of Pharmacy's October 19, 2009 actions regarding certain drugs and restrictions on particular routes of administration, and because the Medical Board had not approved some of the proposed drugs, the Board of Pharmacy objected to the proposed Formulary. [CHIRO 83-86]. The Board of Pharmacy stated its position: "Prior to the passage of this regulation, approval should be granted by all involved agencies." [CHIRO 86].

Additionally, the 2011 Formulary newly includes "minerals; magnesium" as

"prescription medications for topical use" [16.4.15.11(D)(5) NMAC] — neither this category nor the specific mineral has been approved by the Board of Pharmacy. The Medical Board takes no position on the propriety of this category's inclusion in the Formulary.

Further, several substances in the 2010 Formulary were identified as problematic by Appellants at the June 14, 2010 rulemaking because of questions about the safety of the specific route of administration. Appellant Board of Pharmacy notes that it still has great concerns about these drugs for administration by injection or inhalation being included in the 2010 Formulary without having been approved by the Board of Pharmacy. See, e.g. "substances by injection" procaine HCL [16.4.15.11(F)(5) NMAC], epinephrine HCL [16.4.15.11(F)(6) NMAC], sterile water and sterile saline [16.4.15.11(F)(1)-(2) NMAC]; and glutathione for inhalation [16.4.15.11(G) NMAC]. [CHIRO 83-86, 42-46]. The Medical Board takes no position on the propriety of any of the other "substances by injection" in 16.4.15.11(F) NMAC that were added to the Formulary prior to the rulemaking at issue in this appeal.

In promulgating the Formulary, Appellee ignored both the specific objections of Appellants and the legal requirements of Section 61-4-9.2(B). The Court should thus hold that the Formulary — which has not been approved by

both Appellants — is contrary to law with respect to: (a) all of the newly proposed "drugs for administration by injection" listed in 16.4.15.11(F) NMAC, and (b) the mineral magnesium listed in 16.4.15.11(D)(5) NMAC.

Appellants preserved this issue by submitting written comments and offering oral testimony at Appellee's August 30, 2011 rulemaking hearing that specifically opposed and objected to Appellee's proposed Formulary.

II. A PLAIN READING OF SECTION 61-4-9.2(B) SHOWS THAT EACH OF THE THREE SENTENCES BUILD ON EACH OTHER, AND IMPOSE SEPARATE REQUIREMENTS FOR ADOPTING A FORMULARY

All three sentences of Section 61-4-9.2(B) must be read together to ascertain that statute's meaning. Each sentence builds on the previous one, and further explains what the Legislature intended by involving three professional licensing boards in establishing a chiropractic Formulary. Appellants ask this Court to read all three sentences together to determine the Legislature's intent in crafting this language. In construing this statute, the Court's "primary purpose is to give effect to the intent of the Legislature." Town & Country Food Stores, 2012-NMCA-046, ¶ 9 (cited authority omitted).

The first sentence lays the groundwork for Appellee's basic authority to develop a Formulary: "A formulary that includes all substances listed in Subsection A of this section, including compounded preparations for topical and

oral administration, shall be developed and approved by the board." Section 61-4-9.2(B) (emphasis added). The limitation is that Appellee's Formulary may include substances for "topical and oral" administration. Appellants do not dispute this.

The second sentence then permits Appellee to develop a Formulary that includes injectable drugs: "A formulary for injection that includes the substances in Subsection A of this section that are within the scope of practice of the certified advanced practice chiropractic physician shall be developed and approved by the board." Id. Appellants acknowledge that Appellee's Formulary may include injectable drugs, but subject to the language in the following sentence.

The third sentence clarifies and places limits on Appellee's authority to adopt a Formulary for injection, and unambiguously implicates the involvement of both Appellants once the Formulary expands beyond substances for "topical and oral" administration: "Dangerous drugs or controlled substances, drugs for administration by injection and substances not listed in Subsection A of this section shall be submitted to the board of pharmacy and the New Mexico medical board for approval." Id.

