

MEMORANDUM

TO: MARK B. STEINAGEL, DOPL DIRECTOR

FROM: KEVIN M. MCDONOUGH, ASSISTANT ATTORNEY GENERAL

DATE: JULY 21, 2016

RE: INFORMAL LEGAL OPINION REGARDING PASSIVE VERIFICATION OF PRESCRIPTIONS FOR CONTACT LENSES

BACKGROUND

The Optometrist Licensing Board informed DOPL Bureau Manager, Larry Marx, that it is concerned that Utah statutory law allows sellers of prescription contact lenses (“contacts” or “lens”) to dispense contacts without actually verifying the validity of a prescription. For example, under current Utah law, a seller of contact lenses may send a facsimile to an optometrist, therein requesting verification of a lens prescription, and in the event the optometrist fails to verify the prescription within seventy-two (72)-hours, the seller may dispense contact lenses based upon the proffered prescription (which might be expired, nearly expired, or otherwise invalid). This is known as “passive verification.” As a result of this passive verification procedure, the optometrists believe that their patients are able to purchase contacts inconsistent with the prescription actually issued. They believe that patients are able to secure a supply of contacts that would last well beyond the expiration date of the prescription.

Another side of this controversy is the position of the contact lens suppliers/sellers. Specifically, *1-800-Contacts* is claiming that a large number of optometrists are writing

prescriptions for only one year, without documenting a medically valid reason for said prescriptions not being written for the statutorily mandated two-year period. *1-800-Contacts* has filed over 3,000 complaints with the State of Arizona, and last month it filed 18 complaints with Utah's Division of Occupational and Professional Licensing (the "Division" or "DOPL").

The Optometrist Board would like the Division to promulgate a rule that requires sellers of contact lenses to receive actual verification of a contact lens prescription prior to selling the lenses. Accordingly, you have asked us for an informal legal opinion concerning the Division's authority to promulgate a rule that disallows "passive verification," and would require that a seller of contact lenses honor a prescription only after the prescription has actually/actively been verified by the prescribing optometrist. _____

ISSUE PRESENTED

Does the Division have authority to promulgate a rule requiring sellers of contact lenses to receive actual verification of a prescription prior to consummating a sale of contacts?

INFORMAL LEGAL OPINION

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 requiring sellers of contact lenses to secure actual verification of a prescription prior to making a sale of contacts.

ADJUNCT ISSUE

Does the Division have authority to promulgate a rule that would preclude sellers of contact lenses from refilling a prescription that would provide patients with a supply of contact lenses well beyond the expiration date of the prescription?

INFORMAL LEGAL OPINION

Consistent with the analysis set forth herein below, it is our informal legal opinion that the Division has legal authority to promulgate a rule which would preclude sellers of contact lenses from refilling a prescription that would provide patients with a supply of contact lenses well beyond the expiration date of the prescription.

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.) *Draughon v. Department of Financial Institutions, State of Utah*, 975 P.2d 935 (Utah 1999) is also instructive. (The authority of an administrative agency to promulgate rules or regulations is limited to those which are consonant with the statutory framework, and neither contrary to the statute nor beyond its scope. A rule or regulation that conflicts with the design of a statute should be invalidated.) See also *Crowther v. Nationwide Mut. Ins. Co.*, 762 P.2d 1119, 1122 (Utah Ct. App. 1988) (“agency regulations may not abridge, enlarge, extend or modify [a] 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).

GOVERNING STATUTE

The Utah Legislature's enactment of the *Utah Optometry Practice Act* (Utah Code Ann. § 58-16a-101 et seq.) contains the "governing statute" relative to the issue presented. More specifically, Utah Code Ann. § 58-16a-801 provides, in pertinent part, as follows:

58-16a-801 Contact lens and ophthalmic lens seller or provider.

- (1) A person may sell or provide contact lenses if the person:
 - (a) does so in the ordinary course of trade from a permanently located and established place of business;
 - (b) does not perform refractions, over-refractions, or attempts to traffic upon assumed skill in testing the eye;
 - (c) provides all contact lenses consistent with and in accordance with a valid contact lens prescription;
 - (d) does not fit contact lenses;
 - (e) provides a contact lens to a patient after:
 - (i) receiving an unexpired verbal or written prescription; or
 - (ii) sending a contact lens prescription verification to the prescribing optometrist or physician, regardless of whether the prescribing optometrist or physician responds to or confirms the verification, provided that:
 - (A) the person has all of the information necessary to fill the prescription;
 - (B) the prescribing optometrist or physician has not informed the person that the prescription has expired or is otherwise inaccurate prior to the person shipping or hand-delivering the contact lens to the patient;
 - (C) the person confirms a valid, unexpired contact lens prescription for the patient if the person is aware that the patient provided inaccurate prescription information in his last order; and

(D) the person informs the patient that the prescription has expired or that there is a medical problem associated with the prescription if the information is communicated by the prescribing optometrist or physician to the person within 72 hours of the contact lens prescription verification being sent; and

(f) maintains patient information, including the method and date of any prescription verification, for no less than seven years.
(Emphasis added.)

