

MEMORANDUM

TO: MARK B. STEINAGEL, DOPL DIRECTOR

FROM: KEVIN M. MCDONOUGH, ASSISTANT ATTORNEY GENERAL

DATE: JULY 12, 2016

RE: INFORMAL LEGAL OPINION REGARDING PROCUREMENT
AUTHORITY OF ACUPUNCTURISTS

BACKGROUND

The Acupuncture Licensing Board informed Bureau Manager, Larry Marx, that distributors are denying acupuncturists the ability to procure certain supplies that are necessary for their practice. More specifically, acupuncturists are being denied access to traditional Chinese herbs and homeopathic substances, as well as other supplies such as injection needles, injectable Vitamin B-12, lidocaine, procaine, and epinephrine. Ostensibly, the suppliers are refusing to sell these items to acupuncturists on the grounds that neither the Division of Occupational and Professional Licensing (the "Division" or "DOPL") nor the United States Drug Enforcement Administration ("DEA") has granted acupuncture practitioners prescriptive authority for such items. The acupuncturists, however, maintain that they are not seeking prescriptive authority; rather, merely the ability to procure specific items necessary to practice their profession. Acupuncturists reference acupoint injection therapy as an example of an approved practice which requires the use of hypodermic injection needles, Vitamin B-12, lidocaine and, for safety reasons, immediate access to epinephrine and procaine.

Based upon the foregoing, the Acupuncture Board would like the Division to promulgate a rule granting acupuncturists authority to procure the identified items for utilization in the licensed practice of acupuncture. Accordingly, you have asked us for an informal legal opinion concerning the Division's authority to promulgate such a rule.

ISSUES PRESENTED

- (1) Does the Division have authority to promulgate a rule giving acupuncturists the right to procure certain items¹ they deem necessary to practice acupuncture?
- (2) Does the Division have authority to promulgate a rule giving acupuncturists prescriptive authority to use prescription or legend drugs in their practice of acupuncture?

INFORMAL LEGAL OPINION

(1) Consistent with the analysis set forth herein below, it is our informal legal opinion that the Division has legal authority to promulgate a rule granting acupuncturists the right to procure some of the items they have identified as essential to their practice, to wit, traditional Chinese herbs, homeopathic substances, and injection needles. Moreover, such a rule has already been promulgated and is presently in full force and effect relative to Chinese herbs and homeopathic substances. There is no mention in that rule of injection needles.

As to Issue No. 1, it is also our informal legal opinion that the Division lacks legal authority to promulgate a rule granting acupuncturists the right to procure lidocaine, epinephrine, procaine, and injectable Vitamin B-12.

¹ As presented to us, the Acupuncture Board is seeking procurement authority for specific items it has identified as "traditional Chinese herbs and homeopathic substances and other supplies to include injection needles, injectable Vitamin B-12, lidocaine, epinephrine and procaine."

(2) Consistent with the analysis set forth herein below, it is our informal legal opinion that the Division does not have legal authority to promulgate a rule granting acupuncturists authority to use prescription or legend drugs.

APPLICABLE CASE LAW

It is well recognized and a long-standing principle of administrative law that “an agency’s rules must be consistent with its governing statutes.” *Sanders Brine Shrimp v. Utah State Tax Commission*, 846 P.2d 1304, 1306 (Utah 1993); accord *Rocky Mountain Energy v. Utah State Tax Commission*, 852 P.2d 284, 287 (Utah 1993) (holding that “[r]ules are subordinate to statutes and cannot confer greater rights or disabilities”). See also *Manhattan General Equipment Co. v. Commissioner of Internal Revenue*, 297 U.S. 129, 134, 56 S. Ct. 397, 399, 80 L. Ed. 528 (1936) (administrative bodies have the power to prescribe rules in order to carry into effect the will of the legislature as expressed by statute. In order for a rule to be valid, it must be in harmony with the governing statute.) These basic tenets of law have recently been reaffirmed by the Utah Supreme Court in the case of *Dorsey v. Department of Workforce Services*, 330 P.3d 91, 94 (Utah 2014).