It is this third sentence that precipitated this appeal. As discussed in detail above, Appellants believe this sentence clearly carves a piece from Appellee's authority in adopting a Formulary, and gives Appellants the statutory mandate to,

as required by their practice acts, ensure the public health, safety and welfare as that regards "dangerous drugs," "controlled substances," "drugs for administration by injection," and "substances not listed in [Section 61-4-9.2(A)]." See Section 61-4-9.2(B). Appellee does not agree.

The Legislature created an "advanced practice chiropractic physician" designation for a chiropractor with "prescriptive authority for therapeutic and diagnostic purposes as authorized by statute." Section 61-4-9.1 (2008); see also § 61-4-2(B) (1993, as amended through 2008) (defining "certified advanced practice chiropractic physician" pursuant to Section 61-4-9.1) . The Legislature redefined the term "chiropractic" to include "the administering of a drug by injection by a certified advanced practice chiropractic physician" and to exclude from the definition, presumably for those chiropractors without advanced practice certification, "the prescription or use of controlled or dangerous drugs." Section 61-4-2(C).

The Legislature then set forth the requirements for this "advanced practice chiropractic physician" designation, which specifically includes a minimum educational and clinical component "in pharmacology, pharmacognosy, medication administration and toxicology" obtained "from an institution of higher education approved by [Appellee] and the New Mexico medical board." Section

61-4-9.1(D) (2008) (emphasis added). This language suggests that the Legislature thought it prudent to require an advanced practice chiropractic physician to obtain additional education and clinical training from an institution approved in part by Appellant Medical Board. By placing advanced practice chiropractors in a separate category from other chiropractors, the Legislature recognized that those practitioners seeking to inject drugs into their patients would be held to a higher educational and clinical competency. By requiring the Medical Board to approve any institution at which the advanced practice chiropractors obtained education and clinical training "in pharmacology, pharmacognosy, medication administration and toxicology," the Legislature recognized that this expansion of the practice of chiropractic required the Medical Board's involvement so as to ensure patient safety, health and welfare.

At the same time the Legislature authorized the "advanced practice chiropractic physician" certification, and mandated that such a person obtain additional education and clinical training at an institution approved in part by Appellant Medical Board, see Sections 61-4-9.1 and 61-4-2(C), the Legislature prescribed that person's authority, and authorized, within specified limitations, a Formulary to be developed by Appellee and to be "approved by the New Mexico medical board and the board of pharmacy." Section 61-4-9.2 (2008). As with

Section 61-4-9.1, the Legislature further recognized that this expansion of the practice of chiropractic so as to allow practitioners to "administer a drug by injection" required the involvement of both the Medical Board and the Board of Pharmacy in approving a chiropractic Formulary so as to ensure patient safety, health and welfare. See § 61-4-9.2 (2008); see also § 61-4-2(C) (definition of "chiropractic").

One year later, the Legislature amended Section 61-4-9.2 to add the three sentences of a new Subsection B regarding the particulars of the Formulary's development and, in place of the previous year's statutory language that required Appellee to develop and Appellants to approve a chiropractic Formulary, set forth the three separate steps for developing and approving this Formulary. See § 61-4-9.2(B) (2008, as amended 2009). As argued above, the first sentence addresses Appellee's development and approval of a Formulary for topical and oral drugs, the second sentence addresses Appellee's development and approval of a Formulary for injection, and the third sentence specifically mandates that "[d]angerous drugs or controlled substances, drugs for administration by injection and substances not listed in Subsection A of this section shall be submitted to the board of pharmacy and the New Mexico medical board for approval." Id.

