COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of)
LINDA M. BAHN)
Registration No. PH24912)

PHA-2011-0119

FINAL DECISION AND ORDER

Final Decision

On March 18 – 19, 2015 and May 7, 2015, the Board of Registration in Pharmacy ("Board") held a formal adjudicatory hearing in this matter. On August 17, 2016, the Administrative Hearings Counsel ("AHC") issued a Tentative Decision. On September 21, 2016, the Board received Respondent Linda M. Bahn's ("Respondent") Objections to the Tentative Decision. 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, conclusions of law, and discussion contained therein as the Board's Final Decision. The Board rejects the Respondent's objections 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.

The Board notes clozapine "has potential serious, life-threatening side effects that require careful medical supervision." *Tentative Decision*, ¶ 4. As a result, clozapine is the subject of a Risk Evaluation and Mitigation Strategy ("REMS") that includes Elements to Assure Safe Use ("ETASU"). *Id.*, ¶ 5-6. "The ETASU for clozapine include restricted access, restricted distribution, a medication guide or package insert, and require registering the patient and performing appropriate lab monitoring for the patient." *Id.*

Importantly, a failure to comply with ETASU for any REMS drug, including clozapine, is of grave concern and has potentially life-threatening consequences. The fact that clozapine is a REMS drug with specific standards of care differentiates Respondent's error in this case from many other types of medication errors. Therefore, the Board finds Respondent's failure to comply with accepted professional standards of pharmacy practice for dispensing clozapine warrants discipline. The disciplinary outcome is based on the facts that clozapine is a REMS drug with specific ETASU, with which Respondent did not comply.

The Board voted to adopt the within Final Decision at its meeting held on January 5, 2017, by the following vote:

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

Order

On January 5, 2016, in accordance with the Board's authority and statutory mandate, the Board voted to issue this Final Decision and Order and impose a **REPRIMAND** on Respondent's pharmacist license, PH24912, effective ten days from the Date Issued.

The Board voted to adopt the within Final Order at its meeting held on January 5, 2017, by the following vote:

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

EFFECTIVE DATE OF FINAL DECISION AND 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 her 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: 1/4/17

Notified:

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
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COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of)
LINDA M. BAHN)
Registration No. PH24912)

PHA-2011-0119

Ruling on Respondent's Objections to Tentative Decision

On March 18 – 19, 2015 and May 7, 2015, the Board of Registration in Pharmacy ("Board") held a formal adjudicatory hearing in this matter. On August 17, 2016, the Administrative Hearings Counsel ("AHC") issued a Tentative Decision. On September 21, 2016, the Board received Respondent Linda M. Bahn's ("Respondent") Objections to the Tentative Decision. 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 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:

Objection 1

Respondent argues the Board does not have the authority to discipline her license for failure to comply with recognized standards of pharmacy practice because the Order to Show Cause does not explicitly cite 247 CMR 10.03(1)(v) as grounds for discipline. 247 CMR 10.03(1)(v) provides that "committing an act that violates recognized standards of pharmacy practice" is grounds for discipline.

"Due process requires that, in any proceeding to be afforded finality, notice must be given that is reasonably calculated to apprise an interested party of the proceeding and to afford him an opportunity to present his case." *LaPointe v. License Bd. of Worcester*, 389 Mass. 454, 458 (1983). See also *Langlitz v. Board of Registration of Chiropractors*, 396 Mass. 374, 376 (1985). ,Due process does not require that notices of administrative proceedings be drafted with the certainty of a criminal proceeding as long as the notice is sufficient for persons whose rights may be affected to understand the substance and nature of the grounds upon which they are called to answer. *Langlitz*, 396 Mass. at 377.

Failure to specify the "exact charges" does not render an order to show cause constitutionally deficient. See *Levy v. Board of Registration in Medicine*, 378 Mass. 519, 522, fn5 (1979). Rather, notice may be considered insufficient in those instances where the Respondent lacks a reasonable opportunity to prepare and present evidence and argument. See *Id.* A Respondent needs to demonstrate "surprise" to the extent of "prejudice" to his or her substantial rights. See *Id.* citing *Dwyer v. Commissioner of Insurance*, 375 Mass. 227. 234-235 (1978); see also, *City of Boston v. MCAD*, 47 Mass.App.Ct. 816, 820 (1999). "[W]here the record indicates that [Respondent] and counsel were nevertheless prepared for hearing, and indeed had in their possession, the investigatory file which contained all the facts that gave rise to the complaint... he cannot plausibly claim prejudice." *McDonough v. Alben*, 2015 WL 1468332 (2015); see also, *Cellarmaster Wines of Massachusetts, Inc. v. Alcoholic Beverages Control Commission*, 27 Mass.App.Ct. 25, 28 (1989).

In this case, Respondent was clearly notified of the allegation that she violated recognized standards of pharmacy practice, and she indeed defended against that allegation. The record includes significant exchanges between the parties that eliminate any possibility of surprise or prejudice.

First, the Order to Show Cause ("OTSC") alleged that Respondent acted "not in accordance with pharmacy practice standards." So while 247 CMR 10.03(1)(v) was not specifically included among the stated grounds for discipline, the OTSC does place the Respondent on notice that she is alleged to have violated pharmacy practice standards.

Second, subsequent pleadings in the record provide greater detail on the particular pharmacy practice standards at issue and specifically cite 247 CMR 10.03(1)(v). These pleadings include Prosecuting Counsel Answers to the Respondent's Interrogatories which read as follows:

1. Please describe in detail the "accepted pharmacy standards" referred to in paragraph two of the [OTSC] dated February 1, 2012.

   Answer: A pharmacist must confirm a patient's status prior to dispensing clozapine[1]. A pharmacist must confirm that a prescription is therapeutically appropriate. A pharmacist must confirm with a clozapine registry that the patient is registered; a pharmacist must confirm that the blood test (WBC counts and ANC) for clozapine are at the appropriate levels and are beign monitored; a pharmacy should never assume that a patient had started therapy and should question the appropriateness of a starting dose of cloazapine with the prescriber and confirm that the results of baseline blood test have been received prior to dispensing.

[1] Generic drug clozapine and the brand name drug Clozaril are equivalent. Tentative Decision, ¶4, fn 7. This ruling uses the two terms interchangeably.

