COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY BOARD OF REGISTRATION

 IN PHARMACY

In the Matter of )

Conley’s Drug Store ) PHA-2016-0188

DS2654 )

**FINAL DECISION AND ORDER**

**Final Decision**

 On April 30, 2018, the Board of Registration in Pharmacy (“Board”) issued to Conley’s Drug Store (“Respondent”), DS2654, an Order to Show Cause why it should not take disciplinary action against its pharmacy license. The Order to Show Cause alleged inspectional deficiencies and violations observed during an October 17, 2016 inspection.

On or about January 24, 2019, Respondent and Prosecuting Counsel filed an Agreement of the Parties Relative to Request for Sanction Hearing (“Sanction Hearing Document”) containing stipulations of fact and law along with a request for a sanction hearing before the Board. The Board reviewed the Sanction Hearing Document on or about May 2, 2018 and determined the stipulations in the Sanction Hearing Document were sufficient to stand in place of findings from a hearing. The Board voted to adopt the stipulations and to proceed as the parties requested with a Sanction Hearing before the Board. The Sanction Hearing Document is attached hereto and incorporated by reference into the Final Decision.

 The Board held a Sanction Hearing on September 5, 2019, during which Prosecuting Counsel and Respondent addressed the Board.

During the Hearing, Prosecuting Counsel deferred to the agreed upon facts and violations stated in the Sanction Hearing Document.

During the Hearing, Richard Doyle, the owner and Manager of Record of Conley’s Drug Store, testified on behalf of the Respondent. Mr. Doyle’s testimony may be summarized as follows:

Mr. Doyle and Conley’s Drug Store have been selling compounds containing over the counter medications without a prescription for many years without incident. Mr. Doyle did not know or understand that prescriptions are required for compounds containing over the counter medications. Once Mr. Doyle was advised that his compounding practice violated the law, Mr. Doyle immediately made changes and brought his practice into compliance.

Mr. Doyle noted that inspectors did not cite any deficiency related to compounds containing over the counter medications requiring a prescription during approximately three inspections between 2013 and the October 2016 inspection. He thinks the October 2016 inspection was unnecessarily detailed and critical.

Mr. Doyle testified that he compounded products in order to help patients. He did not intentionally violate any law or regulation. He never hid anything from the Board and was always doing his best. Mr. Doyle stated that he attended compounding education courses and was never advised that compounds containing over the counter medications required a prescription. Additionally, Mr. Doyle had been relying on his son for compounding compliance; he notes that his son also attended compounding education courses.

Mr. Doyle noted that Conley’s Drug Store has been in full compliance at each inspection subsequent to the October 2016 inspection.

Mr. Doyle requested the Board take non-disciplinary action rather than impose formation discipline on his license or the license of Conley’s Drug Store.

The Board carefully considered Mr. Doyle’s testimony. The Board notes that ignorance of the law is not an excuse for a violation and that by 2016, Mr. Doyle and Conley’s Drug Store should have known that compounds containing over the counter medications required a prescription. The Board reasons the 2012 sterile compounding crisis and specific focus on patient specific prescriptions should have alerted Conley’s Drug Store to evaluate its compliance with compounding laws, regulations, and practice standards. It is imperative for Mr. Doyle, even though he is at the end of his career, to be knowledgeable about UPS 795 compliance, as well as laws and regulations surrounding compounding.

The Board carefully considered the following mitigating circumstances: There was a great deal of confusion surrounding compounding requirements in 2013. There is no evidence that Mr. Doyle or Conley’s Drug Store intended to circumvent the law. Mr. Doyle and Conley’s Drug Store had been selling compounds containing over the counter medications without a prescription for decades. Importantly, Conley’s Drug Store underwent approximately three inspections after 2013 and before the October 2016 inspection in which Board investigators did not cite any deficiency related to prescriptions for compounded medications.

Last, the Board notes that at all relevant times Mr. Doyle served as the manager of record of Conley’s Drug Store. As described in 247 CMR 6.07, Mr. Doyle, as manager of record, was responsible for the operation of the Conley’s Drug Store and compliance with 247 CMR 2.00 *et seq*. and applicable state and federal laws and regulations.

The Board voted to adopt the within Final Decision at its meeting on October 3, 2019, by the following vote:

In favor: Susan Cornacchio; Timothy Fensky; Patrick Gannon; Michael Godek; Sebastian Hamilton; Stephanie Hernandez; Julie Lanza; Richard Lopez; Andrew Stein; Kim Tanzer

Opposed: None

Abstained: None

Recused: None

Absent: Leah Giambarresi; Carly Jean-Francois; Dawn Perry

**Order**

 On October 3, 2019, in accordance with the Board’s authority and statutory mandate, the Board voted to issue this Final Decision and Order and place Respondent’s pharmacy license, DS2654, on **PROBATION** for two years (“Probationary Period”). Further, within six months of the Effective Date, Respondent shall submit a report from a third party consultant evaluating its compliance with the revised chapter of USP 795 and USP 800.