Additionally, there are certain well settled principles of law which apply when there appear to be two or more separate statutes purportedly covering the same subject matter. When two statutes are interpreted together, “[w]ell-established principles of statutory construction require that a more specific statute governs instead of a more general statute.” *Pan Energy v. Martin*, 813 P.2d 1142, 1145 (Utah 1991); accord *Jensen v. IHC Hospitals, Inc.*, 944 P.2d 327, 331 (Utah 1997) (“When we are faced with two statutes that purport to cover the same subject, we seek to determine the legislature’s intent as to which applies. In doing this, we follow the general rules of statutory construction, which provide both that ‘the best evidence of legislative

intent is the plain language of the statute’ (citations omitted), and that ‘a more specific statute governs instead of a more general statute.’” (citations omitted)). These basic tenets of law have recently been acknowledged and reaffirmed by the Utah Court of Appeals in *Asset Acceptance LLC v. Utah State Treasurer*, 2016 UT App 25, 367 P.3d 1019, 1022-1023.

GOVERNING STATUTE

The Utah Legislature’s enactment of the *Acupuncture Licensing Act* (Utah Code Ann. § 58-72-101 et seq.) contains the “governing statute” relative to the issue presented. More specifically, Utah Code Ann. § 58-72-102 provides, in pertinent part, as follows:

58-72-102 Acupuncture licensing – Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

• • •

(4)(a) “Practice of acupuncture” means the insertion of acupuncture needles and application of moxibustion to specific areas of the body based on traditional oriental medical diagnosis and modern research as a primary mode of therapy.

(b) Adjunctive therapies within the scope of the practice of acupuncture may include:

- (i) manual, mechanical, thermal, electrical, light, and electromagnetic treatments based on traditional oriental medical diagnosis and modern research; [and]
- (ii) the recommendation, administration, or provision of dietary guidelines, herbs, supplements, homeopathics, and therapeutic exercise based on traditional oriental medical diagnosis and modern research according to practitioner training[.]

ADMINISTRATIVE RULE²

²The Utah Legislature’s enactment of Utah Code Ann. § 58-1-106 expressly grants the Division rulemaking authority, such that it may prescribe and adopt rules for the purpose of administering Title 58 of the Utah Code.

58-1-106 Division - - Duties, functions, and responsibilities.

- (1) The duties, functions, and responsibilities of the division include the following:
 - (a) prescribing, adopting, and enforcing rules to administer this title[.]

The administrative rule that corresponds to the governing statute is the *Acupuncture Licensing Act Rule* (Utah Admin. Code R156-72), which sets forth, in pertinent part, as follows:

R156-72. Acupuncture Licensing Act Rule.

• • •

R156-72-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 72, as used in this rule:

(1) “Administration”, as used in Subsection 58-72-102(4)(b)(ii), means the direct application of an herb, homeopathic, or supplement by ingestion, topical, inhalation, or acupoint injection therapy (AIT), to the body of a patient. Administration does not include: venous injections, immunizations, legend drugs and controlled substances.

(2) “Controlled substance” means a drug or substance as defined in Subsection 58-37-2(1)(f).

(3) “Legend drug” means a prescription drug as defined in Subsections 58-17b-102(30) and (61).³

(4) “Insertion of acupuncture needles” means a procedure of acupuncture and oriental medicine which includes but is not limited to trigger point therapy, Ahshi points and dry needling techniques.

(5) “NCCAOM” means the National Commission for the Certification of Acupuncture and Oriental Medicine.

(6) “Modern research” means practicing according to acupuncture and oriental medicine training as recognized through NCCAOM.

(7) “Provision”, as used in Subsection 58-72-102(4)(b)(ii), includes procurement of the substances listed in Subsection 58-72-102(4)(b)(ii).

R156-72-103. Authority – Purpose.

This rule is adopted by the Division under the authority of Subsection 58-1-106(1)(a) to enable the Division to administer Title 58, Chapter 72.

LEGAL ANALYSIS

³ This administrative rule makes an erroneous cross-reference to the *Pharmacy Practice Act* (Utah Code Ann. § 58-17b-102). Subsections (30) and (61) should appropriately reference Subsections (32) and (64) respectively. (It may be prudent for DOPL to amend Section 102 of the Licensing Act Rule so that it correctly cross-references the *Pharmacy Practice Act*.)

