The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 500, Boston, MA 02114

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Commissioner

July 15, 2015

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
RECEIPT REQUESTED NO. 7014 0510 0001 0375 2138
Paul M. Garbarini, Esq.
Attorney At Law
P.O. Box 1551
Northampton, MA 01061

RE: In the Matter of Mark Rubin, PH License No. 233459
Board of Registration in Pharmacy Docket No. PHA-2012-0005

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 4 of the *Final Order* ("Date Issued"). Your appeal rights are noted on page 4 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	)	
Mark Rubin	)	PHA-2012-0005
Registration No. PH233459	)	
License Expiration Date 12/31/16	)	

FINAL DECISION AND ORDER

FINAL DECISION

On December 2, 2013, January 6, 2014, January 13, 2015 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 Mark Rubin's Objections to the Tentative Decision.[1] Prosecuting Counsel did not file objections or a response to Respondent's objections.

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 ¶ 36, footnote 10, 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; 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 **suspends** Respondent's license to practice as a pharmacist in the Commonwealth, license No. PH233459, for a period of at least three years.

[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.

Respondent is hereby ordered to return any license issued to him by the Board, whether current or expired, to the Board's office at 239 Causeway Street, Boston, Massachusetts 02114, by hand or certified mail, within ten (10) days of the Effective Date set forth below.

Respondent shall not practice as a pharmacist in Massachusetts on or after the Effective Date of this Order. "Practice as a pharmacist" includes but is not limited to, seeking and accepting any paid or voluntary position as a pharmacist, working in any pharmacy related setting, or in anyway representing himself as a pharmacist. Practice as a pharmacist following the Effective Date of this Order and prior to reinstatement of licensure by the Board constitutes unlicensed practice and is grounds for civil and criminal penalties, as provided by M.G.L. c. 112, § 65.

The Board may choose to reinstate Respondent's license if the Board determines in its sole discretion that reinstatement is in the best interests of the public health, safety, and welfare.

The Respondent may not petition the Board for reinstatement of his pharmacist license prior to July 1, 2018. Any petition for reinstatement shall include the following:

1. Documentation demonstrating that Respondent received a passing score on the MPJE within six (6) months prior to any petition for reinstatement;

2. All documentation required pursuant to Board's policy 2011-02 "License Reinstatement following Surrender, Suspension, or Revocation";

3. A performance evaluation sent directly to the Board from each of the Respondent's employers, prepared on official letterhead that reviews the Respondent's attendance, general reliability, and specific job performance during the year immediately prior to the date on which the Respondent submits her petition ("petition date")[2];

4. Authorization for the Board to obtain a Criminal Offender Record Information ("CORI") report of the Respondent conducted by the Massachusetts Criminal History Systems Board.

5. Certified documentation from the state board of pharmacy of each jurisdiction in which the Respondent has ever been registered to practice as a pharmacist, sent directly to the Massachusetts Board

[2] If the Respondent has not been employed during the year immediately prior to the petition date, she shall submit an affidavit to the Board so attesting.

identifying his license status and discipline history, and verifying that his pharmacist license is, or is eligible to be, in good standing and free of any restrictions or conditions.

6. Documentation demonstrating successful completion of all continuing education requirements.

The Board may require the Respondent to submit additional documentation prior to acting on the Respondent's petition for reinstatement.

The Board may condition its approval of Respondent's petition for reinstatement upon Respondent entering into a Consent Agreement of Probation of Respondent's pharmacist license for a period of time, with such restrictions and requirements that the Board may at that time and its sole discretion determine are reasonably necessary to protect the public health, safety, and welfare.

