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July 15, 2015

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
RECEIPT REQUESTED NO. 7014 0510 0001 0375 2152
Paul M. Garbarini, Esq.
Attorney At Law
P.O. Box 1551
Northampton, MA 01061

RE: In the Matter of Royal Palm Specialty Pharmacy, License No. DS89765
Board of Registration in Pharmacy Docket No. PHA-2011-0309

Dear Attorney Garbarini:

Enclosed is the *Final Decision and Order ("Final Order")* and Ruling on Respondent's Objections to Tentative Decision issued by the Board of Registration in Pharmacy (Board) in connection with the above-referenced matter. The effective date of the Board's Order is ten (10) days from the date appearing on page 2 of the *Final Order* ("Date Issued"). Your appeal rights are noted on page 2 of the *Final Order.*

Sincerely,

David Sencabaugh, R. Ph.
Executive Director

Enc.

cc: Richard Banks, Prosecuting Counsel
Jason Barshak, Hearings Counsel

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of	)	
Royal Palm Specialty Pharmacy	)	PHA-2011-0309
Registration No. DS89765	)	
License Expiration Date 12/31/15	)	

FINAL DECISION AND ORDER

FINAL DECISION

On December 2, 2013, January 6, 2014, January 13, and January 15, 2014, the Board of Registration in Pharmacy ("Board") held a formal adjudicatory hearing in this matter before Administrative Hearings Counsel ("AHC") Vivian Bendix. On February 18, 2015, the ACH issued a Tentative Decision containing her findings of fact, credibility determinations, and conclusions of law. On March 27, 2015, the Board received Respondent Royal Palm Specialty Pharmacy's Objections to the Tentative Decision.[1] Prosecuting Counsel did not file objections. On April 27, 2015, Prosecuting Counsel filed Responses to Respondent's Objections.[2]

The Board hereby adopts the Tentative Decision, including all findings of fact, credibility determinations, conclusions of law, and discussion contained therein as the Board's Final Decision, with one correction to a citation. Specifically, in ¶ 39, the ACH used the incorrect citation to the regulation requiring a change of manager of record application to be accompanied by an inventory of controlled substances; accordingly, the citation is changed from "247 CMR 6.07(h)(1)" to "247 CMR 6.03(1)(a)." The Board rejects Respondent's Objections to the Tentative Decision, for the reasons set forth in the Board's Ruling on Respondent's Objections to the Tentative Decision, issued concurrently with this Final Decision and Order.

ORDER

Based on its Final Decision, the Board permanently **revokes** Respondent's pharmacy license, DS89765.

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[1] The objections were timely filed in accordance with an Assented to Motion to Extend the Time to File Objections from March 20, 2015 to march 30, 2015, which the Board allowed.

[2] Prosecution's response to Respondent's objections was timely filed in accordance with an Assented to Motion for Further Enlargement of Time, until April 27, 2015, which the Board allowed.

The Board voted to adopt the within Final Decision at its meeting held on June 30, 2015, by the following vote:

In favor:	Patrick Gannon; Richard Tinsley; Timothy Fensky; Garrett Cavanaugh; Catherine Basile; Susan Cornacchio; William Cox; Michael Godek; Andrew Stein; Phillippe Bouvier; Karen Conley
Opposed:	None
Abstained:	None
Recused:	None
Absent:	Edmund Taglieri

The Board voted to adopt the within Final Order at its meeting held on June 30, 2015, by the following vote:

In favor:	Patrick Gannon; Richard Tinsley; Timothy Fensky; Garrett Cavanaugh; Catherine Basile; Susan Cornacchio; William Cox; Michael Godek; Andrew Stein; Phillippe Bouvier; Karen Conley
Opposed:	None
Abstained:	None
Recused:	None
Absent:	Edmund Taglieri

EFFECTIVE DATE OF ORDER

This Final Decision and Order becomes effective upon the tenth (10th) day from the Date Issued below.

RIGHT TO APPEAL

Respondent is hereby notified of the right to appeal this Final Decision and Order either to the Supreme Judicial Court pursuant to M.G.L. c. 112, § 64 or to a Superior Court with jurisdiction pursuant to M.G.L. c. 30A, § 14. Respondent must file its appeal within thirty (30) days of receipt of notice of this Final Decision and Order.

Board of Registration in Pharmacy,

David A. Sencabaugh, R.Ph.
Executive Director

Date Issued: 7-15-15

Notified:

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
RECEIPT REQUESTED NO. 7014 0510 0001 0375 2152

Paul M. Garbarini
Attorney At Law
P.O. Box 1551
Northampton, MA 01061

BY HAND DELIVERY

Richard L. Banks
Office of Prosecution
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 500
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COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

IN THE MATTER OF Royal Palm Specialty Pharmacy Registration No. DS 89765 License Expiration Date 12/31/15[1]	Docket No. PHA-2011-0309

TENTATIVE DECISION [2]

I. Procedural Background

On April 26, 2013, the Board of Registration in Pharmacy ("Board") issued an Order to Show Cause ("Order") to Royal Palm Specialty Pharmacy ("Respondent RPSP" or "RPSP"), a pharmacy registered by the Board, Registration No. DS 89765. The Order to Show Cause directed Respondent RPSP to show cause why its registration to operate as a Pharmacy should not be suspended, revoked, or otherwise disciplined pursuant to Massachusetts General Laws ("G.L.") Chapter 112, §§ 40, 42A, and 61 and 247 CMR 2.00 *et seq.*, based upon allegations that related, but were not limited to, failure to properly compound a prescription drug that was dispensed to a patient who suffered a severe adverse reaction; failure to timely report to the Board the improper compounding and dispensing of said drug; failure to adhere to a Plan of Correction presented to the

[1] The original caption in the instant matter reflected the registration expiration date as December 31, 2013. However, Respondent's current record of standing with the Board reflects that Respondent's registration will expire on December 31, 2015, unless renewed. (Exhibit 21; Board records of which the Board takes administrative notice).

[2] Pursuant to 801 CMR 1.01 (11)(c), the Board issues a tentative decision in the first instance. Parties may file objections within thirty (30) days of the filing of the decision. Any objections filed must include written argument in support of the objections as the Board will not hold a hearing on the objections. Each party may file a response to opposing counsel's objections within twenty (20) days of receipt of those objections.

Board following the incident involving the improperly compounded and dispensed prescription; failure to properly label a prescription medication; failure to conduct and file a complete inventory of controlled substances with an application for a change in the Manager of Record; utilization of support personnel in numbers that exceeded staffing ratios established by the Board; and providing practitioners with blank prescription forms referencing the pharmacy. Having been granted an extension of time to file a Request for Hearing and an Answer to the Order to Show Cause ("Answer"), on June 10, 2013, Respondent RPSP filed its Request for Hearing and Answer, admitting certain allegations against and denying others.

On October 28, 2013, Respondent RPSP moved to continue the commencement of hearings scheduled to begin on November 13, 2013. ("Motion to Continue").The Motion to Continue was granted and on December 2, 2013, January 6, 2014, January 13, 2014, and January 15, 2014, a formal adjudicatory hearing was held before Administrative Hearings Counsel Vivian Bendix in accordance with G.L. c. 30A and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01, *et seq.* (A hearing date scheduled for December 9, 2013 was continued when Counsel for Respondent fell ill). Prosecuting Counsel was Richard L. Banks, Jr., Esq. Respondent RPSP was represented by Paul M. Garbarini, Esq.

The instant matter involving Respondent RPSP was heard along with two other related matters against Respondent Agnes S. Rubin, R.Ph. and Respondent Mark J. Rubin, R.Ph. The three matters arose out of a single incident involving a misfilled prescription that resulted in the dispensing of an improperly compounded medication to a [redacted] patient. In light of the substantial overlap of facts, the parties agreed that all evidence presented with respect to each of the cases would be admissible in all three cases so long as the evidence was relevant.

Following the close of the hearing, the record was left open to allow the parties to review, redact, and submit certain exhibits. Briefs were due on February 10, 2014. On February 3, 2014, the Board granted the parties' joint motion to extend the time for filing Briefs. Respondent filed its Brief on March 3, 2014. On March 3, 2014, Prosecuting Counsel filed an assented-to motion to submit a late

Brief, which was granted by the Board. Prosecuting Counsel filed his Brief on March 7, 2014.

The following witnesses testified at the formal adjudicatory hearing:[3]

For the Prosecution
[redacted]
Margaret Cittadino
[redacted]
Cheryl Lathum, Pharm. D
Mother of Patient A
Agnes Rubin
Mark J. Rubin
Leo A. McKenna, Pharm. D, expert witness

For Respondent
Mark J. Rubin

II. Exhibits

Exhibit 1	May 31, 2013 Cover Letter and Amended Order to Show Cause: In the Matter of Agnes S. Rubin (PHA-2012-0006) ["Agnes Rubin Matter"]
Exhibit 2	June 21, 2013 Answer to Amended Order to Show Cause and Request for Hearing (Agnes Rubin Matter)
Exhibit 3	Royal Palm Stipulations, January 6, 2014 (Agnes Rubin Matter; In the Matter of Mark J. Rubin (PHA-2012-0005) ["Mark Rubin Matter]; In the Matter of Royal Palm Specialty Pharmacy (PHA- 2011-0309) ["Royal Palm Matter"]
Exhibit 4	Application to Manage and Operate a New Community Pharmacy with attachments, received by Board of Registration of Pharmacy February 9, 2011
Exhibit 5	Logged Formula Worksheet, July 29, 2011[4]
Exhibit 6	Cover Sheet and Application for Change of Manager with attachments, received by Board of Registration in Pharmacy on August 15, 2011
Exhibit 7	Letter: from Agnes Bergeron, R Ph to Board of Registration in Pharmacy, July 1, 2011

[3] Because the parties agreed that all evidence presented with regard to each of the three related cases before the Board would be admissible in each case so long as it was relevant, all witnesses who testified during the course of the hearing are listed.

[4] The word "wrong" appearing on the *Logged Formula Worksheet* was not part of the original document. Rather, it was handwritten by an unidentified individual at some point after the document was generated. (Testimony of Respondent Mark Rubin; Exhibit 5)

Exhibit 8	Prescription Form for Patient A, July 28, 2011
Exhibit 9	Claim Search Form showing transactions on July 29, 2011 and August 1, 2011 re prescription filled for Patient A
Exhibit 10	State of Florida Board of Pharmacy: Final Order Dismissing Case, Department of Health vs. Agnes Bergeron, RPH, Case No. 2009-20958
Exhibit 11	Pharmacy Board Complaint Form re: Mark and Agnes Rubin with attachments, filed by Patient A's mother, December 13, 2011
Exhibit 12	Inspection Report re: December 29, 2011 Inspection of Royal Palm Specialty Pharmacy
Exhibit 13	Inspection Report re: April 24, 2012 Inspection of Royal Palm Specialty Pharmacy
Exhibit 14	Inspection Report re: January 15, 2013 Inspection of Royal Palm Specialty Pharmacy
Exhibit 15	Investigative Report produced by Cheryl Lathum re Docket Nos. PHA-2011-0309; PHA-2012-0004; PHA-2012-0005; PHA-2012-0006; PHA-2012-0060; PHA-2012-0061; PHA-2012-0065, May 3, 2012
Exhibit 16	May 15, 2013 Cover Letter and Order to Show Cause: In the Matter of Mark J. Rubin (PHA-2012-0005)
Exhibit 17	June 5, 2013 Cover Letter and Respondent Mark J. Rubin's Answer to Order to Show Cause and Request for Hearing
Exhibit 18	United States Pharmacopeia, Chapter 795: Pharmaceutical Compounding – Nonsterile Preparations
Exhibit 19	Agnes S. Rubin Record of Standing, November 25, 2013
Exhibit 20	Mark J. Rubin Record of Standing, November 25, 2013
Exhibit 21	Royal Palm Specialty Pharmacy Record of Standing, November 25, 2013
Exhibit 22	Letter: Beliveau, Esq. to Owner/General Manager Royal Palm Specialty Pharmacy, August 15, 2011
Exhibit 23	December 27, 2011 Fax Cover Sheet and Email re Reporting Error, from [redacte to Massachusetts Board of Pharmacy
Exhibit 24	Certificate of Organization for Royal Palm Specialty Pharmacy LLC (without signature), February 14, 2011
Exhibit 25	April 26, 2013 Cover Letter and Order To Show Cause: In the Matter of Royal Palm Specialty Pharmacy (PHA-2011-0309)
Exhibit 26	June 5, 2013 Cover Letter and Respondent Royal Palm Specialty Pharmacy's Answer to Order to Show Cause and Request for Hearing
Exhibit 27	April 11, 2012 Letter/Request for Information: to [redacte from Lathum
Exhibit 28	Documents submitted to Massachusetts Board of Pharmacy by Royal Palm Specialty Pharmacy in reply to April 11, 2012 request for information

Exhibit 29	December 21, 2011 Letter/Request for Information: to [redacted] from Lathum
Exhibit 30	Documents submitted to Massachusetts Board of Pharmacy by Royal Palm Specialty Pharmacy in reply to December 21, 2011 request for information
Exhibit 31	Email communications between Mother of Patient A and Mark J. Rubin, July 18, 2011
Exhibit 32	Board of Registration in Pharmacy Regulations at 247 CMR 6.00

III. Stipulations The parties agreed that the following stipulations may be accepted as true and entered into the record. Accordingly, the Board adopts Stipulations 1-8 and 10-17 as findings of fact, which are supported by evidence presented at the hearing. With regard to Stipulation 9, the evidence educed at the hearing showed that the prescription was faxed to Royal Palm Specialty Pharmacy by Patient A's physician rather than presented by Patient A's mother. The remainder of the stipulation, in particular relative to the date presented to the pharmacy and the description of the prescribed medication, is supported by the evidence presented at the hearing and adopted by the Board.

