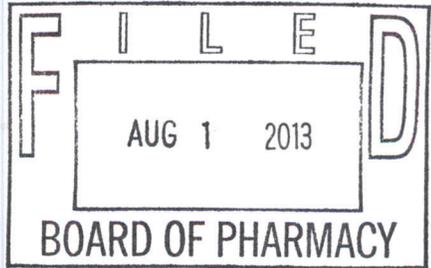


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STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF THE SUSPENSION
OR REVOCATION OF THE LICENSE OF

Administrative Action
FINAL CONSENT ORDER

STEPHEN W. KALINOSKI, R.P.H.
License No. 28RI02241200

TO PRACTICE PHARMACY IN THE
STATE OF NEW JERSEY

This matter was opened to the New Jersey State Board of Pharmacy (hereinafter the "Board") on March 15, 2013, upon receipt of information from MedPrep Consulting, Inc., a pharmacy located at 1540 West Park Avenue, Suite 5, Tinton Falls (hereinafter "MedPrep"), that it voluntarily recalled all magnesium sulfate products compounded at its facility. It subsequently expanded the recall to include all of its products. The recall resulted from MedPrep being

notified by Yale New Haven Hospital that it observed visible particulate contaminants in 50 ml bags of magnesium sulfate intravenous solution belonging to unique and distinct lots compounded and dispensed by MedPrep only to Yale New Haven Hospital. As of this date, no injuries or illness attributable to the contamination has been reported.

At all relevant times Stephen W. Kalinoski, R.PH. ("Kalinoski"), license No. 28RI02241200, was the Registered Pharmacist in Charge ("RPIC") of MedPrep. Gerald Tighe ("Tighe") was the sole owner of MedPrep.

MedPrep and the Board entered into a Voluntary Interim Consent Order filed March 15, 2013 in which MedPrep agreed to refrain from and stop all pharmacy operations through the close of business on Friday, March 22, 2013. Said Order was then extended to April 5, 2013 and again to April 12, 2013.

MedPrep has voluntarily refrained from engaging in compounding activities from March 15, 2013, and it cooperated with an investigation and physical inspection by the Board.

That investigation revealed alleged deficiencies in the labeling of compounded sterile products; product testing; sterility of the cleanroom; assignment of beyond

use dates; compounding recordkeeping (audit trail) and documentation; the ratio of pharmacists to pharmacy technicians; and the filing of joint centralized prescription handling agreements.

MedPrep provided to the Board reports from experts in the field, laboratory data, a summary of corrective measures taken since the recall, and other pertinent information.

On or about April 10, 2013, MedPrep applied for immediate relief from the shutdown order. On April 12, 2013 and April 15, 2013, a Committee of the Board held a hearing on MedPrep's application. The Attorney General opposed the application and cross-moved for the continued closure of the facility. The Attorney General submitted a Certification from Enforcement Bureau Investigator Tony Qi with numerous attachments; a Certification from EB Investigator Leida Martinez with statements from MedPrep personnel attached; a Certification from Executive Director Anthony Rubinaccio; a Certification from DAG Jodi Krugman with numerous attachments. MedPrep also submitted voluminous documentation of its plan for remediation, compliance with all regulations and standards applicable to sterile compounding in New Jersey, and the expert reports of consultants who provided guidance for implementing best

practices. The Committee of the Board heard testimony from MedPrep President Gerald Tighe; Louis Diorio, R.Ph., principal of LDT Health Solutions, Inc., the expert/consultant hired by MedPrep; FDA Investigator Barbara Wilimczyk-Macri; David Newton, Ph.D., the expert for the State; and Enforcement Bureau Investigators Qi and Martinez.

The Committee of the Board heard argument from counsel and deliberated before issuing a verbal Order on April 15, 2013 denying the Attorney General's cross motion and identifying numerous conditions and prerequisites for a graduated, limited re-opening.