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 his 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 2138

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 Mark J. Rubin Registration No. PH 233459 License Expiration Date 12/31/16[1]	Docket No. PHA-2012-0005

TENTATIVE DECISION [2]

I. Procedural Background

On May 15, 2013, the Board of Registration in Pharmacy ("Board") issued an Order to Show Cause ("Order") to Mark J. Rubin ("Respondent MR"), a Registered Pharmacist licensed by the Board, Registration No. PH 233459. The Order to Show Cause directed Respondent MR to show cause why his registration to practice as a Pharmacist should not be suspended, revoked, or otherwise disciplined pursuant to Massachusetts General Laws ("G.L.") Chapter 112, §§ 42A and 61 and 247 CMR 2.00 *et seq.*, based, in part, upon allegations that Respondent MR, while not on site at Royal Palm Specialty Pharmacy, participated as a compounder in the compounding of a prescription for "T-3 10 mcg SR #30 capsules" that Royal Palm Specialty Pharmacy prepared for and dispensed to a patient; that Respondent MR failed to check the *Logged Formula Worksheet* that he created as part of the compounding process and which listed him as the pharmacist; and that the medication was improperly compounded in that instead of

[1] The original caption in the instant matter reflected the license expiration date as December 31, 2014. However, Respondent's current record of standing with the Board reflects that Respondent's license will expire on December 31, 2016, unless renewed. (Exhibits 16, 20; 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.

T-3 10 **mcg** SR #30, the medication was compounded as T-3 10 **mg** SR #30, causing a serious adverse reaction in the patient. The Order further alleged that Respondent MR made no efforts to determine the extent of harm caused to the patient by the dispensing error and did not report the improper compounding and dispensing to the Board. On June 10, 2013, Respondent MR filed a Request for Hearing and Answer to the Order to Show Cause, admitting certain allegations against him and denying others.

On October 28, 2013, Respondent MR 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 MR was present and represented by Paul M. Garbarini, Esq.

The instant matter involving Respondent MR was heard along with two other related matters against Respondent Agnes Rubin, R.Ph. and against Respondent Royal Palm Specialty Pharmacy. 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 MR filed his 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

[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 and all exhibits admitted during the course of the hearing are listed as well.

[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 7	Letter: from Agnes Bergeron, R Ph to Board of Registration in Pharmacy, July 1, 2011
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 [redacted] 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 [redacted] 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 the prescription was 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 pregnant 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 pregnant 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 gave birth to a child on or about [redacted], 2011.

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 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. (Testimony of Respondent MR; Exhibits 16,17, 20; Board records of which the Board takes administrative notice)
2. 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 compounding business. One such pharmacy was Royal Palm Compounding Pharmacy, where Respondent Agnes Rubin 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)
3. Respondent MR is licensed to practice as a pharmacist in eight (8) states. (Testimony of Respondent MR)

4. 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. (Testimony of Respondent AR; Exhibits 1,2, 19; Board records of which the Board takes administrative notice)

5. 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)

6. 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)

7. 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)

8. 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)

9. 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.[5] 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, ¶ 37, below) (Testimony of Respondent AR; Testimony of Cittadino; Testimony of Respondent MR; Testimony of [redacte; Exhibits 3, 4, 6, 24)

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 [redacte; 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 [redacte)
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 10 mcg SR #30 capsules was presented for filling to

[5] 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."

RPSP on July 28, 2011. (Testimony of Respondent AR, Testimony of Respondent MR; Testimony of [redacted], Testimony of Mother of Patient A; Exhibits 3, 8)

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

<u>Duties of a Pharmacist and a Compounder</u>

20. 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. [6]

21. 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)

22. 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)

23. 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)

24. 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

[6] 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.

occurred in the compounding process and that the preparation is suitable for use" (Testimony of McKenna; Exhibit 18)

25. 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)
26. 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)
27. The provisions of Chapter 795 apply to the non-sterile compounding of liothyronine or T-3 medication. (Testimony of McKenna)

Founding, Licensure and Launch of RPSP

28. 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.[7] 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)

[7] As noted in Finding of Fact, ¶ 9, Respondent AR has been the sole owner of RPSP since the pharmacy's incorporation. (Testimony of Respondent AR; Exhibits 4, 6, 24)

29. 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)

30. 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.[8] 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)

31. At all times between February 2011 and May 2011, Respondent AR resided in Florida and knew she was pregnant with her [red who was born on [redacted 2011. At no time between February and May 2011 did Respondent AR advise the Board that with the birth of her child, 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)

32. 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)

33. In mid-June 2011, Respondent AR experienced complications related to her pregnancy and was compelled to return to Florida for medical care.