1. Ms. Rubin knew she was [Redacted] when, in February of 2011, she filed her application with the Board of Registration in Pharmacy to manage and operate a new pharmacy – Royal Palm Specialty Pharmacy (hereafter "Royal Palm").
2. Ms. Rubin knew she was [Redacted] when she appeared before the Board in March of 2011 in support of her application.
3. Ms. Rubin became Manager of Record for Royal Palm Specialty Pharmacy effective on April 29, 2011.
4. Royal Palm Specialty Pharmacy opened its doors for business in late May of 2011.
5. In or around June of 2011, Ms. Rubin contacted the Associate Director of the Board, Margaret Cittadino, and discussed the Board's policies regarding changing a manager of record and taking a leave of absence.
6. In early July of 2011, Ms. Rubin informed the Board's staff by letter that she would be taking a leave of absence from her full-time position and would maintain part-time duty as Manager of Record for Royal Palm.

7. Ms. Rubin did not file an Application for Change of Manager or the required controlled substance inventory or filing fee to effect a change in the Manager of Record for Royal Palm when she sent the letter to the Board in early July of 2011.

8. Ms. Rubin [redacted]

9. On July 28, 2011, the mother of Patient A presented a prescription at Royal Palm for T-3 10 mcg SR #30 capsules.

10. There was no formula or worksheet for compounding 10 mcg capsules of T-3 in the Royal Palm log book or reference materials prior to July 28, 2011.

11. The T-3 medication that was compounded and dispensed by Royal Palm was made with untriturated or undiluted T-3 and, as a result was approximately 1,000 times stronger than what was prescribed.

12. Royal Palm incorrectly compounded Patient A's prescription for T-3 (liothyronine) on July 29, 2011 and dispensed the incorrectly compounded drug on July 29, 2011.

13. On August 1, 2011, [redacted] contacted Patient A's mother on behalf of Royal Palm to report that the T-3 medication which had been dispensed for Patient A was wrongly compounded. Patient A's mother indicated that Patient A had been having heart palpitations and that they were on their way to the hospital.

14. On August 1, 2011, Patient A's mother contacted Royal Palm from the local hospital. She reported that she was with Patient A and she requested more details about the magnitude of the T-3 overdose.

15. On or about August 17, 2011, Royal Palm received a letter from an attorney for Patient A informing Royal Palm that its compounding and dispensing error had caused Patient A significant medical problems which remain on-going to the very moment. The letter asked for information about Royal Palm's insurance carrier and additionally asked that Royal Palm staff "refrain from contacting my clients to discuss this case, but instead, refer any questions or concerns to my attention."

16. Inspections of the Royal Palm pharmacy were conducted by Board investigators on December 21, 2011, April 24, 2012, and January 13, 2013.

17. Telephone line carrier Vocalocity produced call logs reflecting instances of contact or attempted contact between Royal Palm Specialty Pharmacy and Patient A's mother. A list of those calls (with the duration of each call shown in minutes in brackets) follows:

On August 2, 2011 (Tuesday)

@13:48 – call from Royal Palm (x303) to cell phone of Patient A's mother [1]

On August 1, 2011 (Monday)

@19:35 – call from cell phone of Patient A's mother to Royal Palm (main #) [1]

@19:35 – call from cell phone of Patient A's mother to Royal Palm (x303) [2]

@19:11 – call from Royal Palm (x303) to home phone of Patient A's mother [2]

@16:40 – call from Royal Palm (x303) to cell phone of Patient A's mother [3]

On July 31, 2011 (Sunday)

no calls recorded

On July 30, 2011 (Saturday)

@14:30 – call from cell phone of Patient A's mother to Royal Palm (x301) [1]

@14:29 - call from cell phone of Patient A's mother to Royal Palm (main #) [1]

@13:33 – call from cell phone of Patient A's mother to Royal Palm (main #) [1]

@13:32 - call from cell phone of Patient A's mother to Royal Palm (x301) [1]

@13:31 - call from cell phone of Patient A's mother to Royal Palm (main #) [1]

On July 29, 2011 (Friday)

@21:46 – call from Royal Palm to cell phone of Patient A's mother [2]

V. Findings of Fact

Preliminary Findings

1. On or about April 29, 2011, the Board issued to Respondent Royal Palm Specialty Pharmacy (hereinafter "RPSP") a registration to engage in practice as a pharmacy in the Commonwealth of Massachusetts, Registration No. DS 89765. RPSP's registration is current and will expire on December 31, 2015 unless renewed. (Testimony of Respondent AR; Testimony of Cittadino; Exhibits 1,2, 4; Board records of which the Board takes administrative notice)
2. On or about April 20, 2001, the Board issued to Respondent Agnes Rubin (hereinafter "Respondent AR") a registration to engage in practice as a pharmacist in the Commonwealth of Massachusetts ("Commonwealth"), Registration No. PH 25022. Respondent AR's registration is current and will expire on December 31, 2016 unless renewed.[5] (Testimony of Respondent AR; Exhibits 1,2, 19; Board records of which the Board takes administrative notice)
3. Respondent AR is also licensed to practice as a pharmacist in Arizona, Arkansas, Connecticut, Florida, Georgia, Kentucky, Louisiana, Maryland, Nebraska, Oregon, Tennessee, and Virginia. (Testimony of Respondent AR; Exhibits 4, 28)

[5] The original caption in the matter before the Board involving Respondent Agnes Rubin (PHA-2012-0006) erroneously reflected the expiration date of Ms. Rubin's registration as December 31, 2013 rather than as December 31, 2014, the actual expiration date. Respondent Agnes Rubin's current record of standing with the Board reflects that she has renewed her registration and her registration will expire on December 31, 2016, unless renewed. (Exhibits 1,19, Board records of which the Board takes administrative notice).

4. In January 2001, Respondent AR earned a Bachelor of Pharmacy degree from the Massachusetts College of Pharmacy. She has practiced as a pharmacist since 2001. While working in Palm Beach, Florida, Respondent AR trained under a compounding pharmacist who practiced sterile and non-sterile compounding. Since 2008, Respondent AR has had significant compounding experience. Respondent AR served as the MOR (known in Florida as the *Pharmacist in Charge*) at a pharmacy in Palm Beach County, Florida. (Testimony of Respondent AR; Testimony of Respondent Mark J. Rubin)

5. On the application to manage and operate RPSP as a pharmacy in the Commonwealth, filed with the Board in February 2011, Respondent AR identified herself as the Owner and Manager of Record ("MOR") of RPSP. Respondent AR has at all times been the sole owner of RPSP. Moreover, Respondent AR was the MOR of RPSP from April 29, 2011 until September 13, 2011, including in July and August 2011. (See Finding of Fact, ¶ 35, below) (Testimony of Respondent AR; Testimony of Cittadino; Testimony of Respondent MR; Testimony of [redact]; Exhibits 3, 4, 6, 24)

6. On or about April 20, 2011, the Board issued to Respondent Mark J. Rubin (hereinafter "Respondent MR") a registration to engage in practice as a pharmacist in the Commonwealth of Massachusetts, Registration No. PH 233459. Respondent MR's registration is current and will expire on December 31, 2016 unless renewed.[6] (Testimony of Respondent MR; Exhibits 16,17, 20; Board records of which the Board takes administrative notice)

7. Respondent MR has been practicing as a pharmacist since 1997, with a subspecialty in compounding medications. He has compounded medications since 1997. While he does not currently own a pharmacy, Respondent MR has owned compounding pharmacies in Florida that did both retail and

[6] The caption in the matter before the Board involving Respondent Mark Rubin reflected the registration expiration date as December 31, 2014. However, Respondent Mark Rubin's current record of standing with the Board reflects that Respondent Mark Rubin's registration has been renewed and will expire on December 31, 2016. (Exhibits 16, 20, Board records of which the Board takes administrative notice).

compounding business. One such pharmacy was Royal Palm Compounding Pharmacy, where Respondent AR became an employee in 2009. At another pharmacy he owned, Express Care Pharmacy, Respondent MR served as the Pharmacist in Charge or the MOR. (Testimony of Respondent AR, Testimony of Respondent MR)

8. Respondent MR is licensed to practice as a pharmacist in eight (8) states. (Testimony of Respondent MR)

9. Respondent AR and Respondent MR were married in July 2011. In May 2011, they were living together. (Testimony of Respondent AR, Testimony of Respondent MR)

10. [redacted] has been a pharmacist since about 1991. [redacted] has been employed as a pharmacist at RPSP since the pharmacy opened in May 2011. On September 13, 2011, [redacted] became the MOR at RPSP when the Board approved RPSP's Application For Change in Manager (Testimony of [redacted] Testimony of Respondent AR; Testimony of Respondent MR; Exhibit 6)

11. [redacted] is a pharmacist who has held the position of MOR at RPSP since late 2012. (Testimony of [redacted])

12. Margaret Cittadino became the Associate Director of the Board on November 1, 2007. Ms. Cittadino's duties included overseeing the licensing process for new pharmacies, including reviewing applications for the establishment of new pharmacies. (Testimony Cittadino)

13. Cheryl Lathum, Pharm D (Dr. Lathum), has been employed as an investigator for the Massachusetts Department of Public Health, Division of Health Professions Licensure, Office of Public Protection since 2007. Dr. Lathum earned a Bachelor of Pharmacy degree from the Massachusetts College of Pharmacy in 1988 and a Pharm D from the University of Colorado in 2006. Dr. Lathum is board certified in pharmacological therapy. (Testimony of Lathum)

14. In July 2011, Patient A was a [redacted] college student whose physician prescribed for him a thyroid medication known as liothyronine or T-3. The

prescription for T-3 10mcg SR#30 capsules was presented for filling to RPSP on July 28, 2011. (Testimony of Respondent AR, Testimony of Respondent MR; Testimony of [redacte Testimony of Mother of Patient A; Exhibits 3, 8)

15. Patient A resided with his mother ("Mother of Patient A" or "Mother") in [redacted]. Mother of Patient A picked up the medication filled pursuant to Patient A's prescription for T-3 10mcg SR#30 capsules at RPSP on July 29, 2011. (Testimony of [[redacte Testimony of Mother; Exhibit 3)

16. Without objection, Leo A. McKenna, Pharm D ("Dr. McKenna") was qualified as the Prosecution's expert on the provisions of the United States Pharmacopeia ("USP"), specifically Chapter 795 relating to non-sterile compounding and Chapter 797, relating to sterile compounding.

17. Dr. McKenna has a Bachelor of Science and Doctorate in Pharmacy. Additionally, Dr. McKenna has participated in additional training conducted by the United States Food and Drug Administration in compounding sterile and non-sterile medications and the processes related thereto. (Testimony of McKenna)

18. Dr. McKenna has been employed by the Department of Public Health, Division of Health Professions Licensure since 2004. More specifically, Dr. McKenna has worked with the Board of Registration in Pharmacy, currently as an investigator and previously as a quality assurance coordinator. In addition to conducting investigations, Dr. McKenna's duties have included assisting in developing policy related to professional standards in the practice of pharmacy and developing systems aimed at preventing medication errors. (Testimony of McKenna)

19. Dr. McKenna has done hundreds of inspections involving compounding pharmacies. Over a period of 10 years, he has handled matters raising issues related to USP Chapters 795 and 797, many of which involved process and medication errors. (Testimony of McKenna)

Duties of the MOR

20. In accordance with the Board's regulations at 247 CMR 2.00, a pharmacist MOR is "...responsible for the operation of a pharmacy... in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs.

21. In accordance with 247 CMR 6.07, among the responsibilities of a pharmacist MOR are: "the establishment, monitoring, and enforcement of policies and procedures which encourage acceptable standards of practice consistent with Board regulations at 247 CMR 2.00 *et seq.*, and all other applicable federal and state laws and regulations"; "the establishment, monitoring and enforcement of policies and procedures which maintain the standards of professional practice as such standards relate to the dispensing of pharmaceuticals, including the proper supervision of technicians, and the delegation of authority to another pharmacist when not on duty"; "the maintenance of adequate staff in the pharmacy...in order to ensure that the practice of pharmacy shall be carried out in accordance with Board regulations at 247 CMR 2.00 *et seq* and all other applicable federal and state laws and regulations"; and "notification to the Board in writing of his or her termination as pharmacist Manager of Record within ten working days."

22. Board regulations at 247 9.01 (1) and (3) require pharmacists to conduct professional activities in conformance with federal, state, and municipal laws, including the Board's regulations and the standards of the current United States Pharmacopoeia. In accordance with 247 CMR 2.00 and 247 CMR 6.07, the MOR is responsible for ensuring that pharmacists comply with accepted standards of pharmacy practice and the requirements of pertinent federal, state, and municipal statutes and regulations, including the USP. The MOR is further responsible for establishing, monitoring, and enforcing policies and procedures that encourage such compliance.

<u>Duties of a Pharmacist, a Compounder, and a Compounding Pharmacy</u>

23. Board regulations at 247 CMR 9.01 (1) and (3) require pharmacists to conduct professional activities in conformance with federal, state, and

municipal laws, including the Board's regulations and the standards of the current United States Pharmacopoeia. [7]

24. Chapter 795 of the USP ("Chapter 795") defines "compounding" as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug...in accordance with a licensed practitioner's prescription..." (Testimony of McKenna; Exhibit 18)

25. Chapter 795 defines "compounder" as "A professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or a medication order by a licensed prescriber." Such individuals must be proficient in compounding. More specifically, compounders must be appropriately trained and capable and qualified to perform their assigned duties. (Testimony of McKenna; Exhibit 18)

26. Pursuant to Chapter 795, a pharmacist engaged in compounding medication "...is responsible for compounding preparations of acceptable strength, quality, and purity in accordance with the prescription or medication order". Compounding procedures must be adequate to prevent errors. (Testimony of McKenna, Exhibit 18)

27. Pursuant to Chapter 795, a pharmacist engaged in compounding medication is responsible for ensuring that each compounded preparation or medication meets the following criteria: a) "the dose, safety and intended use of the preparation ...has been evaluated for suitability in terms of: the chemical and physical properties of the components, dosage form...; b) "A Master Formulation Record should be created before compounding a preparation for the first time. This record shall be followed each time that preparation is made...; c) "The Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use" (Testimony of McKenna; Exhibit 18)

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[7] Without objection, the Board took official notice of the fact that since 2004, the USP has been widely recognized by the pharmacy profession as setting forth accepted standards of practice in the pharmacy profession.

