BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 4682
ADVANCE OUTCOME MANAGEMENT INC., dba ADVANCE OUTCOME MANAGEMENT PHARMACY SERVICES **Pharmacy Permit No. PHY 49946** and **ADVANCE OUTCOME MANAGEMENT INC., dba ADVANCE OUTCOME MANAGEMENT INCORPORATION** **Sterile Compounding Permit No. LSC 99606** and **CLARENCE LLOYD** **Pharmacist License No. RPH 46890** Respondents.	OAH No. 2013090592

DECISION

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as the decision in the above-entitled matter, except that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), the following technical change is made to Factual Findings, page 2:

> "2. On March 7, 1994, the Board issued Original Pharmacist License Number RPH 46890 to respondent Clarence Lee Lloyd (PIC Lloyd) to practice pharmacy in California."

The technical change made above does not affect the factual or legal basis of the Proposed Decision, which shall become effective on December 26, 2014.

IT IS SO ORDERED this 26th day of November, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

STAN C. WEISSER
Board President

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In the Matter of the Accusation Against: ADVANCE OUTCOME MANAGEMENT INC., dba ADVANCE OUTCOME MANAGEMENT PHARMACY SERVICES Pharmacy Permit No. PHY 49946 and ADVANCE OUTCOME MANAGEMENT INC., dba ADVANCE OUTCOME MANAGEMENT INCORPORATION Sterile Compounding Permit No. LSC 99606 and CLARENCE LLOYD Pharmacist License No. RPH 46890 Respondents.	No. 4682 OAH No. 2013090592

PROPOSED DECISION

Alan S. Meth, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on October 6 through 9, 2014, in San Diego, California,

Nicole R. Trama, Deputy Attorney General, represented complainant Virginia Herold.

Peter S. Gregorovic and John A. Cronin, Attorneys at Law, represented respondents Advance Outcome Management Inc., dba Advance Outcome Management Pharmacy Services, Advance Outcome Management Inc., dba Advance Outcome Management Incorporation, and Clarence Lloyd.

The matter was submitted on October 9, 2014.

FACTUAL FINDINGS

Jurisdiction

1. On August 9, 2013, Virginia Herold, Executive Officer, Board of Pharmacy, Department of Consumer Affairs, State of California (Board) filed Accusation No. 4682 in her official capacity. Respondents filed a timely Notice of Defense.

License History

2. On March 7, 1994, the Board issued Original Pharmacist License Number RHP 46890 to respondent Clarence Lee Lloyd (PIC Lloyd) to practice pharmacy in California.

On June 30, 2009, the Board issued Original Permit Number PHY 49946 to respondent Advance Outcome Management Incorporation, to do business as Advance Outcome Management Pharmacy Services, for a pharmacy located in Garden Grove, California.

On June 25, 2010, the Board issued Original Sterile Compounding Permit Number LSC 99606 to Advance Outcome Management Incorporation to do business as Advance Outcome Management Inc. (AOM), to compound injectable sterile drug products.

PIC Lloyd is the Director, President, Treasurer/Chief Financial Officer and Pharmacist in Charge of AOM and Renee Lloyd is the Director and Secretary of AOM.

Accusation

3. The accusation filed against respondents contains 23 causes for discipline. During the hearing, complainant dismissed the eighteenth cause for discipline. Also during the hearing, respondents admitted the truth of the allegations contained in the fifth, seventh, eighth, and twenty-first causes for discipline. All the causes for discipline allege a violation of Business and Professions Code section 4301, which authorizes the Board to take action against a licensee for unprofessional conduct. Most of the causes for discipline allege a violation of subdivision (o), which authorizes action for a violation of applicable federal or state law or a board regulation governing pharmacy. Where a violation of section 4301, subdivision (o) is alleged, the applicable statute or regulation is referenced. The accusation also alleges violations of subdivision (g) for the making of a false document, subdivision (c) for gross negligence, and subdivision (j) for violating state or federal statutes regulating controlled substances and dangerous drugs.

The accusation was based upon two inspections of the licensed premises that were conducted by Board inspectors on April 23 and 26, 2013.

4. The standard of proof in an administrative disciplinary proceeding seeking to suspend or revoke a professional license is "clear and convincing evidence." (*Ettinger v. Board of Medical Quality Assurance*, *supra*, at 856.) Charges must be established to a reasonable certainty, and proof of the charges cannot be based on surmise or conjecture, suspicion or theoretical

conclusions, or uncorroborated hearsay. (*Pettit v. State Board of Education* (1973) 10 Cal.3d 29, 37.) The obligation to establish charges by clear and convincing evidence is a heavy burden. Clear and convincing evidence requires a finding of high probability. The evidence must be so clear as to leave no substantial doubt. It must be sufficiently strong to command the unhesitating assent of every reasonable mind. (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.)

Order to Cease and Desist

5. Following the inspection on April 26, 2013, the board's inspectors issued an Order to Cease and Desist under the authority of Business and Professions Code section 4127.3 (Code). The Order identified violations of California Code of Regulations, title 16, sections 1751.7, subdivisions (a)(4) and (c), 1751.4, subdivision (a), and 1751.1, subdivision (b) (Regulations). In particular, the Board inspectors found a violation of section 1751.1, subdivision (b)(3) of the Regulations which required there be a certification of the sterile injectable compounded environment. The Order required respondents to immediately cease and desist from furnishing sterile injectable compounded products and ordered that respondents cease furnishing such products until the Board authorized such furnishing. The Order advised respondents that they could submit a corrective plan of action within 14 days.

On April 30, 2013, the Board's inspectors revised the Order to Cease and Desist by adding a provision that notified respondents of their right to request a hearing before the president of the Board to contest the order.

The Board's inspectors vacated the Order after respondents provided evidence of a May 8, 2013, certification of the sterile injectable compounded environment.

The Inspections

6. Valerie Sakamura has been an inspector for the Board since 2000. She received a Bachelor of Science in microbiology from the University of Hawaii in 1992 and a Doctor of Pharmacy from USC in 1997. She is a licensed pharmacist in Nevada and California. As a pharmacist intern, Inspector Sakamura worked at several hospitals, and after receiving her license, worked at the Norris Medical Center, Queen of Angels and Huntington Hospital. She continues to work at Huntington Hospital on a per diem basis and her duties there include sterile compounding. She has compounded throughout her career except for a period between 2000 and 2005. Since becoming an inspector, she has conducted inspections of approximately 50 compounding pharmacies. As an inspector, she is a member of the compliance team and has inspected approximately 1,000 pharmacies. She has received specialized training in compounding. She is familiar with the standard of practice in pharmacy.

Inspectors Sakamura and Robert Kazebee conducted a sterile compounding annual renewal inspection of AOM on April 23, 2013. They returned on April 26, 2013, to perform a follow-up inspection.

7. Before AOM could receive a sterile compounding permit, it had to undergo an inspection of its premises. Anna Yamada, an inspector with the Board, performed that inspection on April 26, 2010, after which she wrote an inspection report. Among the items noted on the inspection report was: "Policy and Procedure: In place-PIC to update QA for end product testing and to include drug recall procedures."

8. Inspector Yamada conducted a follow-up inspection of AOM on June 2, 2010. One of the items reflected in the inspection report was: "Record Keeping Requirements: Blank cleaning logs and refrigerator logs available-Instructed PIC to provide completed logs." Another item in the report was: "Disposal: Spill kit and Sharps container available; Chemo waste container to be properly labeles (sic) as chemo waste."

9. Inspector Kazebee performed an annual inspection of AOM on May 19, 2011, after which he wrote an inspection report. Among the items he listed in his report was "Beyond use date greater than 180-days." A beyond use date is the date after which a compounded medication should be discarded. He also noted that AOM should "remove all outdated drugs and send them off for credit or destruction." Inspector Kazebee also found some problems relating to PIC Lloyd's record keeping, labeling, quality assurance and process validation, end product testing, and cleanliness. He specifically noted that PIC Lloyd was not submitting CURES data.

10. On May 10, 2012, Ben Rustia performed an annual inspection of AOM for the Board. In his inspection report, he noted that the written policies and procedures were not in place, and he instructed PIC Lloyd to check with Atlantic Associates to see if CURES data was being transmitted. He also found that compounding quality assurance was not in place and directed PIC Lloyd to remove expired compounded products from the shelves.

11. Avastin (bevacizumab), Triesence 40 mg/ml (triamcinolone suspension) Trivaris 80 mg/ml (triamcinolone suspension), Decadron (dexamethasone), Voltaren (diclofenac), Mutamycin (mitomycin), Makena (17-hydroxyprogesterone), Vanocin (vancomycin), Fungizone (amphotericin), and Vfend (voriconazole) are dangerous drugs pursuant to Business and Professions Code section 4022.

12. Inspectors Sakamura and Kazebee conducted inspections of AOM on April 23 and 26, 2013. Inspector Sakamura prepared a lengthy investigation report, took photographs, and collected documents. The two inspectors prepared Inspection Reports of the two inspections that listed the violations they found. All these documents were admitted into evidence. Inspector Sakamura testified at the hearing and served as the Board's expert witness.

First Cause of Action-Incorrect Labeling of Chemotherapy Agents

13. Section 1751.2, subdivision (d) of the Regulations provides that "All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic - Dispose of Properly."

14. The inspectors examined the refrigerator in the pharmacy and found many chemotherapy products that did not bear the required warning labels and were not in chemotherapy bags as required to provide extra protection because the chemotherapy products were cytotoxic agents and were hazardous. As Inspector Kazebee removed chemotherapy products from the refrigerator, something leaked onto his hands and after he washed his hands, they started tingling.

The inspectors examined the chemotherapy room and observed many full red containers on the floor. PIC Lloyd told them the containers contained chemotherapy, including mitomycin and Avastin, and he was waiting for a healthcare medical waste disposal and removal service to remove them. The containers were not correctly labeled as chemotherapy medication and did not have the required special disposal label.

There was no reason for PIC Lloyd to store hazardous medications in a clean environment because they could contaminate the environment. They should have been disposed of promptly.

15. The evidence established that respondents violated section 1751.2, subdivision (d), of the Regulations by storing cytotoxic agents in the refrigerator and the chemotherapy room that did not contain the requisite warning label.

Second Cause for Discipline-Unclean Pharmacy

16. Section 1714, subdivision (c), of the Regulations requires that a pharmacy, its fixtures and its equipment "be maintained in a clean and orderly condition."

17. On both inspections, the inspectors found that there was used and dirty compounding equipment and bottles in the sink and that trashcans were overflowing. They found dust and film on some vials that appeared to have been washed, and they believed that the trash and the items they found in the sink on April 23 were the same as they found on April 26. They took photographs of the sink and trashcans.

18. PIC Lloyd testified at the hearing that after he compounds, he cleans his compounding equipment including his bottles, and that he then reuses them. He also cleans the room and throws trash away after filling the trashcans. He testified that the inspectors came to the pharmacy before he had a chance to empty the trashcans and put the equipment away.

19. While the testimony of the inspectors and the photographs taken of the pharmacy at the time of the inspection showed the pharmacy to be messy, the evidence did not establish that the conditions they observed on April 23 or 26 were sufficiently unclean and disorderly to justify disciplinary action.

Third Cause for Discipline-Expired Drugs Not Quarantined

20. Section 4342, subdivision (a) of the Code authorizes the Board to take disciplinary action against a licensee "to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the

United States Pharmacopoeia or the National Formulary...." This prohibition includes expired drugs.

21. On April 23, the inspectors found that more than half the drugs in the refrigerator were expired. An expired drug could be less potent, contaminated or could cause harm. The inspectors told PIC Lloyd not to commingle expired and unexpired drugs to prevent the administration of an expired drug to a patient, and they told him that he should quarantine the expired drugs. They told him that the expired drugs could be quarantined anywhere, but they should be properly labeled and then returned to the supplier or destroyed. The inspectors told PIC Lloyd that they wanted him to provide an action plan within three days describing how he would quarantine expired drugs and then send them off for destruction.

On April 26, the inspectors found that the drugs that were present on April 23 were still there and that more than half of them were expired. They found that one drug had a beyond use date of March 18, 2012. Inspector Sakamura believed this was an easy problem for PIC Lloyd to have fixed--he simply could have moved the expired drugs into one area and labeled them so that he would not commingle them with other unexpired stock. Since these expired drugs would not be used, there was no reason for PIC Lloyd to refrigerate them, and he could have moved them anywhere. Nevertheless, PIC Lloyd did not move the expired drugs or label them in the intervening three days.