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[8] 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.[9] (Testimony of Respondent AR, Testimony of Respondent MR, Testimony of [redacted])

34. On July 14, 2011, Respondent AR gave birth via [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)

35. In August 2011, Respondent AR returned to Massachusetts after receiving her obstetrician's clearance to travel. However, she continued to suffer pain from [redacted], was unable to work, and had to return to Florida for [redact] surgery. 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)

36. 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.[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)

37. In accordance with Findings of Fact, ¶¶ 28–36, above, at all times between April 29, 2011 and September 13, 2011, Respondent AR was MOR of RPSP. Nevertheless, Respondent AR did not work at RPSP at any time between mid-June 2011 and September 13, 2011.

38. At the time of its opening in May 2011, RPSP staff included [redacted], R.Ph and [redacted], a pharmacy technician. Respondent MR worked at the pharmacy for much of the first three (3) weeks that the pharmacy was

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[9] In June 2011, Respondent AR spoke with Ms. Cittadino about the procedure for appointing an interim MOR during an MOR's leave of absence. On July 1, 2011, Respondent AR sent a letter to the Board stating that she was taking a temporary maternity leave of absence (not exceeding 90 days) from her full-time position as MOR and that she would maintain part-time duty as MOR of RPSP. Respondent AR never invoked the Board's process for appointing an interim MOR or a permanent new MOR, and her July 1, 2011 letter to the Board did not effectuate a change in her status as RPSP's MOR. (Testimony of Cittadino, Testimony of Respondent AR; Exhibits 3, 7)

[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.

open.[11] Between mid-June and August 2011, Respondent MR returned from Florida sporadically to work at RPSP. (Testimony of Respondent AR, Testimony of [redact])

39. 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.[12] (Testimony of Respondent AR, Testimony of Respondent MR)

40. [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)

41. Between May 25, 2011 and August 2011, [redacted] was the only full-time pharmacist at RPSP.[13] (Testimony of Respondent AR, Testimony of [redacte])

42. 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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[11] As noted in Finding of Fact ¶32, 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, [red [redacte] recalled that Respondent MR worked at RPSP for much of the first three (3) weeks it was open and thereafter returned from Florida sporadically. There is no evidence in the record indicating that Respondent MR was ever a paid employee at RPSP. (Testimony of [redact]; Testimony of Respondent MR)

[12] 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)

[13] 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 Finding of Fact, ¶¶ 32, 37, and 38, above, 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 d])

43. 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 d], Testimony of Respondent AR)

44. 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])

45. 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 d]. Testimony of Respondent AR, Testimony of Respondent MR)

46. At all times relevant between May 2011 and August 2011, [redacted] 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 Master Formulation Records to fill new prescriptions for compounded medications, and to check for the accuracy and correctness of formulations and dispensed products. (Testimony of [redacte])

47. During the months of June, July, and August 2011, when Respondent MR was not on the premises of RPSP, [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] [redacte] recalls making three (3) or four (4) such calls a day to Respondent MR.[14] 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])

48. 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. (Testimony of [redacte], Testimony of Respondent AR)

49. [redacted] called Respondent MR rather than Respondent AR because Respondent MR had instructed her to do so and because [redacted] observed that Respondent MR "...was the one that was organizing everything and ... making the decisions." Respondent AR, though relatively uninvolved with the pharmacy, was aware of the communications between

[14] Respondent MR conceded that [redacted], with Respondent AR's approval, called him for help with developing Master Formulations on numerous occasions. (Testimony of Respondent MR)