28. A Master Formulation Record is akin to a recipe for compounding a preparation. As a required step in the compounding process, it assures standardization of the product each time it is produced. Among other items a Master Formulation Record must include: the official or assigned name, strength, and dosage form of the preparation; calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients; descriptions of all ingredients and their quantities; generic name and quantity or concentration of each active ingredient; and the quality control procedures and expected results. (Testimony of McKenna; Exhibit 18)
29. Pursuant to the provisions of Chapter 795 relating to *Quality Control*, the USP states that the quality, safety, and performance of compounded preparations rely on..."correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment." (Exhibit 18)
30. The provisions of Chapter 795, to which pharmacies are required to adhere pursuant to G.L. c. 112, § 40, apply to the non-sterile compounding of liothyronine or T-3 medication. (Testimony of McKenna)

Founding, Licensure and Launch of RPSP

31. On or about February 9, 2011, while residing in Florida, Respondent AR filed with the Board an *Application to Manage and Operate a New Community Pharmacy*, RPSP, to be located in Webster, Massachusetts ("Webster"). Respondent AR identified herself as the owner of the pharmacy, as well as the pharmacist charged with the management of the pharmacy.[8] Respondent AR also filed with the Board an *Application for a Certificate of Fitness* in which she identified herself as the Manager of Record for RPSP. (Testimony of Respondent AR; Exhibit 4)

[8] As noted in Finding of Fact, ¶ 5, Respondent AR has been the sole owner of RPSP since the pharmacy's incorporation. (Testimony of Respondent AR; Exhibits 4, 6, 24)

32. In the *Application to Manage and Operate a New Community Pharmacy* that Respondent AR signed under the pains and penalties of perjury and filed with the Board, Respondent AR certified that "...each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned function in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law. (Testimony of Respondent AR; Exhibit 4)

33. In March 2011, while residing in Florida, Respondent AR appeared before the Board in connection with her application to establish a new community pharmacy. Respondent AR represented to the Board that she would be moving to Massachusetts, her home state.[9] The Board approved Respondent AR's application to establish RPSP in Webster and, following a compliance inspection, a registration was issued on April 29, 2011. RPSP opened for business on May 25, 2011 with Respondent AR as Manager of Record. (Testimony of Respondent AR; Testimony of Cittadino)

34. At all times between February 2011 and May 2011, Respondent AR resided in Florida and knew she Redacted [red who was Red on [redact , 2011. At no time between February and May 2011 did Respondent AR advise the Board that w Redacted there would be a period of time that she would not be available to serve as Manager of Record of RSPS. (Testimony of Respondent AR; Exhibit 3)

35. From the opening of RPSP until about mid-June 2011, Respondent AR remained in Massachusetts, staying at her parents' home as her residence continued to be in Florida. During this period, she worked at RPSP. (Testimony of Respondent AR)

36. In mid-June 2011, Respondent AR experienced c Redacted Redacted and was compelled to return to Florida for medical care.

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[9] According to Respondent AR, in late 2010, she and Respondent MR decided to move from Florida to Massachusetts to be closer to their families. They started looking for a home in Massachusetts and a location to open a pharmacy in Respondent AR's home town of Dudley or the neighboring town, Webster. (Testimony of Respondent AR)

Respondent AR was instructed that she had to rest until at least mid-July. (Testimony of Respondent AR, Testimony of Respondent MR; Testimony of [redacted]

37. On July 14, 2011, Respondent AR [redacted]. For the next several weeks, Respondent AR experienced significant pain. She took motrin and Percocet, a drug that can impair judgment and impede normal activity, around the clock. (Testimony of Respondent AR)

38. In August 2011, Respondent AR returned to Massachusetts after receiving her [redacted] clearance to travel. However, she continued to suffer pain from [redacted], was unable to work, and had to return to Florida for [redacted]. Respondent AR remained a Florida resident until about March 2012, when she and her family moved to Webster, MA. (Testimony of Respondent AR; Exhibit 3)

39. In August 2011, RPSP filed with the Board an *Application for Change in Manager* to enable [redacted] to assume the position of MOR. A fee of $525 and an inventory of Schedule II controlled substances were submitted along with the application. No inventories of controlled substances in Schedules III-V were filed with the Board.[10] The Board approved the application on September 13, 2011, at which time [redacted] became Manager of Record of RPSP. (Testimony of Respondent AR; Testimony of Cittadino)

40. In accordance with Findings of Fact, ¶¶ 31–39, above, at all times between April 29, 2011 and September 13, 2011, Respondent AR was MOR of RPSP.[11] Nevertheless, Respondent AR did not work at RPSP at any time between mid June 2011 and September 13, 2011.

41. At the time of its opening in May 2011, RPSP staff included [redacted] R.Ph and [redacted], a pharmacy technician. Respondent MR worked at

[10] Pursuant to 247 CMR 6.07 (h)(1), an Application for Change in Manager of Record must be accompanied by an inventory of controlled substances in Schedules II-V.

[11] In her testimony before the Board, Respondent AR claimed that in 2011, she believed that [redacted] became MOR of RPSP on the day the *Application for Change in Manager* was filed with the Board. Respondent AR testified that she subsequently understood that she remained MOR until the Board approved the *Application for Change in Manager* on September 13, 2011. (Testimony of Respondent AR)

the pharmacy for much of the first three (3) weeks that the pharmacy was open.[12] Between mid-June and August, Respondent MR returned from Florida sporadically to work at RPSP. (Testimony of Respondent AR, Testimony of [redacted])

42. Respondent MR acknowledged assisting Respondent AR in operating RPSP, including with the development and establishment of policies and procedures. According to Respondent MR, he assisted Respondent AR by furnishing PCCA policies and procedures and adapting the PCCA policies and procedures for RPSP.[13] (Testimony of Respondent AR, Testimony of Respondent MR)

43. [redacted] had worked with Respondent MR at the latter's compounding pharmacy in Florida for approximately two (2) years. Respondents AR and MR considered [redacted] to be knowledgeable and well trained in compounding. At Respondent MR's suggestion, [redacted] relocated to Massachusetts to work at RPSP. Once at RPSP, [redacted] trained staff on the pharmacy's policies and procedures. (Testimony of Respondent AR, Testimony of Respondent MR)

44. Between May 25, 2011 and August 2011, [redacted] was the only full-time pharmacist at RPSP.[14] (Testimony of Respondent AR, Testimony of [redacted])

45. Approximately six (6) months before RPSP opened in May 2011, Respondent AR approached [redacted] about working at RPSP. Years earlier, Respondent AR and [redacted] had briefly worked together at a pharmacy

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[12] As noted in Finding of Fact ¶35, above, Respondent AR also worked at RPSP during the 3 weeks following the pharmacy's opening. (Testimony of Respondent AR)
Respondent MR contended that he did not remember whether he was present for the opening of RPSP or how frequently he worked at RPSP following the opening. However, [redacted] recalled that Respondent MR worked at RPSP for much of the first three (3) weeks it was open and thereafter returned from Florida sporadically. (Testimony of [redacted] Testimony of Respondent MR)

[13] Professional Compounding Centers of America (PCAA) is a membership organization that provides compounding assistance to pharmacists by, among other things, answering questions and helping to develop formulas. PCCA also offers educational materials and courses related to compounding. (Testimony of Respondent AR)

[14] There is no evidence in the record that any pharmacists other than [redacted] and Respondents AR and MR worked at RPSP during this period of time. As noted in Findings of Fact, ¶¶ 35, 40 and 41, above, Respondent AR did not work at RPSP after mid-June 2011 and Respondent MR was residing in Florida and was present on site at RPSP on a sporadic basis only.

in Webster. [redacted] provided Respondent AR with her resume and accepted a full-time pharmacist's position at RPSP. (Testimony of [redacte])

46. Respondent AR did not question [redacted] about her compounding experience before hiring [redacted] Respondent AR testified that she was confident that [redacted] could dispense medications, compound medications, or be trained to compound medications. According to Respondent AR, [redacted] had had years of experience in compounding, including adding flavorings, making creams, triturating solutions, and preparing elixirs and suspensions. (Testimony of [redacte], Testimony of Respondent AR)

47. When [redacted] started at RPSP, she had virtually no compounding training or experience, and she had never produced a formulation for a compounded medication. During [redacted]'s 20 years of pharmacy practice, her sole compounding experience consisted of producing a couple of ointments for a Omeprazole Suspension, a process which utilized manufactured contents and involved minimal preparation and calculations. According to [redacted], her resume reflected her practice history as a pharmacist, including her lack of compounding experience. (Testimony of [redacte])

48. Respondent MR and [redacted] considered [redacted], a pharmacy technician, to be more knowledgeable about compounding than [redacted]. Once RPSP was open, [redacted] assisted [redacted] in learning compounding techniques. Additionally, [redacted] was given access to PCAA materials and software that provided additional training in compounding and the *Pharmacist's Letter*, a monthly publication that contained updates on new medications and research, as well as continuing education. (Testimony of [redacte], Testimony of Respondent AR, Testimony of Respondent MR)

49. At all times relevant between May 2011 and August 2011, [reda[redacte had access to the PCAA website and materials. However, [redacted] lacked the knowledge, training, experience, and skill to regularly know whether the

pharmacy had the capability to make a particular compounded medication, to produce formulations to fill new prescriptions for compounded medications, and to check for the accuracy and correctness of the formulation and dispensed product. (Testimony of [redacte d])

50. During the months of June, July, and August 2011, when Respondent MR was not on the premises of RPSP, [red t] [redacted] would call Respondent MR for assistance each time she was presented with a new prescription for a compounded medication that required producing a new formulation. [reda ted] [redacte d] recalls making three (3) or four (4) such calls a day to Respondent MR. Once Respondent MR had provided [redacted] with a Master Formulation for a medication, she followed the formula to make the medication as instructed. [redacted] saw no need to check the formulations for accuracy, assuming there would be no errors because Respondent MR was a "senior" compounding pharmacist. If subsequently presented with another prescription for the identical medication, [redacted] could refer back to the initial formulation provided by Respondent MR and produce the medication according to the formulation. (Testimony of [redacte d])

51. RPSP had no specific formal policy or procedure that stated what a pharmacist should do when presented with a prescription she or he was unsure the pharmacy could fill and that she or he lacked the knowledge and capability of filling. There was no formal policy or procedure that provided for [redacted] to call Respondent MR for assistance in preparing new prescriptions for compounded medications.[15] (Testimony of [redacte d], Testimony of Respondent AR)

52. [redacted] called Respondent MR rather than Respondent AR because Respondent MR had instructed her to do so and because Ms. [redacted] observed that Respondent MR "...was the one that was organizing

[15] Respondent AR acknowledged that RPSP had no policies or procedures that would have prompted [redacted] to contact PCCA for assistance with a prescription for which no Master Formulation existed. However, in stark contrast to [redacted] 's testimony and even to Respondent MR's testimony conceding that [redacted] with Respondent AR's approval, called him for help with developing Master Formulations on numerous occasions, Respondent AR testified that it was [redacted] s custom to rely on PCCA for such aid. (Testimony of [redac], Testimony of Respondent AR, Testimony of Respondent MR)

everything and … making the decisions." Respondent AR, though relatively uninvolved with the pharmacy, was aware of the communications between [redacted] and Respondent MR. (Testimony of [redacte Testimony of Respondent MR)

EVENTS OF JULY 28 – JULY 29, 2011

53. On Thursday, July 28, 2011,[16] RPSP received a prescription for Patient A for liothyronine or T-3 10 mcg SR#30 capsules. Patient A's mother selected RPSP to fill the prescription because local newspaper ads had led her to believe that the pharmacy specialized in compounding medications and the pharmacy was convenient to her home. (Testimony of [redacte Testimony of Mother, Testimony of Respondent AR, Testimony of Respondent MR)

54. At the time, Ms. [redacte was the only pharmacist working at RPSP. (Testimony of [redact)

55. Ms. [redacte did not have the knowledge, training, experience or skill to create the formulation required to compound Patient A's medication. (Testimony of [redacte)

56. Ms. [redacte called Respondent MR to inquire whether the pharmacy could compound the medication. He replied affirmatively and told [redacted] that he would create the formula and send it to her electronically so that she could prepare the medication. [redacted] ordered the liothyronine, which was delivered to RPSP the following day in a concentrated, undiluted form. Patient A's prescription required a diluted or triturated form of liothyronine. (Testimony of [redacte)

57. Respondent MR participated in the compounding of Patient A's medication by remotely logging into the PK Software that was used by RPSP to produce a formulation and by entering the data on the *Logged Formula Worksheet*, the Master Formulation Record he generated for Patient A's medication.[17] On the *Logged Formula Worksheet*, Respondent MR was identified as the

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16 At the request of Prosecuting Counsel, official notice was taken of the 2011 calendar showing that July 29, 2011 was a Friday.