The Attorney General moved for reconsideration based on newly acquired information. The Committee of the Board granted the motion in part, modifying its Interim Order to require prior to re-opening, among other things, a report from the monitor advising of the training of all employees and testing performed at the facility, subject to further order of the full Board. The Order was memorialized in an Interim Order and Report of Hearing Committee ("Interim Order") filed April 19, 2013. The Interim Order permitted MedPrep, subject to approval of the Board after submission of a monitor's report, to gradually re-open with numerous protections, conditions and requirements including

additional training, reduced personnel, enhanced oversight by a dedicated cleanroom supervisory pharmacist, an on-site independent outside monitor, and increased reporting and notification procedures, among other reforms.

The Attorney General submitted an application filed April 22, 2013, for supplementation of the Interim Order proposing fourteen additional protections for inclusion. Also on April 22, 2013, the Attorney General filed an eight count Administrative Complaint against MedPrep and Kalinoski.

At its monthly meeting on April 24, 2013, the Board issued an oral Order, placed on the record, ratifying the Interim Committee Order with clarifications and supplemental conditions. On April 25, 2013, the Attorney General filed a First Amended Complaint against both MedPrep and Kalinoski which added a ninth count alleging violations of the Board's central fill regulation.

On May 2, 2013, the Board filed an Order requiring MedPrep to satisfy enumerated conditions prior to re-opening. On May 7, 2013, the Board advised MedPrep that it could re-open on a limited basis subject to the conditions set forth in its May 2, 2013 Order.

The Board finds that the violations which occurred while Kalinoski bore responsibility as the RPIC created

potential risks to the public as set forth in the Amended Complaint. The Amended Complaint alleges inter alia deficiencies in the labeling of compounded sterile product; product testing; the sterility of the cleanroom; the assignment of beyond use dates; compounding recordkeeping, (audit trail) and documentation; the ratio of pharmacists to pharmacy technicians; and the filing of joint centralized prescription handling agreements.

N.J.A.C. 13:39-11.5(a) and 13:39-6.2 define the responsibilities of the registered pharmacist in charge to insure a safe environment and the adequacy of procedures for compounding of sterile product.

The Attorney General's allegations, if established, provide grounds to take disciplinary action against Kalinoski's license to practice pharmacy in New Jersey.

Kalinoski, being desirous of resolving this matter without the necessity of further formal proceedings, and having waived any right to same, and having agreed and given their voluntary consent to the within Order, without admission of liability or wrongdoing, 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 1 day of ^{August} ~~July~~, 2013,
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ORDERED AND AGREED that

1. Respondent Kalinoski's license to practice pharmacy in the State of New Jersey is suspended for a total period of five years with the first nine months to be served as a period of active suspension beginning March 15, 2013, and the balance to be served as a period of probation. During the entire five-year period of his suspension, he shall not have any ownership interest in any pharmacy in the State of New Jersey.

2. During the period of active suspension, Kalinoski shall cease and desist from engaging in the practice of pharmacy in the State of New Jersey, which includes, but is not limited to the following: he shall not handle, order, inventory, compound, count, fill, refill or dispense any drug; he shall not handle anything requiring a prescription, including devices and medications; he shall not handle prescriptions; he shall not advise or consult with patients, and he is prohibited from being present within any area of a pharmacy which is not open to the general public, including, but not limited to a prescription filling area of a pharmacy.

3. During the entire period of probation, Kalinoski shall not serve as an RPIC, a preceptor or have any ownership interest in a pharmacy in the State of New Jersey involved in the compounding of sterile product.

During a three year period beginning March 15, 2013, Kalinoski shall not serve as an RPIC, a preceptor or have any ownership interest in a pharmacy in the State of New Jersey.

4. In the event that Kalinoski serves as a RPIC, a pharmacist or a preceptor at a pharmacy involved in compounding sterile product, and/or he obtains an ownership interest in any pharmacy located outside of the State of New Jersey during the period of the active suspension imposed by this agreement, the active suspension will be tolled until such time as Kalinoski ceases serving in such positions or relinquishes an ownership interest.