The powers of the Division are derived from and created by statute. The Division has no inherent regulatory powers and can assert only those which are expressly granted or clearly implied as necessary to discharge the rights, duties, and responsibilities given to it by statute. Moreover, any administrative rule promulgated by the Division must be in harmony with said rule's governing statute. The Division's authority to promulgate a procurement rule is limited by the provisions of the governing statute. An analysis of the issues presented must begin with an examination of Utah Code Ann. § 58-72-102, and more specifically, Subsection (4) thereof.

The governing statute defines the "practice of acupuncture" as the "insertion of acupuncture needles and application of moxibustion . . . based on traditional oriental medical diagnosis and modern research as a primary mode of therapy." Significantly, by virtue of enacting Subsection (4)(b) of the governing statute, the Utah Legislature broadened the scope of the practice of acupuncture by granting acupuncturists the legal right to perform "adjunctive therapies." These adjunctive therapies include "the recommendation, administration, or provision of dietary guidelines, herbs, supplements, homeopathics, and therapeutic exercise based on traditional oriental medical diagnosis and modern research according to practitioner training[.]" Thus, in addition to the "primary mode of therapy," i.e., the insertion of acupuncture needles, the Utah Legislature recognized additional modes of therapy which acupuncturists have statutory authority to perform. So long as any proposed administrative rule does not transcend the boundaries of either the primary mode of therapy or an adjunctive mode of therapy prescribed by the Legislature, the Division has authority to promulgate a rule concerning the procurement issue at hand. The Division cannot however, promulgate a rule that would confer greater rights to acupuncturists than are expressly granted or clearly implied by the governing statute. *See Manhattan General Equipment Company*, id. at p. 3.

Traditional Chinese Herbs, Homeopathic Substances, and Injection Needles

Ironically, the existing *Acupuncture Licensing Act Rule*, in conjunction with the governing statute, already gives acupuncturists some of the procurement authority they now seek to secure by further rule. Section 102 of Utah Admin. Code R156-72 is instructive, therein defining specific terms which are used in the governing statute. The first such term is “administration.”

R156-72-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 72, as used in this rule:

(1) “Administration”, as used in Subsection 58-72-102(4)(b)(ii), means the direct application of an herb, homeopathic, or supplement by ingestion, topical, inhalation, or acupoint injection therapy (AIT), to the body of a patient. Administration does not include: venous injections, immunizations, legend drugs and controlled substances.

This definition specifically refers to some of the adjunctive therapies that the Utah Legislature has determined to be within the scope of practice of an acupuncturist, i.e., treatment involving the use of herbs, supplements, and homeopathics. The administrative rule merely clarifies the permissible methods for administering the adjunctive therapies. The permissible methods are by way of (i) ingestion; (ii) topical application; (iii) inhalation; and (iv) injection.

It is particularly noteworthy that this definition of “administration” is well-recognized by federal and state statutes. For example, it mirrors the definition of that term as set forth in Title 21 of the United States Code (*Food and Drugs*). Specifically, Title 21, Chapter 13, Section 802 of the U.S. Code provides that “[t]he term ‘administer’ refers to the direct application of a

controlled substance to the body of a patient . . . whether such application be by injection, inhalation, ingestion, or any other means.” Similarly, the *Utah Controlled Substance Act* provides that “‘Administer’ means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient[.]” *See* Utah Code Ann. § 58-37-2(1)(a). Further, Utah’s *Pharmacy Practice Act* defines administer to mean “the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by other means, to the body of a human patient[.]” *See* Utah Code Ann. § 58-17b-102(1)(a). Section 102 of Utah Admin. Code R156-72 contains the same language used in the referenced federal and state statutes to the extent that all four bodies of law define “administration”/“administer” as meaning the “direct application” of a substance to the body of a patient by way of “ingestion”, “inhalation”, or “injection.” (Emphasis added.) As such, it is readily apparent that the Utah Legislature clearly contemplated that the adjunctive therapy of administering herbs, supplements, and homeopathics necessarily include administration by way of injection. Accordingly, the administrative rule permitting acupoint injection therapy does not transcend the bounds of the governing statute, as it does not confer a greater right than that provided by the governing statute. Rather, it simply clarifies how an adjunctive therapy may be performed. Therefore, acupuncturists have the right to use injection needles so long as the substance they are injecting is within the defined scope of their practice. More specifically, acupuncturists may use injection needles to administer “herbs, supplements, [and] homeopathics,” unless otherwise precluded by a pre-emptive federal law.