[redacted] and Respondent MR. (Testimony of [redacted], Testimony of Respondent MR)

EVENTS OF JULY 28 – JULY 29, 2011

50. On Thursday, July 28, 2011,[15] 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 [redacted], Testimony of Mother, Testimony of Respondent AR, Testimony of Respondent MR)

51. At the time, [redacted] was the only pharmacist working at RPSP. (Testimony of [redacted])

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

53. [redacted] 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 [redacted])

54. 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.[16] On the *Logged Formula Worksheet*, Respondent MR was identified as the pharmacist and individual who entered the data and the space for the name of the person checking the formula was left blank. In accordance with

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

[16] 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)

Respondent MR's testimony, he entered the formulation for Patient A's medication and hit print, knowing that the Master Formulation would print on the premises of RPSP. Respondent MR claimed he expected that [redacted] would review the Master Formulation and "...use it if she thought it was acceptable for her formulation...". (Testimony of [redacted], Testimony of Respondent AR, Testimony of Respondent MR; Exhibit 5)

55. 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 [redacted] 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 [redacted], Testimony of Respondent AR, Testimony of Respondent MR; Exhibit 5)

56. 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 [redacted], Testimony of Respondent AR, Testimony of Respondent MR)

57. 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)

58. 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 [redacted], Testimony of Respondent MR; Exhibits 1, 2, 25, 26)

59. [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 [redacte], Testimony of Mother, Testimony of Respondent AR, Testimony of Respondent MR; Exhibits 1, 2, 5, 16, 17, 23, 25, 26, 28)

60. The Board concurs with Dr. McKenna's testimony that both Respondent MR and [redacted] acted as compounders within the purview of Chapter 795 in filling Patient A's prescription. More specifically, Respondent MR acted as a compounder when, after authorizing [redacted] to accept Patient A's prescription, he participated in the preparation of Patient A's medication by producing and providing to [redacted] the Master Formulation Record that [redacted], also acting as a compounder, relied upon and used to make Patient A's medication. (Testimony of McKenna; Exhibit 18)

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

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

62. 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)

63. 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)

64. 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,[17] [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, [red [redact] contacted Respondent MR in Florida. When Respondent MR

[17] 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 [redact]

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 [redacte, Testimony of Respondent MR; Exhibit 28)

65. 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". [red [redacte 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 [redacte d], Testimony of Mother; Exhibit 28)

66. At about 7:35 p.m., at the request of Patient A's doctor, Mother called [red [redacte 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 [redacte d], Testimony of Mother; Exhibits 3, 11, 15)

67. 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] [redacte d] 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.[18] (Testimony of Respondent MR; Testimony of Mother)

68. 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. 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 14 day old infant, did not attempt to communicate with Patient A or his mother. (Testimony of AR)

69. 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;[19] 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. RPSP first notified the Board of the error made in dispensing Patient A's prescription on December 27, 2011. (Exhibit 28)

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[18] 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 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. Moreover, following the initial calls Respondent MR made to mother and the three (3) calls [redacted] made to Mother on August 1 and 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. (Testimony of [redact Testimony of Mother, Testimony of Respondent AR, Testimony of Respondent MR; Exhibit 3)

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)

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

70. 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)

71. 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)

72. 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)

73. 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.[20] (Testimony of Mother; Exhibits 11, 15)

74. 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

[20] 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 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)

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 T-3 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)

Credibility of the Witnesses[21]

75. 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, ¶¶ 76-87, 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.

76. 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.

77. 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

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

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

78. 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.

79. 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.

80. 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.

81. 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)

82. Respondent AR was disingenuous in testifying that she conducted an investigation of the misfill of Patient A's prescription.[22] 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 distracted by her own recovery from childbirth 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.

83. After acknowledging the lack of a written investigative report, Respondent AR subsequently testified that the form entitled *Customer Complaint Record* constituted an investigative report. The assertion that the *Customer 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.[23]

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[22] While the Order to Show Cause in the matter involving Respondent MR 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.

