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BOARD OF PHARMACY

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

IN THE MATTER OF THE PERMIT OF

Administrative

MedPrep Consulting Inc.
Permit No.28RS00615400

Order Adopting Prior
Order of Hearing
Committee with
Modifications

TO OPERATE AS A PHARMACY
IN THE STATE OF NEW JERSEY

This matter was initially heard before a Committee of the State Board of Pharmacy on April 12 and 15, 2013 consisting of Edward G. McGinley, R.P., Board President and Richard Palumbo, R.P. The Committee entered an Interim Order and Report ("Committee's Order") allowing MedPrep Consulting Inc. ("MedPrep") to preliminarily resume limited operations without dispensing and subject to extensive controls and restrictions. Dispensing was to begin only following approval of reports required to be submitted to the Board by a third party monitor. The Attorney General sought to supplement the Committee's Order seeking clarification on fourteen separate points. MedPrep submitted a response agreeing to nearly all of these points.

The Committee's Order was presented to the full Board of Pharmacy on April 24, 2013 for determination of whether to ratify, reject or modify the action taken by the Committee.

The full Board has reviewed the Committee's Order and the record established in this matter including documents submitted into evidence, a transcript of the hearing and supplemental submissions by the State and by MedPrep. The Board hereby adopts in full and without modification the Summary of Evidence and Discussion sections of the Committee's Order. The Board finds the reasoning outlined at length in the Committee's Order convincingly supports the Committee's conclusion, and now this Board's conclusion, that the record thus far indicates MedPrep can be trusted to implement improvements and safeguards to ensure safe practices. The Board is assured that the public would not be placed at risk of harm if MedPrep resumes operation pursuant to a controlled plan which significantly impacts production as outlined below. Whether or not MedPrep was the root cause of the Yale contamination, compliance with the steps outlined herein will alleviate any concerns regarding prior practices that might exist.

The Board is confident that the requirements ordered by the Committee are sufficiently protective of the public at this time. However, we take this opportunity to respond to the

supplemental submissions by the parties and to clarify elements of the Order to even further enhance the public safety.

On the morning of April 24, 2013, immediately prior to Board consideration of the Committee's Order and subsequent to the submissions of the parties, the State sought to provide the Board with a letter raising new evidence not previously in evidence. MedPrep objected to counsel based upon lack of advance notice and inability to review and formulate a meaningful response. When advised that the State sought to provide a letter containing new information, and cognizant that MedPrep had no time to meaningfully respond, the Board indicated it did not want the letter included in the record at that time. In lieu of submitting the letter to the Board, the parties agreed on the record to the following: (1) There is no current impediment to MedPrep's operation from any recent or pending State or Federal agency investigation and that if such an impediment arises, MedPrep shall so advise the Board; (2) MedPrep will advise the FDA before resuming the production of sterile product; (3) An administrative complaint was filed in this matter with the Board on April 22, 2013; (4) A committee, in lieu of the full Board, may review any information submitted by MedPrep in this matter to avoid any unnecessary delay in approving resumption of operations by MedPrep; and (5) If any

formal action is taken by any jurisdiction regarding Medprep, the company will notify the Board forthwith.

The parties also agreed to the following clarifications and amendments which were sought by the State in its April 22, 2013 Application to Supplement the Committee's Order which we hereby adopt and incorporate herein: (1) Prior to resuming operation, Medprep shall obtain Board approval of the new pharmacist-in-charge and the pass-through cabinet; (2) Any individual who will be present on-site on behalf of the Monitor shall be approved in advance by the Board; (3) MedPrep shall adhere to the Policy and Procedure Manual prepared by LDT Health Solutions, Inc.; (4) MedPrep shall initially restrict batch sizes to 500 units or less and limit its hours of operation to one shift of personnel per day, five days per week; (5) No recalled product, and only product compounded after the Board approves MedPrep to reopen, shall be dispensed; and (6) Any significant failure to honor the terms and conditions set by the Board shall result in the immediate cessation of compounding operations and an opportunity afforded to show cause why the permit to operate a pharmacy should not be revoked or suspended forthwith.

