BEFORE THE IOWA BOARD OF PHARMACY

Re: Nonresident Pharmacy License of)	CASE NO. 2015-6	
PHARMACY CREATIONS, LLC License No. 4185 Respondent.)	NOTICE OF HEARING AND STATEMENT OF CHARGES	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Pharmacy Creations, LLC ("Respondent"), 540 Route 10 West, Randolph, New Jersey, 07869, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa nonresident pharmacy license number 4185 is currently active through December 31, 2015.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 12, 2016, before the Board. The hearing shall be held during the morning session beginning at 9:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 S.W. 8th Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings</u>. Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8th Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

<u>Pre-hearing Conference</u>. Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

<u>Prosecution.</u> The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier Assistant Attorney General Iowa Attorney General's Office 2nd Floor, Hoover State Office Building Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

<u>Communications</u>. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 147, 155A, and 272C, and 657 IAC 36.

<u>Default.</u> If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.21.

C. CHARGES

COUNT I OUT-OF-STATE DISCIPLINE

Respondent is charged with violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"ad".

COUNT II FAILURE TO NOTIFY OF DISCIPLINE

Respondent is charged with failing to notify the board within 30 days after a final decision entered by the licensing authority of another state, territory, or country which decision resulted in a license or registration revocation, suspension, or other disciplinary sanction, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"k".

COUNT III

FAILURE TO NOTIFY OF PHARMACY LICENSE CHANGE

Respondent is charged with failing to timely submit an application for a change in pharmacist in charge, or failing to appoint or notify the board of a temporary pharmacist in charge, in violation of 657 IAC 8.35(6)"c", pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"u".

D. FACTUAL CIRCUMSTANCES

- 1. Respondent became licensed as an Iowa nonresident pharmacy in May 2013. When initially licensed, Respondent was a limited liability company co-owned by two individuals.
- 2. On October 17, 2013, the Indiana State Board of Pharmacy granted Respondent an Indiana nonresident pharmacy permit, but placed it on probation for a minimum period of 16 months. The probationary period was based on Respondent's shipment of medications into Indiana prior to licensure. Respondent reported the discipline to the Board in December 2014.
- 3. On April 1, 2014, Imprimis Pharmaceuticals Inc. acquired 100% of the membership interests of the limited liability company.
- 4. On April 22, 2014, the Ohio State Board of Pharmacy granted Respondent's Ohio nonresident pharmacy permit, but placed it on probation for 12 months and imposed a \$2000 fine. The probationary period and fine were based on Respondent's shipment of medication into Ohio prior to licensure. Respondent reported the discipline to the Board in August 2014.
- 5. The New Jersey Board of Pharmacy issued two Interim Consent Orders, on May 14, 2014, and on July 21, 2014, that related to inspection deficiencies identified by inspectors in June 2013, but neither Consent Order was disciplinary in nature. These Consent Orders were not reported to the Board.
- 6. On June 5, 2014, the North Carolina Board of Pharmacy denied Respondent's application for a North Carolina nonresident pharmacy permit. The denial was based on inspection deficiencies noted by the New Jersey Board of Pharmacy in June 2013. Respondent reported the denial to the Board in December 2014.
- 7. On September 19, 2014, the Missouri Board of Pharmacy denied Respondent's application for a Missouri nonresident pharmacy permit. The denial was based on Respondent's prior discipline. Respondent reported the denial to the Board in December 2014.
- 8. In September 2014, the Board received notification from the pharmacist in charge that he was resigning effective October 10, 2014. The Board received Respondent's renewal indicating a change in pharmacist-in-charge on December 16, 2014. The Board did not receive any information regarding the appointment of a permanent or temporary pharmacist in charge between these two dates.
- 9. On March 16, 2015, the Alabama Board of Pharmacy granted Respondent's Alabama nonresident pharmacy permit, but placed it on probation for a period of one year. The

probationary period was based on Respondent's prior discipline. Respondent reported the discipline to the Board on June 1, 2015.

- 10. On July 28, 2015, the Colorado Board of Pharmacy issued a Letter of Admonition to Respondent for failing to provide timely notification of the Alabama discipline. Respondent timely reported the discipline to the Board on August 6, 2015.
- 11. On August 4, 2015, the Texas State Board of Pharmacy granted Respondent's Texas nonresident pharmacy permit, but placed it on probation for a period of two years and imposed a \$2,200 fine. The probationary period and fine were based on prior discipline and Respondent's failure to disclose all prior discipline. Respondent timely reported the discipline to the Board on September 2, 2015.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

On this 4th day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2nd Floor Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).