STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF HEALTH
HEALTH SERVICES REGULATION
BOARD OF NURSE REGISTRATION AND NURSING EDUCATION
THREE CAPITOL HILL
PROVIDENCE, RI 02908

In the Matter of:	:	
Gerald Dornhecker,	:	**A.H. File No. 12-961**
Respondent.	:	

DECISION

I. INTRODUCTION

The above-entitled matter came before the Board of Nurse Registration and Nursing Education ("Board") pursuant to a Summary Suspension[1] issued on December 5, 2012 by the Board to Gerald Dornhecker ("Respondent"). The Respondent is licensed as a nurse practitioner[2] in the State of Rhode Island pursuant to R.I. Gen. Laws § 5-34-1 *et seq.* A hearing was held before the Board on December 10, 2012. Both parties were represented by counsel and rested on the record.

II. JURISDICTION

The Board has jurisdiction over this matter pursuant to R.I. Gen. Laws § 5-34-1 *et seq.*, *Rules and Regulations for the Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs*, and the *Rules and Regulations of the Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health.*

[1] See Department's Exhibit One (1).
[2] The Respondent is also licensed as a registered nurse, but this decision only relates to his license as a nurse practitioner.

III. ISSUE

Whether the Respondent violated R.I. Gen. Laws § 23-34-24 and if so, what is the appropriate sanction.

IV. TESTIMONY AND MATERIAL FACTS

Patrick Kelly ("Kelly"), Chief of Compliance for the Board of Pharmacy, testified on behalf of the Board. He testified that he is familiar with the New England Compounding Center ("NECC") and that compounding is mixing compounds to make a drug that is not commercially available. On direct and re-direct examination, he testified that NECC issued a voluntary recall on October 4, 2012 and there was also a recall for all NECC products at approximately the same time. See Department of Health ("Department") Exhibits Four (4) and 12. He testified that the NECC recalls were well publicized in the media. He testified that on November 23, 2012, he spoke with the FDA (Food and Drug Administration) liaison who informed him that the FDA had performed an inspection of Skin Essentials which still had NECC products on its premises. See Department's Three (3) (brochure for Skin Essentials).

Kelly testified that he inspected Skin Essentials that day and met with the Office Manager, Donna Tomassi. He testified he searched the treatment rooms where prescriptions were held and observed multiple products including those labeled from NECC. He testified he found a voluntary recall list filled out by the Respondent listing NECC products but indicating that Skin Essentials did not have those products on its premises. See Department's Exhibit Four (4). He testified that the NECC products were supposed to be removed, quarantined, and segregated. He testified that he seized NECC items and photographed what he seized. See Department's Exhibit Nine (9) (photograph

of NECC items). He testified that the NECC items in said photograph were found in patient treatment rooms. He testified that if the products had been segregated and quarantined, they would have been removed from the treatment room and separated out so there was no chance that they would be used. See Department's Exhibits Ten (10) (list of the items seized by Kelly) and 11 (Kelly's investigative report).

On cross-examination and re-cross examination, Kelly testified that some of the items he found were not on the voluntary recall list.

Lorayne McGuiness ("McGuiness") testified on behalf of the Board. She testified that she is a Consumer Safety Officer/Investigator for the FDA and the FDA is a Federal agency that regulates the food, drug, and medical device industries. She testified that on October 6, 2012, NECC voluntarily recalled all of its products and forwarded that information to all of its clients. See Department's Thirteen (13) (NECC letter sent to its clients on October 6, 2012). She testified that she inspected businesses that received NECC products including Skin Essentials on October 23, 2012.

