

KARYN E. POLITO

Lieutenant Governor

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
Board of Registration in Pharmacy
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June 16, 2017

VIA FIRST CLASS & CERTIFIED MAIL NO. 7015 1730 0000 7974 1080, RETURN RECEIPT REQUESTED

Get Well Pharmacy c/o Donna Nevarez

VIA FIRST CLASS & CERTIFIED MAIL NO. 7015 1730 0000 7974 1110, RETURN RECEIPT REQUESTED

Get Well Pharmacy c/o Donna Nevarez

RE:

In the Matter of Get Well Pharmacy, Docket No. PHA-2015-0148 & PHA-2016-0052

License No. DS89862

Dear Ms. Nevarez:

Please find enclosed the **Final Decision and Order by Default** issued by the Board of Registration in Pharmacy on June 16, 2017 and **effective June 26, 2017**. This constitutes full and final disposition of the above-referenced complaints, as well as the final agency action of the Board. The Pharmacy's appeal rights are noted on **page 3**.

Please note that as of the effective date, Get Well Pharmacy's license status will change to **Revoked**. It will remain in **revocation** status until the Board notifies the Pharmacy of a change in license status in accordance with the terms of the order.

Please direct all questions, correspondence and documentation relating to licensure reinstatement to the attention of Lisa Ferguson at the address above. You may also contact Ms. Ferguson at (617) 973 – 0950.

You may contact Samuel Leadholm, Esq., Board Counsel at (617) 973 – 0950 with any questions that you may have concerning this matter.

Sincerely

David Sencabaugh, R. Ph.

Executive Director,

Board of Registration in Pharmacy

Encl.

cc: Eugene Langner, Esq., Prosecuting Counsel

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY		BOARD OF REGISTRATION IN PHARMACY		
In the Matter of)			
Get Well Pharmacy)	Docket Nos.	PHA-2015-0148	
Registration No. DS89862)"		PHA-2016-0052	
Registration Expires 12/31/17)			

FINAL DECISION AND ORDER BY DEFAULT

On December 2, 2016, the Board of Registration in Pharmacy (Board) issued and duly served on Get Well Pharmacy (Respondent) an Order to Show Cause (Show Cause Order)² related to two complaints filed against Respondent's registration. In addition to stating the allegations against Respondent, the Show Cause Order notified Respondent that an answer to the Show Cause Order (Answer) was to be submitted within 21 days of receipt of the Show Cause Order.³ The Show Cause Order also notified Respondent of the right to request a hearing on the allegations, and that any hearing request (Request for Hearing) was to be submitted within 21 days of receipt of the Show Cause Order. Respondent was further notified that failure to submit an Answer within 21 days "shall result in the entry of default in the captioned matter" and, if defaulted, the Board may enter a Final Decision and Order that assumes the truth of the allegations in the [Show Cause Order] and may revoke, suspend, or take other disciplinary action against [Respondent's] registration."

^{1.} The Show Cause Order was subsequently re-issued on January 12, 2017; January 25, 2017 and March 1, 2017.

² Pursuant to 801 CMR 1.01(6)(a).

³ In accordance with 801 CMR 1.01(6)(d)(2).

⁴ Pursuant to M.G.L. c. 112, § 61.

⁵ Respondent was also notified that failure to timely submit a Request for Hearing would constitute a waiver of the right to a hearing.

A copy of the Show Cause Order is attached to this Final Decision and Order by Default

and is incorporated herein by reference.

On December 27, 2016, Prosecuting Counsel sent notice to Respondent to file an

Answer and a Request for Hearing within 21 days. The notice again advised Respondent

that if defaulted, the Board might enter a Final Decision and Order that assumes the truth

of the allegations stated in the Show Cause Order and impose license discipline.

including discipline on any right to renew.

As of the date of this Final Decision and Order by Default, Respondent has failed

to file an Answer or Request for Hearing.

The Board has afforded Respondent an opportunity for a full and fair hearing on

the allegations in the Show Cause Order as required by M.G.L. c. 30A, § 10, and

sufficient notice of the issues involved to afford Respondent reasonable opportunity to

prepare and present evidence and argument as required by M.G.L. c. 30A, § 11(1). The

Board has also notified Respondent of the obligation under 801 CMR 1.01(6)(d) to file an

Answer to the Show Cause Order within 21 days of its receipt and of the consequences of

failing to file an Answer or otherwise respond.

As authorized by M.G.L. c. 30A, § 10(2), the Board may make informal

disposition of any adjudicatory proceeding by default. Upon default, the allegations of the

complaint against Respondent are accepted as true. Danca Corp. v. Raytheon Co., 28

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Mass. App. Ct. 942, 943 (1990).

