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STATE 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 PERMIT OF MedPrep Consulting Inc. Permit No. 28RS00615400 TO OPERATE AS A PHARMACY IN THE STATE OF NEW JERSEY and THE LICENSE OF Stephen W. Kalinoski, R.Ph. License No. 28RI02241200 TO PRACTICE PHARMACY IN THE STATE OF NEW JERSEY	Administrative Action **First Amended COMPLAINT**

Jeffrey S. Chiesa, Attorney General of New Jersey, by Kim D. Ringler, Deputy Attorney General, with offices located at

124 Halsey Street, 5th Floor, Newark, New Jersey, by way of Complaint, says:

General Allegations

1. Complainant, the Attorney General of New Jersey, is charged with the responsibility of enforcing the laws of the State of New Jersey pursuant to N.J.S.A. 52:17A-4(h) and N.J.S.A. 45:1-14 et seq.

2. The New Jersey State Board of Pharmacy (the "Board") is a professional licensing board charged with the duty and responsibility of regulating the practice of pharmacy in the State of New Jersey pursuant to N.J.S.A. 45:1-21, N.J.S.A. 45:14-40 et seq., N.J.S.A. 45:14-48, N.J.S.A. 45:14-69 and N.J.S.A. 45:1-14 et seq. In accordance with N.J.S.A. 45:14-40 and N.J.S.A. 45:14-42, the Board is specifically charged with the permitting, control and regulation of all pharmacy practice sites in this State.

3. In accordance with N.J.A.C. 13:39-4.18(a), all permit holders shall be responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

4. The Board issued permit number 28RS00615400 to the Respondent, MedPrep Consulting Inc. ("Respondent MedPrep"), a

New Jersey corporation, which allows it to operate a pharmacy in the State of New Jersey.

5. Respondent MedPrep operates a pharmacy located at 1540 West Park Avenue, Suite 5, Tinton Falls, New Jersey.

6. Respondent MedPrep serves as an outsourcing compounding pharmacy for physician practices and hospitals. Its volume of sterile compounded product was approximately 6,000 units per day at all times relevant to this Complaint.

7. Respondent MedPrep compounded a number of sterile injectable drug products, including magnesium sulfate, heparin, oxytocin, dexamethasone, vancomycin and phenylephrine.

8. Respondent MedPrep's principal customers are hospitals and large physician practice groups located primarily in New Jersey. It also is licensed to do business in other states including Illinois, Indiana, Iowa, Florida, Maine, Michigan, New Hampshire, New York, Kansas, Texas, Wisconsin, Virginia, Maryland, Pennsylvania, Delaware and Connecticut.

9. Respondent MedPrep compounds sterile medications into syringes, intravenous bags and pumps. The medications are administered to patients intravenously.

10. Some of the drug products compounded by Respondent MedPrep are used in the treatment of patients who have severely

compromised immune systems, such as transplant recipients, patients undergoing chemotherapy and patients suffering from acquired immunodeficiency syndrome, or AIDS.

11. Respondent MedPrep committed multiple violations of applicable law and regulations. Respondent MedPrep's deficiencies were numerous, substantial and created severe risks to patient health and safety.

12. The Attorney General seeks a revocation or suspension of Respondent MedPrep's permit to operate a pharmacy under the provisions of N.J.S.A. 45:14-69(g) and N.J.S.A. 45:14-75(b)(1).

13. Respondent Stephen W. Kalinoski ("Respondent Kalinoski") is a licensed pharmacist in the State of New Jersey. The Board issued his license, No. 28RI02241200, on December 8, 1992. His license is current through April 30, 2015.

14. On March 14, 2003, Respondent MedPrep advised the Board that Respondent Kalinoski would serve as its Registered Pharmacist in Charge ("RPIC"). At all times relevant to this Complaint, Respondent Kalinoski was the RPIC of Respondent MedPrep.

15. In all pharmacies, the RPIC has the responsibility to supervise and ensure that (a) the pharmacy is staffed by sufficient, competent personnel in keeping with the size, scope

and complexity of the pharmaceutical services provided; (b) accurate records of all prescription medication received and dispensed are maintained; (c) policies are in place and followed regarding accurate dispensing and labeling of prescriptions; (d) security of the prescription area and its contents are maintained at all times; (e) no misbranded, deteriorated, adulterated, improperly stored or outdated drugs are dispensed or present in the active stock in the pharmacy; (f) the prescription area is maintained in an orderly and sanitary manner; and (g) the pharmacy and all pharmacy personnel provide pharmaceutical services in accordance with all federal and state statutes and regulations governing the practice of pharmacy. N.J.A.C. 13:39-6.2.