The inspectors found no evidence that respondents sold or dispensed expired drugs.

22. PIC Lloyd testified that after the inspectors left AOM on April 23, he inventoried the bags in the refrigerator and put then into appropriate containers so that they could be returned. He further testified that he kept expired drugs in a bin in the bottom of the refrigerator and they were labeled as being expired or were in another locker where unexpired drugs were not kept. He claimed there were few drugs in the refrigerator at the time of the inspections because he had just returned some drugs. He testified he tried to segregate drugs regularly, but he admitted "we are not perfect."

23. Inspector Sakamura's testimony and report including photographs describing the condition of the refrigerator and the presence of expired and unlabeled drugs was more credible than PIC Lloyd's testimony that expired drugs were segregated and labeled. PIC Lloyd produced no evidence to corroborate his testimony, such as records showing that drugs had been returned before the inspections.

24. The evidence established that respondents violated section 4342, subdivision (a), of the Code by commingling expired drugs with unexpired drugs, failing to label the expired drugs as expired, and failing to quarantine expired drugs. Failing to label, quarantine and return expired drugs created the possibility that they would be accidentally dispensed to patients or used in a compounded medication.

Fourth Cause for Discipline-Failure to Maintain Facilities, Space, Fixture and Equipment

25. Section 1714, subdivision (b), of the Regulations requires licensed pharmacies to "maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed...."

26. The inspectors found chemotherapy containers and sharps container piled up in the chemotherapy hood and near the sink. PIC Lloyd could not explain to the inspectors whether his equipment was cleaned daily or weekly. The inspectors found that the temperature in the main room with the powder hood and drug storage area was 80.1 degrees. That temperature exceeds the maximum temperature permitted by the United States Pharmacopoeia by three degrees, is not a comfortable room temperature, and exceeded the temperatures recorded in the temperature log.

27. PIC Lloyd told the inspectors that a technician he was planning to hire had recorded the temperatures in the log. PIC Lloyd never told the inspectors he had a digital thermometer that provided the precise readings contained in the log. The inspectors did not see a digital thermometer. PIC Lloyd testified that he had a digital thermometer that was used to provide the precise readings shown in the log.

28. PIC Lloyd's testimony regarding the digital thermometer is not credible. The inspectors photographed the wall thermostat and another wall thermometer in the clean room, but they never were shown or observed a digital thermometer. The inescapable conclusion is that the temperature log was fabricated and PIC Lloyd sought to blame someone else for these safety and record-keeping violations.

29. The evidence established that respondents violated section 1714, subdivision (b) of the Regulations when they failed to maintain the pharmacy's facilities, fixtures and equipment in such a way as to ensure that drugs were safely and properly prepared and maintained.

Fifth Cause for Discipline-Failure to Maintain Reports for Compounded Drugs in a Collated Manner

30. Section 1735.8, subdivision (c), of the Regulations requires that "All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula."

31. At the beginning of the inspection on April 23, the inspectors asked PIC Lloyd for the master formulas, compounding worksheets, test results, and certificates of analysis for each product. PIC Lloyd had a difficult time finding the master formulas, compounding worksheets and test results for the selected items. AOM was not collating any of the reports or records together. The inspectors observed that some of the compounding worksheets were stored by patient name while others were stored by drug, and that some test records were placed in a binder and autoclave tests were stored in a small box. The inspectors determined AOM was not organized.

In Inspector Sakamura's opinion, having the reports readily available in a collated manner is necessary in the event there is a recall or of a patient complaint so relevant records can be readily retrieved. She believed that having records organized properly showed a great deal about a pharmacy and that respondents' records did not meet expectations.

Respondents admitted this allegation.

32. The evidence established that respondents violated section 1738.5, subdivision (c), of the Regulations by failing to maintain reports for compounded drugs in a collated manner.

Sixth Cause for Discipline-Knowingly Making a False Document

33. Section 4301, subdivision (g), of the Code provides that unprofessional conduct includes "Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts."

34. The inspectors obtained a logged formula worksheet for "triamcinolone acetonide ophthalmic injection suspension 80 mg/ml inj susp." The drug was compounded on April 20, 2012, but the formula worksheet was created on April 14, 2013, almost a year later. The worksheet showed that the sterile water for the injection was acquired on April 25, 2012, which was five days after the compound was made.

In Inspector Sakamura's opinion, the logged formula worksheet was created after the fact.

35. PIC Lloyd admitted that the worksheet was created on April 14, 2013, and that the drug was compounded on April 20, 2012. PIC Lloyd testified that he redid the worksheet; he blamed the original software company and software program for creating errors in the original worksheet. He replaced software companies and the program and recreated the document. PIC Lloyd testified he was not trying to fool anyone, but rather was trying to improve what he had, and he said he should have caught the erroneous dates.

36. PIC Lloyd's explanation makes no sense. He could not have compounded the drug on April 20, 2012, if he obtained the sterile water five days later, so either the date he compounded the drug was wrong or the date he obtained the sterile water was wrong. PIC Lloyd did not offer any corroboration for his claim that the software program was somehow at fault and created an error. He had nearly a year to correct the error and did not do so. The more reasonable conclusion is that PIC Lloyd knowingly created the worksheet on the date indicated, i.e., April 14, 2013, and that no worksheet was created at the time the drug was compounded.

37. The evidence established that respondents violated section 4301, subdivision (g), of the Code by knowingly making a false document.

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Seventh Cause for Discipline-Failure to Accurately Document Manufacturer and Lot Number

38. Section 1735.6, subdivision (a)(6), of the Regulations requires that for each compounded drug, a pharmacy's records must include, among other things, the manufacturer and lot number of each component.

39. The inspectors discovered worksheets on April 26 that did not have the manufacturer or lot number of the ingredients.

40. Respondents admitted this allegation.

41. The evidence established that respondents violated section 1735.6, subdivision (a)(6), of the Code by failing to have the manufacturer or lot number of compounded drugs on some of the pharmacy records.

Eighth Cause for Discipline—Failure to Keep Records of Master Formula

42. Section 1735.2, subdivision (d), of the Regulations requires that a pharmacy prepare "a written master formula record" that includes a number of enumerated elements before compoundingany product.

43. During the inspection on April 26, the inspectors asked PIC Lloyd for master formulas for unit-dose Avastin, vancomycin, amphotericin b, mitomycin and voriconazole that were compounded in the pharmacy. PIC Lloyd produced handwritten sheets of paper and printed drug information sheets, but they were not put together as a master formula.

44. Respondents admitted this allegation.

45. The evidence established that respondents violated section 1735.2, subdivision (d), of the Code by failing to prepare written master formulas for unit-dose Avastin, vancomycin, amphotericin b, mitomycin and voriconazole that were compounded in the pharmacy.

Ninth Cause for Discipline-Failure to List Equipment on Compounding Records

46. Section 1735.2, subdivision (d)(2), of the Regulations requires that a master formula for any drug compounded in the pharmacy list the equipment to be used.

47. The inspectors on April 23 reviewed some formula worksheets and master formulas. They determined that the equipment used by PIC Lloyd to compound drugs was not documented. Inspector Sakamura explained that having the equipment used to prepare a compounded drug helps to determine a solution if a problem exists.

48. PIC Lloyd testified at the hearing that he did not list any equipment because he did not know what the term meant, and he also blamed his software for this deficiency. PIC Lloyd's explanation does not justify his failure to satisfy this requirement.

49. The evidence established that respondents violated section 1735.2, subdivision (d)(2), of the Code by failing to list regularly the equipment used when he compounded drugs on formula worksheets and master formulas.

Tenth Cause for Discipline—Failure to Have Written Justification of the Chosen Expiration Dates for Compounded Sterile Injectable Products

50. Section 1751.7, subdivision (a)(4), of the Regulations requires that any pharmacy engaged in compounding sterile injectable drug products maintain a written quality assurance including, among other things, "written justification of the chosen expiration for compounded sterile injectable products."

51. Avastin is a chemotherapy drug available only in a liquid form at 25 mg/ml. and its manufacturer only makes four and 16 ml. vials. It does not contain a preservative and is in a single use vial. It is approved by the FDA for use in certain cancers; it is not FDA-approved for use in the eye.

Inspector Sakamura contacted the manufacturer of Avastin and requested data showing that the drug was safe or effective once it was out of the vial and remained in a syringe for any period of time. Inspector Sakamura received no information from the manufacturer on this subject. In determining an expiration date, a pharmacist would typically consider information obtained from the manufacturer or published studies, perform his or own studies, and use his or her professional judgment in considering such things as the nature of the drug, its degradation properties, the drug's packaging, storage conditions, the expiration date of similar products, and so forth.

PIC Lloyd told the inspectors on April 26 that he prepared Avastin syringes straight from the vial in 0.05 ml. or 0.1 ml. syringe sizes. PIC Lloyd said because the drug was expensive, he used the entire vial even if he did not have enough orders for the entire vial. A four ml. vial can make between 40 and 80 syringes. Physician orders ranged from four to 150 syringes at a time.

PIC Lloyd gave the unit-dosed Avastin syringes a one-month expiration date. Inspector Sakamura asked him how he determined one month was appropriate. PIC Lloyd said the expiration date was it was "purely arbitrary." PIC Lloyd said he called the manufacturer and spoke to someone, but received no information, and when he sought information from other sources, he found none. He told Inspector Sakamura that there was no information available to him to assist him in determining how long syringes were good for, so he arbitrarily assigned them an expiration date of one month. PIC Lloyd said he did not perform any testing.

52. The evidence established that respondents violated section 1751.7, subdivision (a)(4), of the Regulations by failing to have written justification for choosing the expiration dates for compounded sterile products.

The lack of accurate information regarding the expiration of Avastin is a serious matter. The syringes PIC Lloyd prepared contained a drug that was used in patients' eyes. Without

accurate information, PIC Lloyd could not know if the drug was potent or sterile after the time it remained in a syringe.

Eleventh Cause for Discipline-Failure to Maintain Adequate Records of Acquisition and Disposition

53. Section 4081, subdivision (a), of the Code requires that a pharmacy maintain "All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices...."

54. PIC Lloyd compounded "preservative free triamcinolone acetonide ophthalmic suspension injections, 80 mg/ml, 0.1 syringes." The solution PIC Lloyd used was 11 ml. PIC Lloyd used it to make 0.1 ml. syringes. He could make 110 syringes from the entire 11 ml. solution. Pharmacy records showed a typical order PIC Lloyd filled for syringes of this solution was 20-40 syringes or 2-4 ml.

Inspector Sakamura asked PIC Lloyd PIC Lloyd if he made 110 syringes during the April 23 inspection. PIC Lloyd said he did not because he wasted most of the 11 ml. Pharmacy records did not show the disposition of the extra drug.

55. PIC Lloyd testified that he did not know that he was required to keep track of the number of syringes he made or the amount of drugs he destroyed. He testified that since the inspection, he has kept track of this information on worksheets and he is looking into a software program to do this for him.

56. The evidence established that respondents violated section 4081, subdivision (a), of the Code by failing to maintain records of the disposition of compounded drugs. This information is important in case something goes wrong and the product needs to be recalled. Without knowing where the entire product went, PIC Lloyd could not implement an effective recall, he would not know how much product he had to recall, and he would not know where the product went.

Twelfth Cause for Discipline-Failure to Meet Labeling Requirements

57. In addition to requiring a warning label for cytotoxic agents, section 1751.2, subdivision (d), of the Regulations requires certain other information be included on the labels of sterile injectable products. Section 1735.4 of the Regulations also contains labeling requirements of compounded drugs.

58. There were several prepared drugs found in the pharmacy that did not have a label or were missing the required information such as preservative free, size or storage information.

59. The evidence established that respondents violated sections 1735.4 and 1751.2 of the Regulations by failing to meet labeling requirements on several drugs in the pharmacy.

Thirteenth Cause for Discipline-False of Misleading Label

60. Section 4078, subdivision (a)(1), prohibits any person from placing "a false or misleading label on a prescription."

61. Rx 1471 was a prescription for dexamethasone sodium phosphate opht 4 mg. that was maintained in the pharmacy. The label does not indicate whether it is topical drops or injection. The label is misleading because it could lead to an incorrect application in the eye.