Get Well Pharmacy DS89862 PHA-2015-0148

Based on the foregoing, the Board enters a default in the above-captioned matter and, consequently, the allegations in the Show Cause Order are deemed to be true and Respondent has waived the right to be heard. In accordance with the Board's authority and statutory mandate, the Board orders as follows:

ORDER

On June 15, 2017, in accordance with the Board's authority and statutory mandate, the Board voted to issue this Final Decision and Order by Default and REVOKE Respondent's Registration, DS89862, effective ten days from the Date Issued, by the following vote:

In favor:

Garrett Cavanaugh, Susan Cornacchio, William Cox, Timothy

Fensky, Patrick Gannon, Michael Godek, Andrew Stein and

Richard Tinsley

Opposed:

Abstained: Recused:

Catherine Basile and Edmund Taglieri

Absent:

Philippe Bouvier, Karen Conley and Ali Raja

EFFECTIVE DATE OF ORDER

The Final Decision and Order by Default shall be effective ten (10) days from the Date Issued.

RIGHT TO APPEAL

Respondent is hereby notified of the right to appeal this Final Decision and Order by Default to the Supreme Judicial Court within thirty (30) days of receipt of notice of this Final Decision and Order by Default pursuant to M.G.L. c. 112, § 64 or by filing a

Get Well Pharmacy DS89862 PHA-2015-0148 PHA-2016-0052 claim for judicial review in Superior Court within thirty (30) days of receipt of notice of this Final Decision and Order by Default pursuant to M.G.L. c. 30A, § 14.

BOARD OF REGISTRATION IN PHARMACY

David Sencabaugh, R.Ph.

Executive Director

Date Issued: June 16, 2017

Notice to:

By first-class and certified mail no. 7015 1730 0000 7974 1080, return receipt requested

Get Well Pharmacy c/o Donna Nevarez

By first-class and certified mail no. 7015 1730 0000 7974 1110, return receipt requested

Get Well Pharmacy c/o Donna Nevarez

By hand

Eugene Langner
Office of Prosecutions
Department of Public Health
Bureau of Health Professions Licensure
239 Causeway Street, Suite 400
Boston, MA 02114

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK (COUNTY
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BOARD OF REGISTRATION IN PHARMACY

Board of Registration in Pharmacy,)
Petitioner,

v.

Get Well Pharmacy
Registration No. DS89862
Registration No. CS89862
Registrations Expires 12/31/17,
Respondent

Docket Nos. PHA-2015-0148 PHA-2016-0052

ORDER TO SHOW CAUSE

Get Well Pharmacy ("Pharmacy," "Get Well," or "You") is hereby ordered to appear and show cause why the Massachusetts Board of Registration in Pharmacy ("Board") should not suspend, revoke or otherwise take action against its registration to operate as a pharmacy in the Commonwealth of Massachusetts, Registration No. DS89862, and its controlled substances registration, Registration No. CS89862, or its right to renew such registrations, pursuant to Massachusetts General Laws (G.L.) chapter 112, § 61 and Code of Massachusetts Regulations (CMR), Title 247, §§ 6.02, 9.01, 9.04, and 10.03, based upon the following facts and allegations:

Factual Allegations

- On or about March 25, 2013, the Board issued to Get Well a registration to operate as a pharmacy in the Commonwealth of Massachusetts, Registration No. DS89862. Get Well's pharmacy registration is current and will expire on December 31, 2017.
- 2. On or about March 25, 2013, the Board issued to Get Well a controlled substances permit, Registration No. CS89862. Get Well's controlled substances registration is current and will expire on December 31, 2017.
- At all times relevant to the allegations in this Order to Show Cause, Get Well
 operated as a pharmacy at 646 Blue Hill Avenue, Dorchester, Massachusetts.
- 4. On or about March 25, 2016, the Board issued to Get Well a Cease and Desist Notice (C & D). A copy of the C & D is attached hereto as Exhibit A and incorporated into this Order to Show Cause by reference.

- On or about March 31, 2016, Get Well agreed to the indefinite continuation of the C & D referenced in the preceding paragraph. The agreement continuing the C & D is attached hereto as Exhibit B and incorporated into this Order to Show Cause by reference.
- 6. On or about July 28, 2016, Get Well closed the pharmacy identified in Paragraph 2 above pursuant to 247 CMR 6.09.
- 7. As a registered pharmacy, Get Well knew or should have known that its responsibilities included the proper keeping and maintenance of records and inventories of controlled substances as required by the Massachusetts Controlled Substances Act (G.L. c. 94C), Board regulations at 247 CMR 2.00 et seq., and all other applicable state and federal laws and regulations.
- 8. As a registered pharmacy, Get Well knew or should have known that its responsibilities included the use of the date on which controlled substances were actually received by or at Get Well as the date of receipt.
- As a registered pharmacy, Get Well knew or should have known that its
 responsibilities included the maintenance on a current basis of complete and
 accurate records of each controlled substance disposed of by or at Get Well.
- 10. As a registered pharmacy, Get Well knew or should have known that its responsibilities included the keeping of a perpetual inventory of each of Get Well's Schedule II Controlled Substances, and the reconciliation of that inventory at least once every ten (10) days.
- 11. As a registered pharmacy, Get Well knew or should have known that it was required to have available for inspection a power of attorney authorizing one or more individuals to order Schedule I and II Controlled Substances on Get Well's behalf.
- 12. As a registered pharmacy, Get Well knew or should have known that it was required to use an automated data-processing system for the storage and retrieval of information pertaining to the refilling of prescriptions for controlled substances in Schedules III through VI, or, in the alternative, to record on any refilled prescription for controlled substance in Schedules III through VI the following information:
 - a. the date of dispensing;
 - b. the amount of the drug dispensed; and
 - c. the initials of the pharmacist refilling the prescription.
- As a registered pharmacy, Get Well knew or should have known that it was
 obligated not to dispense or distribute expired, outdated or otherwise substandard