58-16a-102 Definitions.¹

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

• • •

(3)(a) "Contact lens prescription" means a written or verbal order for contact lenses that includes:

(i) the commencement date of the prescription;

(ii) the base curve, power, diameter, material or brand name, and expiration date;

(iii) for a written order, the signature of the prescribing optometrist or physician; and

(iv) for a verbal order, a record maintained by the recipient of:

(A) the name of the prescribing optometrist or physician; and

(B) the date when the prescription was issued or ordered.

(b) A prescription may include:

(i) a limit on the quantity of lenses that may be ordered under the prescription if required for medical reasons documented in the patient's files; and

¹ The Definitions section of the Utah Optometry Practice Act is helpful to interpreting the governing statute and addressing the issues presented in this informal legal opinion.

(ii) the expiration date of the prescription, which shall be two years from the commencement date, unless documented medical reasons require otherwise.

...

(4) "Contact lens prescription verification" means a written request from a person who sells or provides contact lenses that:

(a) is sent to the prescribing optometrist or physician; and

(b) seeks the confirmation of the accuracy of a patient's prescription.

...

(15) "unexpired" means a prescription that was issued:

(a) for ophthalmic lenses which does not expire unless the optometrist or physician includes an expiration date on the prescription based on medical reasons that are documented in the patient's file; and

(b) in accordance with Subsection (3) for a contact lens.

ADMINISTRATIVE RULE²

The administrative rule that corresponds to the governing statute is the *Optometry Practice Act Rule* (Utah Admin. Code R156-16a), which sets forth, in pertinent part, as follows:

R156-16a. Optometry Practice Act Rule.³

...

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[.]

³ This current administrative rule is rather scant and does not address either of the issues presented in this informal legal opinion; however, it is important to note that the rule indeed exists and makes reference to Title 58 of the Utah Code which gives the Division authority to promulgate rules.

R156-16a-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 16a or this rule:

(1) "Practitioner" means any person or individual licensed in this state as a physician and surgeon, osteopathic physician and surgeon, physician assistant, nurse practitioner, or an optometric physician.

R156-16a-103. Authority – Purpose.

This rule is adopted by the division under the authority of Subsection 58-1-106(1) to enable the division to administer Title 58, Chapter 16a.

FEDERAL LAW

(A) United States Code

Fairness to Contact Lens Consumers Act ("FCLCA") (15 U.S.C.A. § 7601 et seq.)

§ 7603. Prescriber verification

(a) Prescription requirement

A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is –

- (1) presented to the seller by the patient or prescriber directly or by facsimile; or
- (2) verified by direct communication.

• • •

(d) Verification events

A prescription is verified under this chapter only if one of the following occurs:

- (1) The prescriber confirms the prescription is accurate by direct communication with the seller.
- (2) The prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription.
- (3) The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal

Trade Commission, after receiving from the seller the information described in subsection (c) of this section.
(Emphasis added.)

§ 7604. Expiration of contact lens prescriptions

(a) In general

A contact lens prescription shall expire –

- (1) on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription.
- (2) not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription; or
- (3) notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

(B) Code of Federal Regulations

Contact Lens Rule (Title 16, Part 315)

16 C.F.R. § 315.1

§ 315.1 Scope of regulations in this part.

This part, which shall be called the “Contact Lens Rule,” implements the Fairness to Contact Lens Consumers Act, codified at 15 U.S.C. 7601-7610, which requires that rules be issued to address the release, verification, and sale of contact lens prescriptions. This part specifically governs contact lens prescriptions and related issues. Part 456 of Title 16 governs the availability of eyeglass prescriptions and related issues (the Ophthalmic Practice Rules (Eyeglass Rule)).

16 C.F.R. § 315.5

§ 315.5 Prescriber verification.

(a) Prescription requirement. A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is:

(1) Presented to the seller by the patient or prescriber directly or by facsimile; or

(2) Verified by direct communication.

• • •

(c) Verification events. A prescription is verified under paragraph (a)(2) of this section only if one of the following occurs:

(1) The prescriber confirms the prescription is accurate by direct communication with the seller;

(2) The prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; or

(3) The prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section. During these eight (8) business hours, the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request. (Emphasis added.)

16 C.F.R. § 315.11

§ 315.11 Effect on state and local laws.

(a) State and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are preempted. (Emphasis added.)

(b) Any other State or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency.