62. The evidence established that respondents violated section 4078, subdivision (a)(1), of the Code by placing a misleading label on Rx 1471.

Fourteenth Cause for Discipline—Failure to Perform End Product Testing for Sterility and Pyrogens

63. Section 1751.7, subdivision (c), of the Regulations provides:

> (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

A pyrogen is a substance typically produced by a bacterium that produces fever when introduced or released in the blood.

64. Inspector Sakamura asked PIC Lloyd during the inspection of April 26 whether he did pyrogen testing of any of his injectable compounds. PIC Lloyd said he did not because he had not found out until recently that he was supposed to test for pyrogens. PIC Lloyd also said he did not do batch testing and did not quarantine end products until end product testing confirmed sterility and acceptable levels of pyrogens.

65. PIC Lloyd testified that he believed that pyrogens were the same as endotoxins, but he did not demonstrate that he tested for endotoxins. He understood the risks associated with the presence of pyrogens. He testified that he believed that a batch was a quantity of 25 syringes or more based upon the United States Pharmacopoeia. He did not conduct batch testing because he did not produce batches of 25 or more. Pharmacy records demonstrated that this testimony was false.

66. The evidence established that respondents violated section 1751.7, subdivision (c), of the Regulations by failing to subject batch-produced sterile injectable drug products to end product testing for sterility and pyrogens, and that respondents failed to quarantine such products until the testing confirmed sterility and acceptable levels of pyrogens.

This is a serious violation of the regulations because the failure to perform sterility and pyrogen testing on sterile injectable compounded drugs could result in patient harm or death. This violation is particularly serious because PIC Lloyd admitted that he did not know that he was required to have his sterile injectable compounds tested for sterility and pyrogens even though he had been operating AOM for nearly four years without having the required testing done.

Fifteenth Cause for Discipline—Compounding Environment Failed to Meet Criteria for Safe Compounding of Sterile Injectable Drug Products

67. Section 1751.4 of the Regulations provides in part:

> (a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

68. The pharmacy included a clean room that was split into three areas: an ante room and two side-by-side clean rooms. Each clean room had a hood. One of the clean rooms was the chemotherapy room where chemotherapy was made in a hood manufactured by Germfree. The other clean room was where other drugs were prepared in a hood manufactured by Baker, including IV drugs.

The hoods were certified on May 8, 2012. The certification was good for six months and expired in November 2012. Respondents' policies and procedures required certification of the hoods twice a year.

CEPA Company, which had tested the two hoods on May 8, 2012, sent a technician to AOM on April 10, 2013, to test the two hoods. Neither hood passed certification on that day. The technician noted on an inspection report that the exhaust was too low for the Germfree hood, The technician recommended that a "short cone" be brought for the re-test. As for the Baker hood, the inspection report indicated that the technician could not test the hood because there was no power to the hood's outlet.

Micah Hunter performed the inspection of respondents' two hoods on April 11. PIC Lloyd told him that since the test of the Germfree hood the day before, someone had come to fix the hood and the exhaust had been increased. Mr. Hunter tested the Germfree hood and found the exhaust flow was still too low. He did not certify the Germfree hood. He tested the Baker hood and certified it that day.

Mr. Hunter told PIC Lloyd that the exhaust was too low on the Germfree hood and that he needed to repair it to increase the exhaust. He said the hood did not qualify for certification. Mr. Hunter did not complete the certification sticker that was affixed to the hood because it had not certified. He only completed the certification sticker if the hood were certified. PIC Lloyd became irate and asked Mr. Hunter what he should do. Mr. Hunter told him to do what he had to do. PIC

Lloyd asked Mr. Hunter whether he should shut down his pharmacy. Mr. Hunter told him that was what other pharmacies did. Mr. Hunter did not tell PIC Lloyd that the air was sterile because it was not sterile, and he did not tell PIC Lloyd that he could use the hood to compound.

69. CEPA also performed environmental testing on April 10, 2013, and CEPA transmitted the sample it obtained to EMLab P & K. The lab report showed that there were low levels of bacteria growth in the in the chemotherapy and IV rooms and higher levels of bacteria growth in the ante room. There was no bacteria found in the hoods. The bacteria in the ante room could contaminate the clean rooms. PIC Lloyd did not have the rooms tested again before the April 23 inspection; nor did PIC Lloyd test them himself. PIC Lloyd blamed CEPA for bringing in unsterilized equipment into the pharmacy that caused the positive findings.

70. The inspectors on April 23 asked PIC Lloyd for hood certifications. PIC Lloyd did not tell the inspectors that the Germfree hood had not been certified, and the inspectors did not discover that it had not been certified until they reviewed the inspection report related to the inspection on April 10 which showed that the hood did not pass certification because the exhaust was too low. PIC Lloyd said he had problems certifying the Germfree hood and CEPA would be returning that day. The inspectors told PIC Lloyd not to compound in the Germfree hood because it was not certified.

71. The inspectors asked PIC Lloyd during the April 26 inspection whether the Germfree hood had passed certification. PIC Lloyd said it had not been certified. The inspectors reviewed pharmacy records and found eight prescriptions from five different doctors that established PIC Lloyd compounded Avastin between April 12 and April 19. The number of injectables ranged between 24 and 80 per prescription. Inspector Sakamura estimated that PIC Lloyd compounded about 200 syringes between April 10 and April 19, which could mean there were 200 patients who received injections.

PIC Lloyd filled a prescription for 17-hydroxyprogesterone on April 25.

72. PIC Lloyd testified that on April 11, he watched Mr. Hunter perform the tests. After testing, he spoke with Mr. Hunter, who told him that the hood and the floor were sterile but there was a problem with the exhaust and that he had to find out what was wrong with the hood. PIC Lloyd then contacted CEPA and other companies to find out what was wrong with the exhaust and how to fix it. The hood was eventually repaired, and it was certified on May 8.

PIC Lloyd testified that he did not learn that the Germfree hood was not certified until April 19, when he happened to look at the sticker affixed to the hood and saw that there was no certification. He testified he called CEPA and was told that the hood would not be certified until it was fixed. PIC Lloyd testified that he did not do any further compounding using the hood following this conversation. He believed that that the hood nevertheless provided a sterile environment and that it was within the standard of practice to have used it during a period when it was not certified.

When the inspectors arrived at the pharmacy on April 23, according to PIC Lloyd, he immediately told then there was a problem with the hood.

73. PIC Lloyd's testimony that he did not know the Germfree hood had not been certified on April 11 and that he only learned that it had not been certified on April 19 is not credible. It was contradicted by the testimony of Mr. Hunter, and it flies in the face of PIC Lloyd's testimony that he was very involved in the testing process on both April 10 and 11. It is inconceivable that he did not know that the Germfree hood had not been certified on April 10 because CEPA had to return the next day and it is inconceivable that he did not know the hood had not been certified on April 11 because it had not been repaired and the exhaust readings were still too low. Furthermore, PIC Lloyd's testimony that Mr. Hunter told him the hood provided a sterile environment is not credible. Mr. Hunter denied telling PIC Lloyd that and testified he would not have said that because it was not true.

74. The evidence established that respondents violated section 1751.4, subdivision (a), of the Regulations because PIC Lloyd compounded chemotherapy drugs in a the Germfree hood at a time when it was not certified and when he knew or should have known that that environment was not safe for the compounding of sterile injectable drugs.

This is one of the most serious violations disclosed by the inspections because of the harm that could have resulted. PIC Lloyd knowingly put patients at risk rather than shutting down his pharmacy until the hood was repaired. He disregarded the instructions the inspectors gave him on April 23 to stop compounding using the Germfree hood. And at the hearing, he lied about what he knew in order to explain why he continued to compound injectable drugs using the hood.

Sixteenth Cause for Discipline-Gross Negligence

75. This cause for discipline is based upon the facts set forth in the Fifteenth Cause for Discipline.

Inspector Sakamura testified at the hearing and qualified as an expert in the field of compounding pharmacy. In her opinion, it was an extreme departure from the standard of care for PIC Lloyd to compound injectable drugs in a hood that was not certified. In addition, she believed that PIC Lloyd should not have continued to compound injectable drugs in an environment where bacteria had been found.

Jacky Lee testified on behalf of respondents. He received a Doctor of Pharmacy with a Certification of Public Health through an on-line program administered by the Creighton University School of Pharmacy in 2006. He obtained an MBA from UCI in 2012. He is a licensed pharmacist in California who recently opened his own compounding pharmacy.

Mr. Lee testified that if a hood did not pass a certification, there was a risk of contamination from using it and that he would not do it. He testified he would not compound using an uncertified hood even if a technician told him the that air was sterile because he believed he was required to

rely on the written certification. He did not believe it was within the standard of practice to compound in an uncertified hood.

76. The evidence established that PIC Lloyd committed gross negligence when he compounded sterile injectable chemotherapy drugs between April 10 and April 25 in a hood that was not certified and in clean rooms where bacteria was growing.

Seventeenth Cause for Discipline-Inadequate Plan for Recall

77. Section 1735.5, subdivisions (a) and (c)(2), of the Regulations requires any pharmacy engaged in compounding to maintain a written policy and procedure manual and that the manual include, among other things, "Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product."

78. Respondents Policy for Drug Recalls provides:

> A. Drug Recall Notices shall be received, signed by Pharmacist-in-Charge, and maintained in the Pharmacy for seven (7) years.
>
> B. The P.I.C. shall review such Recall Notices from Wholesaler and pull any drugs in Pharmacy inventory which have been recalled.
>
> 1) This drug shall be quarantined and returned to Wholesaler or Manufacturer, as directed on Recall Notice.
>
> C. The P.I.C. shall generate a report from Suite Rx for all prescriptions filled with recalled drug and lot number.
>
> D. Both Prescriber and Patient shall be notified when a prescription was filled using a recalled drug.
>
> 1) Prescription will be replaced upon request of Physician.

79. In Inspector Sakamura opinion, respondents' recall policy was inadequate because it only addressed a recall initiated by a manufacturer; it did not address an internally initiated recall process for compounded products.

80. In Mr. Lee's opinion, respondents' recall policy was adequate because it addressed all recalls. However, he had never done an internal recall.

81. Inspector Sakamura has had far more experience in evaluating the policies and procedures of California pharmacies than has Mr. Lee. She was far more familiar with the standard of care. An examination of respondents' recall policy shows no reference to an internally initiated recall policy.

82. Based upon the wording of respondents' recall policy and the opinion of Inspector Sakamura, it was established that respondents violated section 1735.5, subdivisions (a) and (c)(2), of the Regulations by not having a recall policy that covered internally initiated recalls.

Nineteenth Cause for Discipline-Making and Selling Adulterated Drugs

83. Health and Safety Code section 111295 provides:

> It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

84. Health and Safety Code section 111255 provides:

> Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

85. Health and Safety Code section 111260 provides:

> Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

86. Inspector Sakamura believed that all the drugs PIC Lloyd compounded in the Germfree hood after April 10, 2013, were adulterated or contaminated within the meaning of Health and Safety Code sections 111255 and 111260 because the drugs were prepared in a hood that was not certified; thus, the drugs were not prepared in accordance with current good manufacturing practice standards. Inspector Sakamura testified that this was a serious violation because it could not be determined whether the compounded drugs were prepared in a clean environment and consequently there was a risk of harm or death to patients.

87. Respondents produced and sold adulterated drugs that PIC Lloyd compounded in a chemotherapy hood that was not certified between April 10 and 26, 2013; bacteria grew in the clean rooms and ante rooms on and after April 10, 2013.

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Twentieth Cause for Discipline-Failure to Submit Data to CURES Weekly

88. Health and Safety Code section 11165, subdivision (a), authorizes the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of information regarding the prescribing and dispensing of Schedule II, III, and IV controlled substance by practitioners who are authorized to dispense these controlled substances. Subdivision (d) requires that for prescriptions for a Schedule II, III, or IV controlled substance, the dispensing pharmacy must report to the Department of Justice as soon as reasonably possible but not more than seven days after a controlled substance is dispensed. Subdivision (d) describes the information that must be included in the report.