The provisions of Section 61-4-9.2(B) cannot be read in a vacuum, and must

necessarily be read with all parts of the Chiropractic Physician Practice Act that were enacted one year earlier in 2008 and that relate to advanced practice chiropractors: Section 61-4-2(C) (definition of "chiropractic"); Section 61-4-9.1(D) (Medical Board approval of institutions offering advanced practice chiropractic education and clinical training). In so doing, it is clear that the Legislature was expanding Appellee's authority over its licensees legally qualified to prescribe and use dangerous drugs, subject to approval of those dangerous drugs by Appellants Medical Board and Board of Pharmacy, all with the obvious intent to ensure public health, safety and welfare. See generally § 61-11-1.1(B) (Pharmacy Act statement of purpose); § 61-6-1(B) (Medical Practice Act statement of purpose). In fact, the Legislature signaled its obvious intent to specifically involve Appellants in the Formulary process by only adding language requiring that involvement to the Chiropractic Physician Practice Act, and not to the Pharmacy Act or the Medical Practice Act.

Quite simply, if Appellants have no statutory duty to approve a Formulary containing "[d]angerous drugs or controlled substances, drugs for administration by injection and substances not listed in [Section 61-4-9.2(A)]," there was no reason for the Legislature to include a statutory mandate that these particular drugs — if Appellee wanted to include them in its chiropractic Formulary — "shall be

submitted to the board of pharmacy and the New Mexico medical board for approval." Section 61-4-9.2(B) (emphasis added). Consequently, the Court "must assume the legislature chose [its] words advisedly to express its meaning unless the contrary [intent] clearly appears." State v. Maestas, 2007-NMSC-001, ¶ 22, 140 N.M. 836, 149 P.3d 933 (quoted authority omitted). Here, the Legislature thought it necessary to mandate approval by both Appellants of any dangerous, i.e. prescription, drugs that Appellee wanted to include in its Formulary. To read Section 61-4-9.2(B) any other way is to render that statute invalid. That result is most certainly not the intent of the Legislature in either 2008 or 2009.

Appellants preserved this issue by submitting written comments and offering oral testimony at Appellee's August 30, 2011 rulemaking hearing that specifically opposed and objected to Appellee's proposed Formulary.

CONCLUSION

Both Appellants believe, and have stated as such to Appellee, that the law mandates Board of Pharmacy and Medical Board approval before Appellee may adopt a Formulary containing "dangerous drugs," "drugs for administration by injection," and "substances not listed in [Section 61-4-9.2(A)]." Section 61-4-9.2(B).

Appellee acted contrary to its own practice act and its administrative rules

by its failure to submit to Appellants Board of Pharmacy and Medical Board for their prior approval its proposed Formulary. Because Appellee has adopted a Formulary that has not received the statutorily-mandated approval by Appellants, the court should set aside Appellee's 2011 amendments to its Formulary rule at 16.4.15.11 NMAC.

Respectfully submitted,

GARY K. KING
New Mexico Attorney General
Mary H. Smith
Assistant Attorney General
111 Lomas Blvd NW Ste 300
Albuquerque NM 87102
(505) 222-9000; FAX (505) 222-9006
msmith@nmag.gov

Attorneys for Appellant Board of Pharmacy

for Daniel R. Rubin
Special Assistant Attorney General
NMMB Administrative Prosecutor
2055 S Pacheco, Building 400
Santa Fe NM 87505
(505) 476-7233; FAX (505) 476-7237
dan.rubin@state.nm.us

Attorney for Appellant Medical Board

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Brief in Chief was sent by first class mail on July 19, 2012 to Zachary Shandler, Assistant Attorney General, PO Drawer 1508, Santa Fe NM 87504, attorney for Appellee, and to Charles V. Garcia, Cuddy & McCarthy LLP, 7770 Jefferson St. NE Ste 305, Albuquerque NM 87109, attorney for Appellant International Chiropractors Association. A copy has also been filed by first class mail to Anthony Webb, board administrator for Appellee, 2550 Cerrillos Rd 2nd Floor, Santa Fe NM 87505.

Mary H Smith

Assistant Attorney General