2. Please describe in detail the duties and standards set forth in Board regulations that were violated by Ms. Bahn on December 31, 2010.
Answer: **Please see generally, 247 CMR 9.01(1) and 10.03(1)(a), (b), (e), (k), (u) and (v).** More specifically, a pharmacist must confirm that a prescription is therapeutically appropriate. A pharmacist must confirm with a clozapine registry that the patient is registered; a pharmacist must confirm that the blood test (WBC counts and ANC) for clozapine are at the appropriate levels and are beign monitored; a pharmacy should never assume that a patient had started therapy and should question the appropriateness of a starting dose of cloazapine with the prescriber and confirm that the results of baseline blood test have been received prior to dispensing. (emphasis supplied)

...

4. Please describe in detail the provisions of state or federal statutes or rules or regulations promulgated thereunder related to the practice of the profession that were violated by Ms. Bahn on December 31, 2010.

Answer: **247 CMR 9.01(1) and 10.03(1)(a), (b), (e), (k), (u) and (v).** (emphasis supplied).

After receipt of these answers to her interrogatories, the Respondent filed *Respondent's Reply to Prosecuting Counsel's Opposition to Respondent's Motion to Dismiss*. In that document, the Respondent reiterated her earlier request that the Administrative Hearing Officer dismiss the proceeding on grounds that the Board failed to state grounds for discipline in which she specifically cites to 247 CMR 10.03(1)(v). She avers: "the Board has failed to cite a recognized written standard of pharmacy practice which prohibits dispensing an emergency supply of Clozaril pursuant to a doctor's order to an impatient at a nursing home where the medication is administered by an authorized health care provider. As a result the Board has failed to state a claim for **a violation of 247 CMR 10.03(1)(v)**." (emphasis supplied).

Having argued that failure to identify a written[2] standard of pharmacy practice is fatal to the allegation the she violated 247 CMR 10.03(1)(v), the Respondent cannot credibly establish that she was surprised or unaware that this provision was at issue during the trial. Indeed, she was prepared to the point of

[2] The Board pauses here to note that 247 CMR 10.03(1)(v) speaks to "an act that violates recognized standards of pharmacy practice." It does not say "written" standards nor does the Board see any reason to interpret the regulation to mean "written" standard. Respondent's expert's concurrence with Prosecuting Counsel's expert on the applicable standard in this case demonstrates the industry recognition of professional standards in the absence of any particular written provision.

having an expert witness present at the hearing to testify as to professional standards of pharmacy practice. *Tentative Decision*, ¶ 3.

Based on the foregoing, the Respondent's claim that the Administrative Hearing Counsel added violation of 247 CMR 10.03(1)(v) "sua sponte" – as though it were conjured out of the clear blue sky – ignores the explicit discussion of this regulatory provision in the record. Insofar as the OTSC may have been deficient in failing to cite 247 CMR 10.03(1)(v) and never amended, this deficiency was more than rectified by explicit references in subsequent pleadings in the record, which were filed more than two years before the hearing. Accordingly, Respondent's request that the Board strike the finding that she violated 247 CMR 10.03(1)(v) essentially asks that the Board elevate form over substance, in the absence of any credible showing of surprise or prejudice. The Board declines to do so.

Objections 2 & 7

Respondent also argues her conduct did not have the capacity to place the public health, safety, or welfare at risk and did not rise to the level of conduct that undermines public confidence in the profession's integrity. A reviewing court "must accept the factual determinations made by the agency" if they are supported by substantial evidence." *McGuiness v. Department of Correction*, 465 Mass. 600, 668 (2013), citing *School Comm. of Boston v. Board of Educ.*, 363 Mass. 125, 128 (1973). "Substantial evidence means such evidence as a reasonable mind might accept as adequate to support a conclusion." M.G.L. c. 30A, § 1(6); *Arthurs*, 383 Mass at 304.

Each of the AHC's conclusions that Respondent's conduct placed public health, safety, and welfare at risk and undermined public confidence in the profession's integrity are supported by witness testimony and/or documents in evidence. Experts for both parties testified the standard of care required Respondent to verify the patient is registered with the manufacturer's register (or to register the patient if necessary) and to review the WBC and ANC lab values, prior to dispensing clozapine. *Tentative Decision*, ¶ 10. The record contains substantial evidence that the reason the standard of care for dispensing clozapine includes these steps is because clozapine has potential serious, life-threatening side effects. *Tentative Decision*, ¶ 4-7. Substantial evidence also exists that Respondent violated the standard of care when she dispensed clozapine to Patient A. *Tentative Decision*, ¶ 20. The record further contains evidence that after Patient A ingested the clozapine, he became unresponsive and was hospitalized. *Tentative Decision*, ¶ 21. Thus, there is substantial evidence to support the findings that Respondent's failure to comply with standards of care had the potential to place public health, safety, or welfare at risk and also undermined public confidence in the profession's integrity. Based on the foregoing, the Board finds Respondent's Objections to the Tentative Decision are without merit.

The Board voted to adopt this Ruling on Respondent's Objections to Tentative Decision at its meeting held on December 6, 2016 by the following vote:

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

Board of Registration in Pharmacy,

David A. Sencabaugh, R.Ph.
Executive Director

Date Issued: 1/9/17

Notified:

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
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COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY BOARD OF REGISTRATION IN PHARMACY

IN THE MATTER OF LINDA M. BANH, R.Ph. PH LICENSE NO. 24912 PH LICENSE EXP. DATE 12/31/2016	DOCKET NO. PHA-2011-0119

TENTATIVE DECISION

I. PROCEDURAL BACKGROUND

On February 1, 2012, the Board of Registration in Pharmacy ("Board") issued an Order to Show Cause ("OTSC") to Linda M. Banh ("Banh"), a Registered Pharmacist ("R.Ph.") licensed by the Board (PH Registration No. 24912), why it should not suspend, revoke, or take other action against her registration or right to renew her registration.

The OTSC alleges Banh on December 31, 2010, while employed at North Shore Pharmacy ("Pharmacy"), dispensed a three day supply of Clozaril® (clozapine) 500 mg. not in accordance with accepted pharmacy practice standards in violation of Massachusetts General Laws Chapter 112, §§ 27, 28, 42A, and 61, and Board regulations (247 CMR 9.01 (1) and 10.03 (1) (a), (b), and (k)), and undermined public confidence in the profession's integrity.

On February 23, 2012, Banh filed an answer and request for hearing which was held before this Administrative Hearings Counsel ("AHC") on March 18-19 and May 7, 2015 and was audio-recorded.[1] Banh was present and represented by counsel. Six witnesses testified: [redacted], RN; [redacted], RN; Leo A. McKenna, R.Ph., Pharm. D.; [redacted], Pharmacy Technician; Paul M. Garbarini, J.D., R.Ph.; and Banh. A list of the exhibits entered into evidence is found at the end of this decision. Both parties filed post-hearing briefs.