[23] The *Customer Complaint Form* contains minimal information and was generated for the fundamental purpose of documenting the occurrence of a QRE. It does not reflect the type of investigation contemplated by the Board's regulations for purposes of gathering pertinent data to assess causes and contributing factors, which assessment can then be used to develop responses and systems to prevent future errors. [redacted], herself, testified that she never conducted a

84. 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.[24] Given the gravity of the incident involving Patient A and the resulting proceedings before the Board, 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.

85. 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, ¶¶ 86 and 87, 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.

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formal investigation of Patient A's misfilled prescription and that Respondent AR never asked her to conduct such an investigation nor inquired about the results of such an investigation. The information contained in the *Customer Complaint Form* contains nothing more than the step by step process [redacted] engaged in with Respondent MR as they reviewed the Master Formulation and discovered that the T-3 had not been diluted. (Testimony of [redact; Testimony of Respondent AR)

[24] The Order to Show Cause in the Agnes Rubin matter included an allegation that while Respondent was MOR of RPSP, she failed to make earnest efforts to determine the extent of harm caused to Patient A by the dispensing error and failed to timely report to the Board the improper compounding and dispensing of Patient A's prescription, as required by statute and the Board's regulations. (G.L. c. 112, § 39 D and the Board's regulations provide that such a report must be filed as soon as practicably possible and not more than 15 days of discovering or being informed of the improper dispensing of a medication that results in serious injury, etc.) The issue arises in the instant matter solely in the context of Respondent AR's credibility. (See Footnote 33, below)

86. 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 after ingesting the T-3 medication 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 T-3; 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,[25] stands in stark contrast to testimony by Respondent AR stating 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.

87. With regard to obtaining additional information on Patient A's condition, Respondent AR stated that other than trying to reach Patient A or Mother by telephone, there was "not much else" that RPSP could have done. Respondent AR's testimony reflected Respondent AR's own, as well as RPSP's, troubling lack of concern about Patient A and their irresponsible

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[25] 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. Those documents contained information that in part, expressly described the health consequences of Patient A's ingestion of the misfilled prescription, including hospital records referencing "acute myocardial damage". (Testimony of Respondent AR; Exhibit 11)

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.

88. 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].

89. 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)

90. 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 [redacte, Testimony of Respondent MR)

91. 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.[26]

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 [redact, Testimony of Respondent MR)

92. 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

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[26] 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)

any pharmacist would have done. Given the multitude of times that [red [redacte had sought Respondent MR's assistance in producing Master Formulation Records, Respondent MR would have been well aware of [red [redacte 's limitations as a compounder and would have known that she lacked the knowledge and ability to check the formulation for Patient A's medication. Respondent MR knew that [redacted] was relying upon 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)

93. Further attempting to deflect responsibility for his role in compounding Patient A's medication, Respondent MR speciously maintained that as the dispensing pharmacist, [redacted], not he, bore responsibility for the error. (Testimony of Respondent MR)

94. 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 [red [redacte 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 [redacte, Testimony of Respondent MR)

95. [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.

96. 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.

97. 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.

98. As discussed further in Findings of Fact, ¶¶ 99-101, 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 T-3 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.

99. 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.

100. 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".[27] 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.[28] 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

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[27] 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".

[28] 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)

on Patient A were less severe than indicated by Mother's testimony and the medical records.[29]

101. 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 position with RPSP aimed at promoting products RPSP might sell.[30] 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.[31]

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[29] 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)

[30] 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)

[31] 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.

Respondent MR's Failure to Fulfill His Duties and Responsibilities as a Pharmacist and Compounder

102. In producing a Master Formulation Record that included 1,000 times the dose of T-3 prescribed for Patient A, Respondent MR failed to compound a medication for Patient A that was of acceptable strength and quality in accordance with Patient A's prescription and failed to exercise prudent pharmaceutical judgment.