- drugs or devices or counterfeit drugs or devices to any person or entity not licensed or legally authorized to receive such drugs or devices.
- 14. As a registered pharmacy, Get Well knew or should have known of its obligation under 247 CMR 9.01(3) to observe and comply with the standards of the current United States Pharmacopoeia, including, but not limited to, United States Pharmacopoeia Standard <795> Pharmaceutical Compounding Nonsterile Preparations (USP 795).
- 15. As a registered pharmacy, Get Well knew or should have known that adherence to the requirements of USP 795 included, but was not limited to, assigning applicable beyond-use dates (BUD) to drugs and preparations prepared and dispensed by, at or from Get Well.
- 16. As a registered pharmacy, Get Well knew or should have known that it was responsible for the proper preservation and security of all drugs at Get Well, including the proper refrigeration and storage of said drugs.
- . 17. As a registered pharmacy, Get Well knew or should have known that it was required to ensure that all drugs stored at, prepared by or dispensed from Get Well were properly secured, and to comply with all other security requirements which the Board may deem necessary for the protection of the public.
- 18. As a registered pharmacy, Get Well knew or should have known that it was required to ensure that proper refrigerator temperature (36° to 46°F/2° to 8°C) was maintained at all times through the use of a daily temperature log or certified thermometer equipped with an audible out-of-range alarm for monitoring of refrigerator compartments.
- 19. As a registered pharmacy, Get Well knew or should have known that every prescription was required to be in a format that conformed to the requirements as set forth in 105 CMR 721.020.
- 20. As a registered pharmacy, Get Well knew or should have known that it was required to affix to any package of any controlled substance filled by or at Get

 Well a label displaying all elements required by G.L. c. 94C, § 21.
- As a registered pharmacy, Get Well knew or should have known of its obligation to administer influenza vaccine and other immunizations designated by the Department of Public Health (DPH) as follows:
 - a. only to persons eighteen (18) years of age or older:
 - b. pursuant to the order of a practitioner;
 - c. with a standing order for the administration of single dose emergency epinephrine;

- d. with evidence of current Cardiopulmonary Resuscitation (CPR) certification; and
- e. in accordance with guidelines adopted by DPH, including:
 - (i) requirements for training accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or similar health authority or professional body; and
 - (ii) requirements for vaccine storage and handling.
- 22. As a registered pharmacy, Get Well knew or should have known of its obligation to remedy or correct a violation cited in a deficiency statement by the date specified in the plan of correction (POC) submitted in accordance with 247 CMR 6.13.

March 25, 2015 Inspection

- On or about March 25, 2015, investigators from the DPH Office of Public Protection (OPP) of the Commonwealth of Massachusetts conducted a compliance inspection of Get Well.
 - 24. During the inspection referenced in the preceding paragraph, OPP investigators observed that Get Well's forms for the ordering of Schedule I and II Controlled Substances (Form 222) were not properly completed.
- 25. During the inspection referenced in Paragraph 23 above, OPP investigators observed multiple errors in the reconciliation of Get Well's perpetual inventory of Schedule II Controlled Substances, including, but not limited to, the following:
 - a. reconciliations at intervals greater than ten (10) days:
 - b. inconsistencies between the perpetual inventory and Get Well's transmittals to DPH's Prescription Monitoring Program (PMP):
 - c. entries out of chronological order;
 - d. partially-filled prescriptions for which the balance was not filled; and
 - e. entries indicating a negative or zero balance.
- 26. During the inspection referenced in Paragraph 23 above, OPP investigators observed that a power of attorney authorizing one or more individuals to order Schedule I and II Controlled Substances on Get Well's behalf was unavailable for inspection.
- 27. During the inspection referenced in Paragraph 23 above, OPP investigators observed that Get Well used an automated data-processing system for the storage and retrieval of information pertaining to the refilling of prescriptions for Controlled Substances in Schedules III through VI.
- 28. During the inspection referenced in Paragraph 23 above, OPP investigators observed that the automated data-processing system referenced in the preceding

- paragraph did not enable the provision of end-of-day reports, transfer reports, returns to stock, or voided prescriptions.
- 29. During the inspection referenced in Paragraph 23 above, OPP investigators observed incompletely or inaccurately labeled vials, and blister packs and vials bearing labels from other pharmacies.
- 30. During the inspection referenced in Paragraph 23 above, OPP investigators observed a ninety (90) day beyond-use date assigned to a prescription to which a fourteen (14) day beyond-use date should have been assigned.
- During the inspection referenced in Paragraph 23 above, OPP investigators observed the area used for compounding at Get Well not to be in a clean, orderly or sanitary condition, and not maintained in a good state of repair.
- 32. On or about April 24, 2015, through its Manager of Record (MOR), Get Well submitted a POC to the Board to address the alleged deficiencies described in Paragraphs 24 through 31 above.