16. In compounding pharmacies, the RPIC shall supervise all sterile and non-sterile compounding. N.J.A.C. 13:39-11.5(a).

17. As RPIC in a pharmacy that performs compounding, Respondent Kalinoski had the responsibility for (a) the compounding of all preparations; (b) ensuring that all packaging and labeling of all drugs compounded was performed under the immediate personal supervision of a pharmacist; (c) recording all transactions in accordance with State, federal and local laws and rules in order to maintain accurate control over and

accountability for all pharmaceutical materials; (d) ensuring that preparation and compounding of sterile preparations was performed only by pharmacists or pharmacy technicians trained in aseptic manipulation skills, working under the immediate personal supervision of a licensed pharmacist; and (e) establishing procedures for maintaining the integrity of packaged material. N.J.A.C. 13:39-11.5.

18. As RPIC, Respondent Kalinoski was responsible for ensuring that all personnel were properly trained in aseptic technique pursuant to N.J.A.C. 13:39-11.7.

19. As RPIC, Respondent Kalinoski was responsible for creating, implementing and updating as necessary policies and procedures ensuring documentation of all aspects of the dispensing process, including identification of the pharmacist responsible for each preparation and identification of every individual participating in the compounding, pursuant to N.J.A.C. 13:39-11.9.

20. As RPIC, Respondent Kalinoski was responsible for maintaining a policy and procedure manual detailing the pharmacy's standard operating procedures with regard to compounded sterile preparations ("CSP"). Respondent Kalinoski was required to review the manual no less frequently than every

two years and to amend the manual as needed pursuant to N.J.A.C. 13:39-11.13.

21. Respondent Kalinoski was obligated to ensure that Respondent MedPrep and all its pharmacy personnel complied with all federal and State statutes and regulations governing the practice of pharmacy. N.J.A.C. 13:39-6.2(f)(9). Those controlling authorities include standards of practice for compounding pharmacies contained in United States Pharmacopeia Convention, Inc. General Chapter <797> Pharmaceutical Compounding - Sterile Preparations. United States Pharmacopeia 35-National Formulary 30. Rockville, MD: U.S. Pharmacopeial Convention, Inc. (2013):350-387, known as and hereinafter referred to as "USP."

22. Respondent Kalinoski failed to abide by and conform to the above referenced statute and regulations applicable to the practice of pharmacy in New Jersey. Accordingly, the Attorney General seeks a revocation or suspension of Respondent Kalinoski's license to practice pharmacy under the provisions of N.J.S.A. 45:14-48(a)(6) and N.J.S.A. 45:1-21(d), (e) and (h).

23. On March 15, 2013, three batches of 50 ml bags of compounded magnesium sulfate IV solution dispensed to a Connecticut hospital were found to have floating particulate

matter. The bags were from lots compounded by Respondent MedPrep on three separate dates: February 14, February 21 and February 28, 2013.

24. An additional bag was discovered subsequently with visible contaminant. It contained dexamethasone 8mg in 50mL 0.9% Sodium Chloride (Normal Saline), not magnesium sulfate, and it was compounded on February 28, 2013, the same date on which one of the previously discovered contaminated bags was compounded.

25. Another bag of magnesium sulfate, which did not contain visible particulates, compounded on or about January 31, 2013, has reportedly shown a yet to be unidentified mold growth in the laboratory.

26. Respondent MedPrep and the Board entered into a Voluntary Interim Consent Order filed March 15, 2013 which stopped all pharmacy operations, and the next day Respondent MedPrep issued a recall notice for all magnesium sulfate products it had compounded. It expanded the recall on March 17, 2013 to include all products compounded by Respondent MedPrep.

27. On March 22, 2013, the Board and Respondent MedPrep entered into a Second Voluntary Interim Consent Order which extended to April 5, 2013 the cessation of all operations at Respondent MedPrep. A Third Order continued the terms of the

prior two orders requiring Respondent MedPrep to refrain from and stop all pharmacy operations through April 12, 2013.

28. On April 12, 2013 and April 15, 2013, a Committee of the Board held a hearing on an application by Respondent MedPrep for immediate relief from the shutdown order. The Board thereafter issued an Interim Order and Report of Hearing Committee to the Board ("Interim Committee Order"), filed April 19, 2013, permitting Respondent 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.