5. Kalinoski shall pay administrative fines in the amount of \$10,000 to the Board for violations committed while the RPIC at MedPrep. Payment will be due in twelve installments beginning June 15, 2014 in the amount of \$833 per month for eleven months and the in the amount of \$837 the final twelfth month of payments. Payment shall be made by check or money order made payable to the New Jersey Board of Pharmacy and mailed to the New Jersey State Board of Pharmacy, ATTN: Anthony Rubinaccio, Executive Director, 124 Halsey Street, P.O. Box 45013, Newark, New Jersey 07101.

6. Prior to resuming the active practice of pharmacy, Respondent Kalinoski shall:

a. Appear before the Board or a committee thereof to discuss his readiness to reenter the practice of pharmacy. At that time respondent shall be prepared to propose his plans for future practice in New Jersey and demonstrate compliance with this Order and evidence of rehabilitation to the Board's satisfaction. Following this appearance, the Board shall decide in its discretion whether Respondent should be permitted to reenter practice in the manner he proposes.

b. Complete the NABP Pharmacist Assessment for Remediation Evaluation (PARE) Exam, for the Board's review and follow any recommendations of the Board based on his performance on the PARE Exam.

c. Provide documentation of his successful completion of twelve continuing education credits, including one course each in recordkeeping, ethics, and compounding procedures. The courses must be pre-approved by the Board and may not be counted towards the continuing education credits required for license renewal. Successful completion means that all sessions were attended, all assignments were properly and appropriately completed, and a passing grade was achieved which was unconditional and without reservation.

e. Provide documentation of successful completion of all continuing education credits required by N.J.A.C. 13:39-3A.1- 13:39-3A.7.

f. Provide documentation of successful completion of all application requirements including a Criminal History Background Check and payment of all reinstatement fees.

g. Provide documentation that he has paid the penalty pursuant to this Order and that he has no outstanding costs or penalties due to the Board.

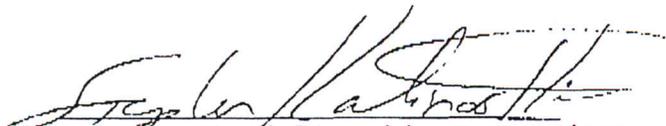
h. Upon reinstatement of Kalinoski's license to practice pharmacy, the Board, in its discretion, may impose any conditions or restrictions on licensure it deems necessary to protect the public health, safety and welfare.

7. The entry of the within Order is without prejudice to the further investigation and/or prosecution by any other regulatory or law enforcement agency, including the Division of Consumer Affairs for the State of New Jersey or other State agency, of any violations by MedPrep, its principal or employees including but not limited to Kalinoski, whether or not currently under investigation.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Thomas F.X. Bender, R.Ph.
President

I have read the within Order,
understand its terms and agree
to be bound by them. I
consent to entry of the Order
by the Board of Pharmacy.


Stephen W. Kalinoski, Respondent

Dated: 7/31/13

Consent as to Form and Content
KANE & ASSOCIATES, LLC


BY: David Kane, Esq.
Attorneys for Respondent Kalinoski

Dated: 8/1/13

7. The entry of the within Order is without prejudice to the further investigation and/or prosecution by any other regulatory or law enforcement agency, including the Division of Consumer Affairs for the State of New Jersey or other State agency, of any violations by MedPrep, its principal or employees including but not limited to Kalinoski, whether or not currently under investigation.

NEW JERSEY STATE BOARD OF PHARMACY

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

I have read the within Order, understand its terms and agree to be bound by them. I consent to entry of the Order by the Board of Pharmacy.

Stephen W. Kalinoski
 Stephen W. Kalinoski, Respondent

Dated: 7/31/13

Consent as to Form and Content
 KANE & ASSOCIATES, LLC

David Kane
 BY: David Kane, Esq.
 Attorneys for Respondent Kalinoski.

Dated: 8/1/13