II. SUMMARY OF TENTATIVE DECISION

On December 31, 2010, Banh dispensed a 3 day supply of clozapine 500 mg. to Patient A contrary to accepted professional standards of pharmacy practice. Her conduct subjects her registration to discipline pursuant to G.L. c. 112, §§ 27-28, 42A, and 61, and

[1] At all times relevant, Banh was registered by the Board to engage in the practice of pharmacy. Banh's license is current and will expire on December 21, 2016. (Board records of which this AHC takes administrative notice, pursuant to G.L. c. 30A, § 11(5)). The Board has jurisdiction. *See Wang v. Board of Registration in Medicine*, 405 Mass. 15 (1989).

Board regulations 247 CMR 10.03 (1) (a), (b), (k), and (v), and also because it undermines public confidence in the integrity of the profession. [2] [3]

III. STATEMENT OF REASONS

A. Findings Of Fact[4]

1. Two witnesses were qualified without objection as experts as to professional standards of pharmacy practice.[5]

2. Leo A. McKenna, R.Ph., Pharm. D. ("McKenna") testified for the prosecution as an expert as to professional standards of pharmacy practice. He has a B.S. in Pharmacy and a Doctorate of Pharmacy. He is licensed as a registered pharmacist in this state and Florida. He is a state commissioned investigator by the US Food and Drug Administration ("FDA") in areas of sterile and non-sterile compounding. Since 2013, he has been employed as the Senior Investigator for the Department of Public Health, Division of Health Professions Licensure investigating complaints against pharmacies and pharmacists. He is involved in clinical practice once a month as the clinical pharmacist on a treatment team for people with developmental disabilities. He has been working in the pharmacy profession for 39 years and has dispensed medications for at least 20 years. During his practice, McKenna has reviewed medication orders and pharmacy profiles, handled high dose alerts, and dispensed thousands of medications with FDA warnings. He is familiar with standards of professional pharmacy practice, including those that can be ascertained from the National Association of Boards of Pharmacy, the FDA, the United States Pharmacopeia (USP), Best Practice Recommendations of the Board, reference books, as well as peer reviewed newsletters. He has served on numerous committees related to pharmacy practice. He dispensed clozapine during his pharmacy career and followed 200 patients on clozapine as the clinical pharmacist and dispensing pharmacist. (McKenna Testimony; Exhibit 12)[6]

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[2] This decision cites to the regulations in effect as of the date of the incident.

[3] Both parties' post-hearing briefs refer to 244 CMR, the Board of Registration in Nursing regulations, instead of 247 CMR, the Pharmacy Board's regulations. This AHC treats references to 244 CMR as typographical errors and reads them as 247 CMR.

[4] The AHC finds these facts and reasonable inferences drawn therefrom based on the credible, reliable evidence established by a preponderance of the evidence. The AHC credits the testimony in these Findings of Fact. Matters not specifically discussed in this tentative decision do not justify a change in the result.

[5] Witnesses used the terms "accepted standards of pharmacy practice", "professional standards of pharmacy practice" and "standards of pharmacy practice" interchangeably and this tentative decision does too.

[6] McKenna was the supervising investigator in a prior case involving Banh. On May 27, 2010, Banh made a medication error when she dispensed 200 mg. of nortriptyline instead of 20 mg. The orders sent to the Pharmacy in that case contained a transcription error. This officer does not find McKenna biased as a

3. Paul M. Garbarini, J.D., R.Ph. ("Garbarini") testified for Banh as an expert as to professional standards of pharmacy practice. Garbarini participated in a dual degree program and received his B.S. in Biology and in Pharmacy. He has been licensed as a Registered Pharmacist in this state since July 1985. He worked as a clinical pharmacist for approximately 21 years, prior to becoming an attorney. He is employed as an attorney with an emphasis on representation of health care professionals. He received his Juris Doctorate Degree and was admitted to the Massachusetts Bar in December 1992. (Garbarini Testimony; Exhibit 10)

4. Clozaril® is an atypical antipsychotic used to treat patients with treatment resistant schizophrenia or who have schizoaffective disorder and are at risk of suicide. Clozaril® has potential serious, life-threatening side effects that require careful medical supervision. The FDA deems Clozaril® and generic brands known as clozapine to be equivalent medications.[7] The Pharmacy dispensed the TEVA brand of clozapine as of December 31, 2010. (McKenna Testimony; Exhibits 4, 11)

5. Beginning in or about 1990, to receive clozapine, a patient's white blood cell ("WBC") counts had to be monitored because of a potentially fatal side effect of agranulocytosis - decreased production of white blood cells. In 2007, the FDA received authority to mandate manufacturers develop and comply with Risk Evaluation and Mitigation Strategies, ("REMS") to evaluate risks associated with medications, come up with a plan to mitigate or limit side effects, and develop a strategy to monitor the patient. (McKenna Testimony; Garbarini Testimony) In 2008, the Federal Register identified clozapine as a drug deemed to have in effect an approved REMS. (McKenna Testimony; Exhibit 21)

6. Clozapine's REMS includes certain requirements, known as Elements to Assure Safe Use ("ETASU"). The ETASU for clozapine include restricted access, restricted distribution, a medication guide or package insert, (Garbarini Testimony; Exhibit 4) and require registering the patient and performing appropriate lab monitoring for the patient. (McKenna Testimony; Garbarini Testimony) This has been referred to as the "no blood, no drug" program. (Exhibit 18; McKenna Testimony)

7. McKenna and Garbarini agreed a pharmacist dispensing clozapine should be familiar with the package insert, which provides: "Patients being treated with clozapine must have a baseline white blood cell (WBC) count and absolute neutrophil count (ANC) before initiation of treatment as well as regular WBC counts and ANCs during treatment and for at least 4 weeks after discontinuation

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result of his involvement in the earlier case. This officer has not relied upon that incident in determining whether Bahn is subject to discipline for the December 31, 2010 incident.