29. On April 24, 2013, the Board issued an oral Order placed on the record ratifying the Interim Committee Order with clarifications and supplemental conditions.

30. Findings by Gibraltar, Inc., the outside laboratory retained by Respondent MedPrep, and findings by the Center for Disease Control confirmed that at least five separate bags of magnesium sulfate contained a mold micro-organism. The organisms have been identified, only one fungus per bag, as

penicillium, neosartoryea hiratsukae, hamigera insecticola and aspergillus.

31. As of the date of the filing of this Complaint, no patient harm has been discovered, and none of the New Jersey hospitals which received product from Respondent MedPrep have reported any infections suggesting patient harm from the fungi identified in the sterile products compounded at Respondent MedPrep.

32. An investigation into a root cause of the fungal contaminants is ongoing, and as of the date of the filing of this Complaint, inconclusive. However, as outlined below, the deficiencies and violations at the Respondent MedPrep's facility were rampant and egregious.

Count I
Incorrect CSP Labeling

33. The General Allegations above are repeated and realleged as if set forth at length herein.

34. Over approximately twenty-four months prior to April 3, 2013, Respondent MedPrep released and distributed to its customers approximately twenty types of compounded sterile products representing hundreds of units of injectable medication, which were incorrectly compounded, incorrectly labeled or incorrectly packaged.

35. Respondent MedPrep's customers returned these drug products due to (a) serious discrepancies between the label and the actual active ingredient strength or product content, (b) the absence of protective bags for light sensitive drug product or (c) the absence of temperature controls for frozen product.

36. In each case of erroneous labeling, the customers of Respondent MedPrep noticed the errors and brought them to the attention of Respondent MedPrep, evidencing the lack of quality control measures in place at Respondent MedPrep.

37. Following discovery of the instances of incorrect compounding, labeling or packaging of product it had shipped to its customers, Respondent MedPrep failed to undertake thorough investigations, or to take corrective or remedial measures to ensure safe practices.

38. Following discovery of the instances of incorrect compounding, labeling or packaging of product it had shipped to its customers, Respondent MedPrep failed to document thorough investigations, or corrective or remedial measures to ensure safe practices.

39. Respondent MedPrep repeatedly created a risk that non-conforming and non-stable injectable drugs would be administered

to patients thereby exposing them to serious injury, illness or death.

40. Respondent MedPrep's labels on products frequently were prepared and dated in advance of the compounding in violation of N.J.A.C. 13:39-11.10(a)(1), which requires the date and time of preparation of sterile compounded product to appear on the label. The affected lots of magnesium sulfate, by way of example, were compounded the day after the date appearing on the lot label.

41. Respondent MedPrep's conduct, as alleged herein, constitutes gross negligence, malpractice or incompetence, and/or constitutes repeated acts of negligence, malpractice or incompetence in violation of N.J.S.A. 45:1-21 (c) and (d).

42. Respondent MedPrep has engaged in professional misconduct in violation of N.J.S.A. 45:1-21(e).

43. Respondent MedPrep's conduct, as alleged herein, violated or failed to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h).

Count II
Inadequate Product Testing

44. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

45. Respondent MedPrep failed to establish scientifically sound sampling plans and test procedures sufficient to ensure that its drug products conformed to appropriate standards of identity, strength, quality and purity.

46. Respondent MedPrep policies and practices did not ensure consistently sterile product, in violation of USP, General Chapter <797> which requires use of a default storage period (also known as "beyond use date" or "use by date") unless certain testing and prerequisites are done as set forth in USP Chapter <71>.

47. The USP standards for medium risk level compounded sterile product require either conformity with USP Chapter <71>, Sterility Tests, or a beyond use date of no longer than thirty hours from the completion of the compounding process, if stored at room temperature.

48. Respondent MedPrep did not conduct sterility testing in conformity with USP <71>. It nonetheless utilized a storage period or use by date of more than thirty hours for medium risk compounded sterile products stored at room temperature. For example, it applied a use by date of forty-five days for magnesium sulfate IV maintained at room temperature.

49. Respondent MedPrep conducted tests for sterility on a mere three units of product per day for a maximum of twelve to fifteen units of product per week. It selected on a random basis one unit from one batch of its products packed into a syringe, one unit from one batch of one of its products packed into an IV bag of solution and one unit from one batch of one of its products provided for administration to a patient via a pump. In so doing, Respondent MedPrep tested only a miniscule amount, about .05%, of the approximately 6,000 sterile drug products it compounded daily.