89. The Board did not have recent CURES data from respondents and consequently during the April 23 inspection, the inspectors asked PIC Lloyd for proof that he had been submitting the data on a weekly basis. PIC Lloyd said he manually did it on his computer and claimed he was compliant. The inspectors asked PIC Lloyd to print proof of his submissions of CURES data, but PIC Lloyd was only able to pull up some information on the computer screen. The screen information did not show weekly submissions and showed only a few transmissions over the previous year.

Respondents had been advised during annual inspections in 2011 and 2012 regarding problems relating to the submission of CURES data.

90. PIC Lloyd testified that he used a computer program to enter relevant data, and that after he finished entering the data he was asked whether he wanted to send the information it to the DEA.[1] When asked that question, PIC Lloyd said then pushed the "send" button. He assumed that the information was then sent to the DEA. He explained that he understood the report relating to the information he provided was first sent to Atlantic Associates, a clearinghouse for the information, and then was transmitted to the DEA. PIC Lloyd said he believed he was in full compliance. He testified that he called the DEA and was told that it had received the information. He said he checked the history of his submissions and they showed that the reports had been submitted. PIC Lloyd believed it was a "computer glitch" and believed the fault was with his software vendor.

PIC Lloyd testified that he has since corrected the problem.

91. PIC Lloyd offered no documentation to corroborate his testimony that he regularly submitted CURES reports before the April 23 inspection from his own computer, Atlantic Associates, or the Department of Justice. In the absence of some corroboration, and particularly in light of the prior warnings to respondents that there had been problems for two years with its CURES submittals, Inspector Sakamura's testimony that she observed only a

[1] PIC Lloyd referred to the DEA a number of times as the recipient of the information he provided in the CURES report. Section 11165 of the Code requires the information to be submitted to the state Department of Justice, not the DEA.

few transmissions in the previous year and found no weekly transmissions on respondents' computer screen is sufficient to establish a violation of section 11165, subdivision (a) of the Code.

Twenty-First Cause for Discipline-Unjustified Expiration Date on Compounded Medication

92. Section 1735.2, subdivision (h), of the Regulations requires that every compounded drug product be given an expiration date (beyond use date) beyond which in the professional judgment of the pharmacist it should not be used, and the expiration date cannot exceed 180 days from preparation of the product or the shortest expiration date of any component unless a stability study supports a longer expiration date.

93. PIC Lloyd compounded vancomycin stock on November 26, 2012. The stock vial indicated the drug expired in December 2012. PIC Lloyd placed a beyond use date on the refrigerated syringes of December 10, 2012. He gave a beyond use date of February 18, 2013, for frozen syringes at -20 degrees.

When asked by the inspectors on April 26 why he extended the beyond use date, PIC Lloyd said that he extended the date because the doctor asked him to do so. PIC Lloyd did not do any testing for potency or stability of the syringes and the pharmacy did not have a freezer that went to -20 degrees. PIC Lloyd provided paperwork to the inspectors that showed frozen syringes could have a longer expiration date, but the product brand used and the diluent used to dissolve the drug were different from the paperwork he provided.

94. Respondents admitted this allegation.

95. The evidence established that respondents violated section 1735.2, subdivision (h), of the Regulations when PIC Lloyd made and sold compounded drugs and provided an expiration date that was unjustified.

In Inspector Sakamura's opinion, this was a serious violation because the expiration date that PIC Lloyd provided was arbitrary; he had no reason to create a date that others would rely on to establish that the drug was not contaminated or remained potent.

Twenty-Second Cause for Discipline-Inadequate Policies and Procedures

96. Section 1751.3 of the Regulations requires any pharmacy engaged in compounding sterile injectable drugs products to maintain a written policy and procedure manual for compounding that includes a lengthy list of enumerated elements as well as the elements required by section 1735.5 of the Regulations.

97. Respondents' recall policy was deficient.

98. The inspectors reviewed respondents' policies and procedures manual and determined that in several respects the manual did not reflect the pharmacy's current business practice:

a. The policies provided that the hoods would be certified every six months but respondents had the hoods certified on May 8, 2012, but no inspection was scheduled until April 10, 2013, and no certification was made of the Germfree hood until May 8, 2013.

b. The policies provided that there would be end product verification every three months or 200th prescription but this was not done.

c. The policies provided that there would be documentation of ingredient lot number and equipment but this was not done.

d. The policies identified a batch as 25 or more and stated that the drug would be quarantined in a sealed container and every product compounded on the 15th of each month would be tested, but this was not done.

e. The policies required ingredient lot number and equipment to be recorded but this was not done. Beyond use dates should have been assigned based testing records but instead were based on risk.

f. The policies required that chemotherapy labels be placed on drug products but this was not always done.

g. The policies required that chemotherapy packages, shelves and storage be labeled but this was not always done.

h. The policies required that hazardous drugs be stored in sealed containers, labeled uniquely and stored separately but this was not always done

i. The policies required that the labels contain certain information, instructions for storage and handling and the chemotherapy label that it must be disposed of properly but this was not always done.

99. Respondents violated section 1751.3 of the Regulations by failing in one instance to have an adequate recall policy in its policies and procedures manual and in another instance by failing to follow its policies and procedures manual in the areas of quality assurance and testing of equipment and products, labeling, beyond use dates, documentation, and product verification.

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Twenty-Third Cause for Discipline-Inappropriate Exercise by PIC Lloyd of Education, Training or Experience as a Pharmacist.

100. Section 4306.5 of the Code defines unprofessional conduct in part as:

> (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

101. In the course of describing to the inspectors on April 23 how he prepared triamcinolone acetonide ophthalmic injection suspension 80 mg/ml., PIC Lloyd said he made 11 ml. instead of a lesser amount than what he actually needed because he only had equipment to weigh large amounts and he could not weigh smaller quantities. To the inspectors, this meant that the pharmacy was not equipped with the appropriate equipment for the products it was compounding. Inspector Sakamura's concern was that using larger equipment to measure a small quantity would not be as accurate and could produce larger variations than the use of more appropriate equipment that could more accurately measure smaller quantities. Based on her training and experience, Inspector Sakamura believed that PIC Lloyd should have purchased a scale that measured lesser amounts of medications, and the failure to do so showed that PIC Lloyd was not using his education, training and experience as a pharmacy.

102. Mr. Lee testified on behalf of respondents that he viewed PIC Lloyd's use of equipment that was better suited for measuring large quantities than equipment designed to measure smaller quantities as appropriate because he believed that when a larger quantity of a medication is made, there would be less variation throughout the product and therefore each syringe created from the larger amount would be more accurate and subject to less variation. Mr. Lee did not see a problem with the method PIC Lloyd used in creating the 11 ml. of triamcinolone acetonide ophthalmic injection suspension.

103. PIC Lloyd testified that after the inspections, he bought a new scale.

104. It was not established that PIC Lloyd violated section 4306.5, subdivision (a), of the Code in his choice of equipment. The testimony and opinions of Inspector Sakamura and Mr. Lee relied solely upon their reasoning and logical assumptions. There was no evidence or corroboration to conclude that one was correct and the other was not. No recognized professional standard of care was established. There was no evidence that the medications PIC Lloyd produced using the larger-measuring equipment were inaccurate. It was his choice to make a larger amount and waste some of it than to purchase equipment that would allow him to make a lesser amount. PIC Lloyd's decision to compound the medications in the manner he chose does not constitute unprofessional conduct.

Subsequent Inspections

105. Immediately after the April 26 inspection, the inspectors prepared an Inspection Report and gave it to respondents. The report contained a list of the violations of the regulations that they found and directives for respondents to follow.

One request the inspectors made was for PIC Lloyd to recall all the items he made in the Germfree chemotherapy hood when it was not certified. April 26 was a Friday. On April 29, the following Monday, PIC Lloyd sent a Recall Notice by fax to the doctors who received the products he produced during the period when the chemotherapy hood was not certified. PIC Lloyd provided a copy of the recall notice to the inspectors.

The inspectors asked for certain prescriptions, including the prescriptions for medications that PIC Lloyd produced during the time the chemotherapy hood was not certified. Respondents faxed them to the inspectors on May 1.

On May 8, respondents sent the inspectors a document entitled "Beyond Use Guidelines for Sterile Compounding Products" that described how the beyond use date would be determined, a copy of a study relating to the six-month stability of Avastin, a protocol for the quarantine of non-sterile to sterile compounding products, a certification from CEPA that showed that the Germfree hood was certified on May 8, revisions to the sterile compounding policies and procedures manual, proof of the recall of Avastin products, and revision to the recall policies and procedures.

106. On May 14, 2013, Inspector Sakamura returned to respondents' pharmacy and gave PIC Lloyd a report that contained a list of all the violations the inspectors found during their inspections on April 23 and 26. She also inspected the pharmacy, after which she wrote an Inspection Report dated May 15, 2013. During this inspection, Inspector Sakamura and PIC Lloyd discussed each item of non-compliance listed in the May 14 report. PIC Lloyd explained how each order was processed, filled and quarantined, and he gave Inspector Sakamura a copy of the study relating to Avastin stability. They discussed the modified policies and procedures created by respondents and beyond use dates. Inspector Sakamura noted that all rooms and hoods were currently certified and the majority of logged formula worksheets had the master formula on them, but needed expiration dating. She asked that PIC Lloyd make sure logged formula worksheets included all steps and equipment used in the compounding process, and to make sure that labels and sheets had legible information.

Inspector Sakamura informed respondents that the cease and desist order was lifted.

Inspector Sakamura asked PIC Lloyd to send her all relevant paperwork before resuming compounding and before any sterile products were sent out of the pharmacy.

107. Inspector Sakamura returned to respondents' pharmacy on June 6, 2013, to conduct a renewal inspection. She noted that there was no compounding being done that day and that the sink was being fixed. PIC Lloyd said that he had not changed the expiration

dating on the syringes from 30 days and they discussed a study about Avastin. She urged PIC Lloyd to make sure that he was able to justify his choice of an extended expiration date.

PIC Lloyd showed Inspector Sakamura an email that he had received from his attorney relating to a discussion the attorney had with Board staff. Inspector Sakamura asked that PIC Lloyd send her all paperwork for sterile injectable products until further notice. They discussed preparing drugs for office use and the relationship of that activity to manufacturing/wholesaling. Inspector Sakamura also spoke to PIC Lloyd's attorney concerning his contact with Board staff and the violations cited in her report.

In Inspector Sakamura's opinion, PIC Lloyd did not understand what it was that he should be doing. She explained that the law was clear relating to master formulas, but PIC Lloyd did not follow the law, which, in her opinion, indicated that PIC Lloyd was not able to comply with his legal obligations.

108. Inspector Sakamura returned to respondents' pharmacy in August 2014 after PIC Lloyd had issued a recall notice. Her impression was that the physical premises were cleaner, the temperature was cooler, the master formulas were better than before, but there was still an issue with growth of bacteria because there had been earlier instances of growth that had been discovered in the pharmacy in January. She viewed this as a trend. Other compounding pharmacies did not have growth.

Inspector Sakamura reiterated that in her opinion, PIC Lloyd did not understand the laws and he still had to make many changes in the way he operated his pharmacy. One example was his failure was his inability to make changes to avoid growth. She did not believe that PIC Lloyd understood the urgency of the changes he was required to make, and she pointed to the long time it took PIC Lloyd to create a good master formula. She noted that PIC Lloyd gave arbitrary beyond use dates without justification, that he used chemotherapy hoods that were not certified, that there was bacteria growing on the pharmacy and that despite this knowledge he did not do anything to resolve these problems. She believed that PIC Lloyd posed a risk to the public.

Respondents' Evidence

109. PIC Lloyd obtained his Doctor of Pharmacy from USC in 1992 and his California pharmacy license in 1994. He was also licensed in Nevada, but he let that license lapse.

Before he started pharmacy school, PIC Lloyd worked at Children's Hospital, and he continued to work there after he started school. He received some training in compounding and he produced sterile IVs. He worked at the pharmacy at Daniel Freeman Hospital and for Thrifty Drugs while he was attending pharmacy school. After he finished school, he managed a Thrifty Drugs store for four years before moving to Pharmerica, a company that provided long term care to patients in Beverly Hills. PIC Lloyd was the chief pharmacist.

PIC Lloyd left that position to become a pharmacist at the Riverside Center for Behavioral Medicine. He advanced to become the assistant director of pharmacy.