17 PK Software, developed by PK Software Corporation, was used to enter prescriptions and formulas while PCCA was used for training and information. (Testimony of Respondent MR)

pharmacist and individual who entered the data and the space for the name of the person checking the formula was left blank on the *Logged Formula Worksheet*. In accordance with Respondent MR's testimony, he entered the formulation for Patient A's medication and hit print, knowing that the Master Formulation Record would print on the premises of RPSP. Respondent MR claimed that he expected that [redacted] would review the Master Formulation Record and "...use it if she thought it was acceptable for her formulation..." (Testimony of [redacte, Testimony of Respondent AR, Testimony of Respondent MR; Exhibit 5)

58. In entering the information for producing the formulation, Respondent MR inadvertently entered "liothyronine sodium", a concentrated form of T-3 rather than "liothyronine triturate", a diluted form of T-3. Hence, the formula Respondent MR electronically sent to [redacted] at RPSP and that [re [redacte used to produce Patient A's medication was incorrect in that as followed, it would have produced T-3 10 mg rather than T-3 10 mcg. (Testimony of [redact, Testimony of Respondent AR, Testimony of Respondent MR; Exhibit 5)

59. Respondent MR did not see the formula that was sent to RPSP, printed out at RPSP, and followed by [redacted] to make Patient A's medication. Neither [redacted] nor any other individual associated with RPSP checked the formula for correctness and accuracy. (Testimony of [redacte Testimony of Respondent AR, Testimony of Respondent MR)

60. In July 2011, RPSP did not have a policy or procedure directing pharmacists to use the triturated form of T-3 when compounding. Respondent AR testified that while such a policy and procedure are presently in place, she does not know why they failed to exist in July 2011. (Testimony of Respondent AR)

61. On Friday, July 29, 2011, [redacted] made Patient A's medication according to the formula she received from Respondent MR. The medication was dispensed to Patient A without having been checked by a second pharmacist. (Testimony of [redacte; Testimony of Respondent MR; Exhibits 1, 2, 25, 26)

62. [redacted] was unaware that Respondent MR had made an error in producing the formula. When followed as written, the formula resulted in the production of a drug that was 1,000 times the strength of the prescribed medication, i.e. T-3 10 mg rather than 10 mcg SR#30 capsules. (Testimony of [redacted], Testimony of Mother, Testimony of Respondent AR, Testimony of Respondent MR; Exhibits 1, 2, 5, 16, 17, 23, 25, 26, 28)

63. Mother picked up Patient A's prescription at around 5:00 p.m. on July 29, 2011. (Testimony of [redacted], Testimony of Mother, Testimony of Respondent MR)

Events of July 31-August 2, 2011 and Effects of T-3 Overdose on Patient A

64. Patient A took the first dose of the medication on Sunday July 31, 2011, as instructed by his physician. He took a second dose on Monday morning, August 1, 2011, as directed by his physician. (Testimony of Mother)

65. At around lunchtime on Monday, August 1, 2011, Patient A reported to his mother that he had an unusually rapid heartbeat. Several hours later, Patient A asked his mother to take him to the hospital. His heartbeat had continued to accelerate and he was experiencing palpitations. (Testimony of Mother)

66. At some point on August 1, 2011 before Patient A and his mother left for the hospital, [redacted] and Respondent MR discovered the error made in filling Patient A's prescription. In reviewing the insurance reimbursement on August 1, 2011,[18] [redacted] was struck that the amount of the reimbursement seemed excessive for a thyroid medication. Being inexperienced in billing compounded medications and thinking she may have made an error, [redacted] contacted Respondent MR in Florida. When Respondent MR instructed [redacted] to read the formulation to him, it became clear that the formula was incorrect in that it called for the use of T-3 10 mg rather than T-3 10 mcg, as prescribed. (Testimony of [redacted], Testimony of Respondent MR; Exhibit 28)

[18] Although Patient A's insurance was billed for the medication on July 29, 2011, [redacted] initially reviewed the reimbursement information on August 1, 2011. RPSP was closed on Saturday and Sunday, July 30 and 31, 2011. (Testimony of [redacted])

67. Respondent MR, who knew there were potentially serious consequences of the error made in filling Patient A's prescription, instructed [redacted] to contact Patient A immediately. [redacted] reached Patient A's mother by telephone at 4:40 p.m. ("4:40 p.m. conversation") and learned that Patient A was on the way to an Emergency Room ("ER") with palpitations, high blood pressure, and, as [redacted] described it, "other signs of high thyroid". [redacted] encouraged Mother to proceed to the hospital with Patient A and stated that the medication error could be responsible for Patient A's cardiac symptoms. (Testimony of [redacted], Testimony of Mother; Exhibit 28)

68. At about 7:35 p.m., at the request of Patient A's doctor, Mother called [redacted] from the ER to inquire about the precise name of the thyroid medication and the dosage dispensed to Patient A. [redacted] told Mother she did not know the precise amount of the overdose, but it was "very big" and could contain 10 mg or more of T-3 rather than 10 mcg. (Testimony of [redacted], Testimony of Mother; Exhibits 3, 11, 15)

69. According to Respondent MR, he also attempted to reach Patient A's mother several times on August 1 and 2, 2011, but was put through to her voicemail. Mother remembered receiving telephone messages from Respondent MR, but was unable to recall the number of messages and specifically when they were left because her focus was on Patient A, who was "in and out of the ER". Mother recollected that in his initial message, Respondent MR stated that he was aware of the dispensing error, and that the prescription had been refilled correctly and was ready for pick-up. Likewise, Mother recalled that at some point following her 4:40 p.m. conversation with [redacted] [redacted] left Mother a message stating that Respondent MR was aware of the dispensing error and wanted Mother to know that RPSP was willing to refill the prescription correctly.[19] (Testimony of Respondent MR; Testimony of Mother)

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[19] Telephone company records for July 29, 2011 through August 2, 2011, to which the parties stipulated, show that on August 1, 2011, other than the 4:40 call from Royal Palm to Mother's cell phone and Mother's calls to RPSP from the hospital at 7:35 p.m., a 2 minute call was made from Royal Palm to Patient A's home at 7:11 p.m. The telephone company records also reflect a one

70. After learning of the error in filling Patient A's prescription, Respondent MR notified Respondent AR that Patient A's prescription had been misfilled and that [redacted] was attempting to reach Patient A.[20] Respondent AR was also aware that Respondent MR made efforts to reach Patient A. Respondent MR did not tell Respondent AR the extent of the overdose, and Respondent AR, who was occupied with her [redacted] Redacte did not attempt to communicate with Patient A or his mother. (Testimony of AR)

71. On August 2, 2011, [redacted] completed a form that was internal to RPSP entitled "Customer Complaint Record". Among other things, [redacted] documented that Patient A's prescription was made with liothyronine 10 mg instead of liothyronine 10 mcg; that Patient A had ingested 3 days of 1,000 times the prescribed dose of the medication;[21] that Patient A sought emergency medical care for heart palpitations; and that [redacted] (when initially speaking with Mother on August 1, 2011), had instructed Patient A's mother to discontinue Patient A's medication and continue on to the Emergency Room. (Exhibit 28)

72. Patient A was discharged home from the ER on the evening of August 1, 2011, but he returned twice the following day, August 2, 2011, with sleeplessness and the same symptoms he had experienced the previous day. During the second visit to the ER, the attending physician ordered that Patient A be transferred by ambulance for admission to another hospital, where he stayed as an inpatient for two (2) days, until August 4, 2011. (Testimony of Mother; Exhibits 11, 15)

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minute call from RPSP to Mother's cell on August 2, 2011. These calls reflect the totality of communications between [redacted] on behalf of RPSP, and Mother following the discovery of the error made in filling Patient A's prescription. (Exhibit 3)

[20] Although [redacted] and Respondent MR testified that they initially learned of the error in filling Patient A's prescription on Monday, August 1, 2011, Respondent AR testified that she first learned about the misfilled prescription on the afternoon of July 29, 2011 or the following day, July 30, 2011. According to Respondent AR, "they" ([redacted] and Respondent MR) were trying to find out whether the medication had been ingested or could be retrieved, and "...it wasn't until sometime I believe on Monday or over the weekend sometime, when [reda finally got ahold of the mom" and learned that Patient A was on his way to the hospital. (Testimony of Respondent AR)

[21] In fact, Patient A had ingested 2 doses of the medication. (Testimony of Mother; Exhibit 11)

73. Laboratory testing results showed that on August 2, 2011, Patient A's T-3 level was 14,982.60 ng/dL, which was "critically high" relative to the reference range of 60-180 ng/dL. (Testimony of Mother; Exhibits 11, 15)

74. On August 7, 2011, Patient A returned to the ER with various complaints, including palpitations, left sided chest pain, and anxiety. Patient A was diagnosed with [redacted]. He was again sent by ambulance to be hospitalized as an in-patient at a hospital that could provide a higher level of care, where he remained for several days. Laboratory testing results on August 7, 2011 showed that Patient A's troponin level was 9.30 ng/mL. Levels greater than or equal to 0.5 ng/mL are consistent with acute myocardial damage. (Testimony of Mother; Exhibits 11, 15)

75. During his hospitalizations, Patient A experienced a range of symptoms, including serious pain for which he was medicated. Patient A was also prescribed a beta blocker to control his heart rate. Mother was told by Patient A's doctors that Patient A was lucky to be alive. (Testimony of Mother; Exhibits 11, 15)

76. Following his hospitalizations, Patient A underwent cardiac rehabilitation therapy for several months with the goal of being able to walk without experiencing cardiac symptoms. Among the multitude of follow-up medical appointments Patient A has had, in March 2012, he was evaluated by an Endocrinologist for thyrotoxicosis secondary to T-3 overdose. Patient A was noted to be experiencing palpitations and generalized weakness. The Endocrinologist stated, "it is very likely that the transient surge of the serum T3 level, which was unusually high, cause *(sic)* a persistent systemic effect. This is a rare condition and there is no sufficient clinical data to predict how long the effects will last." According to Mother, the effects persist to the present, with significant consequences for Patient A. (Testimony of Mother; Exhibit 15)

Failure to Report Error to Board

77. Along with G.L. c. 112, §39D, Board regulations at 247 CMR 6.14 require a pharmacy licensed by the Board "to report to the Board any improper dispensing of a prescription drug that results in serious injury or death, as defined by the Board, as soon as is reasonably or practicably possible but not later than 15 business days after discovery or being informed of such improper dispensing."

78. Board regulations at 247 CMR 6.14 (1)(c) define *serious injury* as "an injury that is life threatening, results in serious disability or death, or requires a patient to undergo significant additional treatment measures." Pursuant to 247 CRM 6.14 (1)(d), *serious disability* is defined as including, but not being limited to, "injuries requiring major intervention and loss, or substantial limitation, of bodily function lasting greater than seven days (*e.g.* bodily function related to breathing, dressing/undressing; drinking; eating; eliminating waste products; getting into and out of bed, chair, *etc.*; hearing; seeing; sitting; sleeping or walking).

79. Following the initial calls Respondent MR made to Mother and the three (3) calls [redacted] made to Mother on August 1 and August 2, 2011, neither Respondent MR, [redacted] nor any other individual affiliated with RPSP, including Respondent AR, attempted to obtain information on Patient A's condition by contacting Patient A or Mother by telephone, email, letter, or by going to their nearby home .[22] (Testimony of [redacte, Testimony of Mother, Testimony of Respondent AR, Testimony of Respondent MR)

80. Respondent MR testified that because Mother did not respond to the messages he left, he assumed that Patient A was fine. Respondent MR did not recall the specific content of the messages he left for Mother. However, he knows that he did not tell Mother that RPSP was required to report the dispensing error if Patient A was seriously injured or harmed. (Testimony of Respondent MR)

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[22] As noted in Finding of Fact ¶ 67, above, Respondent MR was aware of how potentially serious the consequences were of misfilling Patient A's prescription at 1,000 times the prescribed dose. After becoming aware of the error, [redacted] researched the potential side effects of such a T-3 overdose. (Testimony of [redact, Testimony of Respondent MR)

81. [redacted] could not recall the content of any messages she left for Mother.[23] She assumes that, but does not recall whether, she asked Mother to contact her regarding Patient A's condition. [redacted] knows that she did not tell Mother that RPSP was required to report serious injuries from medication errors to the Board. (Testimony of [redacte])

82. Respondent AR did not know how many times RPSP staff or Respondent MR tried to contact Patient A or Mother to find out how Patient A felt. She recalled that several calls were made. Other than trying to reach Patient A or mother by telephone, Respondent AR believed "there's not much else" RPSP could do. (Testimony of Respondent AR)

83. With regard to RPSP efforts to obtain information about Patient A's condition, Respondent AR contended that leaving a message at Patient A's home would have violated the federal Health Insurance Portability and Accountability Act ("HIPAA") and therefore RPSP policy and procedure in that it would have required leaving private, protected, patient specific health care information. (Testimony of Respondent AR)

84. Respondent AR acknowledged that RPSP leaves phone messages at patients' home advising patients that their prescriptions are ready. Respondent AR further acknowledged that in seeking to follow up on a patient's condition following a medication error, it might be possible to leave a carefully worded, appropriate message that maintains patient privacy and is compliant with HIPAA. (Testimony of Respondent AR)

85. On or about August 17, 2011, RPSP received a letter from an attorney representing Patient A and Mother, advising RPSP that the error made in filling Patient A's prescription had caused Patient A "significant medical problems, which remain ongoing to this very moment." The letter, addressed

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[23] [redacted] testified that she believed that after August 1, 2011, she attempted to reach and left messages for Mother 3 or 4 times. However, the Vocalocity call logs to which the parties stipulated reflect a total of 2 calls made to Mother after [redacted] learned that Patient A was on the way to the ER on August 1, 2011. As noted above, these 2 calls were made at 7:11 on August 1, 2011 and at 1:48 p.m. on August 2, 2011. The minor discrepancy in the evidence regarding the number of times [redacted] attempted to reach Mother appears to be attributable to nothing more than a lapse of memory on the part of [redacted]. (Testimony of [redact])

to *Owner/General Manager*,[24] requested that RPSP refrain from any direct contact with Patient A and Mother and direct any questions and concerns to the attorney. (Exhibits 3, 22)