50. Sterile preparations were not visually inspected with a lighted black and white box to detect particulate or foreign matter in violation of USP <797>.

51. Respondent MedPrep did not conduct any stability or potency tests of its product.

52. With respect to magnesium sulfate, Respondent MedPrep relied exclusively on a test of magnesium ion and sulfate ion performed by Eagle Analytical Services Ltd. in 2008 demonstrating stability at 30 days.

53. Respondent MedPrep's failure to perform appropriate testing of its product created a risk that patients would receive non-sterile injectable drugs and hence be exposed to an

unacceptable risk of serious infection, and that patients would receive injectable drugs with incorrect potency and hence receive the wrong drug therapy. Its conduct as alleged herein, constitutes gross negligence, malpractice or incompetence, and/or constitutes repeated acts of negligence, malpractice or incompetence in violation of N.J.S.A. 45:1-21 (c) and (d).

54. Respondent MedPrep has engaged in professional misconduct in violation of N.J.S.A. 45:1-21(e).

55. Respondent MedPrep's conduct, as alleged herein, violated or failed to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h).

Count III
Threats to Sterility of Cleanroom

56. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

57. The conduct set forth above created risks to the asepticity of the compounded sterile products.

58. Other conditions at Respondent MedPrep also threatened aseptic practice including the following:

(a) the faucets in the facility were not hands-free;

(b) a rolling cart containing components to be compounded was not adequately disinfected in its entirety before it entered the cleanroom;

(c) gloves being worn had not been tested for compatibility with alcohol; and

(d) personnel were not required to scrub hands and arms with soap prior to working in the facility's cleanroom.

59. In addition, the same personnel performed both compounding activities and quality control activities in violation of USP <797> and N.J.A.C. 13:39-6.2(f)(9).

60. Respondent MedPrep documented seven injectable compounded sterile products over a twenty-six month period ending April 3, 2013 which contained visually identifiable turbidity or floating particle matter. Respondent MedPrep did not conduct an adequate investigation of the cause of contamination and did not adopt an adequate remediation plan to prevent future similar contamination.

61. Respondent MedPrep recalled all of its products on March 17, 2013, as set forth above, after visible particle matter was found in its CSP delivered to a hospital. Sample testing of returned product identified IV bags of magnesium sulfate compounded on February 14, 21 and 28, 2013 and January

31, 2013, and an IV bag of dexamethasone compounded on February 28, 2013, that were contaminated with fungi. The fungi included hamigera insecticola, neosartorya hiratsukae, aspergillus and penicillium chrysogenum.

62. Respondent MedPrep's disregard of sterility safeguards and procedures along with the findings of contamination in its product and workplace, as alleged herein, constitutes gross negligence, malpractice or incompetence, and/or constitutes repeated acts of negligence, malpractice or incompetence in violation of N.J.S.A. 45:1-21 (c) and (d).

63. Respondent MedPrep has engaged in professional misconduct in violation of N.J.S.A. 45:1-21(e).

64. Respondent MedPrep's conduct, as alleged herein, violated or failed to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h) and N.J.A.C. 13:39-6.2(f)(9).

Count IV
Impermissibly Extended Use By Dates

65. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

66. Respondent MedPrep affixed to the magnesium sulfate compound sterile product which it shipped to its customers use

by dates of forty-five days after compounding, in violation of N.J.A.C. 13:39-11.11 which requires a far shorter use by date of twenty-four hours, absent proof justifying a longer period, but in any case prohibits use by dates in sterile preparations of longer than thirty days.

67. Respondent MedPrep in so doing also violated USP standards contained in Chapters <797> and <71> which require testing for medium risk level CSP stored at room temperature whenever a maximum use by date of greater than thirty hours after compounding is utilized.

68. Respondent MedPrep failed to conduct adequate testing to validate the expiration dates placed on product labels.

69. Respondent MedPrep's utilization of use by dates greater than twenty-four hours without proper analytical testing results and without proper sterility testing, and use by dates longer than thirty days, violated N.J.A.C. 13:39-11.11.

70. Respondent MedPrep's utilization of use by dates greater than thirty hours at room temperature, without proper analytical testing results and without proper sterility testing, violated USP Chapters <797> and <71>.

71. Respondent MedPrep's conduct as alleged herein constitutes gross negligence, malpractice or incompetence, and/or constitutes repeated acts of negligence, malpractice or incompetence in violation of N.J.S.A. 45:1-21(c) and (d); professional misconduct in violation of N.J.S.A. 45:1-21(e) and failure to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h).

