

**STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATIONS**

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

**In the Matter of:
MILLENNIUM PHARMACY
Pharmacy License Nos. PHA00516, CPHA00516**

CONSENT ORDER

Pursuant to Rhode Island General Laws § 5-19.1-21 and the Rules and Regulations promulgated thereunder, the Department of Health and Board of Pharmacy (hereinafter "Department") has investigated a complaint alleging that Millennium Pharmacy (hereinafter "Respondent") committed civil violations of Rhode Island General Laws § 5-19.1-21 and the Rules and Regulations. After consideration by the Department, the following constitutes the Finding of Facts with respect to the professional performance of the Respondent:

1. Respondent is a retail pharmacy licensed to operate in the State of Rhode Island and has a registered location of 33B Appian Way, Smithfield, Rhode Island.
2. Respondent holds license number PHA00516 and Rhode Island Controlled Substances Registration number CPHA00516.
3. Based on a September 6, 2012, inspection by the Department, concerns were observed in the following areas:
 - Distribution of adulterated and misbranded drugs,
 - Holding for dispensing and sale adulterated and misbranded drugs,
 - Accepting returned controlled substances and legend drugs from end users,
 - Permitting pharmacy technicians to perform final verification of prescription refills,

- Dispensing of drugs without receiving a prescription fulfilling all requirements of R5-19.1-PHAR-8.4,
 - Failure to notify the Department and U.S. Drug Enforcement Administration of a suspected or potential loss of controlled substances within 24 hours of discovery,
 - Failure to maintain a mechanism to identify on the prescription label the names of the delivery and central fill pharmacy involved with dispensing prescriptions, and
 - Failure to maintain records of completed technician training.
4. On October 9, 2012, the Department ordered that Millennium Pharmacy cease any and all operations of a retail pharmacy and suspended license number PHA00516 and controlled substances registration number CPHA00516.
 5. Pursuant to Section 5-19.1-21, the above conduct constituted unprofessional conduct.

Based on the foregoing, the parties agree as follows:

1. Respondent admits to the jurisdiction of the Department and hereby agrees to remain under the jurisdiction of the Department.
2. 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.
3. Respondent hereby acknowledges and waives:
 - a) The right to appear personally or by counsel or both before the Department on the underlying complaint;
 - 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.
4. 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.
5. Acceptance by the Respondent and approval by the Department of this Consent Order does not constitute an admission of the facts contained herein.
6. The Summary Suspension heretofore issued against Respondent is hereby vacated as of the date of the Department's approval of this Consent Order, and Respondent may resume practice and operations as a retail pharmacy subject to the following requirements:
- a) Respondent shall retain Affiliated Monitors, Inc. (hereinafter "AM") consistent with a proposal as approved in advance by the Department, which shall include, at minimum, chaperoning program and monitoring services to the Respondent's practice, twice weekly for the first three months, and if all is going well, then once per month for a period of a period of twelve (12) months, and if all is going well, then once every three months for a period of nine (9) more months; and includes unannounced inspections at any time.

- b) All fees and expenses of the monitoring program shall be paid by the Respondent.
 - c) Provided that Respondent is operating in compliance with all State and Federal laws and regulations, the Department may change the frequency of chaperoning and monitoring.
 - d) The Department shall have the authority to change the frequency of on-site chaperoning and 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.
- 7. Respondent shall be linked to and shall utilize the state Prescription Monitoring Program.
 - 8. With regard to non-controlled medications, every prescription order shall be readily retrievable and satisfy the requirements for prescriptions pursuant to Pharmacy and Long Term Care statutes and regulations; and such orders may be either hard copies or be received electronically according to state statute and regulations.
 - 9. With regard to controlled substance prescriptions, every order shall be readily retrievable and satisfy the requirements for such prescriptions pursuant to federal and state controlled substances statutes and regulations.
 - 10. With regard to emergency dispensing of any controlled substance, every prescription shall be readily retrievable and satisfy the requirements for such prescriptions pursuant to federal and state controlled substances statutes and regulations.
 - 11. Every non-controlled prescription order shall be dispensable for no longer than one year after the prescription is written, and a system shall be in place to ensure that the prescription is not honored after the 365th day; and a new order must be requested just prior to the end of the 365 days if still needed.
 - 12. Every Schedule III to V controlled substance shall be dispensable for no longer than 180 days after the prescription is written, and a system shall be

in place to ensure that the prescription is not honored after the 180th day; and a new order must be requested just prior to the end of the 180 days if still needed.