86. Respondent AR was aware that Patient A's attorney had instructed her and RPSP not to contact Patient A or Mother and to address any communications to him (the attorney). According to Respondent AR, the liability carrier for RPSP instructed her, Respondent MR, and RPSP staff not to respond to the letter from Patient A's and Mother's attorney and not to contact Patient A and Mother. Respondent AR does not believe that she told the liability carrier that RPSP had a duty to report dispensing errors resulting in serious harm to the Board. (Testimony of AR)

87. Respondent AR testified that in July-August 2011, she knew that the Board required a pharmacy to notify the Board of a medical error that caused "life threatening injury".[25] Respondent AR never inquired of the Board about how RPSP should proceed if unable to make contact with a patient or his family to follow-up on the patient's condition following a medication error. (Testimony of Respondent AR)

88. Respondent AR testified that she was not sure that Patient A had suffered a serious injury even though she read the letter from Patient A's attorney stating that Patient A had significant and ongoing injuries and even though

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[24] As noted above, Respondent AR asserted that in 2011 she believed that [redacted] had become MOR of RPSP when the Board received the application for a change in MOR on August 15, 2011. (Testimony of Respondent AR)

[25] Respondent AR was asked whether she was aware of the Board's regulation requiring pharmacies to notify the Board of the occurrence of a medical error that resulted in serious harm. Respondent AR initially replied, "I believe it's a life threatening condition". Subsequently, Respondent AR stated that the reporting requirement was triggered solely by "a severe adverse reaction or life threatening condition." Respondent AR did not know whether a condition that required ongoing care triggered the requirement to report a dispensing error. However, subsequently, Respondent AR testified that a disability would also trigger the reporting requirement. She explained that she had not mentioned the disability trigger previously because she did not have the regulation memorized. When questioned whether she knew the time frame for reporting such an event, Respondent AR replied, "Usually within, probably about... a very reasonable time when you find out about the life threatening condition." At a later point, Respondent AR stated that a pharmacy had 7 – 10 days to report a dispensing error. Respondent AR stated that while she did not presently know the precise wording of the regulation, she knew it in August 2011 and she would have known that the allowed period of time for notifying the Board of a reportable error was as soon as was practicabably possible but not more than 15 business days from discovering or learning of the event. (Testimony of AR)

she knew that the type of overdose Patient A received could cause elevated blood pressure and a cardiac event. Respondent AR further represented that she had been assuming that Patient A had not sustained a serious injury because RPSP had not heard from Patient A's mother after attempting to contact her after learning of Patient A's visit to the ER. According to Respondent AR, she first learned of Patient A's medical status in about August 2012, when the liability carrier received medical records for Patient A. Prior thereto Respondent AR contended, neither Patient A's and Mother's attorney nor anyone else had provided details of Patient A's condition.[26] (Testimony of AR)

89. Respondent AR acknowledged that in December 2011, Board investigators apprised her of the complaint Mother filed with the Board regarding the dispensing error and shared documents related to the complaint with her.[27] (Testimony of AR)

90. On or about December 27, 2011, RPSP first notified the Board of the error made in dispensing Patient A's medication. In her report to the Board, [redacted] stated that the medication error had not been previously reported to the Board "due to an oversight." (Exhibit 23)

91. Although the misfill of Patient A's prescription resulted in serious injury, including the need for significant treatment measures for cardiac symptoms and for a Myocardial Infarction, and serious disability, Respondents AR and RPSP failed to report the incident to the Board as soon as was reasonably and practicably possible and/or within 15 business days of discovering that Patient A's prescription had been improperly dispensed.

Plan of Correction and Failure to Comply with Corrective Actions

92. Respondent AR testified that subsequent to the incident involving Patient A, RPSP put corrective measures in place. Although Respondent AR could not

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[26] Respondent AR testified that between August 2011 and August 2012, RPSP "would periodically check up on the case" with its liability carrier, but "everything was pending and there was no information". (Testimony of AR)

[27] Documents that Mother filed with her complaint expressly described the health consequences of Patient A's ingestion of the misfilled prescription, including hospital records referencing "acute myocardial damage". (Exhibit 11)

recall specific measures the pharmacy implemented, she remembered that the staff was informed about the dispensing error made in filling Patient A's prescription, quality assurance meetings took place, and the staff discussed the handling of medication errors that might occur in the future. (Testimony of Respondent AR)

93. In reporting the medication error to the Board on or about December 27, 2011, [redacted] represented that RPSP had "taken steps to greatly reduce the probability of error." (Exhibit 23)

94. A Plan of Correction developed by [redacted], approved by Respondent AR, and filed with the Board provided that RPSP would immediately upon receipt label bottles of bulk liothyronine "for trituration only" and store such bottles apart from other products. The Plan of Correction stipulated that all calculations would be checked by a second technician. (Testimony of [redacted] Testimony of Lathum, Testimony of Respondent AR; Exhibit 15)

95. On April 24, 2012, the Board conducted an inspection of RPSP. Ms. Lathum observed that a bottle containing liothyronine sodium 500 mg was not labeled "for trituration only" and was stored in close proximity to other liothyronine products, bottles of T3 and T4. Ms. Lathum also observed a technician checking her own calculations rather than a second technician performing the check. (Testimony of Lathum; Exhibit 15)

96. Respondent AR acknowledged that although she was not the MOR of RPSP in April 2012, as the pharmacist owner of the pharmacy, she was responsible for ensuring compliance with the Plan of Correction. Respondent AR is not sure what steps she took to encourage compliance with the Plan of Correction because she was not present in the pharmacy at the time. (Testimony of Respondent AR)

Additional Findings Upon Inspection of RPSP

97. On April 24, 2012, Ms. Lathum found liquid HCG 6K in RPSP's refrigerator that was not labeled with a lot number or expiration date as required by the USP. (Testimony of Lathum; Exhibit 15)

98. Additionally, during April 2012, and to a lesser extent, during a January 2013 inspection of RPSP, Ms. Lathum observed pre-printed prescription forms that were filled out and signed by prescribers and that bore the RPSP logo and/or name of the Florida pharmacy owned by MR. (Testimony of Lathum)

99. The Board's regulation at 247 CMR 9.01 (13) prohibits a pharmacist and pharmacy from providing any practitioner with prescription blanks that refer to any pharmacist or pharmacy.

Credibility of the Witnesses[28]

100. While at times Respondent AR presented credible testimony, on multiple occasions her testimony on key issues was implausible, inconsistent, elusive, and defensive, reflecting a lack of candor aimed at avoiding responsibility for her failures as owner and MOR of RPSP. As set forth in Findings of Fact, ¶¶ 101-113, below, Respondent AR exhibited a pattern of failing to be truthful and/or accurate in her communications with the Board, starting even before the commencement of these proceedings.

101. In or about November 2010, Respondent AR approached [redacted] about working at RPSP. In response, [redacted] provided Respondent AR with her resume, which clearly indicated [redacted] s utter lack of training, experience, and skill as a compounding pharmacist. Nevertheless, without even questioning [redacted] about her compounding qualifications, Respondent AR hired [redacted] to practice as a compounding pharmacist at RPSP without the requisite training and level of skill.

102. In the *Application to Manage and Operate a New Community Pharmacy* that Respondent AR filed with the Board in February 2011, Respondent AR falsely certified to the Board, under pains and penalties of perjury, that each RPSP staff member involved in any prescription drug distribution activity would have "the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug quality, safety, and security will

[28] The Board makes no findings relative to [redacted] testimony as it was limited to a single issue and was not relevant to or relied upon in any of the Board's findings.

at all times be maintained as required by law." (Testimony of Respondent AR; Exhibit 4)

103. Respondent AR's testimony that [redacted] had years of experience in compounding medications was expressly contradicted by the resume [redacted] provided to Respondent AR before Respondent AR hired [redacted]. Moreover, following the opening of RPSP, the confidence that Respondent AR purportedly had in [redacted]'s compounding knowledge and skills should have been dispelled by [redacted]'s frequent and regular reliance upon Respondent MR when faced with prescriptions for which there was no Master Formulation. Additionally, Respondent AR's expectation that [redacted], a pharmacy technician, would provide compounding training to [redacted], a pharmacist, indicated a level of awareness of [redacted]'s shortcomings as a compounder.

104. Respondent AR was not truthful when she testified that the practice at RPSP, although not a formal policy or procedure, was for [redacted] to call PCCA or to reference PCCA material at the pharmacy for answers to compounding questions and accessing formulas. The evidence establishes that [redacted] called Respondent MR for assistance each time she was presented with a new prescription for compounded medication that required producing a new formulation and that such calls routinely transpired as frequently as three (3) or four (4) times a day. By her own admission, Respondent AR was aware of the occurrence of these communications.

105. Respondent AR's testimony that [redacted] did not often contact Respondent MR for assistance was untruthful and contradicted Respondent AR's acknowledgement that she knew of the communications between [redacted] and Respondent MR.

106. In describing the events of July 29, 2011, Respondent AR initially stated that there was a "mathematical error in the compounding" of Patient A's medication. Upon further questioning, Respondent AR explained that she viewed the error made "...as a mathematical error because of the decimal point." However, ultimately Respondent AR conceded that the error made by

her husband, Respondent MR, in producing the formula for Patient A's medication was not simply a mathematical mistake. (Testimony of Respondent AR)

107. Respondent AR was not credible in testifying that in 2011, she believed [redacted] became the MOR of RPSP when RPSP filed with the Board an *Application for Change in Manager* in mid-August 2011. By virtue of its title, the document was simply an application, connoting the need for approval before becoming effective. Moreover, earlier that same year Respondent AP experienced the application and approval process when she filed with the Board an application to manage and operate a new pharmacy and the application was approved by the Board two (2) months later, following Respondent AR's appearance before the Board.

108. Respondent AR was disingenuous in testifying that she conducted an investigation of the misfill of Patient A's prescription.[29] Respondent AR neither produced a written investigative report nor was able to answer the most basic questions about her investigation. She was so unfamiliar with the facts that she was at various times during her testimony unsure and wrong about the day on which [redacted] and Respondent MR discovered the error. While it is understandable that at the time Respondent AR was redacted and the care of a new baby, one may reasonably assume that following an investigation of such a grave incident, Respondent AR, as MOR, would have known the sequence of important events associated with the misfill of Patient A's prescription, including the day on which the error was discovered and RPSP learned that Patient A required emergency medical care for cardiac symptoms.

109. After acknowledging the lack of a written investigation report, Respondent AR subsequently testified that the form entitled *Customer Complaint Record* constituted an investigation report. The assertion that the *Customer*

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[29] While the Order to Show Cause in the instant matter does not contain allegations related to a failure to conduct an investigation of the error in filling Patient A's prescription, the Order to Show Cause in the Agnes Rubin matter charges that Respondent AR failed to conduct such an investigation, as required by 247 CMR 15.01 *et seq.* Hence, the issue arises in the instant matter solely for the purpose of assessing Respondent AR's credibility.

Complaint Record completed by [redacted] with no input from Respondent AR, constituted an investigative report was an obvious fabrication designed to allow Respondent AR to avoid responsibility for a gross failure in her capacity of MOR of RPSP.

110. Respondent AR was not credible in claiming that in 2011 she was thoroughly familiar with the Board's regulations requiring that pharmacies report the improper dispensing of a prescription drug resulting in serious injury or death, as defined by the Board. Given the gravity of the incident involving Patient A and these resulting proceedings, one would reasonably anticipate that Respondent AR would have retained any knowledge she had of the reporting requirements. However, her testimony reflected otherwise, indicating Respondent AR's ongoing failure to adequately familiarize herself with the statutes and regulations governing the operation of RPSP and the responsibilities of its MOR.

111. Despite the fact that Respondent AR was unfamiliar with the particulars of the Board's reporting requirements in 2011, she did appear to know that "a severe adverse reaction" from an improperly filled prescription had to be reported to the Board. Hence, Respondent AR was not plausible when she maintained that she and RPSP complied with the law when they failed to report the misfill of Patient A's prescription until confronted by the Board's investigators months later. In citing various unpersuasive and false reasons to show her conduct was not unlawful (see Findings of Fact, ¶¶ 112-113, below), Respondent AR's testimony appeared aimed at concealing a deliberate effort to circumvent the statutory and regulatory reporting requirements and to deceive the Board so as to sidestep any responsibility for the incident.

112. In defending her failure to report the misfill of Patient A's prescription in a timely manner, Respondent AR perpetuated her lack of candor by testifying that she was not sure that Patient A had suffered a serious injury in that nobody provided RPSP with details of Patient A's condition prior to August 2012, when RPSP's liability carrier received Patient A's medical records.

Such testimony was wholly inconsistent with the fact that Respondent AR, Respondent MR and [redacted] were fully aware of the potentially serious consequences of ingesting such a massive overdose of T3; with the information relative to Patient A's condition and need for medical attention Mother conveyed to [redacted] on August 1, 2011; and with the reference to serious and ongoing medical problems contained in the August 17, 2011 letter from Patient A's attorney to RPSP. Despite having the type of information that clearly might have triggered the reporting requirement, after August 1 or 2, 2011, neither Respondent AR, nor Respondent MR, nor any other individual associated with RPSP made a genuine effort to obtain from Patient A, his mother, or his attorney additional information on Patient A's status. Moreover, the fact that RPSP finally reported the incident to the Board in December 2011 when it received the complaint filed by Patient A's mother with the Board, stands in stark contrast to Respondent AR's assertion that it was not until August 2012 that she and RPSP acquired the type of information that would have required them to report the incident to the Board.

