

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
VILLAGE FERTILITY PHARMACY)
335 Bear Hill Road)
Waltham, MA)

PHA-2013-0020

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Village Fertility Pharmacy ("Village Fertility" or "Licensee"), DS89658, 335 Bear Hill Road, Waltham, Massachusetts, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of Village Fertility's record maintained by the Board:

1. Village Fertility acknowledges that a complaint has been opened by the Board against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2013-0020.¹
2. The Board and Village Fertility acknowledge and agree to the following facts:
 - a. Board investigators conducted an unannounced inspection of Village Fertility on or about November 26 & 27, 2012. During the inspection, Board investigators observed deficiencies pertaining to the compounding of sterile medications, including violations of United States Pharmacopoeia ("USP") Chapter 797 standards. Additionally, investigators noted that Village Fertility was not appropriately licensed in states other than Massachusetts into which it shipped medications.
 - b. As a result of the November 2012 inspection, Village Fertility was required to submit a plan of correction to the Board.

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

c. On or about February 20, 2013, Village Fertility informed the Board that it received a customer complaint of visible black particulate matter in vial of sterile compounded product. As a result, Board investigators inspected Village Fertility on or about February 21, 22, 25, and 28, 2013 ("February 2013 inspection").

d. During the February 2013 inspection, Board investigators observed Village Fertility to be non-compliant with 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding – Sterile Preparations, with regard to its compounding of sterile medications. Additionally, Village Fertility acknowledges that, between at least November 2012 and February 2013, it shipped compounded sterile products into states in which it did not hold required non-resident licenses.

e. On or about April 26, 2013, the Board approved Village Fertility's written plan of correction dated April 2, 2013 to resume the compounding of low risk sterile products.

3. Village Fertility agrees that its pharmacy license shall be placed on PROBATION for 36 months ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
4. Village Fertility agrees that all pharmacists and pharmacy technicians working at Village Fertility in any capacity shall each complete five contact hours of continuing education in sterile compounding on or before December 31, 2013.
5. During the Probationary Period, the Village Fertility 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.
6. Village Fertility agrees to refrain from all medium and high risk sterile compounding unless and until it receives written approval from the Board to resume the preparation and dispensing of medium and high risk sterile compounded medications. Board approval shall not be granted unless and until Village Fertility demonstrates, upon inspection by Board investigators, that it is fully compliant with United States Pharmacopeia standards pertaining to medium and high risk sterile compounding and all other state and federal laws and regulations pertaining to the practice of pharmacy.

7. The Board agrees that in return for Village Fertility's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.
8. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate **36 months** after the Effective Date upon written notice to the Licensee from the Board².
9. 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 Village Fertility's pharmacy license pursuant to Paragraph 9(a)(iii), the suspension shall remain in effect until:
 - i. the Board provides Village Fertility written notice that the Probationary Period is to be resumed and under what terms; or
 - ii. the Board and Village Fertility 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.

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 February 2013 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.

10. Village Fertility agrees that if the Board suspends its pharmacy license in accordance with Paragraph 9, it will immediately return its current Massachusetts pharmacy license to the Board, by hand or certified mail. Village Fertility 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.
11. Village Fertility 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.
12. The Licensee acknowledges that it has been represented by legal counsel in connection with the Complaint and this Agreement.
13. 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.

14. 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.

Village Fertility Pharmacy, Inc.

Vicki Payer 8-12-13
Witness (sign and date)

[Signature] Levine 8-12-13
Signature and Date

SYUARD LEVINE
Print Name
Village Fertility

Margy Cittadino (HAE)
Margaret Cittadino
Associate Director
Board of Registration in Pharmacy

8-19-13
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 8-20-13 by
Certified
Mail No. 7012 3460 0001 7330 9743