Several items were requested by the State in its Application to Supplement the Committee's Order and objected to by MedPrep: (1) The State requested a prohibition on all IV compounding. The Board does not consider this a necessary

safeguard. MedPrep has represented that it will limit its operation to low risk syringes for the foreseeable future and there has been no evidence of contamination in syringe products recalled by MedPrep. MedPrep has agreed that it will refrain from compounding continuous infusion bags until such time as successful completion of a media fill validation and receipt of written approval from the Board; (2) The State requested that the current pharmacist-in-charge be barred from engaging in all pharmacy related duties. The Board is hesitant to impose such a restriction, which would be tantamount to termination of employment, without affording the pharmacist-in-charge an opportunity to be heard. The Board agree with the Committee that concerns regarding lack of professional judgment can be addressed by providing that he shall not serve as the pharmacist-in-charge and clarifying that, regardless of official title, the duties of the current pharmacist-in-charge shall not include managing or supervising other pharmacists regarding their pharmacy practice. However, if he successfully completes all training required as outlined in this Order, the current pharmacist-in-charge is not precluded from preparing sterile compounds in the cleanroom as a staff pharmacist. The new pharmacist-in-charge, cleanroom supervising pharmacists and owner are required to submit affidavits that they understand the new role of the current pharmacist-in-charge; and (3) The State

has also requested that MedPrep be required to retain units of product from each and every batch of compounded sterile product for a period of thirty days beyond the Use-By Date and inspect those retained units for visible contamination at two week intervals. Retention of product in this manner is not required by State regulation or the USP and product can be contaminated even when there are no visible particulates. Nonetheless, given the undisputed contamination of product compounded and dispensed by MedPrep and in an abundance of caution, the Board finds that imposing this requirement for a minimum of six months is an appropriate additional safeguard.

Finally, at the hearing in this matter, MedPrep agreed to run sterility tests on a sample of every batch of drug produced and agreed to refrain from shipping to out-of-state pharmacies until they have valid central fill agreements approved by the Board. These terms were inadvertently omitted from the verbal order read into the record on April 15, 2013 and the Board agrees with the Committee's recommendation that they be incorporated into this Order.

The Board unanimously voted to adopt in its entirety, the Interim Order and Report of the Hearing Committee modified only by additional protective amendments requested subsequent to the Committee's Order as discussed above.

ACCORDINGLY, IT IS, on this 2nd day of May, 2013,

ORDERED, as announced orally on the record and effective April 24, 2013:

The Board adopts the Order of its Committee filed on April 19, 2013 (effective April 15, 2013) with the additional conditions and clarifications included as amendments below:

1. MedPrep shall contract with a third party monitor ("the Monitor") pre-approved by the Board to fulfill the monitoring and reporting requirements outlined in this Order for a minimum period of six months and until further Order of the Board. For the purposes of this Order, LDT Health Solutions, Inc. is Board-approved. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, MedPrep.

2. Prior to commencement of a simulated production week as described in this Order and prior to commencement of fulfillment of customer orders, all compounding, packaging and labeling employees shall perform three core training modules provided by LDT and complete the first two modules (18 CEU) of the Critical Point Internet-based USP <797> training program. Each employee shall certify in writing that they have completed the training and the certifications will be provided to the Board by the Monitor.

3. Prior to commencement of fulfillment of customer orders MedPrep must submit written evidence to the Board showing they have conducted sporadic inspection and cleansing which is acceptable to the Board. MedPrep must also submit a proposed standard operating procedure for ensuring routine cleansing of the pharmacy to include but not be limited to sporacides and consistent with the USP and Board of Pharmacy regulations.

4. Prior to commencement of fulfillment of customer orders the Monitor shall validate, in writing, to the Board that all compounding, packaging and labeling employees have been visually observed by the Monitor to have proper aseptic techniques and gowning, garbing and gloving processes for a minimum of 4 production simulation days. The simulation shall include observation of all processes conducted in a normal production week including but not limited to orders of large batch quantities to simulate expected order volume and type (such as syringes and bags). Media may be used.

5. During the simulated production week, there shall be validation of environmental monitoring with dynamic air testing conducted with twelve people in the clean room. Results shall be reported in writing by the Monitor to the Board.

6. Prior to commencement of fulfillment of customer orders, a new pharmacist-in-charge shall be in place. The pharmacist-in-charge and the pharmacist supervising the clean

room may not be the same person. Neither position can be filled by or report to the current pharmacist-in-charge. The names of the individuals assigned each title shall be reported in writing by the Monitor to the Board. The new pharmacist-in-charge,¹ the cleanroom supervising pharmacist(s) and the owner of MedPrep shall submit affidavits indicating they understand that they may not report to the current pharmacist-in-charge and that the current pharmacist-in-charge shall not supervise or manage any pharmacists.