103. In failing to review and check the Master Formulation Record for correctness and accuracy while knowing that [redacted] was not competent to do so, Respondent MR failed to ensure that errors did not occur in the process of developing the Master Formulation Record, failed to ensure that the medication produced from the Master Formulation Record would conform to the prescribed dosage for Patient A and be safe and suitable for its intended use, and failed to exercise prudent pharmaceutical judgment.

104. In participating in the compounding of Patient A's medication in the manner described in Finding of Facts, ¶¶ 102 and 103, above, Respondent MR failed to adhere to the requirements for compounders and compounding set forth in Chapter 795.

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.

IV. Rulings of Law [32]

1. Based upon Finding of Fact ¶ 1, above, the Board has jurisdiction to hear this disciplinary matter involving Respondent MR, Registration No. PH 233459.
2. With regard to Patient A's medication, Respondent MR's conduct in failing to fulfill his duties as a compounding pharmacist in conformance with the USP, Chapter 795, as set forth in Findings of Fact ¶¶ 2, 14-95, and 98-104 above, constituted malpractice and gross misconduct, establishing grounds for pursuant to G.L. c. 112, § 61 and 247 CMR 10.03 (1).
3. With regard to Patient A's medication, Respondent MR's conduct in failing to fulfill his duties as a compounding pharmacist in conformance with the USP, Chapter 795, as set forth in Findings of Fact ¶¶ 2, 14-95, and 98-104, above, violated 247 CMR 9.01 (1), constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(a) and (b) and G.L. c. 112, §§ 42A and 61.
4. With regard to Patient A's medication, Respondent MR's conduct in failing to fulfill his duties as a compounding pharmacist in conformance with the USP, Chapter 795, as set forth in Findings of Fact ¶¶ 2, 14-95, and 98-104, above,

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[32] Paragraph 9 of the Order to Show Cause issued in the instant matter alleged that Respondent MR failed to make efforts to determine the extent of harm to Patient A caused by the dispensing error and failed to report the improper compounding and dispensing of the prescription drug to Patient A to the Board.

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." The evidence demonstrated that Respondent MR made extremely limited efforts to contact Mother and no efforts to contact Patient A to inquire about his condition and that the dispensing error was first reported to the Board in December 2011. Moreover, Dr. Lathum's testimony established that during a Board inspection of the RPSP premises in August 2011, neither [redacted] nor Respondent MR, who were present when Dr. Lathum discussed the law regarding quality events, raised the dispensing error involving Patient A's medication. Nevertheless, pursuant to G.L. C. 112, § 39 D, 247 CMR 6.14, and 247 CMR 15.00 *et seq.*, the duty to report the dispensing error to the Board fell to RPSP and Respondent AR, as MOR of RPSP. Hence, the Board finds no violations of law with regard to Paragraph 9 of the Order to Show Cause.

violated 247 CMR 9.01 (3), constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(a) and (b) and G.L. c. 112, §§ 42A and 61.

5. With regard to Patient A's medication, Respondent MR's conduct in failing to fulfill his duties as a compounding pharmacist in conformance with the USP, Chapter 795, as set forth in Findings of Fact ¶¶ 2, 14-95, and 98-104, above, had the capacity to and did place the public health, safety, and welfare at risk, constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(k) and G.L. c. 112, §§ 42A and 61.
6. With regard to Patient A's medication, Respondent MR's conduct in failing to fulfill his duties as a compounding pharmacist in conformance with the USP, Chapter 795, as set forth in Findings of Fact ¶¶ 2, 14-95, and 98-104, above, violated recognized standards of the pharmacy profession, constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(v) and G.L. c. 112, §§ 42A and 61.
7. With regard to Patient A's medication, Respondent MR's conduct in failing to fulfill his duties as a compounding pharmacist in conformance with the USP, Chapter 795, as set forth in Findings of Fact ¶¶ 2, 14-95, and 98-104, above, violated ethical standards of the pharmacy profession, including standards of practice set forth in 247 CMR 9.01 (*Code of Conduct for Registered Pharmacists...*), constituting grounds for discipline pursuant to 247 CMR 10.03 (1)(w) and G.L. c. 112, §§ 42A and 61.
8. With regard to Patient A's medication, Respondent MR's conduct in failing to fulfill his duties as a compounding pharmacist in conformance with the USP, Chapter 795, as set forth in Findings of Fact ¶¶ 2, 14-95, and 98-104, above, constituted 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, §§ 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)