In 2009, PIC Lloyd opened AOM. While awaiting the permit for AOM, PIC Lloyd worked at Long Beach Memorial in the outpatient pharmacy. PIC Lloyd learned about sterile compounding from a Professional Compounding Centers of America education course he took in 2009. He purchased blueprints and hired Clean Rooms West to build AOM. During the construction, PIC Lloyd learned about air flow, gauges, and so forth. He worked with the chief engineer of the company and eventually had AOM certified by CERTS. PIC Lloyd read law books relating to compounding, took a self-assessment, joined academies of compounding pharmacists, and joined the California Pharmacists Association. He has been a member of the association for 10 years, and he served as the president of the local chapter. He also joined the California Compounders for the Advancement of Pharmacy in order to share information. He joined an international academy about two years ago. PIC Lloyd keeps up with the changes in state and federal law by participating in webinars. PIC Lloyd is the President, CFO and Pharmacist-In-Charge of AOM. Renee Lloyd is the Secretary and handles the clerical work. The two are partners.

110. The thrust of respondents' defense was devoted to establish mitigation and to show that in response to the inspections on April 23 and 26, respondents have changed the way AOM operates and now complies with the regulations and statutes regulating compounding pharmacies. This evidence was presented through the testimony of PIC Lloyd and the introduction of documents. PIC Lloyd testified as follows:

Anna Yamada was the inspector who performed the pre-license inspection and insisted that the chemotherapy containers remain in the chemotherapy room. She told PIC Lloyd to obtain a kit to clean up waste and to keep it in the chemotherapy room. PIC Lloyd followed her directions, and no one ever told him that he should not do that. She reviewed his policies and procedures and concerning the recall procedure and believed that it covered a self-recall. He has followed this procedure, and his recalls have recovered all the recalled inventory within a week. Inspector Yamada also inspected his equipment and found nothing deficient.

Inspector Kazebee conducted the 2012 annual inspection. He did not tell PIC Lloyd to remove the waste from the chemotherapy room. PIC Lloyd viewed anything Inspector Kazebee said as being a suggestion to him for improvement of the pharmacy.

PIC Lloyd upgraded some of equipment. He spent several thousand dollars fixing the chemotherapy hood exhaust. The inspection that led to the finding of a defective exhaust could not be completed on April 10 because CEPA did not have the necessary equipment and they did not do any studies that day. PIC Lloyd did not get the CEPA reports until much later, and pointed out that it frequently took weeks after an inspection before he received

CEPA reports. He believed he did not see the April 11 inspection report until after the exhaust problem was fixed.[2]

After the CEPA inspections, PIC Lloyd switched testing companies because he did not believe the CEPA technicians were properly trained, and he blamed them for introducing contamination into the pharmacy. He talked to a friend who had experienced the same problem. PIC Lloyd now uses TSS to perform its testing. In addition, he switched detergents and had TSS test for contamination. PIC Lloyd was pleased with the manner that TSS conducted its testing. He believed that he had done everything to avoid contamination, including cleaning the sink. A report he received from TSS for samples obtained in September 2014 showed no contamination. PIC Lloyd believed this finding validated his suspicion that the source of contamination was from CEPA, and he hoped that by changing to TSS he eliminated this external source of contamination.

PIC Lloyd changed his procedure. He now schedules inspections or cleanings at the time of the inspection or cleaning for six months in the future.

PIC Lloyd introduced all the documents that he had prepared in response to the inspections. He created a plan of action on April 23 or 24 to address labeling, CURES reports, collating documents, and many of the other problems the inspectors found. He said he tried to do all the things the inspectors told him to do as promptly as he could, including working with his software to improve the CURES reporting and fixing the hood. He wrote a protocol to handle workflow. He created new and separate labels for chemotherapy drugs. In response to instructions from Inspector Sakamura, he now has two labels on syringes, although several doctors have complained to him that two labels make it difficult to use the syringes.

PIC Lloyd provided a Return Authorization from Guaranteed Returns listing drugs that he had returned. He provided an equipment master cleaning/maintenance/calibration chart that indicated what type of cleaning was performed and how often equipment would be cleaned. PIC Lloyd pointed out that the during the 2012 inspection, the data relating to cleaning had been approved by the inspector.

PIC Lloyd created beyond use date guidelines for sterile compounding products based on his discussions with Inspector Sakamura. He provided the Avastin six-month stability study to the inspectors, which she said was good and needed to be followed exactly.

PIC Lloyd created a Protocol for Quarantine and a policies and procedures manual for sterile compounding. He provided a report from CEPA showing that the hood had been fixed. He created a procedure for collating records. He sent a recall notice to all the doctors for whom he provided Avastin, and created a record of his contacts with the doctors and the return of the Avastin. He obtained a list of medications that were returned. He wrote a

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[2] According to the inspectors, PIC Lloyd gave them the inspection report on April 23. It was from the report that they learned the hood had not been certified.

policy for drug recalls that included internally-created drugs. He created refill prescription logs and master formula worksheets. He documented the return of expired drugs. He had previously submitted all these documents to the Board or the inspectors.

When PIC Lloyd applied for the renewal of his compounding permit in 2014, he submitted new and more detailed policies and procedures manual.

PIC Lloyd was present when a liquid spilled on Inspector Kazebee's hands on April 23 when he inspected the refrigerator. The inspector did not tell him what to do with the bag, and PIC Lloyd saw no evidence of a leaking bag. After the inspectors left, he inventoried the bags, placed them in appropriate containers, and intended to return them.

PIC Lloyd recognized that he had not put warning labels on the syringes containing chemotherapy drugs and that the information had been placed only on the bags that contained the syringes. After the inspections, he started placing the warning labels on the syringes. He never received a complaint from any doctor about the labels before he made the change, but after he started adding the second label to the syringes, doctors complained that they had trouble holding the syringes.

PIC Lloyd filed his master formulas separately from the worksheets in accordance with what he believed Inspector Kazebee had told him to do two years before the April 2013 inspections. After those inspections, he collates the worksheets and keeps them together. He also revised the master formulas to comply with the directions he received from Inspector Sakamura.

PIC Lloyd believed he that he had provided every document requested of him by the inspectors and that he did everything he could to remediate the deficiencies that they found.

PIC Lloyd was never told by any doctor that a patient had been injured by a product that he provided. He has never had any claims or lawsuits filed against him. He has never compounded a drug that was found to be contaminated. He has never produced Avastin that was not sterile. He segregated expired drugs from unexpired drugs, and he had never dispensed an expired drug to a patient.

PIC Lloyd now knows that he cannot compound medications in an uncertified hood.

PIC Lloyd decided to open a compounding pharmacy because he wanted to do something important and obtain satisfaction by personalizing medication for a patient. He has a passion for pharmacy and views it almost as a ministry. He did not enter the field haphazardly. He does pro bono work for low income, high risk pregnant women who need medications who are not covered by Medi-Cal.

111. Renee Lloyd has been married to PIC Lloyd for 30 years, and has been his partner in AOM for 10 years. She has a bachelor's degree in biology from UCLA and has

taken courses in microbiology. She worked for a year at a clinical pathology lab after she graduated from UCLA, and she has worked in various positions over the years.

Mrs. Lloyd testified that she helped PIC Lloyd open AOM in 2008 by filling out the application and obtaining the lease for the premises. She helped him obtain an SBA loan to build the pharmacy. She and PIC Lloyd are repaying the loan at the rate of $2,900.00 a month.

Mrs. Lloyd was present on April 23 during the inspection and kept of list of things that the inspectors wanted them to do. She observed PIC Lloyd make the changes, including changes in the paperwork. She explained that PIC Lloyd dictated to her how the new documents were to be prepared and she entered the information into their computer program.

Mrs. Lloyd described PIC Lloyd's efforts to have the Germfree hood fixed and represented that the Board was notified immediately after it was fixed She prepared the recall notice that the inspectors demanded on April 26, and heard PIC Lloyd call several doctors offices that afternoon. PIC Lloyd faxed all the documents that the inspectors requested.

Mrs. Lloyd testified that the pharmacy is the only source of income for their family and that without licenses, all aspects of the pharmacy would be shut down, including consulting services. She described the debts they incurred when they opened the pharmacy, and she did not believe they would be able to repay those debts if the pharmacy closed.

112. Mr. Lee visited AOM on Sept 14, 2014, to observe its operation. He examined the clean rooms, equipment, and workflow. He found the clean rooms were well-maintained and updated; the pressure was correct.

Mr. Lee reviewed the Avastin stability study, which he believed was a valid study and could be used to support a beyond use date.

Mr. Lee believed respondents' recall policy was adequate and addressed all types of recalls. He believe respondents' current policies and procedures were adequate. He could not comment on the master formulas because he needed to observe PIC Lloyd actually compound medications.

Costs

113. The Board incurred costs of investigation of this matter in the amount of $10,455.00. and it incurred costs of enforcement in the amount $18,037.50 for the services of the Attorney General. The total cost of investigation and enforcement is $28,492.50, and that is a reasonable amount for the investigative and prosecution services that were provided in this disciplinary proceeding.

LEGAL CONCLUSIONS

1. Business and Professions Code section 4301 provides in part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> [¶] . . .
>
> (c) Gross negligence.
>
> (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
>
> [¶] . . .
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> [¶] . . .
>
> (*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

2. Cause was established to revoke or suspend respondents' licenses and permits pursuant to Business and Professions Code sections 4301, subdivision (o), violation of state or federal laws or regulations governing pharmacy.

3. Cause was established to revoke or suspend respondents' licenses and permits pursuant to Business and Professions Code sections 4301, subdivision (g), knowingly making a false document.

4. Cause was established to revoke or suspend respondents' licenses and permits pursuant to Business and Professions Code sections 4301, subdivision (c), gross negligence.

5. Cause was not established to revoke or suspend respondents' licenses and permits pursuant to Business and Professions Code sections 4301, subdivision (o).

6. Cause was established to require respondents to pay the Board's costs of investigation and enforcement of this matter in the amount of $28,492.50.

7. California Code of Regulations, title 16, section 1760 provides that in reaching a decision on a disciplinary action, the Board's Disciplinary Guidelines should be considered.

The Board's Guidelines provide in part:

> Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.
>
> In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:
>
> 1. actual or potential harm to the public
> 2. actual or potential harm to any consumer
> 3. prior disciplinary record, including level of compliance with disciplinary order(s)
> 4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
> 5. number and/or variety of current violations
> 6. nature and severity of the act(s), offense(s) or crime(s) under consideration
> 7. aggravating evidence
> 8. mitigating evidence
> 9. rehabilitation evidence
> 10. compliance with terms of any criminal sentence, parole, or probation
> 11. overall criminal record
> 12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
> 13. time passed since the act(s) or offense(s)
> 14. whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
> 15. financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

8. The Guidelines divide violations of pharmacy laws into categories and provide a recommended minimum and maximum penalty for each category. The evidence established violations of Categories II and III, which carry a minimum penalty of revocation, stayed and three years probation, and a maximum penalty of revocation. The evidence in light of the above factors demonstrated the following:

a. There was potential harm to the public, but no actual harm was established. There was no evidence that PIC Lloyd produced any contaminated products.

Because of the nature of the work performed by compounding pharmacies, the potential harm could have been great, particularly in those instances when PIC Lloyd compounded medications in an uncertified hood and when bacteria was growing in the ante room and the clean rooms. There was potential harm to the public when he failed to test for pyrogens and when he arbitrarily selected beyond use dates.

b. There have been no prior disciplinary actions or warnings issued against respondents. However, prior inspections revealed some problems with the operation of AOM, such as the failure relating to CURES reporting, which were again revealed during the April 2013 inspections

c. The evidence established 20 violations of the Pharmacy Law and the regulations passed by the Board. Some violations were for minor transgressions and some involved different violations for the same conduct. Nevertheless, the evidence established a large number of violations, several of which were serious.