[7] Witnesses referred interchangeably to "Clozaril®" and "clozapine" as does this tentative decision.

of treatment." "Clozapine is available only through a distribution system that ensures monitoring of WBC count and ANC according to the schedule described below prior to delivery of the next supply of medication." (McKenna Testimony; Garbarini Testimony; Exhibit 4)[8] The "distribution system" requires the patient, physician, and pharmacy be registered with the clozapine national registry for the brand being dispensed. (McKenna Testimony)

8. Each manufacturer of clozapine has its own registry that monitors and holds WBC and ANC lab values. There is a National Non Re-challenge Registry run by Novartis, the manufacturer that marketed Clozaril®, to allow for consultation to determine if a patient has previously taken clozapine and had problems while on the medication. A patient who had previously been on clozapine, and had WBC and ANC counts that had dropped too low, could never be re-challenged, that is, take clozapine again. (McKenna Testimony)

9. Teva has its Clozapine Patient Registry. (McKenna Testimony) The dispensing information for pharmacists and pharmacies contained in the Teva Clozapine Patient Registry documentation, Exhibit 11, provides:

   (1) "Patients must be registered with the TEVA Clozapine Patient Registry prior to dispensing TEVA clozapine. Patients must also be assigned to a dispensing pharmacy and a treating physician." and

   (2) "A current and acceptable WBC count and ANC value is required prior to dispensing clozapine and for 4 weeks after discontinuation of treatment." (McKenna Testimony; Exhibit 11, pp. 4 and 6).[9]

10. McKenna and Garbarini each testified professional standards of pharmacy practice required a pharmacist to verify a patient is registered with the manufacturer's registry, or register the patient if necessary, *prior* to dispensing clozapine. Each also testified those standards required a pharmacist to review WBC and ANC lab values and verify they are at appropriate levels *prior* to dispensing clozapine, with both standards applying to emergency supplies. (emphasis added) (Garbarini Testimony; McKenna Testimony)

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[8] WBC represents the totality of white blood cells a person has at a given time as a defense against infection. ANC is specific to defending against bacterial or fungal infections. Agranulocytosis can occur if these blood levels drop too low during clozapine treatment. (McKenna Testimony; Exhibits 4, 18)

[9] The record contains two Teva Clozapine Dispensing Information documents, which are identical in pertinent part: both require patient registration and obtaining lab values before dispensing clozapine. Nothing in the record suggests the Teva dispensing information changed at any time relevant to this incident. I find that Exhibit 17, the dispensing information distributed 4 days after the incident by the Pharmacy to all pharmacists via a January 4, 2011 memorandum (see below), as well as Exhibit 11, provide Teva dispensing information applicable at the time of the incident. ([redacte Testimony; Exhibits 11, 17)

Banh Violated Professional Standards of Practice on December 31, 2010

11. In 2000, the Board registered Banh as a Registered Pharmacist, License No. PH24912. (Exhibit 1). Banh worked as a retail pharmacist until in or about February 2010, when she began working as a wholesale pharmacist at the Pharmacy. On December 31, 2010, she was working at the Pharmacy. (Banh Testimony) That day, Patient A was a resident of Wakefield Care and Rehabilitation Center ("Wakefield"), a skilled nursing and rehabilitation center licensed by the Department of Public Health. Patient A had been readmitted to Wakefield from a hospital the previous day. (Stipulation No. 3; [redact Testimony)

12. On December 31, 2010, Patient A's nurse at Wakefield, [redacted], printed out and reviewed Patient A's medication order, authorized by his physician, Dr. [redacted], which included clozapine 500 mg daily. [10] [11] (Stipulation No. 5; [redac Testimony; [redacted] Testimony; McKenna Testimony; Exhibit 27) [redact d] had access to Patient A's medical records including his medical history, prior medications, and physician's admission note. [redact wrote on the bottom of the order "STAT" in large letters. "STAT" is an abbreviation for urgent, which means the patient needs the medication(s) right away and within four hours. (Exhibit 9;[redact Testimony; Banh Testimony; Garbarini Testimony) [redact d] wrote "Readmit" on the order which indicated Patient A had been a previous patient at Wakefield. [redact d] faxed the order to the Pharmacy. (Exhibit 9)

13. After the Pharmacy received the order, a pharmacy technician, most likely [redacted], called Wakefield, spoke to [redact d], and asked her for either the Clozaril® levels, the Clozaril® labs, or WBC and ANC lab values.[12] [redacte confirmed the clozapine order and requested the Pharmacy send an emergency 3 day supply to get Patient A through the weekend until the labs could be drawn. (Roach Testimony) [redact d] entered an order into Wakefield's electronic medical record system for a blood test to be done on Monday, January 3, 2011 to obtain Patient A's "Clozaril® level." ([redac t d] Testimony; Exhibit 15, p. 64.)

14. On December 31, 2010, [redacted] worked as a pharmacy technician at the Pharmacy, reviewed Patient A's order, and keyed it into the computer system. She called Wakefield and asked to speak with the person taking care of Patient A. She spoke to "[red ", whom she assumed was Patient A's nurse. [redacted

[10] The term order is used even though it referenced more than one medication.

[11] Patient A's order included a prescription for another antipsychotic, Seroquel (100 mg. daily). (Exhibit 9; Garbarini Testimony) It is not alleged the Seroquel order or its dispensing was a medication error.

[12] The evidence differs on exactly what the technician requested. Resolution of this issue is not necessary.

requested either Patient A's Clozaril® labs or WBC and ANC labs[13] and was told the labs were being drawn on Monday. [redacted] told [redacted] the Pharmacy would send an emergency supply of clozapine. [redacted] made a note on the order that read "Labs Being Drawn Mon Per [redacted] – Send 3 Days". ([redacted] Testimony)

15. Banh heard [redacted]: speak on the telephone, ask to speak with Patient A's nurse, verify Patient A's clozapine order, and ask for either Patient A's WBC and ANC counts or Clozaril® labs. [redacted] told Banh Patient A's labs were being drawn on Monday and his nurse was requesting an emergency supply of clozapine. (Banh Testimony)

16. Before dispensing clozapine for Patient A, Banh received and read a high dose alert warning message for the clozapine prescription which stated: "The prescribed daily dose of 500.mg/DAY is above the maximum SAFE daily dose of 450mg/DAY. The prescribed single dose of 500mg is above the maximum SAFE daily dose of 450mg." (Exhibit 17 at p. 27) In response, Banh looked up dosing information on *Clinical Pharmacology*, an on-line database that informed her an appropriate dose should not exceed 900 mg per day. In her practice, Banh was familiar with daily dosing of clozapine in the 500-600 mg range. (Banh Testimony)

17. In response to the high dose alert, Banh also looked at Patient A's profile maintained by the Pharmacy. She noted the diagnoses of Patient A including delusional disorder. The profile included a prior order for a tapering dose of Seroquel, another antipsychotic, which she believed would be consistent with the patient being on a higher dose of clozapine because Seroquel was not working. (Banh testimony) Clozapine did not appear on the profile which went back two weeks to when Patient A was first admitted to Wakefield. (Exhibit 14 at pp. 1-3.) Based on her experience, Banh believed Patient A might have his own supply of clozapine at Wakefield which would not appear on the profile. Banh believed the process upon admission to Wakefield is for any medication a patient has to be thrown away and re-ordered, but believed the reality is patients may retain their medications. Banh believed Patient A was taking clozapine. (Banh Testimony)[14]

18. In her statement after the December 31, 2010 incident to the Institute for Safe Medication Practices, Banh wrote "the pharmacist hesitated because it was a relatively high dose with no history in the patient profile." (Exhibit 22) Banh had concerns about whether she should fill the order; whether it was the right thing to do, but believed Patient A needed this medication, and was concerned about his

[13] The evidence differs on exactly what [redacted] requested. Resolution of this issue is not necessary.