July 23, 2015 Inspection

- 33. On or about July 23, 2015, OPP investigators conducted a compliance inspection of Get Well.
- 34. During the inspection referenced in the preceding paragraph, OPP investigators observed that, on multiple occasions in July, the Get Well refrigerator temperature was below thirty-six degrees Fahrenheit (36° F) as reflected in the Get Well refrigerator temperature log.
- 35. During the inspection referenced in Paragraph 33 above, OPP investigators observed that the refrigerator thermometer out-of-range alarm was not set.
- 36. During the inspection referenced in Paragraph 33 above, OPP investigators observed that Get Well did not have an action policy and procedure to respond to any out-of-range temperature reading.
- 37. During the inspection referenced in Paragraph 33 above, OPP investigators observed six (6) 0.5 ml influenza virus vaccines pre-drawn into 3 ml syringes, with no label, with the vial accompanying the syringes bearing an expiration date of June 2014.
- 38. During the inspection referenced in Paragraph 33 above, OPP investigators did not observe any order from a practitioner for the administration of influenza vaccines.

- 39. During the inspection referenced in Paragraph 33 above, OPP investigators observed a telephone prescription pad that did not permit a practitioner to instruct a pharmacist to dispense a brand name drug product by indicating "no substitution."
- 40. During the inspection referenced in Paragraph 33 above, and notwithstanding the POC referenced in Paragraph 32 above, OPP investigators observed incompletely or inaccurately labeled vials, and vials bearing labels from other pharmacies.
- 41. On or about August 20, 2015, through its MOR, Get Well submitted a POC to the Board to address the alleged deficiencies described in Paragraphs 34 through 40 above.

October 29, 2015 Inspection

- 42. On or about October 29, 2015, OPP investigators conducted a compliance inspection of Get Well.
- During the inspection referenced in the preceding paragraph, OPP investigators observed that Get Well was using a refrigerator or freezer that was not self-defrosting.
- 44. During the inspection referenced in Paragraph 42 above, OPP investigators observed controlled substances packaged in containers whose labels were photocopies stapled to the packages.
- 45. During the inspection referenced in Paragraph 42 above, and notwithstanding the POCs referenced in Paragraphs 32 and 41 above, OPP investigators observed controlled substances packaged in containers whose labels bore incorrect quantities and/or dates.
- 46. On or about November 23, 2015, through its MOR, Get Well submitted a POC to the Board to address the alleged deficiencies described in Paragraphs 43 through 45 above.

March 24, 2016 Inspection

- 47. On or about October 29, 2015, OPP investigators received a complaint that Get Well had violated duties and standards set out in Board regulation 247 CMR.
- 48. In connection with the complaint referenced in the preceding paragraph, OPP investigators requested controlled substance inventory, dispensing and patient receipt/delivery records from Get Well.

- 49. The documentation received by OPP investigators in response to the request referenced in the preceding paragraph revealed inaccuracies and inconsistencies, including, but not limited to, the following:
 - a. missing perpetual inventories for five (5) Schedule II Controlled Substances upon the MOR's assumption of MOR duties at Get Well on or about May 6, 2014;
 - b. inventories for three (3) Schedule II Controlled Substances that the MOR had indicated were not in stock at Get Well upon his assumption of MOR duties at Get Well on or about May 6, 2014;
 - c. duplicate fills for controlled substances with the same prescription numbers, including one (1) prescription for which the delivery date preceded the fill date;
 - multiple discrepancies between delivery logs and prescription fill/refill
 and Controlled Substance reports relative to the number of prescriptions
 filled;
 - e. delivery log entries corresponding to dates on which Get Well was closed and no pharmacist was on duty;
 - f. multiple dates for which no delivery logs were provided;
 - g. dispensing or delivery of prescriptions, including maintenance medications and Schedule II Controlled Substances, more than thirty (30) days after the date the prescriptions were written; and
 - h. delivery of one (1) prescription for a Schedule II Controlled Substance on two (2) consecutive dates.
- 50. On or about March 24, 2016, OPP investigators conducted a compliance inspection of Get Well.
- During the inspection referenced in the preceding paragraph, and notwithstanding the POC referenced in Paragraph 32 above, Board investigators observed that Get Well's perpetual inventory of Schedule II Controlled Substances contained multiple errors that were either whited out or crossed out.
- 52. During the inspection referenced in Paragraph 50 above, and notwithstanding the POC referenced in Paragraph 32 above, OPP investigators observed entries in Get Well's perpetual inventory of Schedule II Controlled Substances that indicated that expired Schedule II Controlled Substances had been removed from Get Well's inventory prior to the date they were shipped.
- During the inspection referenced in Paragraph 50 above, OPP investigators observed expired Schedule II Controlled Substances for which complete and accurate disposal or destruction records were not maintained.
- 54. During the inspection referenced in Paragraph 50 above, OPP investigators observed records indicating that the date of receipt of controlled substances by

Get Well was not the date on which the controlled substances were actually received.

