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BOARD OF
PHARMACY

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)	PHA-2011-0084
WEST RIVER PHARMACY)	PHA-2012-0251
DS3572)	PHA-2013-0099

SECOND CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and West River Pharmacy ("West River" or "Licensee"), DS3572, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of West River's record maintained by the Board:

1. The Board and West River agree that this Agreement supersedes any and all Agreements previously entered into by the Board and West River.
2. The Board and West River acknowledge and agree to the following facts:
 - a. As a result of multiple regulatory violations observed on inspection in March 2011 and July 2011, the Board opened a Complaint against West River's pharmacy license, Docket Number PHA-2011-0089. The Board and West River entered in to a Consent Agreement for Probation on or about December 20, 2011 ("2011 Consent Agreement") in resolution of this Complaint. In the 2011 Consent Agreement, the Board and Licensee agreed that Licensee's pharmacy license would be placed on probation for at least two years ("Probationary Period").

Licensee: West River Pharmacy, DS3572
 Docket Numbers: PHA-2011-0084, PHA-2012-0251, PHA-2013-0099
 Date: December 9, 2013

b. Subsequent to the execution of the 2011 Consent Agreement and during the Probationary Period, Board investigators conducted an unannounced sterile compounding inspection of West River on or about December 19 & 20, 2012. During the inspection, Board investigators observed deficiencies pertaining to the compounding of sterile medications, including violations of 247 CMR 9.01 and United States Pharmacopoeia ("USP") Chapter 797 standards. Violations included, but were not limited to, the lack of a Class 8 (or better) ante room. As a result of this inspection, the Board opened a second Complaint against West River's pharmacy license, Docket Number PHA-2012-0251.

c. Subsequent to the execution of the 2011 Consent Agreement and during the Probationary Period, a Board investigation revealed evidence that West River allowed other pharmacies to fill prescriptions that were received by West River after-hours, without formally transferring those prescriptions, as required by, and in violation of, 247 CMR 9.02. As a result of this investigation, the Board opened a third complaint against West River's pharmacy license, Docket Number PHA-2013-0099.

d. In the 2011 Consent Agreement, the Board and West River agreed that any violation of any state or federal law or regulation governing the practice of pharmacy during the Probationary Period would be grounds for suspension of the license or other disciplinary action necessary. The deficiencies and practices described in Paragraph 2b and Paragraph 2c constitute violations of the 2011 Consent Agreement.

3. In resolution of the violation of the 2011 Consent Agreement and the two pending Complaints, PHA-2012-0251 and PHA-2013-0099, West River agrees that its pharmacy license shall remain on PROBATION until December 20, 2015 ("Probationary Period").¹
4. During the Probationary Period, West River further agrees that it shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.

¹ The term "license" applies to both a current license and the right to renew an expired license.

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5. The Board agrees that in return for West River's execution and successful compliance with the requirements of this Agreement it will not prosecute Complaints PHA-2012-0251 and PHA-2013-0099 and will not prosecute the violation of the 2011 Consent Agreement.
6. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate on December 20, 2015, upon written notice to the Licensee from the Board².
7. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint³ during the Probationary Period, the Licensee agrees to the following:
 - a. The Board may upon written notice to the Licensee, as warranted to protect the public health, safety, or welfare:
 - i. EXTEND the Probationary Period; and/or
 - ii. MODIFY the Probation Agreement requirements; and/or
 - iii. IMMEDIATELY SUSPEND the Licensee's pharmacy license.
 - b. If the Board suspends the West River's pharmacy license pursuant to Paragraph 7(a)(iii), the suspension shall remain in effect until:
 - i. ~~the Board provides West River written notice that the Probationary Period is to be resumed and under what terms; or~~
 - ii. the Board and West River sign a subsequent agreement; or

² In all instances where this Agreement specifies written notice to the Licensee from the Board, such notice shall be sent to the Licensee's address of record.

³ The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the December 20, 2012 inspection, which (1) alleges that the Licensee engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Licensee shall have an opportunity to respond.

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- iii. the Board issues a written final decision and order following adjudication of the allegations (1) of noncompliance with this Agreement, and/ or (2) contained in the Subsequent Complaint.
8. West River agrees that if the Board suspends its pharmacy license in accordance with Paragraph 7, it will immediately return its current Massachusetts pharmacy license to the Board, by hand or certified mail. West River further agrees that upon said suspension, it will no longer be authorized to operate a retail drug store in the Commonwealth of Massachusetts and shall not in any way represent itself as a retail drug store or pharmacy until such time as the Board reinstates its pharmacy license or right to renew such license.
9. West River understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication it would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in the Massachusetts Administrative Procedures Act, M.G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 et seq. The Licensee further understands that by executing this Agreement it is knowingly and voluntarily waiving its right to a formal adjudication of the Complaints.
10. The Licensee acknowledges that it has the right to be represented by legal counsel in connection with the Complaints and this Agreement.

11. The Licensee acknowledges that after the Effective Date, the ~~Agreement constitutes a public record of disciplinary action by the~~ Board. The Board may forward a copy of this Agreement to other licensing boards, law enforcement entities, and other individuals or entities as required or permitted by law.

12. The Licensee certifies that it has read this Agreement. The Licensee understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal or judicial review.

[Signature] 9/11/14
Witness (sign and date)

[Signature] 9-11-14
Signature and Date

Peter DePaola
Print Name
West River

[Signature]
David A. Sencabaugh, R.Ph.
Executive Director
Board of Registration in Pharmacy

September 23, 2014
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on Sept 29th, 2014
Certified
Mail No. 7014-0510-0001-0374-6150