[14] McKenna opined because of the seriousness of clozapine treatment, a pharmacist is required to verify a patient is registered, or register the patient if necessary, and review WBC and ANC lab values and verify they are at appropriate levels, before dispensing clozapine -- even if a pharmacist assumed the patient was on clozapine and was concerned the patient's condition might decompensate if the patient did not continue to receive what the pharmacist assumed was a maintenance dose of clozapine. (McKenna Testimony)

condition and whether he would decompensate without clozapine for 3 days. (Banh Testimony)

19. Banh, as a Pharmacy PV 1 pharmacist, was able to register patients on the clozapine registry on her own. ([redacted] Testimony)

20. Prior to dispensing the clozapine to Patient A, Banh did not (1) verify Patient A was registered with the manufacturer's registry, or register Patient A; or (2) review Patient A's WBC and ANC lab values and verify they were at appropriate levels. At no time was Patient A registered on a clozapine registry.[15] Banh dispensed a 3 day supply of clozapine 500 mg. to Patient A with instructions "Must send labs for refill" (Banh Testimony; Exhibit 7)

21. Patient A received one dose of clozapine 500 mg., became unresponsive and was hospitalized. (Stipulation 4; [redacted] Testimony; [redacted] Testimony; Exhibit 25)

22. A Pharmacy representative, [redacted], was involved with the Pharmacy's Sentinel Root Cause Analysis regarding the clozapine dispensed for Patient A.[16] [17] [redacted] testified as follows as to Pharmacy practice as to dispensing clozapine. As of December 31, 2010, the Pharmacy had no written policy on how to dispense clozapine. Pharmacy practice, including for emergency supplies, was to register new patients with the clozapine registry and obtain WBC and ANC labs prior to dispensing, but if the patient was registered and the pharmacist could document the patient was on a high dose of clozapine for a long period and there could be an adverse event without the medication, the pharmacist could make a judgment call to dispense an emergency supply and wait for labs. ([redacted] Testimony; Exhibits 17, 25)

23. On January 4, 2011, the Pharmacy's Manager of Record, Fred Rowe, R.Ph., issued a memorandum entitled **"CLOZARIL DISPENSING UPDATE"** to "All Pharmacists" stating:

    (1) "Effective IMMEDIATELY we will **no longer be dispensing** Clozaril® on an emergency supply **without bloodwork**. We will adhere to the 'Drugs with R.E.M.S. and Other Special Prescribing/Dispensing Requirement' for dispensing Clozaril."

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[15] The record indicates the order received by the Pharmacy for Patient A contained an error and Patient A was not on clozapine. (Exhibits 13, 17; McKenna Testimony)

[16] A Sentinel Root Cause Analysis is an investigation of an incident to prevent an error from happening again. ([redacted] Testimony; Exhibit 25)

[17] [redacted] is a RN, pharmacy technician, and was General Manager of the Pharmacy at the time, but not a pharmacist.

(2) Prescribers must register and are responsible for registering the patient and obtaining WBC and ANC values. "The pharmacist must be supplied with this info (sic) (drawn within 7 days) **BEFORE DISPENSING."**

(3) "Pharmacists must verify that patients with prescriptions for Clozapine **are registered with CNR prior to dispensing."**

(4) "We will follow the dispensing guidelines as outlined for Clozaril. Attached is the dosing guideline and Clozapine professional."

(Exhibit 17 at p. 53; [redacted] Testimony) (Emphasis in original)

24. By this memorandum, the Pharmacy changed its practice to require WBC and ANC values on emergency supplies prior to dispensing clozapine and addressed its practice as to registering patients. ("January 4 memo") (Exhibit 17 at p. 53; [redacted] Testimony)

25. Banh testified she had no training in dispensing clozapine or REMS drugs. This testimony was not contradicted. (Banh Testimony)

26. Banh understood the normal process flow for dispensing clozapine at the Pharmacy as of December 31, 2010 was as follows. A pharmacist would review the order, review WBC and ANC lab values to verify they were at appropriate levels, and then dispense. If the lab values were not received, a technician would call the physician or nurse to obtain them and if they were at appropriate levels, it was enough information to dispense. (Banh Testimony). Prescribers needed to register the patient and if not registered, the Pharmacy would have the prescriber register the patient and would get a clozapine Patient ID number from the prescriber for the Pharmacy to use to subsequently, mainly during downtime, insert the lab values into the registry. (Banh Testimony) There was extensive testimony as to steps taken by Banh prior to dispensing. The record is devoid of evidence Banh requested the prescriber to register Patient A or that she obtained the clozapine Patient ID number, and I find she did not do so.

27. At the time of the hearing, Banh was aware professional standards of pharmacy practice as of December 31, 2010 required a pharmacist to verify the patient is registered before dispensing clozapine, and register the patient if the prescriber has not done so, and obtain and review lab values prior to dispensing clozapine, even for emergency supplies. However, as of December 31, 2010 Banh was not fully aware accepted standards required pharmacists to verify the patient was registered, or register if needed, and obtain and review lab values prior to dispensing clozapine even for emergency supplies. (Banh Testimony)

28. Banh acknowledged (1) the Pharmacy's practice of dispensing emergency supplies of clozapine before obtaining lab values was not in accordance with

professional standards of pharmacy practice; [18] and (2) she is supposed to follow professional standards of pharmacy practice. (Banh Testimony)

29. I find, that as of December 31, 2010, accepted professional standards of pharmacy practice required a pharmacist to do the following before dispensing clozapine (including emergency supplies): (a) verify the patient was registered with the applicable manufacturer's registry, and if necessary register the patient; and (b) verify the WBC and ANC labs were at appropriate levels. I base this finding on the reliable and credible testimony of both parties' experts, McKenna and Garbarini. (Garbarini Testimony; McKenna Testimony)

