

**STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATIONS**

**DEPARTMENT OF HEALTH
HEALTH SERVICES REGULATION
BOARD OF PHARMACY**

**In the Matter of:
PHARMERICA
LICENSE #PHA00446, CPHA00446**

CONSENT ORDER

Pursuant to Rhode Island General Laws § 5-19.1-21 and the Rules and Regulations promulgated thereunder, the Department of Health (Department), Board of Pharmacy (Board) has investigated a complaint charging PharmERICA (Respondent), with violations of RIGL § 5-19.1-21 and § 27 of the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors*. After consideration by the Board, the following constitutes the Findings of Fact with respect to the professional performance of the Respondent:

1. Respondent is licensed as a retail pharmacy in the State of Rhode Island and holds license number PHA00446 and controlled substances registration CPHA00446.
2. Respondent has a registered location of 83 Vermont Avenue, Unit 2, Warwick, RI and operated as a retail pharmacy at all relevant times outlined below.
3. On January 4, 2013 the Department conducted an inspection of Respondent pharmacy at its registered location of 83 Vermont Avenue, Unit 2, Warwick, RI and observed the following:
 - Respondent, on days and dates between 12/28/12 and 1/4/13, permitted individuals who were licensed Massachusetts Pharmacy Technicians to practice as pharmacy technicians and engage in the compounding of sterile pharmaceutical compounds at its registered location without being licensed in Rhode Island in violation of R5-19.1-PHAR-27.1(9).
 - Respondent failed to maintain the anteroom and sterile room in a clean, sanitary, and orderly manner to the degree mandated by R5-19.1-PHAR-13.4.

- Respondent failed to conduct environmental surface and air monitoring for viable microorganisms on a monthly basis as required for medium risk sterile compounding in violation of R5-19.1-PHAR-19.28.
 - Respondent failed to submit documentation that the sterile compounding anteroom met the minimum standards of an ISO class 8 environment in violation of R5-19.1-PHAR-19.26.
 - Respondent failed to conduct and maintain annual training competencies for staff performing sterile compounding prior to 2012 in violation of R5-19.1-PHAR-19.19.
 - Respondent, on days and dates between October, 2009 and April, 2010, had a contractual relationship with MedCall for the filling of after-hour prescriptions for patients in residential long-term care facilities for which it failed to obtain approval from the State of Rhode Island.
4. On January 10, 2013 the Department issued an Immediate Compliance Order on Respondent, prohibiting the compounding and distribution of any and all sterile compounded preparations.
 5. Pursuant to § 5-19.1-21, this conduct constitutes unprofessional conduct in the State of Rhode Island.

Based on the foregoing, the parties agree as follows:

1. Respondent is a retail pharmacy that is licensed and able to conduct business under the laws of the State of Rhode Island.
2. Respondent admits to the jurisdiction of the Department and hereby agrees to remain under the jurisdiction of the Department.
3. Respondent has read this Consent Order and understands that it is a proposal of the Department and is subject to the final ratification by the Department. This Consent Order and the contents thereof are not binding on Respondent until final ratification by the Department.
4. Respondent hereby acknowledges and waives:

- a) The right to appear personally or by counsel or both before the Department;
 - b) The right to produce witnesses and evidence in its behalf at a hearing;
 - c) The right to cross-examine witnesses;
 - d) The right to have subpoenas issued by the Department;
 - e) The right to further procedural steps except for those specifically contained herein;
 - f) Any and all rights of appeal of this Consent Order;
 - g) Any objection to the fact that this Consent Order will be presented to the Department for consideration and review;
 - h) Any objection to the fact that it will be necessary for the Department to become acquainted with all evidence pertaining to this matter in order to adequately review this Consent Order;
 - i) Any objection to the fact that the Department reviewing this Consent Order may be the same as the hearing committee presiding over this matter should it later be brought to an administrative hearing; and
 - j) Any objection to the fact that potential bias against the Respondent may occur as a result of the presentation of this Consent Order to the Department.
5. This Consent Order shall become part of the public record of this proceeding once it is accepted by all parties and accepted by the Department.
6. Acceptance by the Respondent and approval by the Department of this Consent Order constitutes an admission of the facts contained herein.
7. Effective upon the date of ratification of this consent order by the Department, and fulfillment of any and all stipulations required herein, the Immediate Compliance Order issued against Respondent on January 10, 2013 shall be vacated.
8. Respondent agrees to a two (2) year period of probation of its retail pharmacy license. The probationary term is to commence upon ratification of this Order by

the Board and will abate for the duration of any period in which Respondent ceases to operate as a retail pharmacy in this State.

9. Respondent shall retain a third party compliance monitor (monitor) consistent with a proposal as approved in advance by the Department, which shall include, at minimum, on site monitoring services to the Respondent's practice as a retail pharmacy during the two (2) year period of probation.
 - a. On site monitoring shall consist of a minimum of eight (8) hours monthly and shall be unannounced and shall occur during any of Respondent's operating hours.
 - b. All fees and expenses of the monitoring program shall be paid by the Respondent.
 - c. All reports and findings by the monitor of Respondent's practice shall be forwarded to the Department on a monthly basis.
10. Prior to commencement of monitoring services, the Department must review and approve the proposal between the monitor and Respondent including the individual(s) who shall be conducting on site monitoring services.
11. The Department shall have the authority to change the frequency of on-site monitoring services based upon Respondent's compliance, or lack thereof, with all State and Federal laws and regulations governing the practice of pharmacy in this State.
12. Respondent shall, in writing, request relief from probation in order to return to active unrestricted status upon completion of the two (2) year period of probation. Once Respondent's request is approved by the Department, Respondent may return to full and unrestricted status provided that it operates in conformity with all laws and regulations governing the practice of pharmacy in this State.
13. Respondent agrees to a Formal Reprimand of its retail pharmacy license.
14. That should Respondent violate the terms of this Consent Order, Respondent shall be subject to further disciplinary sanctions.

PHARMERICA
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8/19/13
Date

Heidi Kari
Pharmerica
License # PHA00446 & CPHA00446

9/19/13
Date

Jonathan M. Mundy
Jonathan M. Mundy, RPh
Chairperson
Rhode Island Board of Pharmacy

Approved on this 11 day of October, 2013

Michael Fine
Michael Fine, MD
Director of Health
Rhode Island Department of Health