- 55. During the inspection referenced in Paragraph 50 above, and notwithstanding the POCs referenced in Paragraph 46 above, OPP investigators observed that prescription labels were printed on plain paper and taped to the back of the corresponding prescriptions.
- 56. The labels referenced in the preceding paragraph did not reflect the correct number of refills or the correct date on which the prescriptions had been filled or refilled.
- 57. During the inspection referenced in Paragraph 50 above, and notwithstanding the POCs referenced in Paragraphs 32 and 41 above, OPP investigators observed unlabeled filled blister packs and vials.
 - 58. During the inspection referenced in Paragraph 50 above, and notwithstanding the POCs referenced in Paragraphs 32 and 41 above, OPP investigators observed medications with labels from other pharmacies.
 - 59. On or about April 13, 2016, through its MOR, Get Well submitted a POC to the Board to address the alleged deficiencies described in Paragraphs 51 through 58 above.

April 14, 2016 Inspection

- 60. On or about April 14, 2016, OPP investigators conducted a compliance inspection of Get Well.
- 61. During the inspection referenced in the preceding paragraph, OPP investigators observed overstocked bottles.
- 62. During the inspection referenced in Paragraph 60 above, OPP investigators observed capsules from two (2) manufacturers in a single bottle.
- 63. During the inspection referenced in Paragraph 60 above, OPP investigators observed medications that Get Well had indicated were for disposal being stored in an area of Get Well that was not designated as quarantined.

Legal Basis for Discipline

- A. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to G.L. c. 112, § 61 for being guilty of deceit, malpractice, gross misconduct in the practice of the profession, or of any offense against the laws of the Commonwealth relating thereto.
- B. Your conduct, practices and operations, as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to G.L. c. 112, §§ 40, 42A and 61; 247 CMR 6.02(6), 9.01(1), (3), (5), (6), (10) and (14), 9.04(6), and 10.03(1).
- C. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 6.02(6)(h) for failing to comply with all other security requirements which the Board may deem necessary for the protection of the public.
 - D. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.01(1) for failing to conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board.
 - E. Your conduct as alleged, without limitation, in Paragraphs 14 and 31 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.01(3) and USP 795 for failing to observe and comply with the standards of USP 795.

¹ It is well-settled administrative law that due process requires that "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," and does not require Prosecuting Counsel to provide a detailed description of evidence he intends to introduce at a disciplinary hearing. Langlitz v. Board of Registration of Chiropractors, 396 Mass. 374, 376-377 (1985). See Lapointe v. License Board of Worcester, 389 Mass. 454, 458 (1983) ("Due process requires notice of the grounds on which the board might act rather than the evidentiary support for those grounds"). Certainly, notice pleadings do not require Prosecuting Counsel to match factual allegations to grounds for discipline. Accordingly, where, as here, there exists significant overlap between factual allegations and grounds for discipline contained within the Order to Show Cause, Prosecuting Counsel's matching of factual allegations to grounds for discipline are offered as suggestions, and not as an exhaustive characterization of the evidence to be adduced at a hearing.

- F. Your conduct as alleged, without limitation, in Paragraphs 14-15 and 30-31 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.01(3) and USP 795 for failing to assign applicable BUD to drugs and preparations prepared and dispensed by, at or from Get Well.
- G. Your conduct as alleged, without limitation, in Paragraphs 16-18, 29, 40, 52-54, 57-58 and 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.01(5) for failing to be responsible for the proper preservation and security of all drugs in the pharmacy or pharmacy department, including the proper refrigeration and storage of said drugs.
- H. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.01(6) for engaging in any fraudulent or deceptive act.
- I. Your conduct as alleged, without limitation, in Paragraphs 13-15, 16-18, 20-21, 29-31, 34-38, 40, 43, 45, 54, 56-58 and 61-63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.01(10) for dispensing or distributing expired, outdated or otherwise substandard drugs or devices or counterfeit drugs or devices to any person or entity not licensed or legally authorized to receive such drugs or devices.
- J. Your conduct as alleged, without limitation, in Paragraphs 9-10, 25, 49 and 51-52 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.01(14) for failing to keep a perpetual inventory of each controlled substance in Schedule II which you received, dispensed or disposed of in accordance with law, and to have failed to reconcile this inventory at least once every ten days.
- K. Your conduct as alleged, without limitation, in Paragraphs 9, 12, 20, 27-29, 40, 44-45, and 55-57 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 9.04(6) for failing properly, as an alternative to the provisions of 247 CMR 9.04(4) and (5), to use an automated data-processing system for the storage and retrieval of information pertaining to the refilling of prescriptions for controlled substances in Schedules III through VI.

