

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of )  
Conley's Drug Store )  
DS2654 )

PHA-2016-0188

**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.

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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

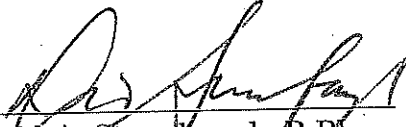
Date Issued.

Conley's Drug Store  
DS2654  
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**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,

  
\_\_\_\_\_  
David A. Sencabaugh, R.Ph.  
Executive Director

Date Issued: 10/16/19

Notified:

**VIA FIRST CLASS & CERTIFIED 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**

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250 Washington Street, 7<sup>th</sup> Floor  
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Chief Administrative Magistrate  
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Office of the General Counsel  
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Boston, MA 02108

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of  
CONLEY'S DRUG STORE

DS No. 2654  
Registration expires 12/31/19

Docket No. PHA-2016-0188

AGREEMENT OF THE PARTIES  
RELATIVE TO REQUEST FOR SANCTION HEARING

Now comes Conley's Drug Store located in Ipswich, Massachusetts ("Respondent") and Counsel for the Respondent and Prosecuting Counsel and jointly file the following in response to *the Order After January 15, 2019 Telephone Conference*:

- 1) The Respondent (after conferring with its counsel) hereby officially declares that it waives its right to a full adjudicatory hearing and requests a Sanction Hearing on all violations being pursued by the Prosecution;

The Respondent (after conferring with its counsel) and the Prosecutor agree that the following facts (hereafter the "*Agreed Facts*") are true and may be relied upon for purposes of conducting the Sanction Hearing:

- a. At all times relevant to the allegations in this Order to Show Cause Conley's Drug Store (Conley's Ipswich) was located at 146 High Street, Ipswich, Massachusetts.
- b. A non-sterile compounding (USP 795/ISP-6209) inspection was conducted at Conley's Ipswich on October 17, 2016

- c. During the October 17, 2016 inspection, records existed which established that Conley's Ipswich sold compounded non-sterile preparations without patient specific prescriptions;
- d. During the October 17, 2016 inspection, records existed which established that Conley's Ipswich lacked references or studies for compounded non-sterile preparations;
- e. During the October 17, 2016 inspection, records existed which established that Conley's Ipswich extended "beyond use dates" without substantial evidence or validation for extending those dates;
- f. During the October 17, 2016 inspection, it was determined that Conley's Ipswich failed to store compounded non-sterile preparations in accordance with the instructions on the labels;
- g. During the October 17, 2016 inspection, it was determined that Conley's Ipswich did not maintain quality assurance records relating to compounded products;
- h. During the October 17, 2016 inspection, it was determined that Conley's Ipswich failed to ensure that compounded non-sterile products were properly labeled in accordance with USP 795;
- i. During the October 17, 2016 inspection, it was determined that Conley's Ipswich maintained incomplete or inaccurate compounding logs;
- j. During the October 17, 2016 inspection, it was determined that Conley's Ipswich failed to maintain formulation records addressing instructions for compounding and quality assurance.

The Respondent (after conferring with its counsel) and the Prosecutor agree that the *Agreed Facts* constitute bases for a finding that each of the regulations cited in the Order to Show Cause was violated. More specifically, the Respondent and the Prosecutor agree that the Respondent's acts and/or omissions violated:

- a. M.G.L. c112, §42A for violating rules of the profession;
- b. M.G.L. c112, §61 for violating regulations of the Board governing the practice of the profession;
- c. Regulation 247 CMR 10.03(1)(a) for 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;
- d. Regulation 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

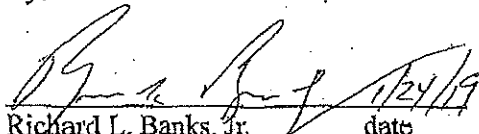
e. Regulation 247 CMR 10.03(1)(v) by committing one or more acts that violate recognized standards of pharmacy practice; and

f. Regulation 247 CMR 10.03(1)(x) by violating M.G.L. c. 94C or a rule or regulation promulgated thereunder;

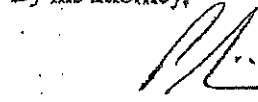
2) The Respondent acknowledges that its license to practice as a Pharmacy is subject to the jurisdiction of the Board and that the Board has the right and authority to discipline its license in light of the acknowledged violations.

3) The Respondent acknowledges and agrees that the purpose of the Sanction Hearing is determine what, if any, discipline is appropriate in light of the violations, not whether the Board has a basis or the right to discipline the Respondent.

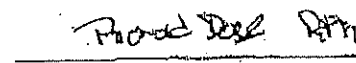
Respectfully submitted,  
For the Prosecution  
By:

  
Richard L. Banks, Jr. date 1/24/19  
Mass. Department of Public Health  
Garbarini  
Office of the General Counsel  
239 Causeway Street  
Boston, MA 02114

Respectfully submitted,  
For the Respondent,  
By his attorney,

  
Paul Garbarini, Esq. date 1/24/19  
Offices of Attorney Paul  
P.O. Box 1551  
Northampton, MA 01061  
BBO #561400

Respectfully submitted,  
By Owner/Authorized Signer for  
Respondent,

  
Richard Doyle, R.ph. date 1/23/19  
(Authorized Signer for Pharmacy)