30. The finding in the previous paragraph is further supported by the following evidence:

    a. Banh agreed standards of pharmacy practice, as of December 31, 2010, required the pharmacist to verify the patient is registered, or register the patient if needed, and verify WBC and ANC lab values are at appropriate levels, prior to dispensing clozapine, even for emergency supplies. (Banh Testimony)

    b. The Teva clozapine dispensing information provides: "Patients must be registered with the TEVA Clozapine Patient Registry prior to dispensing TEVA clozapine" and "A current and acceptable WBC count and ANC value is required prior to dispensing clozapine and for 4 weeks after discontinuation of treatment." (McKenna Testimony; Exhibit 11 p. 4, ¶ ¶2 and 5, and repeated at p. 6, ¶ ¶2 and 3; Exhibit 17, p. 53)

    c. Pharmacy Manager of Record Fred Rowe's January 4, 2011 memorandum to all pharmacists states pharmacists must be supplied with the WBC and ANC values for the patient before dispensing, and must verify patients are registered with the Clozapine National Registry prior to dispensing. (Exhibit 17, p. 53)

    d. The Teva Clozapine Pharmacy Registry Form, "Responsibilities of the Pharmacy/Pharmacist" section, states "all patients on Teva clozapine should be registered with the Teva Clozapine Patient Registry..."; and

[18] Regarding the Pharmacy's practice, Garbarini testified : "I think it's an abhorrent practice. I think North Shore Pharmacy never should have engaged in that or encouraged their employees to do that. But that's exactly what they did, at least according to that statement on the January report, that he was changing the procedures, that from now on they won't be giving these things out." "Because it negated patient safety. It put a premium on dispensing medications as opposed to ensuring that the dispensing of the medication was appropriate." "[Y]ou're driving along blind and that's really, they encouraged their or they sort of told their employees to do that, to get the prescriptions out, to fill those prescriptions without that. We'll get them later, okay. Well, if the information doesn't bear out what it should, then you've got a problem and it's patient safety. While the risk is insignificant, the harm is tremendous. " (Garbarini Testimony)

"a current and acceptable WBC count and ANC value is required prior to dispensing clozapine...." The Teva Clozapine Single Patient Registration Form contains the same language in a section labeled "Responsibilities of Physicians and Pharmacists" (Exhibits 36, 37)

31. I find on December 31, 2010 Banh acted contrary to accepted professional standards of pharmacy practice in two independent manners in dispensing the 3 day supply of clozapine for Patient A: (a) Failing to verify Patient A was registered with Teva's registry, or register Patient A if necessary before dispensing ("Failure to Check the Registry); and (b) Failing to review WBC and ANC lab values and verify they were at appropriate levels before dispensing ("Failure to Check the Labs"). As a result, Banh's registration is subject to discipline as detailed below.

B. Legal Analysis

The role of the Board is to take primary responsibility in the regulation of the profession in order to promote the public health, welfare and safety. *Levy v. Board of Registration in Medicine*, 378 Mass. 519, 524 (1979). The Board has broad authority to regulate the conduct of pharmacists. *Strasnick v. Board of Registration in Pharmacy*, 408 Mass. 654, 659-660 (1990) ("the Legislature granted broad powers to the Board of Registration in Pharmacy for the same reason they were granted to the Board of Registration in Medicine: in order to 'promote the public health, welfare, and safety.'")

Pertinent Provisions of Law

The OTSC alleges Banh's registration warrants discipline pursuant to G.L. c. 112, §§ 27, 28, 42A, and 61, Board regulations 247 CMR 9.01 (1) and 10.03 (1) (a), (b), and (k), and as conduct that undermines public confidence in the integrity of the profession. These provisions respectively state the following in material part.

- G. L. c. 112, § 42A: "The Board may make such rules and regulations as it deems necessary ..." and "may suspend or revoke any certificate, license, registration ... for any violation of the rules and regulations established hereunder..."

- G. L. c. 112, § 61: The Board, "after a hearing, may . . . suspend, revoke or cancel any certificate, registration, ..." for "deceit, malpractice, gross misconduct in the practice of his profession, or of any offense against the laws of the commonwealth relating thereto . . ."

- G. L. c. 112, §§ 27-28: The "board shall hear all complaints made to it against any person registered as a pharmacist charging him .... with violating any of the rules or regulations of the board or any laws of the commonwealth" and

"may suspend the effect of his certificate of registration as a pharmacist for such term as it fixes."

- Board Regulation 247 CMR 10.03 (1) *Grounds for Discipline*, states: "The Board may impose disciplinary action … on one or more of the grounds for discipline listed in M.G.L. c. 112, § 61 or one or more of the following grounds" including:

    - Violating any of the duties and standards set out in Board regulations (247 CMR 2.00 *et seq.)* or any rule or written policy adopted by the Board. *247 CMR 10.03 (1) (a)*;

    - Violating any provision of G.L. c. 112, §§ 24 through 42A or any provision of state or federal statutes or rules or regulations promulgated thereunder related to the practice of the profession. *247 CMR 10.03 (1) (b)*;

    - Engaging in conduct that has the capacity or potential to place the public health, safety or welfare at risk. *247 CMR 10.03 (1) (k)*; and

    - Committing an act that violates recognized standards of pharmacy practice. *247 CMR 10.03 (1) (v)*

- "A registered pharmacist shall at all times conduct professional activity in conformity with federal, state and municipal laws, ordinances, and/or regulations, including regulations of the Board." 247 CMR 9.01 (1)

- The Board has authority to discipline for conduct which undermines public confidence in the profession's integrity. *See Sugarman v. Board of Registration in Medicine*, 422 Mass. 338, 342 (1996)

Bahn's Registration is Subject to Discipline Pursuant to 247 CMR 10.03 (1) (k)

Banh's Failure to Check the Registry and her Failure to Check the Labs each had the capacity or potential to place the public health, safety or welfare at risk and each subjects her registration to discipline under 247 CMR 10.03 (1) (k). Indeed, Patient A was hospitalized and became unresponsive because of the dispensing error.

Bahn contends other professionals more significantly contributed to Patient A being administered the clozapine, asserting: Patient A's physician authorized the order; Nurse [redacted] had previously taken care of him, reviewed the order, and faxed it to the Pharmacy; when asked to verify the order, [redacted] did not question the order but asked for an emergency supply pending lab work; and the clozapine was administered by a nurse who had full access to his medical records and history. Even if one speculates if other professionals had acted differently Patient A may not have been administered the

clozapine, it is clear had Banh taken the proper steps, this incident would not have happened. Bahn is not excused from performing her duties as a pharmacist.

Bahn contends she did not place the public, health, safety or welfare at risk, because the registry is designed to help reduce the risk of clozapine induced agranulocytosis which develops over time and Patient A's bloodwork taken a few days before the incident evidenced he was not at any risk of agranulocytosis. Without making a finding whether Patient A's lab values were such, the argument misses the point because 247 CMR 10.03 (1) (k) authorizes discipline for conduct with the "capacity or potential" to place public health, safety or welfare at risk. Each of Banh's failures had such capacity or potential.

