

**STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF HEALTH
THREE CAPITOL HILL
PROVIDENCE, RHODE ISLAND 02908**

In the Matter of:

New England Healthcare Solutions,

Respondent.

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**Board of Pharmacy
File No. C15-264**

DECISION

I. INTRODUCTION

This matter arose pursuant to an Administrative Hearing Notice (“Notice”) issued to New England Healthcare Solutions (“Respondent”) on November 23, 2015 by the Department of Health (“Department”). The Respondent holds a license (“License”) as a wholesale distributor pursuant to R.I. Gen. Laws § 5-19.1-1 *et seq.* A hearing was scheduled for December 18, 2015 at which time the Respondent did not appear at hearing. Pursuant to Section 5.6 of the *Rules and Regulations of the Department of Health Regarding Practices and Procedures Before the Department of Health* (“Hearing Regulation”), service may be made by hand-delivery or first class mail and service is complete upon mailing, even if unclaimed or returned, when sent to the last known address of the party. In this matter, the Notice was sent to the Respondent’s last known addresses by first class and certified mail.¹ Since the Respondent was adequately noticed of hearing, a hearing was held before the undersigned on December 18, 2015.² Additionally, Section 12.9 of the Hearing Regulation provides that a judgment may be entered based on pleadings and/or

¹ See below as to the testimony regarding the addresses used to try to contact the Respondent including the Notice.

² Pursuant to R.I. Gen. Laws § 5-19.1-5, the Board of Pharmacy (“Board”) delegated its authority to hear this matter to the undersigned.

evidence submitted at hearing by a non-defaulting party. The Department was represented by counsel who rested on the record.

II. JURISDICTION

The administrative hearing was held pursuant to R.I. Gen. Laws § 42-18-1 *et seq.*, R.I. Gen. Laws § 23-1-1 *et seq.*, R.I. Gen. Laws § 5-19.1-1 *et seq.*, R.I. Gen. Laws § 42-35-1 *et seq.*, *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors* (“Licensing Regulation”), and the Hearing Regulation.

III. ISSUES

Whether the Respondent violated R.I. Gen. Laws § 5-19.1-13 and R.I. Gen. Laws § 5-19.1-21 and if so, what sanction(s) should be imposed.

IV. TESTIMONY AND MATERIAL FACTS

Scott Campbell, Chief Compliance Officer, testified on behalf of the Department. He testified that prior to the License being issued to the Respondent, he inspected the premises. See Department’s Exhibits One (1) (application) and Two (inspection report). He testified that the Respondent’s application listed three (3) contact addresses: mailing address, location address, and home address. He testified that after the License was issued, he tried to schedule a follow up inspection so sent notices to the Respondent at the mailing address, the location address, and home address, but that all the letters were returned marked as “return to sender.” See Department’s Exhibits Four (4); Five (5); and Six (6). He testified that he then inspected the licensed premises and discovered there was a new business now located at the Respondent’s facility address. See Department’s Exhibit Eight (8) (photograph). He testified that licensees are not permitted to change premises without informing the Board and that no notice was given to the Department of a change of address. See Department’s Exhibit Seven (7) (licensing printout).

V. DISCUSSION

A. **Legislative Intent**

The Rhode Island Supreme Court has consistently held that it effectuates legislative intent by examining a statute in its entirety and giving words their plain and ordinary meaning. *In re Falstaff Brewing Corp.*, 637 A.2d 1047, 1049 (R.I. 1994). If a statute is clear and unambiguous, “the Court must interpret the statute literally and must give the words of the statute their plain and ordinary meanings.” *Oliveira v. Lombardi*, 794 A.2d 453, 457 (R.I. 2002) (citation omitted). The Supreme Court has also established that it will not interpret legislative enactments in a manner that renders them nugatory or that would produce an unreasonable result. See *Defenders of Animals v. Dept. of Environmental Management*, 553 A.2d 541 (R.I. 1989) (internal citation omitted). In cases where a statute may contain ambiguous language, the Supreme Court has consistently held that the legislative intent must be considered. *Providence Journal Co. v. Rodgers*, 711 A.2d 1131 (R.I. 1998). The statutory provisions must be examined in their entirety and the meaning most consistent with the policies and purposes of the legislature must be effectuated. *Id.*