7. Upon approval by the Board of the reports required to be submitted by the Monitor, MedPrep may commence production of fulfillment of customer orders² subject to the following:

A. Staffing

i. MedPrep shall abide by a 2:1 pharmacy technician to pharmacist ratio as set forth in N.J.A.C. 13:39-6.15 until such time that MedPrep submits and the Board approves a modification of that ratio;

ii. MedPrep shall limit the number of personnel within the clean room to 12 until the completion of environmental testing under dynamic conditions that supports an increase in that number.

¹ At the April 24, 2013 meeting, the Board reviewed the C.V. of Nancy McIlvaine, R.P. and approved her appointment as the new pharmacist-in-charge.

² No recalled products shall be distributed. Only product compounded after the Board approves MedPrep to resume operation shall be distributed. MedPrep shall not ship to out-of-state hospitals or pharmacies until they have a valid central fill agreement approved by the Board.

iii. MedPrep shall implement an additional layer of inspections through the creation of a dedicated supervisory pharmacist position within the cleanroom.

iv. MedPrep shall temporarily reassign those staff members directly involved in the compounding of the contaminated bags in question.

v. Compounding operations shall be limited to one shift of personnel per day, five days per week. A shift shall consist of no more than the number of hours per day a shift was comprised of prior to March 15, 2013.

B. Operations

i. MedPrep shall cease use of all Baxter Viaflex bags until further Board Order;

ii. MedPrep shall compound continuous infusion bags no earlier than two weeks following reopening and only after written Board approval following validation by the completion of a USP <71> compliant media fill process under the most challenging conditions in a dynamic environment using tryptic soy media incubated to show that the process can be conducted under control;³

iii. MedPrep shall dedicate a specific work station for the compounding of penicillin and beta-lactam drugs;

³ MedPrep has represented that it will limit its operation to low risk syringes for the foreseeable future.

iv. The dedicated supervisory pharmacist position within the cleanroom will be responsible for the following activities: secondary check of batch kit upon introduction to cleanroom; confirmation of compounding components prior to beginning of compounding; primary inspection of completed batch including visual inspection of final containers, confirmation of components used, accuracy of labels, proper completion of batch record/audit trail;

v. All compounding staff will be required to don sterile gowns;

vi. All staff will be required to maintain dedicated scrubs and shoes for the workplace. No street clothes will be permitted in the cleanroom or the area immediately outside the cleanroom;

vii. All staff performing wipe down of supplies immediately before introduction to the cleanroom will be required to wear a hairnet, mask, smock and sterile gloves;

viii. All staff performing labeling, packaging and inspection of final containers will be required to wear hairnet and smock; and

ix. MedPrep shall implement the following measures with respect to cleaning and disinfection:

a. Policy and Procedures clearly describing routine cleaning schedules, include among other things,

appropriate training, cleaning, sanitizing and maintenance of the new pass-through.

b. Preparation of cleaning solutions will be reviewed and updated to clearly describe acceptable detergents and disinfectants (to include sporacidal cleansers), including proper preparation.

c. Sterile 70% Isopropyl Alcohol will be used for all disinfection of critical work surfaces, critical injection sites, gloved hands and all supplies that are introduced into the cleanroom.

d. Only disposable cleaning supplies will be used.

C. Labeling

i. Labeling accompanying the compounded product will follow the product throughout the process in a sealable plastic bag;

ii. The label accompanying the compounded product will state the date and time that the product was prepared; and

iii. MedPrep shall utilize a process by which the label and the compounded product will be checked at least six times, in the manner described below:

a. There will be a pre-compounding inspection of the compounding batch kit by a pharmacist.

- b. The Clean Room Supervising Pharmacist will perform the same check, as in section a above, but in the clean room;
- c. The registered pharmacy technician in the clean room at the compounding station will perform an identical check as in section a above.
- d. The Clean Room Supervising Pharmacist will perform an in-process check of the drug and diluent prior to compounding;
- e. The Clean Room Supervising Pharmacist will inspect the completed batch for appropriateness and accuracy. This check will include, but is not limited to the clarity of the compound, dose, label, and spent vials.
- f. After labeling, the pharmacist outside the clean room will perform a final check of each dose for integrity, clarity, label accuracy, and the proper recordation of information. The audit trail shall identify each person involved in any way with the production of compounded sterile product from beginning to end.