Count V
Failure to Document

72. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

73. Respondent MedPrep failed to comply with audit trail requirements in order to create a documented record of the specific personnel who participated in the sterile compounding process. It failed to maintain adequate or accurate records regarding the compounding process such that, among other things, the records fail to accurately reflect who participated in the compounding of drugs and where within the facility's cleanroom the drugs were compounded.

74. Respondent MedPrep did not list the all of the individuals, in addition to those listed on the audit trail documentation, who handled components and assisted in

compounding the magnesium sulfate CSP, in breach of N.J.A.C. 13:39-11.9(c).

75. Equipment calibration and maintenance logs were not signed and dated by the operator in violation of USP Chapter <797>.

76. Although seven injectable drug products compounded by Respondent MedPrep over a twenty-six month period ending April 3, 2013 had visually identifiable turbidity or floating particle matter, Respondent MedPrep did not document an adequate investigation of the cause of contamination and/or an adequate remediation plan.

77. Notwithstanding its duty to review and amend as necessary the company policy and procedure manual no less frequently than every two years pursuant to N.J.A.C. 13:39-11.13, Respondent MedPrep did not do so in a timely manner.

78. Respondent MedPrep's failure to comply with audit trail documentation regulations violated N.J.A.C. 13:39-11.9. Respondent's failure to comply with USP standards regarding record-keeping constituted professional misconduct in violation of N.J.S.A. 45:1-21(e) and a failure to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h).

Count VI
False Representations

79. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

80. In the course of the investigation into the magnesium sulfate contamination, Respondent MedPrep produced to the Board conflicting information about which personnel, pharmacists and pharmacy technicians were personally involved in compounding the batches of magnesium sulfate during the critical period in February 2013.

81. Additional persons who handled the components and assisted in compounding the CSP magnesium sulfate on February 13-14, 20-21, and 27-28, 2013 were not reflected in the audit trail documentation required by N.J.A.C. 13:39-11.9(c). The documentation provided by Respondent MedPrep contained false representations that only two pharmacists and one pharmacy technician had prepared the lots of the magnesium sulfate which was later found contaminated.

82. A pharmacy technician's initials were placed on the audit log whether or not that technician worked on the compounding.

83. False representations on Respondent MedPrep's website and on a marketing brochure claimed that it complied with all USP Chapter <797> practices when, in fact, it had not so complied.

84. Respondent MedPrep's misrepresentations on required documentation and in its marketing regarding its sterility safeguards and procedures as alleged herein, constituted engaging in misrepresentation in violation of N.J.S.A. 45:1-21(b); false advertising in violation of N.J.A.C. 13:39-7.14(f); professional misconduct in violation of N.J.S.A. 45:1-21(e); and failing to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h).

Count VII
Impermissible Ratio of Pharmacists to Technicians

85. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

86. Respondent MedPrep exceeded the permissible ratio of pharmacists to pharmacy technicians by having more than two pharmacy technicians for every one pharmacist, in violation of N.J.A.C. 13:39-11.6.

87. Although Respondent MedPrep applied to the Board for an expanded ratio, such permission was never granted and

Respondent MedPrep continued to operate with an impermissible ratio.

88. Respondent MedPrep staffed its compounding facility with too few licensed pharmacists for the number of pharmacy technicians working there. Its conduct as alleged herein violated N.J.A.C. 13:39-11.6 and constitutes professional misconduct in violation of N.J.S.A. 45:1-21(e) and a violation or failure to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h).

Count VIII
Breach of Duty by RPIC

89. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

90. Respondent MedPrep designated Respondent Kalinoski as its RPIC. As such, he was responsible for the oversight and supervision of the sterile compounding facility and its operations.

91. Respondent Kalinoski's failure to discharge his responsibilities as RPIC pursuant to N.J.A.C. 13:39-11.5(a) caused and/or contributed to the violations alleged above.

92. Respondent Kalinoski's conduct violated N.J.A.C. 13:39-6.2, which provides in relevant part that an RPIC bears responsibility to supervise and ensure that (a) the pharmacy is staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided; (b) accurate records of all prescription medication received and dispensed are maintained; (c) policies are in place and followed regarding accurate dispensing and labeling of prescriptions; (d) security of the prescription area and its contents are maintained at all times; (e) no misbranded, deteriorated, adulterated, improperly stored or outdated drugs are dispensed or present in the active stock in the pharmacy; (f) the prescription area is maintained in an orderly and sanitary manner; and (g) the pharmacy and all pharmacy personnel provide pharmaceutical services in accordance with all federal and State statutes and regulations governing the practice of pharmacy.