113. With regard to obtaining additional information on Patient A's condition, Respondent AR's statement that there was "not much else" that RPSP could have done reflected Respondent AR's own, as well as RPSP's, troubling lack of concern about Patient A and their irresponsible conduct in handling the incident. In an effort to step back from her statement, Respondent AR asked the Board to believe that she and RPSP failed to leave a message on Patient A's home phone out of paramount consideration for Patient A's privacy rights under HIPAA. Crediting that testimony would require nothing less than a leap of faith considering Respondent AR's and RPSP's indifference to Patient A's well-being. Additionally, Respondent AR eventually agreed that there probably was an appropriate means of wording a message seeking a return phone call without compromising patient privacy. Moreover, Respondent AR acknowledged that RPSP regularly left telephone messages for patients at home advising them that their medications were ready for pick up. To preserve her implausible reliance on privacy and HIPAA considerations,

Respondent AR attempted to hedge her testimony by stating that RPSP knew a lot of its customers and "...there's always the familiarity there and comfort level what information we would leave". It is utterly inconceivable that Respondent AR actually believed that RPSP was permitted to alter patient privacy/HIPAA requirements merely because certain patients were known to them, and the Board views such testimony as another attempt by Respondent AR to escape responsibility for her dereliction of duty and responsibility as MOR and owner of RPSP.

114. Respondent MR also exhibited a tendency toward avoiding testimony that would impact negatively on himself, Respondent AR, and RPSP. He was frequently less than truthful and forthright in responding to questions from Prosecuting Counsel. On multiple occasions he implausibly claimed to have no memory of certain events, and at other times, he attempted to shift blame for his failings from himself to [redacted].

115. Respondent MR was initially evasive in testifying about the extent to which he assisted and advised Respondent AR in getting RPSP operational. While Respondent MR first stated that he "probably" gave Respondent AR advice and assistance with running RPSP, he subsequently acknowledged providing her with PCCA policies and playing a role in adapting said policies for use at RPSP. (Testimony of Respondent MR)

116. Respondent MR testified that from time to time someone from RPSP would call him for advice or assistance, but he could not recall how frequently he received such calls. Such testimony stood in stark contrast to the credible testimony of [redacted], who openly avowed that she sought Respondent MR's assistance three (3) or four (4) times a day when she was faced with a new prescription for compounded medication requiring the production of a new Master Formulation. (Testimony of [redacted], Testimony of Respondent MR)

117. Likewise, Respondent MR was not credible when he claimed that he did not know why [redacted] called him for assistance with Patient A's prescription. That assertion was undermined by [redacted]'s credible testimony that MR

had instructed her to call him for assistance with questions.[30]

Nor was Respondent MR believable when he repeatedly maintained that [redacted] was capable of compounding Patient A's medication herself - including producing the Master Formulation - because any pharmacy school graduate would possess the know-how to prepare such a prescription and "all pharmacists are compounding pharmacists." Apart from the incredible nature of such statements, they are incongruous with Respondent MR's testimony that Pharmacy Technician [redacted] was more knowledgeable about compounding than [redacted] as well as with the fact that [redacted] relocated to Massachusetts from Florida at the urging of Respondent MR because of his compounding skills and ability to train staff. (Testimony of [redacted], Testimony of Respondent MR)

118. Respondent MR attempted to deflect responsibility for his error in compounding Patient A's medication and to shift the blame for the blunder to [redacted]. Asserting that his role in assisting [redacted] was "more of a software" matter, Respondent MR claimed that [redacted] had the knowledge and ability to produce the Master Formulation and to check it, as any pharmacist would have done. Given the multitude of times that [redacted] had sought Respondent's assistance in producing Master Formulation Records, Respondent MR would have been well aware of [redacted]'s limitations as a compounder and would have known that she lacked the knowledge, training, and ability to check the formulation for Patient A's medication. Respondent MR knew that [redacted] was relying on him to produce and provide the Master Formulation Record for Patient A's medication precisely because she lacked the knowledge and ability to create the formulation herself. (Testimony of Respondent MR)

119. Further attempting to deflect responsibility for his role in compounding Patient A's medication, Respondent MR speciously maintained that as the

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30 Upon questioning by Prosecuting Counsel, Respondent MR acknowledged that both he and Respondent AR accepted and approved the process of [redacted] turning to Respondent MR to produce formulations for prescriptions requiring new Master Formulations, and that [redacted]'s request that Respondent MR produce the formulation for Patient A's prescription was not the first instance in which [redacted] had sought such assistance. (Testimony of MR)

dispensing pharmacist, [redacted], not he, bore sole responsibility for the error. (Testimony of MR)

120. Respondent MR was not credible when he testified that he believed Patient A was "okay" because he did not hear from Patient A's mother after leaving messages for her on or around August 1 and 2, 2011. Given that Respondent MR knew the potentially serious consequences of ingesting Patient A's medication at 1,000 times the prescribed dose, it is simply implausible that Respondent MR would have made such an assumption based solely on the fact that Mother did not return his calls. Clearly, knowing the potential consequences of such an overdose and knowing from [redacted] that Patient A was seeking care in the ER for a rapid heartbeat, elevated blood pressure, and "other signs of high thyroid", would have at least raised lingering questions as to Patient A's well-being and perhaps have suggested that Patient A's mother was too occupied with Patient A's care to return telephone calls. (Testimony of [redacted], Testimony of Respondent MR)

121. [redacted] was a credible and reliable witness. Her testimony was forthright and open. Despite the fact that in initially reporting the error at issue to the Board in December 2011, [redacted] described the failure to file an earlier report with the Board as merely an "oversight," much of her testimony at the hearing shed a poor light on her own practice. Moreover, Respondent MR testified that he had no indication that [redacted] harbored any animosity toward him. [redacted]'s continuing employment at RPSP is further evidence of the absence of any such animosity toward Respondents AR and MR, and might have led one to expect that she would have presented evidence that favored her employers, place of employment, and own practice. The fact that [redacted]s testimony reflected no such effort or bias further bolstered her credibility.

122. Ms. Cittadino was a candid witness and her testimony on direct-examination and cross-examination gave the Board no reason to think that it was anything other than credible and reliable.

123. Dr. Lathum was a frank and genuine witness. While she had some memory lapses related to dates and while there was a lack of clarity in a few questions posed during her examination, these factors did not detract from her credibility. The Board has relied upon her testimony to the extent that it was clear and dependable, and/or supported by other testimonial or documentary evidence.

124. As discussed further in Findings of Fact, ¶¶ 125-127, below, the Board credits the testimony given by Patient A's mother. More specifically, but without limitation, the Board credits Mother's testimony relative to: the submission of Patient A's prescription to RPSP; the "pick-up" of the medication from RPSP; Patient A's ingestion of the medication on July 31, 2011 and August 1, 2011; the extent of the T3 overdose; the effects of the overdose on Patient A, including, but not limited to, Patient A's emergency room visits and hospitalizations; and communications (including voice mail messages) between Mother and [redacted] and between Mother and Respondent MR on or around August 1 and 2, 2011.

125. Respondents introduced no evidence disputing or contradicting Mother's testimony that Patient A's prescription was submitted to RPSP for filling; that she picked up the prescription from RPSP; that Patient A ingested two (2) doses of the medication on July 31, 2011 and August 1, 2011; and that the amount of T-3 in the medication exceeded by approximately 1,000 times that prescribed. Nor did Respondent contest Mother's testimony regarding communications or efforts at communication between Mother and individuals affiliated with RPSP immediately following the onset of Patient A's symptoms. In fact, much of Mother's testimony on these subjects was consistent with and corroborated by testimony from [redacted] and Respondents AR and MR. Additionally, Respondent did not challenge Mother's testimony regarding Patient A's multiple ER visits and hospitalizations or her testimony associated with Patient A's medical records.

126. In what appeared to be an effort to undermine Mother's credibility with regard to the overall impact of the overdose on Patient A's health, Respondents

produced a July 18, 2011 email sent by Mother to Respondent MR inquiring about RPSP's ability to provide approximately 12 items Patient A's physician was prescribing. While Mother testified that prior to ingesting the overdose of T-3, Patient A was a healthy young man who engaged in normal activities for youth of his age, the email stated that Patient A had "health issues". Other than what is contained in the email, the record is devoid of any evidence indicating the nature of these "health issues".[31] There is not a scintilla of evidence suggesting that any of the "health issues" Mother referenced bore a relationship to the cardiac effects of the T-3 overdose Patient A ingested.[32] Moreover, Patient A's medical records noting the degree of the overdose and extent of injury to Patient A, including a Myocardial Infarction, establish beyond all doubt the extremely serious and disabling cardiac consequences of Patient A's T-3 overdose, thereby corroborating Mother's testimony. Respondent introduced no evidence showing that the effects of the overdose on Patient A were less severe than indicated by Mother's testimony and the medical records.[33]

127. Respondents' attempts to cast doubt on Mother's truthfulness by examining her on issues unrelated to Patient A's condition were likewise ineffectual. Respondents endeavored, but failed to, show that Mother lacked authority to pay for Patient A's misfilled prescription with a credit card belonging to Patient A's great-grandmother. Additionally, Respondents were unsuccessful in demonstrating that Mother fabricated or exaggerated her testimony relative to her son's overdose of T-3 because she harbored a grudge or resentment after Respondent MR rejected Mother's overtures to secure a consulting

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[31] Respondents introduced the email after Mother had testified and never sought to examine her with respect to the email, including what she meant by "health issues".

[32] Other than a reference to thyroid medication, the items prescribed by Patient A's physician appear to be mainly nutritional supplements. There is no indication of any need for medications related to a cardiac condition. (Exhibit 31)

[33] While some of Mother's more detailed testimony on the longer-term effects of the overdose on Patient A's health might be highly relevant in litigation pending in another forum, for purposes of the instant proceeding, Patient A's medical records along with Mother's testimony regarding the more proximate effects of the overdose constitute ample evidence that the overdose caused Patient A serious and debilitating injury. (Testimony of Mother; Exhibits 11)

position with RPSP aimed at promoting products RPSP might sell.[34] Certainly, there was no indication that any such sentiments affected the veracity of Mother's testimony relative to Patient A's overdose, its effects on Patient A, or Mother's interactions (including conversations and attempts at communication) with anyone associated with RPSP in the days following Patient A's overdose.[35]

Respondent RPSP's Failure to Fulfill Its Duties and Responsibilities As a Registered Pharmacy in the Commonwealth

128. [redacted]'s position as the sole pharmacist to compound medications on site at RPSP was inappropriate, irresponsible, and contrary to the requirements of Chapter 795. [redacted] was utterly wanting and deficient

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[34] The communications between Mother and Respondent MR about a consulting position occurred at some point in time between the February 2011 filing of the Application to Manage and Operate a New Community Pharmacy and the opening of RPSP in late May 2011. (Testimony of Mother, Testimony of Respondent MR)

[35] Respondents also sought to impeach Mother's credibility by offering into evidence a Superior Court Memorandum and Decision in a civil matter wholly unrelated to the case before the Board. The Superior Court's ruling granted motions for sanctions and attorney fees against two attorneys who represented Mother in a civil action involving a familial dispute over property owned by Mother's grandmother. In its ruling, the Court referenced other litigation between Patient A's family members and made certain observations about Mother's prior conduct as it related to that other matter. Prosecuting Counsel objected to the admission of the Superior Court's decision. Upon review of the parties' positions, the Board declines to admit the exhibit.

First, we note again that while seeking to undermine Mother's credibility in general, Respondents have failed to specify and demonstrate what particular parts of her testimony with regard to the incident at issue lack credence. Moreover, as previously stated, the undisputed medical records clearly establish the serious and debilitating effects Patient A suffered after receiving 1,000 times the prescribed dose of T-3, Hence, if Respondents' goal was to cast doubt on Mother's testimony on that issue, their purpose is thwarted by the ample evidence of the effects of the overdose that was presented at the hearing and that supports and corroborates Mother's testimony.

Additionally, having offered no evidence of Mother's purportedly bad character based on reputation or criminal conviction, Respondents seek to discredit Mother by means of a Superior Court decision alluding to her questionable or dishonest conduct in connection with a familial transaction that bears no material relationship to the instant case. Well established law in the Commonwealth precludes the admission of such extrinsic evidence. Other than by offering a conviction, a party may not impeach a witness' credibility by introducing evidence of prior specific bad acts that purportedly reflect a lack of truthfulness and integrity or by introducing evidence seeking to show that a witness has testified untruthfully in another matter. *Commonwealth v. Walker*, 442 Mass. 185 (2004); *Commonwealth v.* Perez, 390 Mass. 308, 316-318 (1983); *Commonwealth v.* Frey, 390 Mass. 245, 249 (1983); *Commonwealth v. Bohannon*, 376 Mass. 90, 93 (1978) Finally, in so far as Respondents may have sought to show prior statements made by Mother that were inconsistent with statements she made while questioned by Counsel for Respondents about the Superior Court's Memorandum of Decision and Order, it was abundantly clear that Mother was unfamiliar with and did not comprehend the Court's language and ruling.

in the training, skills, and qualifications for such a job, and RPSP lacked the policies and procedures that would have served as a check to ensure [redacted] was adequately trained and skilled to perform her job as a compounding pharmacist.