D. Monitoring

i. The Monitor will have at least one individual physically present at MedPrep during all production⁴ to witness all aspects of the operation and monitor MedPrep's implementation of the corrective action plan, implementation of new policy and procedures, documentation procedures, including the documentation of information pursuant to the audit trail, and the laboratory testing agreed to by MedPrep. The Monitor will submit weekly reports to the Board for the first month of operations, followed by bi-weekly reports during the second and third months of operations, followed by monthly reports thereafter;

ii. The Monitor will assist MedPrep in the training and/or recruitment of a permanent Quality Manager; and

iii. MedPrep will implement a formalized Variance Reporting procedure by which there will be immediate notification of MedPrep's President, as well as the Monitor, of any incident. The Monitor will notify the Board of Pharmacy in writing and via telephone within 48 hours of any out-of-limit variances.

iv. MedPrep shall adhere to the Policy and Procedure Manual prepared by the Monitor.

⁴ Prior to any individual, other than Louis Diorio, R.P., serving as the on-site monitor, the Monitor shall submit that person's credentials to the Board and obtain pre-approval.

E. Beyond-Use Dating and Sterility Testing

i. MedPrep shall adhere to the guidelines set forth by N.J.A.C. 13:39-11.11(as they currently appear or subject to modification of the regulation), USP General Chapter <797>, and Med Prep Policy # 06-02.01 - Sterile Formula Stability and Beyond-Use Dating (BUD) Guidelines to determine the Use-by Date for all compounded sterile preparations (CSPs) compounded by Med Prep as follows:

a. Absent sterility testing, MedPrep shall assign a maximum Use-by Date of 9 days from the date the product was compounded for medium risk products in cold temperature storage and a maximum Use-by Date of 45 days from the date the product was compounded for medium risk products in a frozen state.

b. Additionally, MedPrep shall assign a maximum Use-by Date pursuant to the protocols described below, based on samples obtained by Gibraltar Laboratories of Fairfield, NJ (Gibraltar Laboratories) up through March 22, 2013:

1. Gibraltar Laboratories has or will conduct method suitability testing of all USP <71> sterility tests conducted by Gibraltar for CSPs compounded by the Pharmacy;

2. Following these method suitability tests, a USP <71> Sterility test will be conducted to assure that MedPrep can compound the CSP under sterile conditions;
3. The final step in determining a valid Beyond-Use Date will be for MedPrep to request that the contracted laboratory conduct a container closure integrity test, as described by the USP; or
4. alternatively by conducting three consecutive USP <71> compliant sterility tests on day(s) 1, 15, and 30.

ii. MedPrep shall run USP <71> compliant sterility tests on a sample of every batch of drug produced.

iii. For a minimum of six months and until further Order of the Board, MedPrep shall retain units of product from each and every batch of controlled sterile product for a period of thirty days beyond the Use-By Date and inspect those retained units for visible contamination at two week intervals.

F. Batch Size

Batch Size shall be limited to five hundred units. Any increases in size of compounding batches above five hundred units shall be subject to Board approval following validation by the completion of a media fill process under the most challenging conditions in a dynamic environment using tryptic

soy media incubated under USP <71> conditions to show that the process can be conducted under control.

8. MedPrep shall immediately (within 48 hours) advise the Board orally and in writing of any impediment to its operation and any formal action taken against it by any government entity in any jurisdiction.

9. MedPrep shall advise the Food and Drug Administration orally and in writing at least 24 hours before resuming the production of sterile product.

10. Any significant failure to honor the terms and conditions set forth in this Order shall result in the immediate cessation of compounding operations and an opportunity afforded to MedPrep on no less than three days notice to show cause why the permit to operate a pharmacy should not be revoked or suspended forthwith.

11. In all instances in which this Order requires Board approval, the Board authorizes the Board President and/or a committee of the Board to issue such approval.

NEW JERSEY STATE BOARD OF PHARMACY

Edward G. McGinley R.P.

By: _____

Edward G. McGinley, R.P.
Board President