In favor: Susan Cornacchio; Timothy Fensky; Patrick Gannon; Michael Godek; Sebastian Hamilton; Stephanie Hernandez; Julie Lanza; Richard Lopez; Andrew Stein; Kim Tanzer

Opposed: None

Abstained: None

Recused: None

Absent: Leah Giambarresi; Carly Jean-Francois; Dawn Perry

**Effective Date of Order**

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

**Right to Appeal**

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

Board of Registration in Pharmacy,

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David A. Sencabaugh, R.Ph.

Executive Director

Date Issued: 10/16/2019

Notified:

### **VIA FIRST CLASS & CERITIFIED MAIL NO. 7019 0700 0000 1846 4726,**

**RETURN RECEIPT REQUESTED**

Paul M. Garbarini, PC

Attorney at Law

PO Box 1551

Northampton, MA 01061

## **BY HAND DELIVERY**

Richard Banks, Esq.

Department of Public Health

Office of General Counsel

250 Washington Street, 7th Floor

Boston, MA 02108

Jason Barshak, Esq.

Chief Administrative Magistrate

Department of Public Health

Office of the General Counsel

250 Washington Street, 2nd Floor

Boston, MA 02108

### **COMMONWEALTH OF MASSACHUSETTS**

# **SUFFOLK COUNTY BOARD OF REGISTRATION**

 IN PHARMACY

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In the Matter of )

CONLEY’S DRUG STORE )

 ) Docket No. PHA-2016-0188

DS No. 2654 )

Registration expires 12/31/19 )

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#### ORDER TO SHOW CAUSE

 **Conley’s Drug Store** 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, Registration No. DS2654, or its right to renew that registration, pursuant to Massachusetts General Laws (G. L.) Chapter 112, §§ 42A and 61 and Board regulations 247 CMR 10.00 et seq. based upon the following facts and allegations:

1. On or about August 21, 1996, the Board granted Conley’s Drug Store in Ipswich, Massachusetts (Conley’s Ipswich) the authorization to practice as a registered Pharmacy, Registration No. DS2654. Conley Ipswich is located at 146 High Street, Ipswich, Massachusetts.
2. On October 17, 2016, investigators for the Board conducted a USP <795> non-sterile compounding (ISP-6209) inspection at Conley’s Ipswich.
3. During the ISP-6209 inspection conducted on October 17, 2016, investigators for the Board identified the following deficiencies:

a. Conley’s Ipswich sold compounded non-sterile preparations without patient specific prescriptions;

b. Conley’s Ipswich lacked references or studies for compounded non-sterile preparations;

c. Conley’s Ipswich extended “beyond use dates” without substantial evidence or validation for extending those dates;

d. Conley’s Ipswich failed to store compounded non-sterile preparations in accordance with the instructions on the labels;

e. Conley’s Ipswich did not maintain quality assurance records relating to compounded products;

f. Conley’s Ipswich failed to ensure that compounded non-sterile products were properly labeled in accordance with USP 795;

g. Conley’s Ipswich maintained incomplete or inaccurate compounding logs;

h. Conley’s Ipswich failed to maintain formulation records addressing instructions for compounding and quality assurance.

\* \* \*

1. The acts and omissions of Conley’s Ipswich warrant disciplinary action by the Board against its registration as a Pharmacy pursuant to the following Board regulation:
	1. For failing to maintain signage relating to the sale of prescription lock boxes in violation of 94C, §21B(b) as shown by Paragraphs 2 & 3 of this Order to Show Cause and evidence to be adduced at a hearing;
	2. For failing to ensure that pharmacy technicians were properly licensed when performing pharmacy duties in violation of 247 CMR 8.07(3)(b) as shown by Paragraphs 2 & 3 of this Order to Show Cause and evidence to be adduced at a hearing;
	3. violating 247 CMR 10.03(1)(a) by violating any of the duties and standards set out in Board Regulations (247 CMR 2.00: Definitions) or any rule or written policy adopted by the Board as shown by Paragraphs 2 & 3 of this Order to Show Cause and evidence to be adduced at a hearing;
	4. violating 247 CMR 10.03(1)(b) by violating one or more provisions of M.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 as shown by Paragraphs 2 & 3 of this Order to Show Cause and evidence to be adduced at a hearing;
	5. violating 247 CMR 10.03(1)(v) by committing an act that violates recognized standards of pharmacy practice as shown by Paragraphs 2 & 3 of this Order to Show Cause and evidence to be adduced at a hearing;
	6. violating 247 CMR 10.03(1)(x) by violating M.G.L. c. 94C or a rule or regulation promulgated thereunder as shown by Paragraphs 2 & 3 of this Order to Show Cause and evidence to be adduced at a hearing;

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 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 registration as a Pharmacy and right to renew your Pharmacy registration. 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 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. 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 therein and on any Board disciplinary action.

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 as a Pharmacy in the Commonwealth of Massachusetts, including any right to renew that registration.**

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

Richard L. Banks, Jr., Esq.

 Department of Public Health

Office of the General Counsel

 239 Causeway Street, 4th Floor

 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) 624-5236 to schedule a time that is mutually convenient for the review.

 Board of Registration in Pharmacy,

 Michael J. Godek, R.Ph, President

 By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Richard L. Banks, Jr., Esq.

 Department of Public Health

Date: April \_\_\_, 2018