LEGAL ANALYSIS

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, and pursuant to the case law cited herein, any administrative rule promulgated by the

Division must be in harmony with said rule's governing statute. Therefore, the Division's authority to promulgate a rule requiring sellers to secure actual/active verification of a contact lens prescription is limited by the provisions of the governing statute. Any rule promulgated by the Division must be consonant with the statutory framework of the *Utah Optometry Practice Act*, and cannot be contrary to the governing statute. See *Draughon v. Department of Financial Institutions, State of Utah*, id. at p. 3. Therefore, an analysis of the issues presented must begin with an examination of the *Utah Optometry Practice Act* (Utah Code Ann. § 58-16a-101 et seq.), and more particularly, Section 801 thereof.

The governing statute clearly and unequivocally allows a seller of contact lenses to verify a prescription passively. Utah Code Ann. § 58-16a-801(1)(e)(ii) provides that a seller of contact lenses may "provide a contact lens to a patient after . . . sending a contact lens prescription verification to the prescribing optometrist or physician, regardless of whether the prescribing optometrist or physician responds to or confirms the verification[.]" (Emphasis added.) Accordingly, the intent of the Utah Legislature is patently clear, and the Division does not have authority to promulgate a rule that would conflict with, or be contrary to this provision of the governing statute.

Inasmuch as the Division does not have authority to promulgate a rule as desired by the Optometrist Licensing Board, under usual circumstances the Board's remedy would be to lobby the Utah Legislature for an amendment to the governing statute, such that actual/active verification of a prescription is required. In this instance however, such a remedy is not available to the Board because of federal preemption. Federal preemption is the invalidation of a U.S. state law that conflicts with federal law. See Supremacy Clause of the United States Constitution, (Article VI, clause 2). In this matter, there is federal law that squarely addresses

the issue of active vs. passive verification. Specifically, the *Fairness to Contact Lens Consumers Act* sets forth that a seller of contact lenses may sell contacts so long as the prescription is verified, and that such verification occurs when “[t]he prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information [germane to the prescription].” See 15 U.S.C.A. § 7603(d)(3). Moreover, the U.S. Code of Federal Regulations provides that “[s]tate and local laws and regulations that . . . restrict prescription release or require active verification are preempted.” Accordingly, any administrative rule or statute requiring actual/active prescription verification would be invalidated under the Supremacy Clause of the United States Constitution.

Adjunct Issue

The same sort of legal analysis is applied relative to the adjunct issue, ie, whether the Division has authority to promulgate a rule precluding sellers of contact lenses from refilling a prescription that would provide patients with a supply of contacts well beyond the expiration date of the prescription. Again, the analysis must begin with an examination of the governing statute, Utah Code Ann. § 58-16a-801 (*Contact lens and ophthalmic lens seller or provider*). With this issue however, the focus is upon Subsection 801(1)(c), which provides that “[a] person may sell or provide contact lenses if the person . . . provides all contact lenses consistent with and in accordance with a valid contact lens prescription[.]” (Emphasis added.) As with the primary issue addressed above, it is necessary to determine whether a proposed administrative rule would conflict with the governing statute; or conversely, if a rule could be promulgated such that it would be in harmony with the governing statute.

The Definitions Section of the *Utah Optometry Practice Act* defines “Contact Lens Prescription” to mean an order for contact lenses that includes, inter alia, the “expiration date” of

the prescription. The term "expiration date," standing alone, is arguably subject to more than one interpretation, and appears to be a point of contention between optometrists and sellers of contact lenses. The following scenario is instructive: On July 1, 2016, a patient is prescribed two years' worth of contacts, said prescription having an expiration date of July 1, 2018. On May 1, 2018, he goes to a contact lens seller and attempts to purchase another two years' worth of contact lenses, asserting that his prescription does not expire until July 1, 2018. The position of the contact lens sellers is that because the expiration date has not yet come, the patient ought to be able to purchase the entire lot of a two year supply. The Board however, believes this position is ill founded, and that, in this scenario, twenty-two months' worth of the prescription has expired, and the patient ought to be permitted to procure only a two month supply of contacts.

It appears that the position held by the Board is correct. That is, Subsection 801(1)(c) requires a seller to "provide all contact[s] . . . in accordance with a valid contact lens prescription." (Emphasis added.) The sale of a full two years' worth of lenses (pursuant to a prescription that expires in two months) would run afoul of Subsection 801(1)(c) because not all of the lenses would be used by the expiration date, and twenty-two months' worth of that supply would not be "in accordance with a valid contact lens prescription." Inasmuch as the governing statute does not specifically address this issue, it is within the purview of the Division to promulgate a rule clarifying "expiration date" and/or "valid prescription." Such a rule could be drafted and promulgated so that it is not contrary to the governing statute, nor beyond its scope. Rather, it could easily be drafted to be in harmony with Subsection 801(1)(c).

CONCLUSION

Based upon the foregoing, it is our informal legal opinion that:

1) The Division does not have legal authority to promulgate a rule requiring sellers of contact lenses to secure actual verification of a prescription prior to making a sale of contacts;
and

2) The Division has legal authority to promulgate a rule which would preclude sellers of contact lenses from refilling a prescription that would provide patients with a supply of contact lenses well beyond the expiration date of the prescription.