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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 **A C C U S A T I O N**

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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