McGuiness testified that when she went to Skin Essentials, she met with the Respondent and asked to speak with the most responsible person at the business and he told her to meet with Tomassi, the office manager, but when she spoke to Tomassi and told her that she was there for the drug recall, Tomassi told her to speak with the Respondent. She testified that the Respondent told her that he received the NECC letter (Exhibit 13) and that he had no NECC products on hand and that he only carried two (2) products from NECC but she told him she had a list of invoices from NECC showing its products sent to Skin Essentials so the Respondent then said he had some NECC products and came back with two (2) bottles, one of Hyaluronidase and one of Gyalic Acid. She

testified that he also obtained a NECC bottle from a refrigerator and also took her to a patient room where there were nine (9) NECC bottles on a shelf. She testified that she told him that she was upset that the bottles were not separated and quarantined. She testified that she told him all NECC products should be quarantined and segregated and when she left, the nine (9) bottles were on the counter. She testified that the situation got tense and she recommended a referral to the State. See Department's Exhibit 14 (McGuiness investigation report).

On cross-examination, McGuiness testified that of the other businesses that she inspected that day that had NECC products, those NECC products were segregated and shrink wrapped. She testified that she did not have authority to seize the NECC products.

The Respondent testified on his behalf. He testified that he filled out Exhibit Four (4) on October 26, 2012, approximately two (2) days after McGuiness came to the office. He testified that he was aware of the NECC recall of all products but he was not aware of what to do with the products until the FDA investigator came. He testified that he never used any of the NECC products after the recall of October 6, 2012. He testified that he can use certain medicines because of his license and that Dr. Grande (who is associated with Skin Essentials) does not use medicine and the other nurse at Skin Essentials has not worked there for ten (10) months so he is the only one using the products.

On cross-examination, the Respondent testified that he knew the recall was for all NECC products. He testified that he did not quarantine and segregate the products after receiving the notice of recall because he tried to contact NECC multiple times to find out what segregate meant. He testified it was only after McGuiness came out and he asked her what quarantine meant and she told him to put all the products aside. He testified that

he then put all the NECC products identified in Exhibit Four (4) aside in a cabinet away from all the common spaces in the facility. He testified that Kelly found the Hyaluronidase in the refrigerator and triple anesthetic cream in another treatment room since he (Respondent) forgot about them since they were "so outdated." He testified that he quarantined the products "to the best of his knowledge" underneath a cabinet inside a room that only he utilized and he does not have any locked facilities. He testified that Kelly did find the products in patient room in a cabinet since he felt they were segregated because they were away from other people working in his facility but he did not mark them because he is the only one who uses them.

The Respondent testified that for Exhibit Four (4), he listed the NECC products as not having them because he was going to dispose them but he poured one (1) of them down the sink and then he decided that he could not dispose of them like that. He testified it would have been accurate to check off on Exhibit Four (4) that he had those products but he had intended to dispose the products. He testified that he is the only using the medicine so he would be responsible for segregating the medicine. He testified that Dr. Grande is not the Medical Director but signs for medicine when the manufacturer requires a doctor's signature.

On redirect examination, the Respondent testified that his intent on Exhibit Four (4) was to identify what was in the building which he why he included the lot numbers in the list on the exhibit. He testified that except for two (2) products that he forgot, the products included on Exhibit Four (4) were what the Department seized.

Upon questioning from the Board, the Respondent testified that he is the owner of Skin Essentials.

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 (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. DEM*, 553 A.2d 541 (R.I. 1989) (citation omitted). In cases where a statute may contain ambiguous language, the Rhode Island Supreme Court has consistently held that the legislative intent must be considered. *Providence Journal Co. v. Rodgers*, 711 A.2d 1131, 1134 (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. Statutes

R.I. Gen. Laws § 5-34-24 states in part as follows:

> Grounds for discipline of licensees. – The board of nurse registration and nursing education has the power to deny, revoke, or suspend any license to practice nursing; to provide for a non-disciplinary alternative only in situations involving alcohol or drug abuse or to discipline a licensee upon proof that the person is:
>
> ***
>
> (6) Guilty of unprofessional conduct which includes, but is not limited to, all of the above and also:
>
> ***
>
> (v) Willful disregard of standards of nursing practice and failure to maintain standards established by the nursing profession.

