

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of	)	
H.L. WARDLE DRUG COMPANY	)	PHA-2014-0060
DS6250	)	

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and H.L. Wardle Drug Company ("Licensee" or "Pharmacy"), DS6250, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Licensee's record maintained by the Board:

1. Licensee acknowledges that the Board opened a complaint against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2014-0060.<sup>1</sup>
2. The Board and Licensee acknowledge and agree that substantial evidence exists which if proven at hearing would demonstrate the following:
  - a. Between August 1, 2012 and August 5, 2013, H.L. Wardle Drug Company filled approximately 123 oxycodone prescriptions totaling 20,400 dosage units for a single patient ("Patient A").
  - b. Information regarding the medications dispensed to Patient A by H.L. Wardle Drug Company from 2005 until July 31, 2013 was maintained at the pharmacy and available to all pharmacists at the pharmacy.

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

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- c. Patient A's oxycodone prescriptions were written by a single prescriber ("Prescriber"). H.L. Wardle Drug Company had letters written by Prescriber dated December 29, 2005, July 16, 2007, February 16, 2010, and April 19, 2013 indicating that large doses of narcotics were medically necessary for Patient A. H.L. Wardle Drug Company also had a letter written by Prescriber dated January 12, 2012 stating that Patient A may refill his Oxycodone 5 mg and Oxycodone 30 mg prescriptions early.
  - d. During an inspection on July 31, 2013, Board Investigators observed the following deficiencies pertaining to H.L. Wardle Drug Company's controlled substances inventories:
    - i. The most recent biennial inventory did not include Schedule II controlled substances;
    - ii. The Schedule II perpetual drug inventory was not preformed every 10 days; and
    - iii. Certain Schedule II drug inventory overages were not reconciled.
  - e. During an inspection on July 31, 2013, Board Investigators observed the following violations of Board Policy No. 2011-01:
    - i. Food items were stored in the refrigerator used for drug storage;
    - ii. The drug storage refrigerator/freezer unit did not have a certified thermometer; and
    - iii. Medications were stored in a "dorm style" refrigerator.
  - f. During an inspection on July 31, 2013, Board Investigators observed several expired and potentially hazardous drugs and/or chemicals stored in the basement of the pharmacy.
3. Licensee agrees that its pharmacy license shall be placed on PROBATION for three years ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").

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4. During the Probationary Period, the Licensee 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.
5. The Board agrees that in return for Licensee's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.
6. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate three years after the Effective Date upon written notice to the Licensee from the Board.<sup>2</sup>
7. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint<sup>3</sup> 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 Licensee's pharmacy license pursuant to Paragraph 7(a)(iii), the suspension shall remain in effect until:
    - i. the Board provides Licensee written notice that the Probationary Period is to be resumed and under what terms; or

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<sup>2</sup> 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.

<sup>3</sup> The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the Effective Date, 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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- ii. the Board and Licensee sign a subsequent agreement; or
  - 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. Licensee 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. Licensee 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. Licensee 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 Complaint.
10. The Registrant acknowledges that it has been represented by legal counsel in connection with the Complaint 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 understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal, or judicial review.

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13. The individual signing this Agreement certifies that he/she is authorized to enter into this Agreement on behalf of the Pharmacy, and that he/she has read this Agreement.

Sheryl Pearson 5-8-14  
Witness (signature and date)

Peter F. Levangie President 5-8-14  
H.L. Wardle Drug Company  
(signature and date)

Peter F. Levangie  
Print Name

David Sencabaugh  
David Sencabaugh, R. Ph.  
Executive Director  
Board of Registration in Pharmacy  
5-15-14  
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 5/15/14 by  
Certified  
Mail No. 7012 3460 0001 7331 3559