129. Respondent RPSP had no policy and procedure that would have provided appropriate and lawful direction to a pharmacist who did not know whether Respondent RPSP could prepare a prescription for a compounded medication and/or who did not know how to produce the medication, including the development of a Master Formulation. Respondent RPSP failed to provide for basic patient safety consistent with the requirements of Chapter 795 in that there existed at the pharmacy a routine practice whereby: [redacted] would remotely call upon Respondent MR to produce Master Formulations for new prescriptions requiring compounding for which no such formulations existed; from his Florida home, Respondent MR would electronically send the Master Formulations to [redacted] in order that she could produce the medications on site at RPSP; neither Respondent MR nor [redacted], who lacked the training and skills to do so, would review for accuracy and correctness the Master Formulations that [redacted] printed out and used to produce the compounded medication; and requisite second checks were not performed before compounded medication was dispensed to a patient.

130. Respondent RPSP did not have a policy or procedure to ensure that the T-3 used to compound Patient A's prescription would be triturated as required to maintain the safety and intended efficacy of the medication, as required by Chapter 795.

131. Respondent RPSP failed to report to the Board in a timely manner the improper dispensing of a prescription that resulted in a serious and debilitating injury to Patient A, in accordance with regulatory and statutory requirements. RPSP personnel, including its owner/MOR and staff wholly failed to make adequate efforts to obtain information to ascertain the extent of injury and disability to Patient A from the T-3 overdose.

132. Respondent RPSP failed to adhere to the Plan of Correction adopted after the incident involving Patient A. Nine months later, a Board inspection revealed a failure to segregate and label "for trituration only" a bottle of liothyronine sodium 500 mg and a failure to implement a practice whereby in each and every instance a second person would check calculations.

133. Respondent RPSP failed to adhere to USP (Chapter795) requirements by storing in its refrigerator liquid HCG 6K that was not labeled with a lot number or expiration date.

134. Respondent RPSP failed to abide by Board regulations when RPSP provided practitioners with prescription blanks that bore the RPSP logo and/or the name of the Florida pharmacy owned by Respondent MR.

135. In August 2011, by conducting and filing with the Board only an inventory of Schedule II controlled substances, Respondent RPSP failed to perform and file with the Board a complete inventory of controlled substances Schedules II – V along with an Application for Change of Manager of Record, as required by the Board's regulations at 247 CMR 6.03 (1).

IV. Rulings of Law

1. Based upon Finding of Fact ¶ 1, above, the Board has jurisdiction to hear this disciplinary matter involving Respondent RPSP, Registration No. DS89765.

2. Respondent RPSP engaged in gross misconduct and malpractice in that it lacked proper managerial oversight, qualified staff, and adequate policies and procedures to ensure compliance with the requirements of Chapter 795 relative to the production and dispensing of compounded medications and in

that it allowed to exist a practice of compounding medication whereby Respondent MR and [redacted], who lacked the requisite training, knowledge and ability, filled and dispensed Patient A's prescription for T-3 10 mcg SR #30 at 1,000 times the prescribed strength, in the manner set forth in Findings of Fact ¶¶ 14, 15, 20-76, 100-121, 124-130, above, constituting grounds for discipline pursuant to G.L. c. 112, § 61 and 247 CMR 10.03 (1).[36]

3. Respondent RPSP's conduct as described in Ruling of Law 2, above, constitutes grounds for discipline pursuant to G.L. c. 112, §§ 40 and 42A and 247 CMR 10.03 (1)(a) and (b).
4. Respondent RPSP's failure to report the improper dispensing of Patient A's prescription to the Board as soon as reasonably and practically possible, and not more that fifteen (15) days after discovering and being informed of such improper dispensing, as set forth in Findings of Fact ¶¶ 77-91 and 131, above, violated G.L. c. 112, § 39D and 247 CMR 6.14 and 15.05, constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(a) and (b) and G.L. c. 112, §§ 40, 42A and 61.
5. Respondent RPSP's failure to adhere to the Plan of Correction it filed with the Board following the incident involving Patient A, as required under 247 CMR 6.13 and 15.02 and as set forth in Findings of Fact, ¶¶ 92-96 and 132, constitutes grounds for discipline pursuant to 247 CMR10.03 (1)(a) and (b) and G.L. c. 112, §§ 40, 42A and 61.
6. In accordance with Rulings of Law 2, 3 and 5, above, Respondent RPSP engaged in conduct that had the capacity to, and/or did, place the public health, safety, or welfare at risk, constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(k) and G.L. c. 112, §§ 40, 42A, and 61.

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[36] As set forth in the Findings of Fact referenced in Ruling of Law 2, above, RPSP lacked established policies and procedures to ensure the safety of medication dispensed by the pharmacy, including, but not limited to, a policy or procedure addressing circumstances when a staff pharmacist was unsure whether RPSP could fill a prescription and/or was incapable of filling the prescription herself. Exacerbating the situation was the practice whereby [redacted] lacking necessary and required training, knowledge and ability, would routinely rely upon Respondent MR to remotely produce Master Formulations for new prescriptions for compounded medications for which no Master Formulation existed and whereby [redacted] would produce the medication in accordance with the formulation Respondent MR provided and dispense the medication without anyone associated with RPSP checking for accuracy and correctness.

7. Respondent RPSP's conduct as set forth in Rulings of Law, ¶¶ 2-5, above, constitutes the type of conduct that undermines public confidence in the integrity of the pharmacy profession, constituting grounds for discipline pursuant to 247 CMR 10.03 (1) (u) and G.L. c. 112, §§ 40, 42A and 61. *Kvitka v. Board of Registration in Medicine*, 407 Mass. 140, cert. denied, 498 U.S. 823 (1990) ("The board has the authority to protect the image of the profession."); *Raymond v. Board of Registration in Medicine*, 387 Mass. 708, 713 (1982)
8. Respondent RPSP's conduct as set forth in Rulings of Law, ¶¶ 2 and 3 constitutes conduct that violated recognized standards of pharmacy practice, constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(v) and G.L. c. 112, §§ 40, 42A and 61.
9. Respondent RPSP's failure to conduct and include with the Application for a Change of Manager of Record filed with the Board in August 2011, a complete inventory of controlled substances in Schedules III-V, as set forth in Findings of Fact, ¶¶ 39 and 135, above, violated 247 CMR 6.03 (1)(a), constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(a) and (b) and G.L. c. 112, §§ 40, 42A, and 61.
10. Respondent RPSP in providing to practitioners prescription blanks bearing RPSP's logo and/or the name of a Florida pharmacy owned by Respondent MR, as set forth in Findings of Fact ¶¶ 98, 99, and 134, above, violated 247 CMR 9.01 (13)[37], constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(a), (b) and (w) and G.L. c. 112, §§ 40, 42A and 61.

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[37] The Board's ruling that RPSP violated 247 CMR 9.01 (13) is the sole Ruling of Law finding a violation of the Code of Conduct at 247 CMR 9.01. Given the rulings set forth in Rulings of Law 2-8, above, the Board need not address additional allegations in the Order to Show Cause related to violations of 247 CMR 9.01 (1) and (3). Hence, such allegations, as stated in paragraphs 20 (d), (e), and (f) of the Order to Show Cause, are dismissed without prejudice. (Regarding the alleged violation of law set forth in paragraph 20 (d) of the Order to Show Cause, the Board notes that the alleged underlying conduct, i.e. Respondent RPSP's storage of liquid HCG 6K that was not labeled with a lot number or expiration date as required by the USP [Findings of Fact ¶¶ 30, 97, and 133, above], would constitute grounds for discipline pursuant to G.L. c. 112, §§ 40, 42A, and 61 and 247 CMR 10.03 (1)(b). However, paragraph 20 (d) of the Order to Show Cause simply alleges a violation of 247 CMR 9.01)

Discussion

Pursuant to G. L. c. 112, § 61, the Board has the authority to discipline a pharmacy for engaging in deceit, malpractice, fraud, or gross misconduct in the conduct of her profession. Chapter 112, § 61 reads in pertinent part:

[E]ach board of registration . . .may . . . suspend, revoke or cancel any certificate, registration, license or authority . . . if it appears . . . that the holder of such certificate, registration, license or authority, . . . is guilty of deceit, malpractice, gross misconduct in the practice of his profession, or of any offense against the laws of the commonwealth relating thereto . . .

"The term 'gross misconduct' has been interpreted broadly." *Leigh v. Board of Registration in Nursing*, 395 Mass. 670, 675 (1985). The Supreme Judicial Court has recently stated: "This Court has granted agencies discretion in determining what misconduct falls into this category." *Dlugosz v. Board of Registration in Nursing*, Supreme Judicial Court, No. 1996-0500, May 24, 2002 (Memorandum and Order), at pp. 9 -10. In addressing the difference between "misconduct" and "gross misconduct," the Court in *Hellman v. Board of Registration in Medicine*, 404 Mass. 800, 804 (1989) explained that gross misconduct "...is more than that conduct which comes about by reason of error of judgment or lack of diligence." Gross misconduct is flagrant, inexcusable misconduct, or implies willed and intentional wrongdoing and behavior that shows a lack of concern for one's conduct, amounting to utter indifference to legal duty. See *Hellman v. Board of Registration in Medicine*, 404 Mass. 800, 804 (1989). Gross misconduct in the practice of the profession may include all conduct of the

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Additionally, the Board dismisses the alleged violation of law set forth in paragraph 20 (c) of the Order to Show Cause, determining that the regulation [247 CMR 8.06 (3)(a)] is inapplicable in the instant matter involving a pharmacy.

practitioner in carrying out his or her professional activities, and is not limited to behavior involving the diagnosis or treatment of a patient. *Forziati v. Board of Registration in Medicine*, 333 Mass. 125, 129, 128 N.E.2d 789 (1955).

Consistent with its mandate to promote the public health, safety and welfare, the Board also has authority to discipline pharmacies for violations of its regulations, unprofessional conduct and conduct undermining public confidence in the integrity of the profession. *Kvitka v. Board of Registration in Medicine*, 407 Mass. 140, cert. denied, 498 U.S. 823 (1990) ("The board has the authority to protect the image of the profession."); *Raymond v. Board of Registration in Medicine*, 387 Mass. 708, 713 (1982); *Reed v. Board of Registration of Psychologists,* Suffolk Superior Court, No. 96-5242-B, August 19, 1997 (Memorandum of Decision and Order) at p. 15 (board has authority to sanction licensee for conduct which it finds to be unprofessional or unethical); *aff'd, Reed v. Board of Registration of Psychologists*, Massachusetts Court of Appeals, No. 97-P-2137, April 12, 1999, citing *Sugarman v. Board of Registration in Medicine*, 422 Mass. 338, 342 (1996) ("the board has broad authority to regulate the conduct of the...profession, ...[which] includes its ability to sanction [professionals] for conduct which undermines public confidence in the integrity of the...profession.")

Pursuant to G.L. c.112, Sec. 40, the Board has authority to discipline registered pharmacies for any violation of the law pertaining to the drug business or any violation of the Board's regulations. Additionally, in accordance with G.L. c. 112, Sec. 42A, the Board has the authority to impose discipline on pharmacies that violate its regulations, including standards of conduct for Registered Pharmacists and Pharmacies set forth at 247 CMR 9.01. Failure to conform to such standards, or any other laws and regulations related to the practice of pharmacy, constitutes grounds for discipline pursuant to G.L. c. 112, §§ 40, 42A and 61. Furthermore, 247 CMR 10.03, entitled *Grounds for Discipline*, specifies conduct, in addition to that stated in G.L. c. 112, §61, for which the Board may impose discipline.[38] Such conduct includes, but is not limited to, violating any of

[38] Pursuant to 247 CMR 10.03 (2), nothing set forth in 247 CMR 10.03 limits the Board's ability to adopt policies and grounds for discipline through adjudication and rulemaking.

the duties and standards articulated in the Board's regulations or any rule or written policy adopted by the Board [247 CMR 10.03 (1)(a)]; violating any provision of G.L. c. 112, §§ 24-42A or any provision of state or federal statutes or rules or regulations promulgated thereunder related to the practice of the pharmacy profession [247 CMR 10.03 (1)(b)]; engaging in conduct that has the capacity or potential to place at risk the public health, safety, or welfare [247 CMR 10.03 (1)(k)]; engaging in conduct which undermines public confidence in the integrity of the pharmacy profession [247 CMR 10.03 (1)(u)]; engaging in conduct that violates recognized standards of pharmacy practice [247 CMR 10.03 (1)(v)]; and failing to adhere to recognized ethical standards of the pharmacy profession, including, but not limited to, the standards of practice set forth in the *Code of Conduct at* 247 CMR 9.01 (247 CMR 10.03 (1)(w)].

Underlying the Board's regulations and the USP with which pharmacies are required to comply pursuant to G.L. c. 112, § 40, is the need to protect the public health and safety by ensuring that pharmacies, pharmacists and other pharmacy personnel operate in a manner that results in the dispensing of safe drugs in accordance with the specifications of patients' prescriptions. The USP explicitly states a goal of promoting compound preparations that are of "acceptable strength, quality and purity" and are "in accordance with the prescription medication order". To that end, the USP addresses issues such as, but not limited to, adequate training for compounders; responsibilities of a compounder; the compounding process; component selection, handling, and storage; compounding documentation; standard operating procedures that "...assure accountability, accuracy, quality, safety, and uniformity in compounding"; and quality control. With regard to *Quality* Control, the USP provides that the safety, quality, and performance of compounded preparations rely on "... correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment." To realize its goals, the USP recognizes that personnel engaged in compounding must be "...appropriately trained and ... capable of performing and qualified to perform their assigned duties." Furthermore, the USP requires that each procedure and

phase of the process, including the Master Formulation Record that is integral to the process, be checked to ensure the absence of errors and the suitability of the preparation for use. As noted above, pursuant to G.L. c. 112, § 40, pharmacies are mandated to conform to federal law pertaining to the drug business, including the USP.

