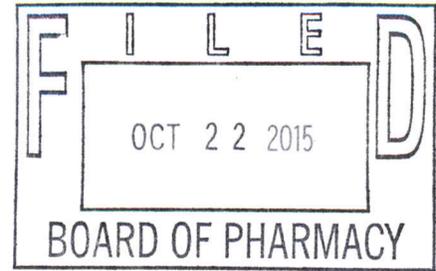


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STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF
THE REGISTRATION OF

WEDGEWOOD VILLAGE PHARMACY, INC.
Registration No.: 28RS00316800

Administrative Action

CONSENT ORDER

TO OPERATE A PHARMACY
IN THE STATE OF NEW JERSEY

This matter was opened to the New Jersey Board of Pharmacy ("the Board") upon receipt of reports of inspection of the facility at Wedgewood Village Pharmacy, Inc. ("Wedgewood") which occurred on November 14 and 15, 2012. The reports document potential violations of the Board's regulations regarding sterile compounding. Wedgewood engages in high risk sterile compounding.

Among other things, the inspection reports highlighted routine professional practices suggesting that thousands of units of medication were dispensed with disregard for the following regulatory requirements:

- Use-by dates exceed 30 days after preparation in violation of N.J.A.C. 13:39-11.11.
- Failure to include date and time of preparation on prescription labels in violation of N.J.A.C. 13:39-11.10(a)(1).
- Failure to include the use-by date and use-by time on prescription labels as required by N.J.A.C. 13:39-11.10(a)(7).

No evidence of contamination was found. Wedgewood denies the allegations of violations and has been fully cooperative with the Board's investigation. There have been significant changes in management of Wedgewood since the time of the events in question. The pharmacy permit holder at the time of these events is now deceased and his wife now holds the permit. Wedgewood has agreed to replace the registered pharmacist-in-charge. Wedgewood represents that it is now in compliance with New Jersey statutes and regulations and with the USP guidelines. Wedgewood further represents that 100% of all sterile compounds are currently being tested for sterility and that all use-by dates are properly supported. Accordingly, the Board has determined that the monitoring requirements imposed herein are sufficient to protect the public health, safety and

welfare.

The parties, having agreed to resolution of this matter without formal proceedings, and Wedgewood, having agreed and given voluntary consent to the within order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 22nd day of OCTOBER, 2015,

ORDERED AND AGREED that

1. Wedgewood shall contract with a third-party monitor (the "Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. For the purposes of this Order, LDT Health Solutions, Inc. is an approved Monitor. Within 30 days of the entry of this Order, the Monitor shall furnish the Board directly with a report which demonstrates review of all processes and procedures, and attests to compliance with all Board regulations and USP standards. Wedgewood shall conduct environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi and make these test results available to the Monitor prior to the Monitor issuing its report and directly to the Board. Wedgewood shall continue to contract with the Monitor and the Monitor will submit reports directly to the Board on the first day of each month until the Monitor

reports directly to the Board that Wedgewood has complied with all recommendations made by the Monitor and is operating in full compliance with all Board regulations and USP standards. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Wedgewood.

2. Within 30 days of the entry of this order, Wedgewood shall appoint a new pharmacist-in-charge and shall ensure that a pharmacist with sterile compounding expertise (either the pharmacist-in-charge or another employee) directly supervises the daily sterile compounding operations to further ensure the quality and integrity of their products. "Directly supervise" for the purpose of this paragraph means ensure that all proper checks and balances are being performed during the compounding process; help identify and eliminate errors and mistakes; ensure training and testing of personnel testing is occurring; and generally help to ensure that proper aseptic technique is being used to help implement a Quality System and Environment to produce compounded sterile product.

3. Prior to hiring any pharmacist-in-charge or pharmacist to directly supervise daily sterile compounding operations, Wedgewood shall ensure that the individual is competent and that his/her license is not restricted in such a way as to preclude them from fulfilling their job responsibilities.

Wedgewood shall not hire an individual to be pharmacist-in-charge or to directly supervise the daily sterile compounding operations if Wedgewood is aware that the individual is subject to a pending Board investigation.

4. Wedgewood agrees to pay the Board the sum of \$500,000.00 in two equal installments due on or before November 31, 2015 and December 31, 2015. This payment will reimburse the Board for attorney's fees and investigative costs and the remainder will be applied toward the Board's ongoing efforts to inspect, investigate and educate pharmacies involved in sterile compounding. Wedgewood and the Board acknowledge and agree that the payment described herein is not a fine, sanction, warning letter or penalty, or payment in lieu thereof. Payment shall be made by bank check, money order, wire transfer or credit card made payable to the New Jersey Board of Pharmacy.

5. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability of the pharmacy.

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr. RPh
Thomas F.X. Bender,
R.Ph., President

I have read the within
Order and understand it. I
agree to be bound by its
terms and hereby consent to
it being entered by
the New Jersey Board of
Pharmacy.

Ludmilla P Malmberg
Ludmilla P Malmberg, Owner
and Permit Holder of
Wedgewood Village Pharmacy

Consent as to form and
entry:

Angelo Cifaldi
Angelo Cifaldi, Esq.
Attorney for
Wedgewood Village Pharmacy