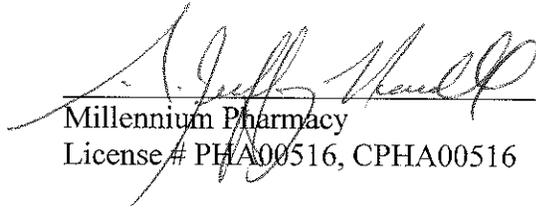
13. Every Schedule II controlled substance shall be dispensable for no longer than 90 days after the prescription is written, and a system shall be in place to ensure that the prescription is not honored after the 90th day; and a new order must be requested just prior to the end of the 90 days if still needed.
14. Respondent shall no longer accept returned prescription medications once dispensed to the end user, and thus shall no longer redistribute them upon return, unless in accordance with prevailing rules and regulations, which allows for return of any medications that are not adulterated and have been rejected by any nursing home at the time of delivery; but Respondent shall be permitted to accept the return of any manufacturer-packaged or -sealed medications within fourteen (14) days of dispensing. Any returned medications not manufacturer-packaged or sealed shall not be dispensed any later than sixty (60) days after their return, or any later than their expiration date, whichever is later.
15. All canisters placed in the automated dispensing machines may be filled by pharmacy technicians but must be verified by a Rhode Island-registered pharmacist; and all medications that are dispensed by the machines shall be verified by a Rhode Island-registered pharmacist, and a log shall be kept so that each prescription and the pharmacist who validated it is tracked and readily retrievable.
16. Respondent shall maintain a perpetual inventory of all schedule II controlled substances for a period of five (5) years effective upon date of ratification of this Order by the Department. Said perpetual inventory shall be maintained at Respondent's registered location and be available for review by the Department. Respondent shall notify the Department of Health and the United States Drug Enforcement Administration in writing

about any significant suspected or unexplained loss or diversion within twenty four (24) hours.

17. Prescription medications shall not be obtained, purchased or dispensed from any wholesaler or manufacturer who is not licensed in Rhode Island. Bulk-compounded medications shall be ordered from a Rhode Island-licensed manufacturer.
18. Respondent may not store or dispense any prescription medications dispensed or compounded by another pharmacy.
19. Respondent shall not act as a prescriber for prescriptions of medications to another pharmacy if they have not previously been filled by Respondent.
20. Respondent shall not dispense any medications that are expired.
21. Respondent shall conduct and maintain readily retrievable records of technician training that satisfy the state's pharmacy rules and regulations.
22. Respondent shall identify on all prescription labels the names of the delivery and central fill pharmacies involved in dispensing prescriptions.
23. Respondent agrees to a two (2) year period of probation of its retail pharmacy license and controlled substances registration. The probationary term is to commence upon ratification of this Order by the Department and will remain in full effect pending any further order or action of the Department.
24. That should Respondent fail to comply with the laws and regulations governing the practice of pharmacy during its two (2) year probationary term, it shall face further disciplinary action.
25. 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 continues to be in conformity with all laws and regulations governing the practice of pharmacy in this State.
26. That in the event that the Department alleges that Respondent has violated the terms of this Consent Order, the parties shall meet forthwith to discuss

the allegation and possible remedies to forestall any potential suspension. However, if the Director of the Department of Health suspends Respondent for the alleged violation, Respondent shall have the right to an administrative hearing within forty-eight (48) hours. In the event that the Department institutes non-emergency disciplinary proceedings, Respondent shall be entitled to a hearing within twenty (20) days on the issue of the violation of this Consent Order, and the finding of facts enumerated in the first section above shall not be subject to relitigation between the parties to this Consent Order but may be noticed and considered by the hearing officer and appellate court who hear any violation allegation.

10/12/2012
Date


Millennium Pharmacy
License # PHA00516, CPHA00516

Approved on this 10 day of October, 2012.


Michael Fine, M.D.
Director
Rhode Island Department of Health