Bahn's Registration is Subject to Discipline Pursuant to 247 CMR 10.03 (1) (v)

Banh's Failure to Check the Registry and her Failure to Check the Labs each subjects her registration to discipline pursuant to 247 CMR 10.03 (1) (v), because each was an act in violation of recognized standards of pharmacy practice. A procedural note follows. The OTSC does not expressly cite 247 CMR 10.03 (1) (v), but it applies. The OTSC alleges Banh acted "not in accordance with pharmacy practice." In the pre-hearing memorandum, each party anticipated its respective expert would opine on whether Banh's conduct was within the standards of pharmacy practice. Prosecuting Counsel's Opposition to Motion to Dismiss identified (among others) 10.03 (1) (v) as an applicable provision. A significant amount of evidence on professional standards was adduced by both parties at hearing. The issue of whether Banh's conduct was in accordance with professional pharmacy standards was clearly raised and tried and addressed by both parties who had sufficient notice and opportunity to prepare and present evidence and argument on that issue. G.L. c. 30A, § 11.

Banh's Registration is Subject to Discipline
Pursuant to G. L. c. 112, §§ 27-28, 42A, and 61,
247 CMR 10.03 (1) (a), and 247 CMR 10.03 (1) (b)

By violating 247 CMR 10.03 (1) (k) and (v), Banh's registration is also subject to discipline pursuant to G. L. c. 112, §§ 27-28, 42A, and 61,[19] 247 CMR 10.03 (1) (a); and 247 CMR 10.03 (1) (b), as each of these provisions is triggered by a violation of a Board regulation.[20]

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[19] Banh's regulatory violations warrant discipline under Section 61 as "offense[s] against the laws of the Commonwealth relating" to the practice of the profession. *See Giroux v. Board of Dental Examiners*, 322 Mass 251, 252 (1948)

[20] By violating 247 CMR 10.03 (1) (k) and (v), Bahn violates 247 CMR 9.01 (1), which in turn subjects her license to discipline pursuant to G. L. c. 112, §§ 27-28, 42A, and 61, 247 CMR 10.03 (1) (a) and 247 CMR 10.03 (1) (b), as each of these provisions is triggered by a violation of a Board regulation.

Banh's Registration is Subject to Discipline for Conduct
Undermining Public Confidence in the Profession's Integrity

Banh's Failure to Check the Registry and Failure to Check the Labs each undermines public confidence in the profession's integrity. *See Sugarman v. Board of Registration in Medicine*, 422 Mass. 338, 342 (1996) ("Conduct which undermines public confidence in the integrity of the medical profession is an independently sufficient ground for the board to sanction a physician... The board has broad authority to 'protect the image of the medical profession' ..."). Violations of standards of practice, in particular those aimed at patient safety, tarnish the image of the profession and its practitioners and casts doubt on the integrity of the profession subjecting her registration to discipline upon this additional ground.

The AHC rejects Banh's arguments to the contrary. A new standard of practice is not being applied. The record establishes, as of December 31, 2010, professional standards of pharmacy practice required a pharmacist before dispensing clozapine (including emergency supplies) to: (a) verify the patient was registered and if necessary register the patient; and (b) verify the WBC and ANC labs were at appropriate levels. Banh's registration is subject to discipline even if there is no statute, regulation, ordinance, or policy specifically prohibiting a pharmacist from dispensing clozapine without performing such acts. See *Massachusetts General Hospital v. Commissioner of the Division of Medical Assistance, 66 Mass. App. Ct. 485 (2006)* ("practical necessities of discharging the business of government inevitably limit the specificity with which [a regulatory agency] can spell out prohibitions"). *Gurry v. Board of Public Accountancy, 394 Mass. 118, 126-130 (1985)* (regulation disciplining accountant for acts "discreditable to the profession" was not impermissibly vague).

Other Claims Pursuant to G.L. c. 112, § 61 are Dismissed

Any other claims under G.L. c. 112, § 61 are dismissed for the following reasons. Prosecuting Counsel represented she is not pursuing the allegation of malpractice. No evidence was presented to support a finding of deceit. The record does not establish Banh committed "gross misconduct." To prove "gross misconduct", the Board must show "extreme" or "flagrant" conduct that is willful or done with utter indifference to a present legal duty. *Hellman v. Board of Registration in Medicine*, 404 Mass. 800, 804-806 (1989) Gross misconduct "...is more than that conduct which comes about by reason of

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Banh erroneously argues 247 CMR 9.01 (1) is inapplicable. She asserts 247 CMR 9.07 (3) (i) makes 247 CMR 9.00, including 9.01 (1), inapplicable. Banh's argument relies on an incorrect version of 9.07 (3) (i) that has been corrected, effective back to 1998 to change its reference from "247 CMR 9.00" to "247 CMR 9.07". 247 CMR 9.07 requires pharmacists to, among other things, conduct a prospective drug utilization review, maintain certain patient records, and offer a patient counseling when presenting new prescriptions. 247 CMR 9.07 (3) (i) relieves the pharmacist of the duty to comply with 247 CMR 9.07 when dispensing to an inpatient at a nursing home where the medication is administered by an authorized individual ("exclusion"). As corrected, 9.07 (3) (i)'s exclusion does not impact any provisions other than within 244 CMR 9.07.

error of judgment or lack of diligence." *Id.* Banh's conduct is quite disturbing and extremely dangerous. But Banh made an effort to determine the appropriateness of dispensing the clozapine, believed Patient A was on clozapine, was concerned Patient A's condition would deteriorate if he went without the medication over the weekend, and as of December 31, 2010 was not aware of the extent of the requirements as to registry and lab values *prior* to dispensing the clozapine. Her conduct does not meet the criteria of gross misconduct established by the Supreme Judicial Court.

IV. SANCTION CONSIDERATIONS

This section does not repeat any matters addressed above pertinent to sanction.

1. Banh contends her intent was to do what was in the best interest of the patient and her conduct does not constitute intentional misconduct.

2. She submits due to the competitive job market, any disciplinary action for a medication error, even a reprimand, will have an adverse impact on Banh's ability to obtain new professional opportunities. Banh's position is the matter should be closed with no disciplinary action, but should the Board decide additional monitoring is warranted, the Board should impose a non-disciplinary stayed probation, which Banh asserts is consistent with precedent in other cases involving either more than one medication error or medication errors resulting in patient hospitalization. Because the role of the AHC does not include recommending a specific sanction, I do not address the cases cited by Banh in her post-hearing brief, other than to identify for the Board's consideration that Banh references numerous Board decisions.