- L. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(a) for 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.
- M. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(b) for 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.
- Your conduct as alleged, without limitation, in Paragraphs 22, 32, 40-41, 45-46, 51-52 and 55-58 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(d) for failing to remedy or correct a violation cited in a deficiency statement by the date specified in the POC submitted in accordance with 247 CMR 6.13.
- O. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(e) for engaging in misconduct in the practice of the profession.
 - P. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(k) for engaging in conduct that has the capacity or potential to place the public health, safety or welfare at risk.
 - Q. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(*l*) for engaging in conduct that has the capacity or potential to deceive or defraud.
 - R. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(u) for engaging in conduct which

undermines public confidence in the integrity of the profession.

- S. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(v) for committing an act that violates recognized standards of pharmacy practice.
- T. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(w) for failing to comply with recognized ethical standards of the profession, including, but not limited to, the standards of practice of pharmacists, pharmacy interns, pharmacies and pharmacy departments set forth in 247 CMR 9.01: Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments.
- U. Your conduct as alleged, without limitation, in Paragraphs 7-10, 12, 20, 25, 27-29, 40, 44-45, 49, 51-52, and 55-57 above, and any other evidence that may be adduced at hearing, warrant disciplinary action by the Board against your registration to operate as a pharmacy and your controlled substances permit pursuant to 247 CMR 10.03(1)(x) for violating G.L. c. 94C or any rules or regulations promulgated thereunder.
- V. Your conduct as alleged in Paragraphs 4 through 63 above, and any other evidence that may be adduced at hearing, also constitute unprofessional conduct and conduct which undermines public confidence in the integrity of the profession. Sugarman v. Board of Registration in Medicine, 422 Mass. 338, 342 (1996); see also, Kvitka v. Board of Registration in Medicine, 407 Mass. 140, cert. denied, 498 U.S. 823 (1990); Raymond v. Board of Registration in Medicine, 387 Mass. 708, 713 (1982).

You have a right to an adjudicatory hearing (hearing) on the allegations contained in the Order to Show Cause before the Board determines whether to suspend, revoke, or impose other discipline against your license. G.L. c. 112, § 61. Your right to a hearing may be claimed by submitting a written request for a hearing within twenty-one (21) days of receipt of this Order to Show Cause. You must also submit an Answer to this Order to Show Cause in accordance with 801 CMR 1.01(6)(d) within twenty-one (21) days of receipt of this Order to Show Cause. The Board will give you prior written notice of the time and place of the hearing following receipt of a written request for a hearing.

Hearings shall be conducted in accordance with the State Administrative Procedure Act, G.L. c. 30A, §§ 10 and 11, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 and 1.03, under which you are granted certain

rights including, but not limited to, the rights: to a hearing; to secure legal counsel or another representative to represent your interests; to call and examine witnesses; to cross-examine witnesses who testify against you; to testify on your own behalf; to introduce evidence; and to make arguments in support of your position.

The Board will make an audio recording of any hearing conducted in the captioned matter. In the event that you wish to appeal a final decision of the Board, it is incumbent on you to supply a reviewing court with a "proper record" of the proceeding, which may include a written transcript. New Bedford Gas and Light Co. v. Board of Assessors of Dartmouth, 368 Mass. 745, 749-750 (1975). Upon request, the Board will make available a copy of the audio recording of the proceeding at your own expense. Pursuant to 801 CMR 1.01(10)(i)(1), upon motion, you "may be allowed to provide a public stenographer to transcribe the proceedings at [your] own expense upon terms ordered by the Presiding Officer." Those terms may include a requirement that any copy of the transcript produced must be sent immediately upon completion, and on an ongoing basis, directly to the Presiding Officer by the stenographer or transcription service. The transcript will be made available to the Prosecutor representing the Board. Please note that the administrative record of the proceedings, including, but not limited to, the written transcript of the hearing, is a public record and subject to the provisions of G.L. c. 4, § 7 and G.L. c. 66, § 10.

Your failure to submit a written request for a hearing within twenty-one (21) days of receipt of this Order to Show Cause shall constitute a waiver of the right to a hearing on the allegations herein and on any Board disciplinary action. Your failure to submit an Answer to the Order to Show Cause within twenty-one (21) days of receipt of the Order to Show Cause shall result in the entry of default in the captioned matter.

Notwithstanding the earlier filing of an Answer and/or request for a hearing, your failure to respond to notices or correspondence, your failure to appear for any scheduled status conference, pre-hearing conference or hearing dates, or your failure to otherwise defend this action shall result in the entry of default.

If you are defaulted, the Board may enter a Final Decision and Order that assumes the truth of the allegations in this Order to Show Cause, and may revoke, suspend, or take other disciplinary action against your registration to operate as a pharmacy and your controlled substances permit in the Commonwealth of Massachusetts, including any right to renew your license.