The Board has a mandate to discipline pharmacies whose businesses are characterized by incompetence, neglect, haphazardness, malpractice, and disregard of the law in the practice of pharmacy, thereby placing patients at risk. In the instant case, the evidence demonstrates a pattern of pharmacy operations that reflects an utter disregard for process and safety, constituting gross misconduct and malpractice. RPSP lacked established policies and procedures needed to run an orderly and safe pharmacy. Moreover, Respondent AR's abdication of her duties as MOR left a gaping hole in management that undermined the orderly and safe conduct of business at RPSP. On a sporadic basis, Respondent MR appeared to haphazardly function as an often remote, de facto MOR, an arrangement that failed to promote and ensure the lawful and safe operation of the pharmacy. The grave error made in filling Patient A's prescription was a foreseeable consequence of such circumstances.

Although the *Application to Manage and Operate a New Community Pharmacy* filed with the Board in February 2011 represented that all RPSP staff engaged in any drug distribution activity would possess sufficient education, training, and experience to perform his or her job in a manner that would assure the quality and safety of their products, [redacted] was placed in a position where she was called upon to accept assignments that were beyond her training, knowledge, and ability to perform. As the sole pharmacist on the premises, [red [redacte , possessing insufficient knowledge, was left to decide whether RPSP could accept prescriptions for compounded medications. Additionally, despite an acute lack of training, knowledge, experience, and skill, [redacted] was charged with producing compounded medications that she was utterly unqualified to compound. RPSP had no policy or procedure that addressed a situation where a

pharmacist was unsure whether RPSP could compound a particular medication or did not know how to create a Master Formulation for a newly received prescription for which no Master Formulation existed. Rather, to compensate for [redacted] 's shortcomings, the pharmacy relied upon a sloppy and risky practice pursuant to which [redacted] would call upon Respondent MR to produce and electronically send her a Master Formulation. [redacted] 's testimony established that such requests occurred daily and multiple times each day. Having received a Master Formulation from Respondent MR, [redacted] would follow the formulation like a recipe to produce a medication. Lacking the knowledge and qualifications to perform a check for correctness and accuracy herself, [redacted] assumed that the formulation was correct and accurate based upon Respondent MR's significant compounding experience. Nobody associated with RPSP would perform a check for safety and accuracy before such a compounded medication was dispensed.

Such was the situation on July 28, 2011, when RPSP received Patient A's prescription for a thyroid medication, T-3 10 mcg SR#30 capsules. [redacted] asked Respondent MR whether RPSP could compound the medication and if so, whether he could produce and send her the Master Formulation for the medication. At Respondent MR's direction [redacted] placed an order for the liothyronine that was a component of Patient A's medication. The following day, the liothyronine was delivered to RPSP in a concentrated form; however, Patient A's prescription required use of a triturated form of liothyronine. RPSP had no policy or procedure regarding the use of the triturated form of T-3 when compounding medication.

Using a Master Formulation that was created and provided electronically by Respondent MR, [redacted] prepared the compounded medication precisely as directed by MR's Master Formulation. The medication, containing 1,000 times the prescribed strength of T-3, was dispensed to Patient A's mother without either Respondent MR or [redacted] performing the checks required to ensure the safety and quality of the product. Respondent MR never saw the printed Master Formulation from which [redacted] worked and neither he nor another individual,

including the unqualified [redacted], ever checked his calculations to guard against errors.

Following their discovery of Respondent MR's error in preparing the Master Formulation, [redacted] and Respondent MR learned that Patient A was experiencing cardiac symptoms and required emergency medical care. Respondent MR advised Respondent AR that an overdose of T-3 had been dispensed to Patient A and informed Respondent AR of his and [redacted]'s efforts to contact Patient A. Respondent MR did not tell Respondent AR how great the overdose was, nor is there any evidence indicating that she asked. Remaining uninvolved, Respondent AR left her husband and [redacted] to handle the situation. Following the two (2) telephone conversations between [redacted] and Mother on August 1, 2011 and a few voice mail messages left by [redacted] and Respondent MR for Mother on August 1-2, 2011, no attempts, including via telephone, email, or at Patient A's nearby home, were made by any individual associated with RPSP to obtain information regarding the progression of Patient A's condition following his initial cardiac symptoms. Nor did anybody from RPSP inform mother –or subsequently RPSP's liability carrier- that the pharmacy was required by law to report any improper dispensing of a prescription drug that resulted in serious injury. Moreover, after having received the August 17, 2011 letter from Patient A's attorney alluding to Patient A's continuing "significant medical problems", RPSP still made no effort to obtain additional information about Patient A's condition for purposes of complying with the Board's reporting requirement.

Even in the wake of the serious events that led to a 19 year old suffering a heart attack, RPSP failed to adequately alter its errant ways by adhering to a Plan of Correction, as evidenced when a Board inspection nine (9) months later revealed a failure to segregate and label "for trituration only" a bottle of liothyronine sodium 500 mg and a failure to implement a practice whereby in each and every instance a second person would check calculations for a compounded medication. These inspectional findings reflect a disquieting pattern of sloppiness and inattention to critical safety measures.

Finally, the carelessness, ineptitude, and inattentiveness to duties imposed by law that characterized RPSP's operations were also reflected in RPSP's failure to conduct and file the required controlled substances inventories with the *Application for Change in Manager* filed with the Board in August 2011 and in the pharmacy's conduct in providing prescription blanks bearing the RPSP logo and/or name of the Florida pharmacy owned by Respondent MR.

Patients are entitled to trust that pharmacies will adhere to the law and take all steps to ensure that the medications dispensed to them conform to their prescriptions and will not sicken or harm them as a result of error. Respondent RPSP breached that trust in an egregious manner. Conduct that constitutes a flagrant violation of law and accepted standards of practice and that thereby places the public's health, safety, and well-being at risk is precisely the type of conduct that undermines public confidence in the integrity of the pharmacy profession. The misfill of Patient A's prescription was a direct consequence of the way in which Respondent RPSP was operated and managed. Moreover, it is alarming that nine months later, the pharmacy was still plagued by serious failures to adhere to the Plan of Correction developed in the aftermath of such a grave incident. Such circumstances demonstrate the pharmacy's unfitness to operate in a safe and competent manner that conforms to the requirements of the law.

Accordingly, Respondent RPSP's conduct warrants discipline of its registration to operate as a pharmacy pursuant to the Board's regulations at 247 CMR 10.03 and G.L. c. 112, §§ 40, 42A and 61, and the Board enters the following Order:

[order to be entered by the Board]

Date issued: February 18, 2015

Notice to:

Via First Class and Certified Mail 7010 1870 0002 2380 7923
Paul Garbarini, Esq.
P.O. Box 1551
Northampton, MA 01061

By Hand
Richard L. Banks, Esq.
Office of Prosecutions
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 500
Boston, MA 02114

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of	)	
Royal Palm Specialty Pharmacy	)	PHA-2011-0309
Registration No. DS89765	)	
License Expiration Date 12/31/15	)	

Ruling on Respondent's Objections to Tentative Decision

On December 2, 2013, January 6, 2014, January 13, and January 15, 2014, the Board of Registration in Pharmacy ("Board") held a formal adjudicatory hearing in this matter before Administrative Hearings Counsel ("AHC") Vivian Bendix. On February 18, 2015, the ACH issued a Tentative Decision containing her findings of fact, credibility determinations, and conclusions of law. On March 27, 2015, the Board received Respondent Royal Palm Specialty Pharmacy's Objections to the Tentative Decision.[1] Prosecuting Counsel did not file objections. On April 27, 2015, Prosecuting Counsel filed Responses to Respondent's Objections.[2]

The Board has reviewed and carefully considered the Tentative Decision, Respondent's objections, and Prosecuting Counsel's responses to the objections. The Board has determined that the Final Decision in this matter should correct a citation to Board regulations in Finding of Fact ¶ 39, but that no other changes to the Tentative Decision are warranted, as the objections are without merit.

The Board is not required to address each of Respondent's objections or provide a specific response for rejecting objections. See *Arthurs v. Board of Registration in Medicine*, 383 Mass. 229, 315-316 (2005) and *Weinberg v. Board of Registration in Medicine*, 443 Mass. 679, 687 (2005). While declining to address each of Respondent RPSP's objections individually, the Board responds as follows:

The basis for Respondent's objection to Finding of Fact ¶39 is unclear. However, it is noted the AHC used the incorrect citation to the regulation requiring a change of manger of record application to be accompanied by an inventory of controlled substances. The citation should be changed from "247 CMR 6.07(h)(1)" to "247 CMR 6.03(1)(a)."

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[1] The objections were timely filed in accordance with an Assented to Motion to Extend the Time to File Objections from March 20, 2015 to march 30, 2015, which the Board allowed.

[2] Prosecution's response to Respondent's objections was timely filed in accordance with an Assented to Motion for Further Enlargement of Time, until April 27, 2015, which the Board allowed.

Respondent's Counsel objects to numerous other findings of fact and determinations of credibility, but fails to identify any legal reason why the evidence relied upon by the AHC was erroneously admitted, excluded, or considered. A reviewing court "must accept the factual determinations made by the agency" if they are supported by substantial evidence." *McGuiness v. Department of Correction*, 465 Mass. 600, 668 (2013), citing *School Comm. of Boston v. Board of Educ.*, 363 Mass. 125, 128 (1973). "Substantial evidence means such evidence as a reasonable mind might accept as adequate to support a conclusion." M.G.L. c. 30A, § 1(6); *Arthurs*, 383 Mass. at 304. Each of the AHC's Findings of Fact are supported by witness testimony and/or documents in evidence. Respondent Counsel's objections do not identify any legal error; rather, the objections are simply a further attempt argue the facts of the case. As such, the Board finds the objections are without merit.

Respondent's Counsel also objects to the AHC's determinations of credibility. However, the Board "may not reject a [hearing officer's] tentative determinations of credibility of witnesses personally appearing." 801 CMR 1.01(11)(c)(2). Accordingly, the Board finds Respondent Counsel's objections to the AHC's determinations of credibility are without merit.

Finally, Respondent's Counsel objects to Rulings of Law ¶¶ 2 – 10. The Board notes that the Rulings of Law are adequately supported by the Findings of Fact and Discussion and the objections are without merit.

The Board voted to adopt this Ruling on Respondent's Objections to Tentative Decision at its meeting held on June 2, 2015, by the following vote:

In favor:	Patrick Gannon; Edmund Taglieri Jr.; Richard Tinsley; Timothy Fensky; Garrett Cavanaugh; Catherine Basile; Susan Cornacchio; William Cox; Michael Godek; Andrew Stein; Phillippe Bouvier
Opposed:	None
Abstained:	None
Recused:	None
Absent:	Karen Conley

Board of Registration in Pharmacy,

David A. Sencabaugh, R.Ph.
Executive Director

Date Issued: 7-15-15

Notified:

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
RECEIPT REQUESTED NO.

Paul M. Garbarini
Attorney At Law
P.O. Box 1551
Northampton, MA 01061

BY HAND DELIVERY

Richard L. Banks
Office of Prosecution
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 500
Boston, MA 02114

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

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Opposed:	None
Abstained:	None
Recused:	None
Absent:	Karen Conley

Board of Registration in Pharmacy,

David A. Sencabaugh, R.Ph.
Executive Director

Date Issued: 7-15-15

Notified:

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
RECEIPT REQUESTED NO.

Paul M. Garbarini
Attorney At Law
P.O. Box 1551
Northampton, MA 01061

BY HAND DELIVERY

Richard L. Banks
Office of Prosecution
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 500
Boston, MA 02114

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
ROYAL PALM)
SPECIALTY PHARMACY)
[redacted])
)
)

PHA-2011-0309

CEASE AND DESIST AND QUARANTINE NOTICE

Royal Palm Specialty Pharmacy ("Royal Palm") is hereby notified to IMMEDIATELY CEASE AND DESIST engaging in the compounding and/or dispensing of liothyronine sodium.

This Notice is issued pursuant to the authority of the Department of Public Health ("Department") through the Board of Registration in Pharmacy ("Board"), pursuant to M.G.L. c. 94, § 189A, M.G.L. c. 94C, §§ 13 and 14, M.G.L. c. 112, §§ 39 and 42A, and Board Regulation 247 CMR 10.08, related to observed pharmacy practices and conditions at Royal Palm Pharmacy Registration No. DS26808, located at [redacted]

Royal Palm was observed to be non-complaint with required plan(s) of correction and/or standard operating procedure(s) pertaining to the labeling and storage of liothyronine sodium on April 24, 2012 and January 15, 2013. Such non-compliance constitutes an immediate threat to public health and safety.

Royal Palm must immediately cease the compounding and dispensing of liothyronine sodium. Royal Palm must immediately QUARANTINE ALL liothyronine sodium located on Royal Palm premises.

Pursuant to this Notice, no dispensing of liothyronine sodium may occur without the express approval of the Department. No disposition may be made of ANY liothyronine sodium without the express approval of the Department. An EMBARGO ORDER may be issued by the Department, pursuant to M.G.L. c. 94C, § 13, if necessary. Removal or disposition of the above-described articles without permission from the Department shall be subject to applicable statutory and regulatory penalties.

Royal Palm may not resume the compounding or dispensing of liothyronine sodium without the express approval of the Department. Royal Palm shall conduct an orderly transition of patient care and pharmacy related compounding services.

In accordance with 247 CMR 10.08, a hearing limited to the determination of the necessity of this Notice shall be afforded to the licensee within 15 business days of the issuance of this Notice.

Direct questions to Heather Engman, Board Counsel, 617-973-0992, or Madeleine Biondolillo, M.D., Director, Bureau of Health Care Safety and Quality, Department of Public Health, 617-753-8100.

BOARD OF REGISTRATION IN PHARMACY

James T. DeVita

James T. DeVita, R.Ph
President
Effective Date: February 19, 2013

Acknowledgement of receipt by Royal Palm

Date: 2/27/13
Time: 1:36pm

Print Name: Kathe Fafalla