Discussion

Pursuant to G. L. c. 112, § 61, the Board has the authority to discipline a pharmacist for engaging in deceit, malpractice, fraud, or gross misconduct in the conduct of his 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 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 pharmacists 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.")

Board regulations at 247 CMR 9.01 set forth standards of conduct for pharmacies and registered pharmacists, with which licensees are required to comply. Failure to conform to such standards, or any other laws and regulations related to the practice of pharmacy, constitutes grounds for discipline pursuant to 247 CMR 10.03 (1)(a), (b) and (w) as well as G.L. c. 112, §§ 42 A and 61. Pursuant to the *Code of Professional Conduct*, pharmacists must at all times observe the standards of the United States Pharmacopoeia (247 CMR 9.01[3]) and conduct professional activities in conformity with federal, state, and municipal laws, ordinances and/or regulations, including the regulations of the Board (247 CMR 9.01[1]). 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.[33] Such conduct includes, but is not limited to, violating any of 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

[33] 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.

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 licensees are required to comply, 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 compounding process, be checked to ensure the absence of errors and the suitability of the preparation for use. As

noted above, the Board's regulations compel pharmacists to conform to USP standards.

Carelessness, neglect, haphazardness, malpractice, poor professional judgment, and disregard of the law in the practice of pharmacy are antithetical to the type of conduct that promotes patient health, safety, and well-being. Hence, the Board has a mandate to discipline licensees who engage in such conduct and thereby place patients at risk.

Respondent MR's role and conduct with regard to the operation of RPSP and the compounding of Patient A's medication reflects a cavalier attitude and an appalling lack of responsibility, prudence, and professional judgment. In reply to the Prosecution's question inquiring why Respondent MR did not own and act as MOR of RPSP, Respondent's testimony was that "I was busy ... with a pharmacy I had in Florida". While it is clear that Respondent MR played a role in launching and operating RPSP from even before the inception of the pharmacy's physical existence, he informally stepped in to assume some of the duties of the MOR when Respondent AR's pregnancy and health precluded her from working at and managing RPSP. In doing so, Respondent MR frequently acted at his own direction and was at least on one critical occasion remiss in failing to communicate in a full and open manner with Respondent AR[34], who retained all the responsibilities of an MOR until mid-September 2011.

Whether he was too busy with the Florida pharmacy or whether for another reason or combination of reasons, Respondent MR's involvement with RPSP was characterized by unprofessionalism, negligence, sloppiness, and a lax, "just get by" approach. Although he did not bear the responsibilities and duties of an MOR, Respondent was complicit in leaving RPSP in the hands of a single pharmacist who lacked the background, knowledge, and skill to fulfill her duties as the sole compounding pharmacist located on the premises of RPSP. Knowing of [red [redacte's shortcomings, Respondent MR directed her to call upon him and rely upon him to create and provide to her Master Formulations for new compounded

[34] Respondent MR initially failed to convey to Respondent AR the extent of the overdose of T-3 to which Patient A was exposed by the misfill of Patient A's prescription. Nor did Respondent AR ask Respondent MR about the size of the overdose.

prescriptions for which no Master Formulations existed. [redacted] sought such assistance from Respondent MR multiple times on a daily basis.