The most serious violation was PIC Lloyd's decision to continue to compound chemotherapy in the Germfree hood when it had not been certified. PIC Lloyd's actions put patients at risk because of the harm that could have resulted, and his misconduct was aggravated when he disregarded instructions from the inspectors on April 23 and continued to compound chemotherapy drugs using the hood. Other serious violations included pyrogen testing of batches exceeding 25, the lack of accurate information to support an accurate expiration date for Avastin, and the selection of arbitrary beyond use dates for vancomycin

d. PIC Lloyd's testimony must be considered an aggravating circumstance. On a number of occasions, he simply lied. In an effort to justify his continued compounding of medications after the Germfree hood failed to pass inspections on April 10 and 11, he falsely claimed that the technician did not tell him that the hood did not pass and he falsely claimed the technician told him the room was sterile. Mr. Hunter's testimony to the contrary was far more credible than PIC Lloyd's false representations. On the subject of the hood, PIC Lloyd testified that he immediately told the inspectors that the hood had not passed the inspection, but Inspector Sakamura credibly testified that the inspectors learned of the lack of

certification only after they reviewed the inspection report. Inspector Sakamura's testimony was more credible than PIC Lloyd's evasive testimony to the contrary. PIC Lloyd testified that he did not create batches in excess of 25 when his records clearly demonstrated he did so. When he was asked to explain this discrepancy, his testimony was evasive. PIC Lloyd testified that he kept expired and labeled drugs segregated from unexpired and unlabeled drugs in the refrigerator. Inspector Sakamura's testimony and the photographs established that was not the case.

While PIC Lloyd testified that he took responsibility for the operations of AOM, he frequently blamed others for the deficiencies that were discovered during the inspections. He blamed a part-time volunteer employee for recording the fabricated temperatures in the temperature log. He blamed his software for many errors, including the transmission of the CURES data, the false worksheet, and the failure of his worksheets to list the equipment he used. He blamed CEPA for introducing bacteria into the ante room and clean rooms during its inspection of the hoods.

Another aggravating circumstance was PIC Lloyd's failure to comply with the statutes and regulations even though he had been specifically told that his work did not satisfy existing requirements. He had been told twice in the past that there were problems with his CURES reporting, but it appears he did nothing to correct the problem until after the April 2013 inspections. He was advised about proper beyond use dates and labeling requirements in prior inspections, but he continued to violate those requirements.

PIC Lloyd's failure to do pyrogen and sterility testing, and his admission that he had never done it because he did not know he was required to perform such testing, is an aggravating circumstance. His admission meant that he had been compounding batches in excess of 25 for nearly four years without any pyrogen testing being performed. Pyrogen testing is necessary to determine whether there is any substance in the medication that could cause fever, and testing is an important requirement that helps ensure that medications are safe. PIC Lloyd's failure to know that he was required to perform this testing is inexcusable.

It is also an aggravating circumstance that after the inspection on April 23, PIC Lloyd did not take immediate steps to cure even the simple problems found by the inspectors, such as removing expired drugs from the refrigerator before the second inspection. And, after the second inspection, AOM continued to experience problems with bacteria growth and had to recall products twice in 2014.

e. Respondents presented a considerable amount of documentary evidence in mitigation, and PIC Lloyd testified at great length about the efforts he has made to improve his pharmacy. But two caveats must be considered. Based on the numerous instances where PIC Lloyd's testimony was found to be false, it is difficult to accept everything he said about the changes that he claims he has made. Another caveat came from Mr. Lee. When he was asked whether AOM could be used for sterile compounding after he reviewed respondents' policies and procedures, logs, certifications, and master formulas, he testified that he could not say that was the case without watching PIC Lloyd work, and added that anything could

be "written pretty." Thus, the only credible evidence of mitigation was that offered by respondents and corroborated by Inspector Sakamura. Her testimony, while confirming some improvements in the operation of AOM, was certainly not the glowing testimonial that PIC Lloyd's testimony attempted to paint.

It is noteworthy that PIC Lloyd did not undertake any retraining in compounding, and there are no character letters from other pharmacists or doctors familiar with his work. Mr. Lee offered some testimony in support of respondents, but he had little experience as a compounding pharmacist and he had no first-hand knowledge about PIC Lloyd or his operations.

f. The evidence established one instance of gross negligence committed by PIC Lloyd. There was no evidence of incompetence.

g. The inspections were performed about 18 months ago; subsequent inspections have demonstrated some improvements and some continuing problems.

h. The only violations that resulted in a financial benefit to respondents involved the hood certification. Mr. Hunter described a scene in which PIC Lloyd was angrily confronted with the possibility that he would have to close the pharmacy until the hood was certified. Instead of closing the pharmacy, PIC Lloyd chose to keep the pharmacy open and to continue to produce and sell medications that might be contaminated, thereby placing his financial needs above the safety of the patients who would receive the possibly injurious medications he produced.

9. The issue in this case is whether PIC Lloyd's sterile compounding permit should be revoked or placed on probation. The weight of the evidence in light of the disciplinary factors considered in Legal Conclusion 7 points to the conclusion that the sterile compounding permit must be revoked.

Because the operation of sterile compounding pharmacies is fraught with such risk, California requires that a licensee must undergo an inspection before the permit is issued and every year thereafter before the permit may be renewed. By the time of the hearing, respondents had been inspected twice before the permit was issued, once in 2011, once in 2012, twice in April 2013 that is the basis for the accusation, two later times in 2013, and once in 2014. In a sense, respondents have been on probation for four years. There is a track record of performance that can be judged.

Inspector Sakamura performed five of the inspections and was familiar with the inspections performed before 2013. She required that PIC Lloyd provide her with the relevant paperwork before he could dispense compounded products at the time of the May and June 2013 inspections in order to be sure he was meeting his obligations. She had served in the capacity of a probation monitor of the Board in the past, and in that role she conducted quarterly inspections.

In her opinion, probation would not work in this case. She did not believe that PIC Lloyd understood what he should be doing. She felt that PIC Lloyd did not take the initiative to comply with the pharmacy laws and needed his hand held to get him to comply with them. She explained that the law relating to master formulas was clear, but he did not follow the law, which Inspector Sakamura believed meant that PIC Lloyd could not comply with his obligations. She pointed to the continued problems AOM experienced regarding bacteria growth and the recent need for recalls, and she concluded that PIC Lloyd had still not made the changes that were necessary to operate AOM safely. She also did not believe that PIC Lloyd understood the urgency of the changes that he was required to make. She testified that he failed to appreciate the seriousness of the lack of certification of the hood when he knowingly continued to compound chemotherapy products with an uncertified hood. She concluded by testifying that she believed PIC Lloyd posed a risk to the public.

Inspector Sakamura's opinions and her reasoning are persuasive. Beyond that, the potential for harm that could arise in a variety of ways is significant, as was the number and variety of violations discovered in the April 2013 inspections. Another factor was that PIC Lloyd had been placed on notice in prior inspections that there were problems with AOM, yet he failed to correct those problems. PIC Lloyd's decision to continue to compound chemotherapy medications after he learned that the Germfree hood had not been certified and even after he had been instructed by the inspectors on April 23 not to use it is particularly disturbing, as was his admission that he did not know he had to test for pyrogens and that he had not done so for nearly four years.

Finally, PIC Lloyd's credibility must be considered. He testified falsely on numerous occasions during the hearing, and this willingness to stray from the truth raises the suspicion that despite what the policies and procedures, or logs, or master formula worksheets, or protocols relating to beyond use date might provide on paper, he will not comply with the rules governing those policies and procedures. A further concern is that PIC Lloyd on several occasions blamed others for the problems discovered during the inspections.

All of these considerations taken together compel the conclusion that insofar as the sterile compounding permit is concerned, probation is not a satisfactory vehicle to protect the public. The only reasonable disciplinary order relating to the sterile compounding permit is revocation.

10. There are different considerations relating to PIC Lloyd's pharmacist license and the pharmacy permit but the ultimate conclusion is the same. On one hand, all the violations found during the inspections related to PIC Lloyd's sterile compounding work and the operation of AOM as a compounding pharmacy. PIC Lloyd has been licensed for 20 years; this is the first disciplinary action brought against his license. Most of the causes for discipline related to technical requirements imposed on pharmacists operating sterile compounding pharmacies. No patient was harmed.

These considerations, however, are outweighed by the conclusion that the evidence established that PIC Lloyd was a dangerous practitioner and a person who could not be

trusted. These considerations are not limited to his operation of one type of pharmacy or another. The public has a right to expect that a pharmacist will act in accordance with the laws and regulations governing the profession in order to continue his or her practice. PIC Lloyd's conduct as a compounding pharmacist established that he was unwilling or unable to follow the laws and regulations governing compounding pharmacies and established professional incompetence. If he is incompetent in one area of pharmacy, there is every reason to believe he is incompetent in other areas.

Trust is an important component in the issuance of a license. The public has a right to trust licensed pharmacists to follow the laws and regulations and to behave honestly. PIC Lloyd's testimony at the hearing established that he cannot be trusted either to follow the law or act honestly. He continually lied, blamed others, and acted to promote his self-interest at the expense of his customers. The clearest example of PIC Lloyd placing his economic interests above those of the public was his decision to continue to compound chemotherapy drugs when his hood was not certified and after he had been instructed to stop.

For the reasons that required revocation of the sterile compounding permit and the above considerations, it is concluded that in order to adequately protect the public, PIC Lloyd's pharmacist license and the pharmacy permit must also be revoked.

11. Cause to order respondents to reimburse the Board for its costs of investigation and enforcement of this matter in the amount of $28,492.50 was established by reason of Finding 113.

ORDER

1. Original Sterile Compounding Permit Number LSC 99606 issued to Advance Outcome Management Incorporation to do business as Advance Outcome Management Inc. to compound injectable sterile drug products is revoked.

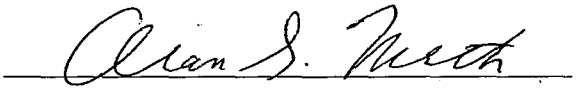
2. License number RPH 46890, issued to respondent Clarence Lee Lloyd (respondent Lloyd) is revoked.

3. Original Permit Number PHY 49946 issued to respondent Advance Outcome Management Incorporation, to do business as Advance Outcome Management Pharmacy Services, Clarence Lee Lloyd, Director, President, Treasurer/Chief Financial Officer and Pharmacist in Charge and Renee Lloyd, Director and Secretary (respondent AOM) is revoked.

//

4. Respondents shall pay to the board its costs of investigation and prosecution in the amount of $28,492.50 within 90 days of the effective date of this decision.

DATED: October 30, 2014



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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ADVANCE OUTCOME MANAGEMENT INC, DBA ADVANCE OUTCOME MANAGEMENT PHARMACY SERVICES** **12792 Valley View Street, Ste. A** **Garden Grove, CA 92845** **Pharmacy Permit No. PHY 49946** **and** **ADVANCE OUTCOME MANAGEMENT INC., dba ADVANCE OUTCOME MANAGEMENT INCORPORATION** **12792 Valley View Street, Ste. A** **Garden Grove, CA 92845** **Sterile Compounding Permit No. LSC 99606** **and** **CLARENCE LLOYD** **12792 Valley View Street, Suite A** **Garden Grove, CA 92845** **Pharmacist License No. RPH 46890** Respondents.	Case No. 4682 **ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about June 30, 2009, the Board of Pharmacy issued Pharmacy Permit Number PHY 49946 to Advance Outcome Management Inc, dba Advance Outcome Management Pharmacy Services (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2014, unless renewed.

3. On or about June 25, 2010, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99606 to Advance Outcome Management Inc, dba Advance Outcome Management Incorporation (Respondent). The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2014, unless renewed. On or about April 26, 2013, Respondent was issued an order to cease and desist sterile compounding pursuant to Business and Professions Code section 4127.3, until such time that the Board of Pharmacy authorizes such furnishing.

4. On or about March 7, 1994, the Board of Pharmacy issued Pharmacist License Number RPH 46890 to Clarence Lee Lloyd (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2015, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

7. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

8. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

10. Section 4076 of the Code states:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used.

Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of

this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

11. Section 4078 of the Code states:

(a) (1) No person shall place a false or misleading label on a prescription.

(2) No prescriber shall direct that a prescription be labeled with any information that is false or misleading.

(b) Notwithstanding subdivision (a), a person may label a prescription, or a prescriber may direct that a prescription be labeled, with information about the drug that is false under either of the following circumstances:

(1) If the labeling is a necessary part of a clinical or investigational drug program approved by the federal Food and Drug Administration or a legitimate investigational drug project involving a drug previously approved by the federal Food and Drug Administration.