Your Answer to the Order to Show Cause and your written request for a hearing must be filed with Eugene Langner, Prosecuting Counsel, at the following address:

Eugene Langner, Esq.
Prosecuting Counsel
Department of Public Health
Office of the General Counsel, 5th Floor
239 Causeway Street
Boston, MA 02114

You or your representative may examine Board records relative to this case prior to the date of the hearing during regular business hours at the office of the Prosecuting Counsel. If you elect to undertake such an examination, then please contact Prosecuting Counsel in advance at (617) 973-0838 to schedule a time that is mutually convenient.

BOARD OF REGISTRATION IN PHARMACY Edmund J. Taglieri, R.Ph., MSM, NHA, President

Bv:

Eugene Languer, Esq

Prosecuting Counsel

Department of Public Health

Date: Prij December: 2 , 2016

<u>CERTIFICATE OF SERVICE</u>

I hereby certify that a copy of the foregoing Order to Show Cause was served upon the Respondent:

Get Well Pharmacy c/o Donna Nevarez

by first class mail, postage prepaid, and by Certified Mail No. 7016 1370 0001 4117 6872

This $\frac{2^q}{}$ day of December, 2016.

Eugene Languer Prosecuting Counsel

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COMMONWEALTH OF MASSACHUSETTS

SUFFC			

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of GET WELL PHARMACY Registration No. DS89862 Expires December 31, 2017

Docket No. PHA-2015-0148

CEASE AND DESIST NOTICE

The Board of Registration in Pharmacy ("Board") hereby notifies Get Well Pharmacy, Registration No. DS89862, located at 646 Blue Hill Avenue in Dorchester, Massachusetts ("Get Well"), to IMMEDIATELY CEASE AND DESIST all packaging, repackaging and re-dispensing of any controlled substance.

- 1. The Board issues this Notice pursuant to M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.08. The restrictions shall be non-disciplinary.
- 2. During an unannounced compliance inspection on March 24, 2016, Board Investigators observed violations of Board regulations, including but not limited to:
 - Unlabeled blister packages filled with controlled substances that cannot be verified as to manufacturer and expiration date;
 - b. Unlabeled vials of medications in return to stock basket;
 - A prescription bottle from CVS for Diclofenac intermingled with other labeled and unlabeled vials of medication in return to stock basket;
 - d. Prescription bottles from other pharmacies intermingled with other labeled and unlabeled medication vials that have not been quarantined and were found in blister packaging area;
 - e. One unlabeled vial of mixed medications found in blister packaging area;
 - f. Unlabeled organizer holding assorted drugs grouped by appearance and stored out in the open in the blister packaging area;

- g. Cut open medication packaging that is missing the lot number and expiration date found in blister packaging area;
- h. Blister packaging with labels bearing hand-written instructions that are photocopied and easily removable;
- i. Blister packaging found for patient that is incorrectly filled.
- 3. The observations and conditions described in Paragraph 2 constitute violations of laws and regulations governing the practice of pharmacy, including but not limited to M.G.L. c. 94C, § 21; 247 CMR 9.01(2); 247 CMR 9.01(4); 247 CMR 9.01(5); 247 CMR 9.01(10); 247 CMR 9.01(3) and Board Policy No. 98-011, Policy on Customized Patient Packaging. The conditions described in Paragraph 2 are grounds for discipline pursuant to M.G.L. c. 112, §§ 42A and 61 and 247 CMR 10.03(1)(b), (k), (v), and (x).
- 4. Get Well's continued or further packaging, repackaging and re-dispensing of any controlled substance presents an immediate or serious threat to the public health, safety, or welfare warranting the issuance of this Cease and Desist Notice as set forth in 247 CMR 10.08.
- 5. Get Well must immediately cease all activities related to or constituting the packaging, repackaging or re-dispensing of any controlled substance. Pursuant to this Notice, Get Well may NOT conduct any activity that constitutes a specialty repackaging program or repackage or re-dispense any controlled substance without the express approval of the Board.
- 6. Get Well may NOT resume packaging, repackaging or re-dispensing controlled substances without the express written approval of the Board.
- 7. Get Well shall conduct an orderly transition of patient care consistent with 247 CMR 9.02 that is related to its packaging or repackaging of controlled substances or any specialty packaging program consistent.
- 8. In accordance with 247 CMR 10.08, a hearing limited to the determination of the necessity of this Notice to immediately Cease and Desist those pharmacy operations specifically delineated shall be afforded to Get Well within 15 business days of the issuance of this Notice.

BOARD OF REGISTRATION IN PHARMACY

President Effective Date: March 25, 2016

Acknowledgement of receipt Todd Matthews, R.Ph. Manager of Record, Get Well.