B. **Standard of Review for an Administrative Hearing**

It is well settled that in formal or informal adjudications modeled on the Federal Administrative Procedures Act, the initial burdens of production and persuasion rest with the moving party. 2 Richard J. Pierce, *Administrative Law Treatise* § 10.7 (2002). Unless otherwise specified, a preponderance of the evidence is generally required in order to prevail. *Id.* See *Lyons v. Rhode Island Pub. Employees Council 94*, 559 A.2d 130, 134 (R.I. 1989) (preponderance standard is the “normal” standard in civil cases). This means that for each element to be proven, the fact-finder must believe that the facts asserted by the proponent are more probably true than false. *Id.* When there is no direct evidence on a particular issue, a fair preponderance of the

evidence may be supported by circumstantial evidence. *Narragansett Electric Co. v. Carbone*, 898 A.2d 87 (R.I. 2006).

C. Relevant Statutes and Regulation

R.I. Gen. Laws § 5-19.1-21 states in part as follows:

Refusal, suspension and revocation of licensees. – The board of pharmacy, with the approval of the director, may deny, suspend, revoke or otherwise discipline the licensee upon proof that:

(6) The licensee's conduct is incompetent, or negligent which shall include, but not be limited to, any departure from or failure to conform to the minimal standards acceptable and prevailing pharmacy practice as determined by the board;

(11) The licensee has engaged in unprofessional conduct by failing to maintain the standards of practice or by such other conduct as prescribed in regulation;

(13) On or after July 1, 1994, good and sufficient cause shall exist for the refusal to renew and/or for the revocation of any pharmacy license if, after a hearing, the board of pharmacy determines that:

(iii) Any other causes as set forth in regulations.

R.I. Gen. Laws § 5-19.1-13 provides as follows:

Wholesalers' license – Fees – Display – Declaration of ownership and location. – The owner of each place of business, located within or outside this state, which distributes legend drugs and nonprescription drugs, at wholesale in this state, shall pay a license fee to be determined by the director, and thereafter, on or before a date to be determined by the director, a fee to be determined by the director, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs at wholesale at the specified location for the period ending on a date to be determined by the board, and each such owner shall at the time of payment of such fee file with the department, on a provided form, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of the ownership of such place of business mentioned in the form. It shall be the duty of the owner to immediately notify the department of any change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in such place of business. In the event such license fee remains unpaid on the date due, no renewal or new license shall be issued except upon payment of the license renewal fee. A license shall be issued to the owner and premise listed on the form and shall not be transferred. If a change in owner or premise listed on the form occurs, the license becomes null and void.

Section 26 of the Licensing Regulation requires in part as follows:

26.1 Pursuant to the provisions of §§5-19.1-12 and 5-19.1-13 of the Act, every wholesale distributor and/or manufacturer, wherever located, who engages in wholesale distribution into, out of, or within this state, must be licensed by the Board in accordance with the laws and regulations of this state, before engaging in wholesale distribution of prescription drugs.

26.2 Wholesale Distributors and/or Manufacturers - The Board requires the following from each wholesale drug distributor or manufacturer as part of the initial licensing procedure, and as part of any renewal of such license:

- (a) The name, full business address, and telephone number of the owner;
- (b) All trade or business names used by the owner;
- (c) Addresses, telephone numbers, and the names of contact persons for the facility used by the license for the storage, handling and distribution of prescription drugs;
- (d) The type of ownership or operation (i.e. partnership, corporation or sole proprietorship);
- (e) The names(s) of the owner and/or operator including:
 - (1) If a person, the name of the person;
 - (2) If a partnership, the name of each partner, and the name of the partnership;
 - (3) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any; and
 - (4) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.
- (f) the FDA manufacturing license number

26.4 Changes in any information required by §26.0 of these Regulations shall be submitted to the Department within fifteen (15) days of change.

26.6 The Board will consider the following factors in determining eligibility for licensure of persons who engage in the wholesale distribution or manufacturing of prescription drugs:

(g) Compliance with the requirements to maintain and/or make available to the state licensing authority or the federal, state, or local law enforcement officials those records to be maintained by wholesale drug distributors and manufacturers; and

Section 27 of the Licensing Regulation requires in part as follows:

27.1 In accordance with the provisions of §5-19.1-21 of the Act, the Board, with the approval of the Director, may deny, suspend, revoke or otherwise discipline the licensee upon proof that:

(6) The licensee's conduct is incompetent, or negligent which shall include, but not be limited to, any departure from or failure to conform to the minimal standards acceptable and prevailing pharmacy practice as determined by the Board.