(2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.

(c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and retain for three years from the date of making, a record stating the manner in which the information on the prescription label varies from the actual drug in the container and documenting the order of the prescriber to so label the container. The prescriber shall make, and retain for at least three years, a record of his or her order to so label the container.

12. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

13. Section 4127.3 of the Code states:

(a)Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding injectable sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding injectable sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c)The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d)Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

14. Section 4301 of the Code states in part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

(c) Gross negligence.

. . . .

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . . .

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

. . . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

. . . .

15. Section 4306.5 of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

16. Section 4342 of the Code states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

17. Health and Safety Code section 11165 states in pertinent part:

. . . .

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

18. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

19. Health and Safety Code section 111260 states:

Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

20. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

21. Health and Safety Code section 111395 states:

Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug.

(b) It is offered for sale under the name of another drug.

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

22. Health and Safety Code section 111440 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

STATE REGULATORY PROVISIONS

23. California Code of Regulations, title 16, section 1714 states:

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

24. California Code of Regulations, title 16, section 1735.2 states:

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all

compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

25. California Code of Regulations, title 16, section 1735.3 states:

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

26. California Code of Regulations, title 16, section 1735.4 states:

(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

27. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

28. California Code of Regulations, title 16, section 1735.8 states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of

compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

29. California Code of Regulations, title 16, section 1751.2 states:

In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

(b) Name and concentrations of ingredients contained in the sterile injectable product.

(c) Instructions for storage and handling.

(d) All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic - Dispose of Properly."

30. California Code of Regulations, title 16, section 1751.3 states:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

(1) Compounding, filling, and labeling of sterile injectable compounds.

(2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.

(3) Equipment and supplies.

(4) Training of staff in the preparation of sterile injectable products.

(5) Procedures for handling cytotoxic agents.

(6) Quality assurance program.

(7) Record keeping requirements.

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

(c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.

(2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.

(3) Policies and procedures must address at least the following:

(A) Competency evaluation.

(B) Storage and handling of products and supplies.

(C) Storage and delivery of final products.

(D) Process validation.

(E) Personnel access and movement of materials into and near the controlled area.

(F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).

(G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.

(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

(I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.

(J) Sterilization.

(K) End-product evaluation and testing.

31. California Code of Regulations, title 16, section 1751.4 states:

(a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

(e) Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

32. California Code of Regulations, title 16, section 1751.7 states:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before

being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

COST RECOVERY

33. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUGS

34. Avastin is a brand name for bevacizumab and is a dangerous drug pursuant to Business and Professions Code section 4022.

35. Triesence 40mg/ml is a brand name for triamcinolone suspension and is a dangerous drug pursuant to Business and Professions Code section 4022.

36. Trivaris 80mg/ml is a brand name for triamcinolone suspension and is a dangerous drug pursuant to Business and Professions Code section 4022.

37. Decadron is a brand name for dexamethasone and is a dangerous drug pursuant to Business and Professions Code section 4022.

38. Voltaren is a brand name for diclofenac and is a dangerous drug pursuant to Business and Professions Code section 4022.

39. Mutamycin is a brand name for mitomycin and is a dangerous drug pursuant to Business and Professions Code section 4022.

40. Makena is a brand name for 17-hydroxyprogesterone and is a dangerous drug pursuant to Business and Professions Code section 4022.

41. Vancocin is a brand name for vancomycin and is a dangerous drug pursuant to Business and Professions Code section 4022.

42. Fungizone is a brand name for amphotericin and is a dangerous drug pursuant to Business and Professions Code section 4022.

43. Vfend is a brand name for voriconazole and is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

First Inspection: April 23, 2013

44. On April 23, 2013, Board of Pharmacy inspectors conducted a sterile compounding[1] annual renewal inspection of Advance Outcome Management Inc., located at 12792 Valley View Street, Ste. A in Garden Grove, California. The owner and Pharmacist-in-Charge (PIC), Clarence Lloyd, was present during the inspection.

45. During that inspection, a Board inspector removed several compounded injectable drug products from the pharmacy's refrigerator and requested the master formulas, compounding worksheets, test results and certificates of analysis for each of the products. PIC Lloyd had a difficult time locating the master formulas, compounding worksheets and test results for the requested products. Board inspectors observed that Respondents did not collate any of the reports

[1] Compounding is the pharmacy practice of mixing, combining, or altering ingredients to create a drug product. Pursuant to California Code of Regulations, title 16, section 1735, compounding is defined as: (1) altering the dosage form or delivery system of a drug; (2) altering the strength of a drug; (3) combining components or active ingredients; (4) preparing a drug product from chemicals or bulk drug substances. "Sterile" compounds require sterility and are typically injectables for direct administration to the patient.

or records for the products, that the pharmacy was disorganized, several of the compounding worksheets were stored by patient name while others were stored by the type of drug, and some test records were placed in a binder while autoclave tests were stored in a small box.

46. During the removal of the compounded products from the refrigerator, one of the products leaked on the Board inspector's hands. The Board inspector washed his hands, which later tingled from the product. The Board inspector then discovered that the products were chemotherapy drug products. However, Respondents did not have chemotherapy bags or chemotherapy warning labels on any of the products. The products were also not sealed adequately, which allowed leakage.

47. Board inspectors also noticed a large amount of expired products in the refrigerator. The expired drugs were not quarantined and had not been sent back regularly for destruction.

48. After reviewing the compounded products made by Respondents and the master formulas provided by Respondents, the Board inspectors noted several issues, including the product labeling not matching the worksheet, the labeling on the finished product was confusing, and the formula worksheets did not state the amount of product yielded from the batch. Board inspectors discovered that Respondents had compounded "preservation free triamcinolone acetonide ophthalmic suspension injection, 80mg/ml, 0.1ml syringes," but the formula worksheet indicated "triamcinolone acetonide ophthalmic suspension injection, 80mg/ml inj susp" 11ml. Respondents then used the 11ml to make 0.1ml syringes, which was not logged on the formula worksheet. When asked if 110 syringes were made from the 11ml, PIC Lloyd stated that he did not make 110 syringes because he wasted most of the 11ml. However, Respondents did not have records on how many ophthalmic syringes were made in each batch and did not keep records showing the disposition of the extra drug.

49. After reviewing Respondents' recall policy, Board inspectors discovered that Respondents' recall policy only addressed a recall initiated by a manufacturer. Respondents' recall policy did not address an internally initiated recall process for compounded products. Moreover, Respondents did not have enough information on the formula worksheet to be able to implement any type of recall on their products.

50. During the inspection, Board inspectors also observed that Respondents used two computer systems-PCCA and another software vendor. Because Respondents used two computer systems, Respondents had two different types of master formulas and compounding worksheets. Upon review of the additional formula worksheets, Board inspectors discovered that none of the equipment used for compounding was being documented by Respondents. Board inspectors also discovered that the disposition records of the compounded sterile drugs did not accurately show the wasted lot numbers of the destroyed products.

51. Board inspectors also examined Respondents' "clean" room, which was split into three areas, an ante room which led to two side-by-side clean rooms, each with a hood. One of the clean rooms was the chemotherapy room in which chemotherapy drugs were compounded in a "GERMFREE" hood and the other clean room was the regular area where other drugs were compounded in a "BAKER" hood.[2] Board inspectors inspected the hoods and discovered that both hoods were last certified on May 8, 2012 with the certification valid for six months. The certifications had expired in November 2012, almost six months prior. The Board inspector then reviewed the documentation of the hood certifications and discovered that the GERMFREE hood, which was tested recently by a certification company on April 10, 2013, did not pass certification. The documentation from the certification company showed that the BAKER hood could not be tested because there was no power to the hood's outlet. Both hoods had been re-tested by the certification company on April 11, 2013 and only the BAKER hood passed certification. PIC Lloyd told inspectors that the certification company would be coming out that day (April 23, 2013) to do another inspection of the GERMFREE hood.

52. PIC Lloyd also told Board inspectors that environmental testing in the clean room and ante room was performed on April 10, 2013, which showed bacteria growth in those rooms. Environmental testing showed bacteria growth in the air in the chemotherapy room, IV room and ante room. Since the positive test results for bacteria growth, the certification company had not returned to the pharmacy to recheck the bacteria.

[2] GERMFREE and BAKER are the names of the manufacturer of the hoods.

53. During the inspection of the chemotherapy room, Board inspectors discovered many full red containers on the floor. PIC Lloyd told Board inspectors that the containers contained chemotherapy and he was waiting for Stericycle[3] to take them. Respondents did not correctly label several chemotherapy agents, including mitomycin and Avastin. The chemotherapy drugs also did not have the required special labeling stating, "Chemotherapy-Dispose of Properly."

54. Board inspectors also discovered different sheets/logs taped to the walls in various places in the pharmacy. PIC Lloyd told inspectors that he writes on the logs when he checks or services a piece of equipment or needs to document temperature. However, PIC Lloyd was not able to tell inspectors which pieces of equipment he services weekly versus daily.

55. It was also discovered that Respondents did not regularly submit CURES. When asked to print proof of his submissions to CURES, PIC Lloyd could only pull up information on his computer screen. The information on the screen did not show weekly submissions to CURES as required by law, and instead only showed a few transmissions for the past year. At the conclusion of the inspection on April 23, 2013, Respondents were asked to provide a written action plan and were notified that Board inspectors would re-inspect the pharmacy within two weeks. The Board inspectors asked Respondents not to do chemotherapy compounding until the hood was fixed and to do a deep cleaning on a weekly basis. Respondents did not submit an action plan within three days after the first inspection.

Second Inspection: April 26, 2013

56. Three days later, on April 26, 2013, the Board inspectors returned to the pharmacy for re-inspection. PIC Lloyd was present for the second inspection on April 26, 2013. The Board inspectors inspected the pharmacy refrigerator and discovered that the same expired drugs which were found on April 23, 2013 were still located in the refrigerator and were not quarantined, segregated, or disposed.

57. As they had previously observed during the first inspection on April 23, 2013, Board inspectors again observed during the second inspection, unclean conditions in the pharmacy.

[3] Stericycle provides healthcare medical waste disposal and removal services.

Specifically, there were pieces of used and soiled compounding equipment in the sink which had not been washed for several days, the trash cans were overflowing, and there were amber vials on a drying rack, which were covered in a dust/film.

58. During the second inspection, Board inspectors also noted that the temperature in one of the rooms in the pharmacy that contained the powder hood and drug storage area, was warm. The thermostat in the pharmacy was set to 50 degrees and it showed that the temperature was 74 degrees. Board inspectors took the temperature in the room with their own portable device, which showed the temperature was 80.1 degrees. Respondents' temperature log showed fluctuations in the room temperature in April between 71 to 77 degrees.

59. Board inspectors also observed that there were chemotherapy containers and sharps containers that were not disposed of regularly, which were piled up in the chemotherapy hood and outside near the sink.

60. During the re-inspection on April 26, 2013, Board inspectors questioned PIC Lloyd about whether the GERMFREE chemotherapy hood had passed certification. PIC Lloyd stated that it was still not certified. Board inspectors discovered that even though Respondents' GERMFREE chemotherapy hood did not pass certification from April 10, 2013 to April 26, 2013, and there was bacteria in the clean rooms and ante rooms on April 10, 2013, Respondents still compounded sterile injectable chemotherapy between April 10, 2013 and April 26, 2013 as follows:

Date	RX	MD	Drug	Strength	Amount
4/18/2013	1431	Winston	Avastin	1.25/0.05	30
4/12/2013	1585	Pirouz	Avastin	2.5/0.1	24
4/19/2013	1585	Pirouz	Avastin	2.5/0.1	24
4/19/2013	1584	Adrean	Avastin	2.5/0.1	24
4/18/2013	1549	Small	Avastin	2.0/0.08	80
4/12/2013	1577	Grant	Avastin	2.5/0.1	24
4/19/2013	1577	Grant	Avastin	2.5/0.1	24

4/12/2013	1584	Adrean	Avastin	2.5/0.1	24
4/12/2013	1594	Shabatian	Avastin	1.25/?	11
4/11/2013	1600	Chao	mitomycin	0.2mg/ml	1
4/16/2013	1596	Dang	Avastin	2.5/0.1	4
4/25/2013	1556	Kim	Avastin	1.25	3

61. Board inspectors examined the unit-dosed Avastin that was compounded by Respondents. Board inspectors asked PIC Lloyd about the one month expiration date that he provided on the unit-dosed Avastin syringes. PIC Lloyd admitted that the expiration date was "purely arbitrary" and that there was "no information out there" on how long the syringes were good for, so he arbitrarily assigned them an expiration date of one month. When asked if he had sent any of the syringes for sampling, PIC Lloyd stated that he had not. PIC Lloyd also admitted that he did not do pyrogen testing on any of the compounds because he did not know until recently that he was required to test for pyrogens. Some of the Avastin discovered in the pharmacy had a "beyond use date" of two months, even though PIC Lloyd told Board inspectors he gave Avastin a one month expiration date. In addition, Board inspectors found that Respondents' labeling of some of the Avastin syringes was confusing and inconsistent, in that it had two expiration dates and had missing batch numbers.