3. Prosecuting Counsel does not seek a specific sanction, but recommends the Board considers the facts, including mitigating factors, in determining a sanction.

4. In 2014, Banh completed fifteen hours of pharmacy continuing education courses including courses on treatment of geriatric patients and minimizing prescription errors. (Exhibit 23) [21]

5. Banh testified since December 2010, she has had no Board complaints filed against her and has not committed any medication errors when dispensing medication. Prosecuting Counsel presented no evidence to the contrary. Following the incident with Patient A, Banh filed a report with the Institute for Safe Medication Practices so other pharmacists could learn from her error. (Exhibit 22)

6. Banh has two prior Board complaints. On December 8, 2008, the Board issued a reprimand for not completing continuing education requirements during 2006 and 2007.

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[21] The courses are as follows: (1) Generalized Treatment Approach to the Geriatric Patient (6 credits); (2) Minimize Prescription Errors and Maximize Patient Safety (2 credits); (3) Drug Therapy Management Series Part III: Geriatric Disorders (5 credits); and Prevention of Medication Errors in the Older Adult Patient (2 credits).

(Exhibit 26) On January 28, 2011, the Board issued Banh an Advisory Letter concerning a medication dispensing error she committed on May 27, 2010 while employed at the Pharmacy. (Exhibit 16) Banh dispensed 200 mg. of nortriptyline to an 89 year old Wakefield patient instead of 20 mg. The medication order sent to the Pharmacy by Wakefield contained a transcription error. The physician ordered 20 mg., but the medication order read 200 mg. (McKenna Testimony) Banh received a high dose alert when dispensing the nortriptyline to the patient, which she overrode. Banh acknowledged that given the high dose she should have verified the dosage amount with the physician before dispensing it. Banh was aware of her nortriptyline medication dispensing error prior to the clozapine dispensing incident on December 31, 2010. (Banh Testimony; Exhibit 32)

V. CONCLUSION

Bahn's registration is subject to discipline. The Board should impose an appropriate sanction.

VI. LIST OF EXHIBITS

1. Respondent's Record of Standing
2. Cover letter, Order to Show Cause & Certificate of Service, dated 2/1/2012
3. Licensee's Answer to the Show Cause Order and Request for a Hearing, dated 2/23/2012
4. Novartis-Clozaril® prescribing information and Box Warning
5. Statement of [redacted]
6. Prescriptions delivered to Wakefield Care and Rehabilitation Center
7. Clozapine label from prescription sent to Wakefield Care and Rehabilitation Center
8. Teva Clozapine Prescribing Information
9. Medication Orders from Wakefield Care and Rehabilitation Center
10. CV - Paul M. Garbarini
11. TEVA-clozapine Patient Registry Information (13 pages)
12. CV – Leo McKenna with published articles and power point presentations
13. Pharmacy Report of Improper Drug Dispensing, dated January 19, 2011
14. Affidavit of the Keeper of the Records for North Shore Pharmacy Profile in response to attached Subpoena Duces Tecum, with attached North Shore Pharmacy Profile for Patient A and cover letter dated January 7, 2015
15. Affidavit of the Keeper of the Records for Wakefield Care and Rehabilitation Center in response to attached Subpoena Duces Tecum, with attached Patient A's Medical Record from Wakefield for December 2010
16. Advisory Letter *In the Matter of Linda Banh, R.Ph.* Docket No. PHA20100106 from Board to Banh dated January 28, 2011
17. February 25, 2011 letter from the Department of Public Health to North Shore Pharmacy and March 22, 2011 response letter from Robert A. Griffith, attorney for North Shore Pharmacy with attachments (78 pages)
18. Pharmacist's Letter - Risk Evaluation and Mitigation Strategy (REMS)
19. **Marked for Identification Only:** U.S. Food and Drug Administration – A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS) with website cover page
20. The Food and Drug Administration Amendments Act of 2007 -Table of contents and Title IX –Enhanced Authorities Regarding Postmarket Safety of Drugs, including Section 505-1. Risk Evaluation and Mitigation Strategies
21. Federal Register regarding FDAAA and Deemed REMs dated March 27, 2008

22. Institute for Safe Medication Practices Error report by Banh
23. Banh Certificates of Completed Continuing Education
24. North Shore Pharmacy Policy 086: Pharmacist Verification Order Entry, Revised as of October 8, 2010
25. Omnicare, Inc. Sentinel Event Root Cause Analysis regarding December 31, 2010 event, with signature of General Manager [redacted]
26. Consent Agreement for Reprimand *In the Matter of Linda Banh*, Docket No. PH-08-091, Board of Registration in Pharmacy, effective date December 8, 2008 (Admitted for Sanction Purposes Only)
27. Investigative Report *In the Matter of Linda Banh*, Docket No. PHA-2011-0119, Board of Registration in Pharmacy, , regarding allegation as to December 31, 2010 incident, report dated May 6, 2011
28. *Clozapine-Induced Agranulocytosis*, Journal Article, The New England Journal of Medicine, July 15, 1993
29. Schematic, The Medication Use Process, US Pharmacopeia 2004
30. 105 CMR: Department of Public Health Licensing of Long-Term Care Facilities, 105 CMR 150.000 et seq., dated 4/1/94, with revisions
31. Pharmacy Board Complaint Form, Complaint # PHA-2010-0163, regarding Banh incident dated May 27, 2010
32. Investigative Report *In the Matter of Linda Banh*, Docket No. PHA-2010-0163, Board of Registration in Pharmacy, regarding allegation as to May 27, 2010 incident, report dated October 19, 2010
33. Massachusetts Board of Registration in Pharmacy, *Best Practice Recommendations To Promote Optimum Pharmaceutical Care In the Commonwealth of Massachusetts*, Amended Date: June 1, 2010 (No. 26)[22]
34. 247 CMR: Board of Registration in Pharmacy; 247 CMR 15.00, Continuous Quality Improvement Program
35. Advisory Letter *In the Matter of North Shore Pharmacy*, Docket No. PHA20100104 from Board of Registration in Pharmacy to North Shore Pharmacy dated January 28, 2011
36. Teva Clozapine Patient Registry, Single Patient Registration Form
37. Teva Pharmacy Registration Form
38. Teva Physician Registration Form

Board of Registration in Pharmacy

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Tentative Decision Issued and Filed: August 17, 2016

Notice issued to: ES, AM, VB

[22] Exhibits 33 and 34 were admitted into evidence, however, it was not established that these Board practices and regulations, respectively, were in effect on the relevant date of December 31, 2010. They were not relied upon by this AHC.

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