D. Arguments

The Department argued that the Respondent's License should be revoked for violations of R.I. Gen. Laws § 5-19.1-13 and R.I. Gen. Laws § 5-19.1-21 and the Licensing Regulation.

E. Whether the Respondent violated R.I. Gen. Laws § 5-19.1-13 and R.I. Gen. Laws § 5-19.1-21

It is undisputed that the Respondent did not notify the Department that it was no longer located at its licensed premises. The failure to notify the Department of a change in location is a violation of R.I. Gen. Laws § 5-19.1-13 and R.I. Gen. Laws § 5-19.1-21(8) and (13)(iii). The failure to notify the Department of a change in location as well as a change in addresses and telephone numbers for the owner are violations of Sections 26 and 27 of the Licensing Regulation.

The Respondent's License expired on September 30, 2015 (Department's Exhibit Seven (7)) and was considered to be null and void pursuant to operation of R.I. Gen. Laws § 5-19.1-13 since there was a change in the premises listed on the application without notifying the Department.

Based on the forgoing, the Respondent violated R.I. Gen. Laws § 5-19.1-13, R.I. Gen. Laws § 5-19.1-21, and Sections 26 and 27 of the Licensing Regulation. The License is considered null and void and has now expired; however, if the Respondent in future applies for another license, the facts and conclusions of this decision shall be considered in a decision to grant or deny such an application.

VI. FINDINGS OF FACT

1. This matter arose pursuant to an Administrative Hearing Notice issued to the Respondent on November 23, 2015 by Department.

2. The Respondent held a license as a wholesale distributor pursuant to R.I. Gen. Laws § 5-19.1-1 *et seq.*

3. A hearing was scheduled for December 18, 2015 at which time the Respondent did not appear at hearing.

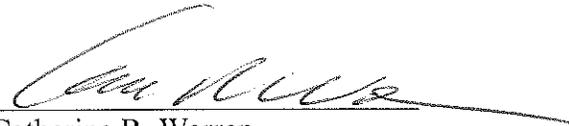
4. As the Respondent was adequately notified of hearing, the hearing went forward.

5. The facts contained in Section IV and V are reincorporated by reference herein.

VII. CONCLUSIONS OF LAW

Based on the forgoing, the Respondent's License is considered null and void and has now expired; however, if the Respondent in future applies for another license, the facts and conclusions of this decision shall be considered in a decision to grant or deny such an application.

Entered this day 19th January, 2016.


Catherine R. Warren
Hearing Officer

ORDER

I have read the Hearing Officer's Decision and Recommendation in this matter, and I hereby take the following action with regard to the Decision and Recommendation:

ADOPT
 REJECT
 MODIFY

Dated: 1/20/16


Nicole Alexander-Scott
Director

NOTICE OF APPELLATE RIGHTS

THIS DECISION CONSTITUTES A FINAL ORDER OF THE DEPARTMENT OF HEALTH PURSUANT TO R.I. GEN. LAWS § 42-35-12. PURSUANT TO R.I. GEN. LAWS § 42-35-15, THIS ORDER MAY BE APPEALED TO THE SUPERIOR COURT SITTING IN AND FOR THE COUNTY OF PROVIDENCE WITHIN THIRTY (30) DAYS OF THE MAILING DATE OF THIS DECISION. SUCH APPEAL, IF TAKEN, MUST BE COMPLETED BY FILING A PETITION FOR REVIEW IN SUPERIOR COURT. THE FILING OF THE COMPLAINT DOES NOT ITSELF STAY ENFORCEMENT OF THIS ORDER. THE AGENCY MAY GRANT, OR THE REVIEWING COURT MAY ORDER, A STAY UPON THE APPROPRIATE TERMS.

CERTIFICATION

I hereby certify on this 29 day of January, 2016 that a copy of the within Decision and Notice of Appellate Rights was sent by first class mail and certified mail to

Eli Manny Diaz
NE Healthcare Solutions, Inc.
91 Point Judith Road, Suite 302
Narragansett, RI 02882

Eli Manny Diaz and
NE Healthcare Solutions, Inc.
645 East Avenue
Warwick, RI 02886

Eli Manny Diaz and
NE Healthcare Solutions, Inc.
201 Monrovia Street
Springfield, MA 01104

and by hand-delivery to Colleen McCarthy, Esquire, Department of Health, Three Capitol Hill, Providence, RI 02908 and Scott Campbell, Inspector, Department of Health, Three Capitol Hill, Providence, RI 02908