The *Acupuncture Licensing Act Rule* also defines the term “provision,” therein specifically referencing “the substances listed” in the governing statute that may be used by acupuncturists as part of an adjunctive therapy.

R156-72-102. Definitions.

In addition to the definitions in § 58-1-102, as used in this Chapter:

• • •

(7) “Provision”, as used in Subsection 58-72-102(4)(b)(ii), includes procurement of the substances listed in Subsection 58-72-102(4)(b)(ii).

As with the term “administration,” the definition of “provision” merely clarifies a term used in the governing statute. In this regard, the administrative rule grants acupuncturists the right to procure herbs, supplements, and homeopathics to be used within their practice of acupuncture.⁴ Again, inasmuch as this portion of the rule does not confer a greater right than that clearly contemplated by the governing statute, the administrative rule is in harmony with the governing statute, and acupuncturists have the right to procure “Chinese herbs, supplements, [and] homeopathics.”

Injectable Vitamin B-12, Lidocaine, Epinephrine, and Procaine⁵

The acupuncturists claim that multiple suppliers are refusing to sell certain items to them based upon the DEA’s failure to grant acupuncture practitioners prescriptive authority for such items. As such, some provisions of federal statutory law were reviewed for purposes of this memorandum. More specifically, the *Federal Food, Drug, and Cosmetic Act* (“FDCA”) (21 USCA § 301 et seq.) was initially examined.

The FDCA is a set of laws passed by Congress in 1938, giving authority to the FDA to oversee the safety of food, drugs, and cosmetics. A primary purpose of enacting the FDCA was to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs,

⁴ It is questionable whether clarification and definition of this term is even necessary. That is, it seems axiomatic that if the Legislature deemed it permissible for acupuncturists to “administ[er]” and “provi[de]” certain substances while acting within the scope of their practice, they have clear implicit authority to procure said substances.

⁵ These items are substances that require a prescription.

devices, and cosmetics.⁶ The focus of the FDCA is upon the composition and makeup of food, drugs, devices, tobacco products, and cosmetics which are introduced into interstate commerce. The Act also focuses on the labeling and branding of the containers which hold foods, drugs, etc. Although the FDA can mandate that certain drugs be designated as “prescription drugs,” prescriptive authority to distribute or dispense most drugs is, in large part, left up to the discretion of the Legislature of each of the individual states. Notwithstanding this differential discretion, 21 CFR § 250.201 is instructive as related to injectable Vitamin B-12:

21 CFR § 250 “Special Requirement for Specific Human Drugs.”

• • •

(b) On the basis of the scientific evidence and conclusions summarized in the statement of the U.S.P. Anti-anemia Preparations Advisory Board as well as pertinent information from other sources, the Commissioner of Food and Drugs finds it is the consensus of well informed medical opinion that:

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(1) The parenteral administration of *cyanocobalamin* or *vitamin B12* is generally recognized as a fully effective treatment of pernicious anemia. Parenteral cyanocobalamin preparations have not been and are not authorized for use except by or on the prescription of a duly licensed medical practitioner. (Emphasis added.)

Additionally, it should be noted that injectable Vitamin B-12 is not a “dietary supplement” that might otherwise be considered a “supplement” acupuncturists have the authority to administer. Section 321 of the FDCA provides that “[t]he term ‘dietary supplement’ means a product that is intended for ingestion . . . and is labeled as a dietary supplement.” *See*

⁶ See legislative history of the FDCA introduced in the U.S. Senate as Senate Bill 5 by Royal Copeland, a 3-term United States Senator from New York.

21 USCA § 321(ff). Injectable Vitamin B-12 is obviously not intended for ingestion; nor does it bear a label identifying it as a dietary supplement.