NOTICE OF HEARING ON CEASE AND DESIST

Get Well Pharmacy, Registration No. DS89862 ("Get Well" or "Respondent"), is also hereby notified that, pursuant to 247 CMR 10.08, an ADJUDICATORY HEARING on the necessity of continuing the Cease and Desist Notice has been scheduled to be held before the Board on Friday, April 8, 2016 at 10:00 a.m. at the Division of Health Professions Licensure, Room 421, 239 Causeway Street, Boston, Massachusetts 02114.

Please be advised that the Respondent may request that the Board reschedule this hearing to a date and time that is mutually agreeable to you and the Board. Note carefully, however, that any rescheduling of the hearing shall NOT operate to lift the Cease and Desist Notice.

The adjudicatory hearing on the necessity for Cease and Desist Notice shall be conducted in accordance with M.G.L. c. 30A, §§ 10, 11, and 12, and the Standard Adjudicatory Rules of Practice and Procedure at 801 CMR 1.01 et seq. under which the Respondent is granted certain rights including, but not limited to: the right to be represented by counsel or other representative, the right to confront and cross-examine witnesses who testify, to call witnesses, to present evidence, to testify on its own behalf, and to present oral argument. At the adjudicatory hearing on the necessity for the Cease and Desist Notice, the Board shall receive oral and documentary evidence limited to determining whether the summary Notice shall continue in effect pending the final disposition of the complaint against Get Well's registration.

The Board will make an audio recording of any hearing conducted in the captioned matter. In the event that the Respondent wishes to appeal a final decision of the Board, it is incumbent on the Respondent to supply a reviewing court with a "proper record" of the proceeding, which may include a written transcript. New Bedford Gas and Light Co. v. Board of Assessors of Dartmouth, 368 Mass. 745. 749-750 (1975). Upon request, the Board will make available a copy of the audio recording of the proceeding at the Respondent's expense. Pursuant to 801 CMR 1.01(10)(i)(1), upon motion, the Respondent "may be allowed to provide a public stenographer to transcribe the proceedings at [your] own expense upon terms ordered by the Presiding Officer." Those terms may include a requirement that any copy of the transcript produced must be sent promptly upon completion directly to the Presiding Officer by the stenographer or transcription service. The transcript will be made available to the Prosecutor representing the Board. Please note that the administrative record of the proceedings, including but not limited to, the written transcript of the hearing is a public record and subject to the provisions of M.G.L. c. 4, § 7 and M.G.L. c. 66, § 10.

All papers filed with the Board in this matter shall be addressed to the attention of:

Jason Barshak, Esq. Chief Administrative Hearings Counsel Division of Health Professions Licensure 239 Causeway Street Boston, Massachusetts 02114

Prosecuting Counsel for this matter is:

Eugene Langner, Esq.
Department of Public Health
Office of General Counsel
239 Causeway Street, Fourth Floor
Boston, MA 02114

The Respondent or the Respondent's representative may examine Board records relative to this matter prior to the date of the hearing during regular business hours at the Office of the Prosecuting Counsel. If the Respondent elects to undertake such an examination, please contact the Prosecuting Counsel in advance at (617) 973-0923 to schedule a time that is mutually convenient.

BOARD OF REGISTRATION IN PHARMACY.

David Sencabaugh, R.Ph.

Executive Director

Board of Registration in Pharmacy

Dated: March 25, 2016

CERTIFICATE OF SERVICE

I, Samuel W. Leadholm, hereby certify that a copy of the foregoing Cease and Desist Notice and Notice of Hearing was served upon the Respondent, Get Well Pharmacy, first-class mail, postage prepaid, and UPS Next Day, tracking number 1Z 014 9VV 22 1000 8226, to the following address:

Get Well Pharmacy 646 Blue Hill Avenue Dorchester, Massachusetts 02121

on this 25th day of March, 2016.

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of GET WELL PHARMACY Registration No. DS89862 Expires December 31, 2017

GET WELL PHARMACY, Respondent

646 Blue Hill Avenue

Docket No. PHA-2015-0148

We, the undersigned, as owner and manager of record of the Respondent in the above-entitled and numbered cause, hereby stipulate that it is necessary to continue the non-disciplinary restrictions on packaging, repackaging and re-dispensing of any controlled substance; imposed on Get Well Pharmacy pursuant to the Cease and Desist Notice issued by the Board of Registration in Phinmacy on March 25, 2016, until the final resolution of this matter.

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Todd Matthews, R.Ph.	Donna Ragdana Lipaan Nevarez
Manager of Record)	Owner
Date: 33//16	
Respectfully submitted.	
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DEPARTMENT OF PUBLIC HEALTH,	GET WELL PHARMACY,
By its attorney:	By its attorney?
Chare Ar	1//- 3
Fugone Languer, BBO# 630701	Paul Garbarini, BBO # 64754+
Prosecuting Counsel	P.O. Box 1551
Department of Public Health	Northampton, MA 01061
Office of the General Counsel	(413) 727-8191
239 Causeway Street, 5th Floor	
Boston, MA 02114	
(617) 973 – 0838)	4
Date: 4/1/16	•

3/31/16

barthi, BBO # 6754-561400 (Ac)