93. Respondent Kalinoski's failure to perform his duties as RPIC further violated N.J.A.C. 13:39-11.7 (personnel must be properly trained in aseptic technique); N.J.A.C. 13:39-11.9 (required documentation of all aspects of the dispensing process and identification of the pharmacist responsible and all

personnel involved in each preparation must be identified by an audit trail); and N.J.A.C. 13:39-11.13 (review and amending as necessary the policy and procedure manual no less frequently than every two years).

94. Respondent Kalinoski's conduct violated the rules and regulations cited above herein and constituted gross negligence, malpractice or incompetence, and/or constituted repeated acts of negligence, malpractice or incompetence in violation of N.J.S.A. 45:1-21 (c) and (d); professional misconduct in violation of N.J.S.A. 45:1-21(e), and repeated violations or failures to comply with the provisions of any act or regulation administered by the Board in contravention of N.J.S.A. 45:1-21(h).

Count IX
Failure to Comply with Requirements
For Centralized Prescription Handling

95. The General Allegations and those of all prior counts are repeated and realleged as if set forth at length herein.

96. Since at least 2002, Respondent MedPrep prepared and provided CSP to hospital pharmacies. At all times relevant hereto, hospitals accounted for approximately seventy-five percent of Respondent MedPrep's business.

97. Respondent MedPrep provides CSP to hospitals, under a "central fill" model. Under the central fill model, Respondent MedPrep serves as the central fill pharmacy preparing the compounded products, but the dispensing to patients is performed by the hospital pharmacy.

98. Since at least 2004, the Board's regulations require pharmacies participating in central prescription handling to have contractual agreements to provide services, and further require the participating pharmacies to make a single application to the Board delineating the scope of practice of each pharmacy that is a party to the arrangement. N.J.A.C. 13:39-4.19(d). Since 2007, out-of-state pharmacies that engage in central fill arrangements with New Jersey pharmacies must be registered with the Board pursuant to N.J.A.C. 13:39-4.20. All pharmacies engaging in central fill prescription handling are responsible for maintaining an audit trail and ensuring that all prescriptions are properly filled. N.J.A.C. 13:39-4.19(d)(2) and (d)(9).

99. Notwithstanding the regulation requiring centralized prescription handling agreements to be approved by the Board, Respondent MedPrep did not seek or receive approval for centralized prescription handling agreements with any

hospital client until 2011. At that time, Respondent MedPrep began filing applications for approval of agreements with its New Jersey hospital clients. To date, Respondent MedPrep has not filed applications for approval of centralized prescription handling arrangements with out-of-state pharmacies.

100. At least one of Respondent MedPrep's out-of-state hospital pharmacy clients is not registered with the Board, and therefore could not be part of a valid centralized prescription handling agreement.

101. Respondent MedPrep compounds CSP for hospitals in advance of need, and does not obtain patient-specific prescriptions or medication orders at any time, including after dispensing, for these products.

102. Respondent MedPrep does not have access to a common electronic file for patients in violation of N.J.A.C. 13:39-4.19(d)(8).

103. Respondent MedPrep's conduct, as alleged herein, violated or failed to comply with the provisions of any act or regulation administered by the Board in violation of N.J.S.A. 45:1-21(h), and also constituted professional misconduct in violation of N.J.S.A. 45:1-21(e).

WHEREFORE, Complainant Attorney General respectfully demands the entry of an Order against Respondents MedPrep Consulting, Inc. and Stephen W. Kalinoski, R.Ph. as follows:

1. Revoking or suspending the permit to operate a pharmacy issued to Respondent MedPrep;

2. Revoking or suspending the license issued to Respondent Kalinoski to practice pharmacy in the State of New Jersey;

3. Assessing civil penalties against each Respondent for each and every separate unlawful act as set forth in the individual counts above, pursuant to N.J.S.A. 45:1-25;

4. Requiring Respondents to pay costs, including investigative costs, attorney's fees and costs, expert and fact witness fees and costs, costs of trial, and transcript costs, pursuant to N.J.S.A. 45:1-25; and

5. Ordering such other and further relief as the Board of Pharmacy shall deem just and appropriate under the circumstances.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY

By: Kim D. Ringler
Kim D. Ringler
Deputy Attorney General

Dated: April 25, 2013