62. Board inspectors also discovered that Respondents compounded triamcinolone ophthalmic injection which is available commercially as Triesence 40mg/ml and Trivaris 80mg/ml.

63. Board inspectors discovered deviations in the documentation for compounded drugs. They reviewed the logged formula worksheet for "triamcinolone acetonide ophthalmic injection suspension 80mg/ml inj susp." Respondents' records showed that the drug was compounded on April 20, 2012; however, the formula worksheet for the compound was created on April 14, 2013, almost a year after it was compounded. The sheet also showed that sterile water for injection was acquired on April 25, 2012, five days after the compound was made. In the Log Instruction and Notes section, the documentation stated a "beyond use date" of July 19, 2012, which is three months after it was made, yet Step 8 stated that the "beyond use date" was up to 90 days. The

expiration date given on the preparation was 3 days, however, there was no data or explanation for why PIC Lloyd chose an expiration date of 3 days. Respondents' worksheets were not filled out correctly with the manufacturer or lot number of the ingredients. Board inspectors also discovered that Respondents deviated from the triamcinolone master formula and removed benzyl alcohol from the suspending agent, but did not test the product to obtain a new beyond use date or to ensure potency or sterility.

64. PIC Lloyd admitted that Respondents did not do testing on every batch of compounded drug. PIC Lloyd also admitted that he used compounding equipment which was not the correct size for the amount which he needed to compound. Board inspectors asked to see the master formulas for the Avastin, vancomycin, amphotericin b, mitomycin and voriconazole. PIC Lloyd provided the inspectors with a handwritten sheet of paper and drug information sheets, but not a master formula. There were no master formulas for the unit-dosed Avastin, vancomycin, amphotericin b, mitomycin and voriconazole. Moreover, some of the individual compounded items were not labeled and the bags containing the items only had some of the required information on it. For example, Board inspectors inspected the label on RX No. 1471 for Dexamethasone sodium phosphate opht 4mg and discovered that the label did not indicate if the drug was topical or injectable, or whether it could be given intravenously or only in the eye.

65. Board inspectors reviewed Respondents' vancomycin stock vials which expired on December 2012, but were compounded on November 26, 2012. The beyond use date on the label was December 10, 2012; however, PIC Lloyd gave a beyond use date of February 28, 2013 for frozen syringes at -20 degrees. Respondents did not do testing for potency or stability on the syringes and PIC Lloyd admitted that he had extended the beyond use date because the doctor wanted it extended. Respondent also did not have a freezer that went to -20 degrees.

66. Board inspectors reviewed Respondents' policies and procedures and discovered that the policies were not being followed. For example, the policies state that the clean room and hoods will be certified every six months, however, Respondents only had them certified every year. The policies with respect to the recall procedures were inadequate. The policies were also

not being followed with respect to end product verification, compounding records, batch testing, beyond use date, chemo labels, chemo package/shelves/storage, and hazardous drugs and labels.

67. Following the inspection on April 26, 2013, Board inspectors issued an order to cease and desist sterile compounding to Respondents.

FIRST CAUSE FOR DISCIPLINE

(Incorrect Labeling of Chemotherapy Agents)

68. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1751.2, subdivision (d), in that Respondents did not correctly label several chemotherapy agents, including mitomycin and Avastin, as set forth in paragraphs 46 and 53, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Unclean Pharmacy)

69. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1714, subdivision (c), for not maintaining a clean pharmacy in that during the inspections of the pharmacy on April 23 and 26, 2013, there were pieces of used and soiled compounding equipment in the sink which had not been washed for days, the trashcans were overflowing, and amber vials located on a drying rack were covered in a dust/film, as set forth in paragraph 57, which is incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Expired Drugs Not Quarantined and Expired)

70. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of Business and Professions Code section 4342, subdivision (a), Respondents had expired drugs that were not quarantined and sent back regularly for destruction, as set forth in paragraphs 47 and 56, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Facilities, Space, Fixtures, and Equipment)

71. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1714, subdivision (b), in that Respondents failed to maintain its facilities, space, fixtures, and equipment so that drugs were safely and properly prepared, maintained, secured, and distributed as evidenced by the chemotherapy containers and sharps containers that were not disposed of regularly and the temperature being out of range, as set forth in paragraphs 54, 58 and 59, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Properly Maintain Reports for Compounded Drugs in a Collated Manner)

72. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1735.8, subdivision (c), in that Respondents failed to properly maintain its quality assurance records for compounded drugs in an organized and collated manner, as set forth in paragraphs 45 and 50, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Knowingly Making a False Document)

73. Respondents are subject to disciplinary action under section 4301, subdivision (g) for knowingly making or signing a document that falsely represents the existence or non-existence of a state of facts, in that Respondents created triamcinolone ophthalmic formula worksheets on April 14, 2013 for compounding that was actually performed on April 20, 2012 (a year prior), as set forth in paragraph 63, which is incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Accurately Document Manufacturer and Lot Number)

74. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1735.3, subdivision (a)(6), in that Respondents failed to accurately document the manufacturer and lot number for triamcinolone lot, as set forth in paragraph 63, which is incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Keep Records of Master Formula)

75. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1735.2, subdivision (d), in that Respondents failed to keep records of the master formulas for the following compounded drugs prepared by Respondents: unit-dosed Avastin, vancomycin, amphotericin b, mitomycin and voriconazole, as set forth in paragraph 64, which is incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Failure to List Equipment on Compounding Records)

76. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1735.2, subdivision (d)(2), in that Respondents failed to list equipment on the master formula or formula worksheet regularly, as set forth in paragraph 50, which is incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Failure to Have Written Justification of the Chosen Expiration Dates for Compounded Sterile Injectable Products)

77. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1751.7, subdivision (a)(4), in that Respondents deviated from the master formula, but did not test the product to obtain a new beyond use date or to ensure potency or sterility, and instead gave products a new beyond use date, but failed to provide written justification of how those dates were chosen, as set forth in paragraphs 61 and 65, which are incorporated herein by reference.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Records of Acquisition & Disposition)

78. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4081, subdivision (a), for failure to maintain records of acquisition and disposition, in that Respondents did not keep records on how many ophthalmic syringes were made and did not keep records showing the destruction of unused drugs, as set forth in paragraph 48, which is incorporated herein by reference.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Meet Labeling Requirements)

79. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of Business and Professions Code section 4076 and California Code of Regulations sections 1735.4 and 1751.2, for failing to meet labeling requirements, in that Respondents had several prepared drugs which did not have a label or were missing the required information, including telephone number of the pharmacy, chemo labels, directions for use, and volume of drug being dispensed, as set forth in paragraphs 46, 48, 61, and 63, which are incorporated herein by reference.

THIRTEENTH CAUSE FOR DISCIPLINE

(False or Misleading Label)

80. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of Business and Professions Code section 4078, subdivision (a)(1), for placing a false or misleading label on a prescription, in that the label on RX No. 1471 for Dexamethasone sodium phosphate opht 4mg was misleading in that it did not indicate if the drug was topical or injectable, or whether it could be given intravenously or only in the eye, as set forth in paragraph 64, which is incorporated herein by reference.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Perform End Product Testing for Sterility and Pyrogens)

81. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1751.7, subdivision (c), in that Respondents did not test compounded products for pyrogens, did not do testing on batches and did not quarantine batches before sending them out, as evidenced by PIC Lloyd's admissions, as set forth in paragraphs 61 and 64, which are incorporated herein by reference.

FIFTEENTH CAUSE FOR DISCIPLINE

(Compounding Environment Failed to Meet Criteria for Safe Compounding of Sterile Injectable Drug Products)

82. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1751.4, subdivision (a), in that Respondents compounded sterile injectable chemotherapy drugs even though Respondents' GERMFREE chemotherapy hood did not pass certification from April 10, 2013 to April 26, 2013, and bacteria grew in the clean rooms and ante rooms on April 10, 2013, as set forth in paragraphs 51, 52, and 60, which are incorporated herein by reference.

SIXTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence: Compounding Sterile Injectable Products in a Non-Certified Hood)

83. Respondents are subject to disciplinary action under section 4301, subdivision (c) for gross negligence, in that Respondent compounded sterile injectable chemotherapy drugs even though Respondent's GERMFREE chemotherapy hood did not pass certification from April 10, 2013 to April 26, 2013, and bacteria grew in the clean rooms and ante rooms on April 10, 2013, as set forth in paragraphs 51, 52, and 60, which are incorporated herein by reference.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Inadequate Plan for Recall)

84. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations section 1735.5, subdivision (c)(2), in that Respondents' recall policy was inadequate because it did not address an internally initiated process and did not have enough information on the formula worksheet to be able to implement any type of recall on Respondents' products, as set forth in paragraphs 49 and 66, which are incorporated herein by reference.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Compounding and Selling Misbranded Drugs)

85. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violation of Health and Safety Code sections 111440, and Business and Professions Code section 4342, subdivision (a), for compounding and selling misbranded drugs as defined by Health and Safety Code section 111395, in that Respondent made, sold, delivered, held, or

offered to sell triamcinolone injection, an imitation drug which is commercially available as Triesence 40mg/ml and Trivaris 80mg/ml, as set forth in paragraph 62, which is incorporated herein by reference.

NINETEENTH CAUSE FOR DISCIPLINE

(Making and Selling Adulterated Drugs)

86. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violation of Health and Safety Code sections 111295, in that Respondents made, held, sold or offered to sell adulterated drugs as defined by Health and Safety Code sections 111255 and 111260, when Respondents compounded sterile injectable chemotherapy drugs even though Respondents' GERMFREE chemotherapy hood did not pass certification from April 10, 2013 to April 26, 2013, and bacteria grew in the clean rooms and ante rooms on April 10, 2013, , as set forth in paragraphs 51, 52, and 60, which are incorporated herein by reference.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Submit Data to CURES Weekly)

87. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o) for violation of Health and Safety Code sections 11165, subdivision (d), for failing to submit data to CURES on a weekly basis, as set forth in paragraph 55, which is incorporated herein by reference.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Unjustified Expiration Date on Compounded Medication)

88. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, section 1735.2, subdivision (h), in that Respondents an expiration date for sterile vancomycin injection for the eye which was greater than the expiration date of the starting drug, without adequate justification for extending the date, as set forth in paragraph 65, which is incorporated herein by reference.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Inadequate Policies and Procedures)

89. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, section 1751.3, in that Respondents policies and procedures were inadequate and did not reflect Respondent's current business practice, as set forth in paragraph 49 and 66, which are incorporated herein by reference.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Against Respondent PIC Lloyd Only: Inappropriate Exercise of Education, Training, or Experience as a Pharmacist)

90. Respondent is subject to disciplinary action under section 4301, subdivision (o) for violation of Business and Professions Code section 4306.5, in that Respondent inappropriately exercised his education, training and experience as a pharmacist as evidenced by his use of compounding equipment which was not the correct size for the amount which he needed to compound, as set forth in paragraph 64, which is incorporated herein by reference.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 49946, issued to Advance Outcome Management Inc, dba Advance Outcome Management Pharmacy Services;

2. Revoking or suspending Sterile Compounding Permit Number LSC 99606, issued to Advance Outcome Management Inc, dba Advance Outcome Management Incorporation;

3. Revoking or Pharmacist License Number RPH 46890 issued to Clarence Lee Lloyd;

4. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

5. Taking such other and further action as deemed necessary and proper.

DATED: 8/9/13

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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