This make-shift practice posed unacceptable and grave risks to patient safety, with severe results for Patient A. Respondent MR made a critical error in entering the data on the Master Formulation Record for Patient A's thyroid medication, failed to check his own work before sending the Master Formulation Record to [redacted], and knew that [redacted] lacked the skill and ability to check the Master Formulation Record before using it like a recipe to produce and dispense Patient A's medication. As a result, Patient A received and ingested a medication that contained 1,000 times the dose of T-3 prescribed by his physician, with serious and on-going cardiac consequences that included a 19 year old suffering a heart attack.

In engaging in such conduct, Respondent MR, in his role as a compounder, failed to comply with Chapter 795 and the Board's regulations. He failed to compound a medication of acceptable strength and quality. He failed to review the Master Formulation Record to ensure the absence of errors and to ensure the medication would be suitable for its intended use. Moreover, he failed to ensure the safety and quality of the medication by exercising prudent pharmaceutical judgment to ensure the integrity of the data he entered and the integrity of the ingredients that would be used to prepare the medication based on his Master Formulation Record. Such conduct constituted gross misconduct and malpractice.

Respondent MR has yet to accept responsibility for his role in the compounding of Patient A's misfilled prescription; to acknowledge that he recognizes the egregious nature of his actions; and to indicate how he will prevent such incidents in the future. Rather, in testifying before the Board, Respondent MR was evasive and less than truthful. He displayed a selective memory and attempted to shift blame from himself and his wife, Respondent AR, to others, particularly to [redacted]. Respondent sought to portray his involvement in the compounding of Patient A's medication as limited to assisting [redacted] with a software problem. He professed to believe that [redacted] possessed the skill

and ability to check the Master Formulation Record he created for Patient A's medication. While [redacted], too, behaved in an irresponsible and egregious manner, Respondent MR was well aware of her limitations. Even with such knowledge, he was highly complicit in recklessly placing her in a role she was incapable of fulfilling. He relied on her to complete assignments she was incapable of performing while in his own work, he failed to adhere to the mandates of the USP and take all the requisite steps to ensure the safety and quality of medication dispensed by RPSP.

Respondent MR's conduct represents a grave breach of the trust and confidence that patients must be able to place in pharmacists who compound and/or fill their prescription. Respondent MR acted in a manner that flagrantly violated a law intended to assure the safety of compounded medications and to protect the public from errors with dangerous health effects and critical consequences for patients. Respondent MR's conduct represents the type of behavior that undermines public confidence in the integrity of the pharmacy profession. Moreover, Respondent MR's continuing refusal to accept responsibility for his actions, his evasiveness and misrepresentations regarding the operation of RPSP in 2011 (including his and Respondent AR's roles), and his disingenuousness as to the circumstances surrounding the misfill of Patient A's prescription serve to further erode public trust and confidence in the pharmacy profession.

Accordingly, Respondent's conduct warrants discipline of his license to practice as a pharmacist pursuant to the Board's regulations at 247 CMR 10.03 and G.L. c. 112, §§ 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	)	
Mark Rubin	)	PHA-2012-0005
Registration No. PH25022	)	
License Expiration Date 12/31/16	)	

Ruling on Respondent's Objections to Tentative Decision

On December 2, 2013, January 6, 2014, January 13, 2014, 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 Mark Rubin's Objections to the Tentative Decision.[1] Prosecuting Counsel did not file objections or a response to Respondent's objections.

The Board has reviewed and carefully considered the Tentative Decision and Respondent's objections. The Board has determined that the Final Decision in this matter should correct a citation to Board regulations in Finding of Fact ¶ 36, but that no other changes to the Tentative Decision are warranted, as the objections are without merit.

The Board notes 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 in Finding of Fact ¶ 36, footnote 10. The citation should be changed from "247 CMR 6.07(h)(1)" to "247 CMR 6.03(1)(a)."

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's objections individually, the Board responds as follows:

Respondent's Counsel objects to numerous 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

[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.

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's 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's Counsel's objections to the AHC's determinations of credibility are without merit.

Finally, Respondent's Counsel objects to Rulings of Law ¶¶ 2 – 9. 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.

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