

**STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATIONS**

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

VS

MILLENNIUM PHARMACY (LICENSE #PHA00516, CPHA00516)

SUMMARY SUSPENSION

The Rhode Island Board of Pharmacy (hereinafter "Board") has investigated a complaint regarding the professional pharmacy activities of Millennium Pharmacy (hereinafter referred to as "Respondent") located at 33B Appian Way, Smithfield, Rhode Island.

The Board of Pharmacy and the Office of the Director of Health make the following:

Findings of Fact

1. Respondent is licensed as a retail pharmacy in the State of Rhode Island and holds license number PHA00516 and Rhode Island Controlled Substances Registration number CPHA00516.
2. Respondent has a registered location of 33B Appian Way, Smithfield, RI.
3. Respondent has been in operation and has conducted pharmacy business during all relevant times outlined below.
4. The Board conducted an inspection of Millennium Pharmacy on September 6, 2012 and determined the following:
 - **Distribution of adulterated and misbranded drugs in violation of RIGL 21-31-3 and R5-19.1-PHAR-8.3.3.** Inspection revealed the routine procedure of pharmacy staff repackaging prescription drugs into improperly labeled containers, including plastic "sandwich baggies", which did not include lot#, expiration date, or other required labeling. In addition, inspection revealed the routine procedure of pharmacy staff removing prescription drugs from multi-drug single dosing packages and re-stocking inventory with these items. Subsequent interviews with pharmacy staff revealed that the aforementioned misbranded and adulterated prescription drugs were further re-dispensed to patients at nursing facilities in Rhode Island and other States.

- **Holding for dispensing and sale adulterated and misbranded drugs in violation of R.I. Gen Laws 21-31-3 and R5-19.1-PHAR-8.3.3.** Inspection revealed the presence of a significant and excessive quantity of misbranded and adulterated drugs in Millennium's dispensable inventory. Inspection revealed the presence of improperly labeled plastic "sandwich baggies", improperly labeled amber bottles with hand written labels, compounded prescription medications dispensed from other retail pharmacies and a significant quantity of expired stock medications.
- **Accepting controlled substances and legend drugs for return from end users in violation of R5-19.1-PHAR-8.0.** Inspection revealed the routine procedure of pharmacy staff accepting previously dispensed legend prescription drugs and controlled substances for return from end-users at nursing facilities in Rhode Island and other States. Inspection and subsequent interviews with pharmacy staff revealed a routine procedure of re-dispensing these returned medications to patients in nursing facilities in Rhode Island and other States.
- **Permitting pharmacy technicians to perform final verification of prescription refills in violation of R5-19.1-PHAR-24.14.2 and R5-19.1-PHAR-24.17.** Inspection revealed the routine procedure of pharmacy technicians performing final verification, product verification, and dispensing process validation of refilled legend prescription drugs. Inspection and subsequent interviews with pharmacy staff revealed that pharmacy technicians are delegated authority to perform final prescription validation for refilled medications.
- **Dispensing of drugs without receiving a valid prescription fulfilling all requirements of R5-19.1-PHAR-8.4.** Inspection and subsequent interviews with pharmacy staff revealed the routine procedure of Millennium dispensing legend prescription drugs without obtaining or reviewing a valid prescription which satisfies all requirements of R5-19.1-PHAR-8.4.
- **Failure to notify the Board and U.S. Drug Enforcement Administration of a suspected or potential loss of controlled substances within 24 hours of discovery in violation of 21 CFR 1301.76(b) and R.I. Gen Laws 21-28-3.04(2).**
- **Failure to maintain a mechanism to identify on the prescription label the names of the delivery and central fill pharmacy involved with dispensing prescriptions in violation of R5-19.1-PHAR-22.2.4.**
- **Failure to maintain evidence of active licensure for all pharmacy staff in violation of R5-19.1-PHAR-9.4.**
- **Failure to provide at the time of inspection a copy of completed technician training in violation of R5-19.1-PHAR-24.19.1(3).**

5. On October 1, 2012 Board Inspectors performed a second inspection of Millennium Pharmacy where the Pharmacist-In-Charge, and other pharmacy staff members, did obstruct the ability of inspectors to secure samples of potentially misbranded medication in violation of RIGL § 21-31-3(6) and R5-19.1PHAR-27.1(8). Eye witness testimony demonstrates the Pharmacist-In-Charge hid and or conspired to hide suspected misbranded medications held in the dispensable inventory moments prior to Inspectors entering the secured area of the pharmacy.

ORDER

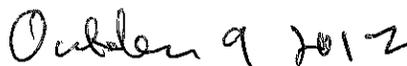
Based upon the foregoing, the Director of Health has determined that the continued operation of Millennium Pharmacy constitutes an immediate danger to the public. Accordingly, the retail pharmacy license and corresponding controlled substances registration of Millennium Pharmacy is hereby **suspended forthwith**. Said suspension shall continue indefinitely pending further Order of the Department of Health.

It is further ordered by the Director of Health, that Millennium Pharmacy fully cooperate with any and all plans to transition and maintain continuity of care for patients directly or indirectly serviced by Millennium Pharmacy.

Respondent is entitled to an administrative hearing in accordance to Rhode Island General Law § 42-35-14(c).



Michael Fine, MD
Director
Rhode Island Department of Health



Date

CERTIFICATION

I hereby certify that a copy of this ORDER was hand-delivered to

A. Jeffrey Newell on this 9th day of October at the following address:

Millennium Pharmacy
33B Appian Way
Smithfield, RI 02917

Millennium Pharmacy

Patricia Reynolds
witness

MARZ
witness