The governing statute is dispositive of whether or not DOPL may promulgate a rule authorizing the procurement of injectable Vitamin B-12, lidocaine, epinephrine, and procaine. In this regard, the Utah Legislature has not promulgated law permitting acupuncturists to administer any prescription drug. Rather, (for purposes of the issue at hand) the adjunctive therapies within the scope of the practice of acupuncture are limited to the administration or provision of “herbs, supplements, [and] homeopathics.” As set forth hereinabove, DOPL cannot promulgate a rule which transcends the practice boundaries articulated by the Legislature. Thus, DOPL cannot promulgate a rule authorizing acupuncturists to procure or prescribe Vitamin B-12, lidocaine, epinephrine, or procaine.

It also noteworthy that in defining “administration,” Utah Admin. Code R156-72-102(1) sets forth that “administration does not include: venous injections, immunizations, legend drugs and controlled substances.” Further, Subsection (3) of the administrative rule prescribe that “‘legend drug’ means a prescription drug as defined in Subsections 58-17b-102(30) and (61)” of the Utah’s *Pharmacy Practice Act*. Those subsections define a “legend drug” as being the same thing as a “prescription drug.” As such, DOPL’s own rule prohibits the administration of any prescription drug. (Merely amending the rule to delete any reference to “legend drug” does not remedy the problem for the acupuncturists, as DOPL remains constrained in promulgating a rule that is at odds with the governing statute.)

Utah’s *Pharmacy Practice Act* provides additional insight. It is a comprehensive body of law, with the definitional section of the said Act containing no less than 73 definitions, including those of “legend drug,” “non-prescription drug,” “prescribe,” “prescription,” and “prescription

drug.” By contrast, the *Acupuncture Licensing Act* has a definitional section containing five definitions; and moreover, the word “prescription” is not mentioned within the entirety of Acupuncture Act.

Another Utah statute which has some instructive value is the *Naturopathic Physician Practice Act* (Utah Code Ann. § 58-71-102 et seq.). As with the *Pharmacy Practice Act*, this Naturopathic Act has an expansive definitional section, including what constitutes a “prescription drug.” Moreover, said Act specifically references a naturopathic physician being authorized to administer a prescription drug as defined in the *Pharmacy Practice Act*. Accordingly, it appears that if the Utah Legislature intended for acupuncturists to have the authority to procure prescription drugs, it would have expressly so indicated.

CONCLUSION

The governing statute, Utah Code Ann. § 58-72-102(4) prescribes that the “practice of acupuncture” includes the administration and provision of herbs, supplements, and homeopathics. The Division may not, by administrative rule, expand this defined scope of practice; however, the Division may promulgate a rule that is in harmony with the governing statute. Based upon the foregoing analysis, it appears that the acupuncturists already have the authority to procure a number of items which they seek procurement of by further rule.

Traditional Chinese Herbs, Homeopathic Substances, and Injection Needles

The governing statute, together with its exiting corresponding administrative rule, clearly give acupuncturists the right to procure Chinese herbs and homeopathics. With regard to injection needles, it appears that the Utah Legislature clearly intended that acupuncturists be permitted to practice an adjunct therapy by using injection needles. As such, it is our informal

legal opinion that DOPL has authority to promulgate a rule clarifying that acupuncturists are authorized to procure hypodermic needles, so long as the same are used solely to inject an authorized substance, ie, Chinese herb or homeopathic substance.

Injectable Vitamin B-12, Lidocaine, Epinephrine, and Procaine

The governing statute does not give acupuncturists authority to administer prescription drugs within the scope of their practice. Accordingly, and based on the foregoing analysis, it is our informal legal opinion that DOPL does not have the authority to promulgate a rule giving acupuncturists the right to procure or prescribe injectable Vitamin B-12, Lidocaine, Epinephrine, or Procaine. In this regard, and particularly related to Vitamin B-12, it is our further opinion that Vitamin B-12 is not a prescriptive “supplement” that the Legislature intended to authorize for acupuncture practice.

Finally, and interestingly, on June 5, 2015, the General Assembly of the State of Colorado enacted Colorado Revised Statute 29-29.5-102 (Colorado’s counterpart to Utah’s *Acupuncture Licensing Act*), therein promulgating legislation allowing acupuncturists to procure and use the same items that are at issue in this memorandum. (Attached hereto is a copy of Colorado’s recently enacted statute.) It is our informal legal opinion that the procurement/prescriptive issues raised by the Utah acupuncturists should appropriately be addressed by the Utah Legislature rather than DOPL.