D. Arguments

In closing, the Respondent argued that it would not be logical to list products on Exhibit Four (4) that he did not have but he forgot about two (2) products that were not on the list but he knew what NECC products were segregated, where they were, and no one else could uses those medicines. In closing, the Department argued that the Respondent admitted he knew about the total NECC recall but did not segregate the products after the recall or even after the FDA inspector warned him. Additionally, the Department argued that the Exhibit Four (4) is misleading and there is no explanation for the Respondent's behavior.

E. Whether the Respondent Violated his Statutory Obligations

The Respondent admitted that he knew about the NECC recall but that he did not do anything until after the FDA inspection. Prior to the FDA coming, he testified that he

did not know what segregate meant. He showed McGuiness the Hyaluronidase but then put it in the refrigerator (where Kelly found it) after being told to segregate all NECC products. NECC products were left out on a counter in a patient room when McGuiness left but when Kelly returned, NECC products were in a cabinet in a patient room. The common understanding of segregation or quarantine would be to separate from other people or from other items.[3] Indeed, McGuiness told the Respondent to quarantine and segregate all NECC products including the nine (9) bottles found on the shelf in a treatment room but yet, Kelly found NECC products again on a shelf in the treatment room.

The Respondent testified that he segregated the NECC products to the best of his ability and was not sure what to do until McGuiness inspected the premises. However, NECC products were still on a shelf in a patient room when Kelly inspected the premises. The NECC letter (Department's Exhibit 13)) which the Respondent received stated to segregate the products and fax the form (Exhibit Four (4)) to a given facsimile number which apparently was never done by Respondent. The Respondent had almost a month between when the FDA and the Department's inspection and in that time, he did not take NECC products out of the patient room, refrigerator, and elsewhere and segregate them elsewhere. Instead, he claimed he segregated them as he understood he should. Despite receiving extra instruction from the FDA on what segregate means, he left the products essentially stored the same way after the FDA came as before as the NECC products were stored in a patient room and refrigerator (etc.) when Kelly came and seized them all.

---

[3] *Random House Webster's Unabridged Dictionary* (2001) defines segregate to include "to separate or set apart from others or from the main body or group; isolate" and "to separate, withdraw, or go apart; separate from main body and collect in one place." "Quarantine" is defined as "a strict isolation imposed to prevent the spread of disease."

It was only after the FDA came that the Respondent filled out the recall form. His explanation for the inaccurate information on the form was that he was going to dispose of those products so he listed them and said he did not have them. Of course, if he was really going to throw out all the products, he would not have to list any of them because he could just have written he did not have any NECC products because he had disposed of them. The Respondent's explanation regarding Exhibit Four (4) is illogical. He listed products that he planned to dispose of so he wrote that he did not have the products that he listed.

Based on the Respondent's actions detailed above regarding the NECC recall, the Respondent did not understand and did not comply with his statutory obligations regarding the handling of the recall when he received notice of the initial recall and even after the FDA inspector told him what to do.

Wherefore, the Board voted unanimously to find the Respondent's actions as detailed above in violation of R.I. Gen. Laws 5-34-24 (6)(v) and that his license as a Nurse Practitioner shall be suspended for six (6) months and that within said six (6) months, he shall submit to the Board for its approval, policy and procedures for his business that ensures adherence to Federal and State regulations regarding inventory.

By Order of the Board,

Peggy Matteson, PhD, RN

Peggy Matteson, RN, PhD, Chair

Entered this 19th day of December, 2012.

NOTICE OF APPELLATE RIGHTS

PURSUANT TO R.I. GEN. LAWS § 5-34-28, APPEALS OF DECISIONS ARE GOVERNED BY THE ADMINISTRATIVE PROCEDURES ACT, R.I. GEN. LAWS § 42-35-1 *et seq.* 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 DECISION 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 19 day of December, 2012 that a copy of the within Order and Notice of Appellate Rights was sent by first class mail, postage prepaid to -

Peter Petrarca, Esquire
330 Silver Spring Street
Providence, RI 02904

↓ electronic mail and

and by hand-delivery to Jennifer Sternick, Esquire, Department of Health, Three Capitol Hill, Providence, RI 02908.

12/19/12