

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

_____ )	
In the Matter of )	Docket Nos. PHA-2011-0286
PALLIMED SOLUTIONS, INC. )	PHA-2012-0045
)	PHA-2013-0046
Drug Store Reg. No. DS 3498 )	PHA-2012-0237
Registration expired 12/31/13 )	PHA-2013-0017
_____ )	

**VOLUNTARY SURRENDER AGREEMENT**

The Massachusetts Board of Registration in Pharmacy ("Board") and Pallimed Solutions, Inc. a pharmacy licensed by the Board (Reg. No. DS3498), and formerly located at 400 West Cummings Park in Woburn, Massachusetts ("Pallimed" or "Pharmacy"), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the record maintained by the Board and relating to the Pharmacy:

1. Pallimed and the Board enter into this Voluntary Surrender Agreement ("Agreement") to resolve the following complaints against the Pharmacy currently pending before the Board: PHA-2011-0286, PHA-2012-0045, PHA-2012-0046, PHA-2012-0237 and PHA-2013-0017.
2. The Board and the Pharmacy acknowledge and agree that the complaints allege the following facts:
  - a. PHA-2011-0286  
The Pharmacy filled (or refilled), compounded, and dispensed prescriptions for "HCG" in September and October of 2011 which were contaminated and which resulted in the patient having pyrogenic reactions when the medications were administered.
  - b. PHA-2012-0045  
The Pharmacy improperly compounded a solution of injectable Lidocaine in February of 2012 which resulted in the Pharmacy dispensing a prescription with the incorrect potency of the medication and causing the patient to suffer harm and be hospitalized (Patient A);

c. PHA-2012-0046

The Pharmacy improperly compounded a solution of injectable Lidocaine in February of 2012 which resulted in the Pharmacy dispensing a prescription with the incorrect potency of the medication and causing the patient to suffer harm and be hospitalized (Patient B);

d. PHA-2012-0237

In and around 2012, the Pharmacy improperly advertised its compounding services and regularly compounded drugs to fill prescriptions that did not specify that a compounded version of the drug was necessary and/or dispensed compounded medications when a commercially produced version of the drug was available. Additionally, the Pharmacy used Sildenafil Citrate designated by its supplier as being for veterinary use in tablets prepared for human consumption.

e. PHA-2013-0017

A 2012 audit determined that the Pharmacy violated standards of practice relating to sterile compounding including, but not limited to, record-keeping failures, inadequate quality assurance policies, and evidence of failure to produce thorough root cause analysis reports. Additional violations including the presence of fifty-six (56) contaminated vials of compounded drugs necessitating a recall of medications from multiple states were identified in early 2013.

3. The Pharmacy acknowledges that sufficient evidence exists such that, if the matters were to proceed to a hearing, the Board could reasonably find that it violated Board regulations including, but not limited to, provisions of 247 CMR 6.02, 9.01 and 10.03.
4. The Pharmacy further acknowledges that in or around May of 2013, it ceased its operations.
5. The Pharmacy hereby voluntarily tenders the surrender of its pharmacy registration (Reg. No. DS 3498) to the Board in resolution of the above-referenced complaints and agrees that said surrender shall become effective immediately upon the execution of this agreement by a duly authorized representative of the Board.
6. The Board hereby accepts the Pharmacy's surrender of its registration and agrees not to advance the prosecution of the above-referenced complaints as consideration for the surrender.

7. The Pharmacy understands and agrees that the decision to enter into this Agreement and to accept any terms and conditions described herein is a final act and is not subject to reconsideration or judicial review.
8. The Pharmacy has consulted legal counsel in connection with the decision to enter into this Agreement.
9. The Pharmacy understands that by executing this agreement it is knowingly waiving any and all rights to a formal hearing during which the Pharmacy would possess the right to call witnesses, to confront and cross-examine witnesses, to present evidence, to provide testimony on its own behalf, to contest the allegations, to present oral argument, to appeal to court in the event of an adverse ruling and all other rights set forth in G.L. c. 30A and 801 CMR 1.01 et. seq. The Pharmacy acknowledges and agrees that executing this document entitled "Voluntary Surrender Agreement" constitutes a knowing and voluntary waiver of any and all rights to a formal hearing and to all of the above-listed rights.
10. The individual signing this document on behalf of the Pharmacy certifies that he is the owner of the Pharmacy (or is properly authorized to act on behalf of the ownership of the pharmacy) and acknowledges that he has read this Agreement, is signing it voluntarily on behalf of the Pharmacy and understands that the Pharmacy's surrender of its registration is a final act and not subject to reconsideration, appeal, or judicial review.

Pallimed Solutions, Inc.

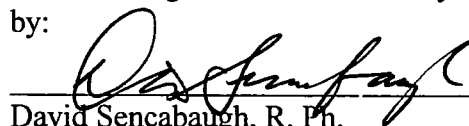
by:

 9/19/2015  
James E. Nahill, R. Ph. Date

Title: \_\_\_\_\_

Board of Registration in Pharmacy

by:

 9/23/2015  
David Sencabaugh, R. Ph. Date

Executive Director

Effective Date of Agreement: 9/23/2015