DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707	6/20/2016-6/28/2016* FEI NUMBER 3012335395

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Douglas L. Dumler , General Manager

FIRM NAME	STREET ADDRESS
Option Care Enterprises	9140 Guilford Rd, Suite K
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbia, MD 21046-1811	Producer of Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, on 06-20-2016, during the walkthrough of the sterile drug preparation suite, the following deficiencies were observed:

- Disinfectants used to clean surfaces and equipment in the ISO 5 hoods, ISO 7 clean room (IV room), and ISO 7 (b) (4) room are non-sterile.
- The non-shedding wipes used to clean surfaces and equipment in the ISO 5 hoods are non-sterile.
- The (b) (4) back grill of the (b) (4) laminar flow hood with the Serial No. (b) (4) (b) (4) had what appeared to be rust and a white crusted material. A white plastic cup containing an opaque white liquid was resting on the workbench within the hood. The cup was uncovered and had remained in the hood at least overnight.
- The (b) (4) laminar flow hood with the Serial No. (b) (4) contained an open plastic cup with a clear liquid. A partially opened container of syringes that had been packaged sterile was placed on top of one of the (b) (4) pumps. There was a small amount of what appeared to be rust on the back grill of the hood. The grate in front of the pre-filter appeared discolored and the pre-filter was a regular household filter that had been deformed to force it to fit into the space designated for the pre-filter. The pre-filter was not sitting flush with the hood.
- The (b) (4) back grill of (b) (4) laminar flow hood with Serial No. (b) (4) had what appeared to be rust. Dirt was also visible through the grill at the front of the (b) (4) workbench of this hood. An open container of prepackaged sterile syringes was placed on top of a (b) (4) pump inside the hood. The shield for the light inside the hood is broken. When it was cleaned, the entire shield was shifted by the pressure applied during wiping. The chair associated

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with this hood appeared to have splashes of liquid material that had dried. After the morning cleaning with (b) (4) wipes and sterile (b) (4) this hood was used to prepare Naficillin 12GM/24hr bags for (b) (4) pursuant to (b) (4), (b) (6)

- The (b) (4) laminar flow hood with the Serial No. (b) (4) is used to prepare TPN. The cords from the (b) (4) run from the interior of the hood to the floor. The workbench surface inside the hood did not appear cleaned and a white powdery substance was visible at the seam between the workbench and the interior left hand wall of the hood. A white crusted residue was also visible on the (b) (4) back grill of the hood.
- Carts are used to store many of the materials used for sterile drug preparation. The carts were cluttered, and appeared to have residues on the surface, particularly on the lower levels.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, there is infrequent monitoring of differential pressures between the ISO 7 (b) (4) room (negative pressure relative to the IV room) and the ISO 7 clean room (IV room), between the ISO 7 clean room (IV room) and the ISO 8 anteroom, and between the ISO 8 anteroom and the unclassified multi-purpose room during the production of sterile drugs.

Differential pressure is supposed to be recorded (b) (4) during operations. However, a review of the differential pressure records between 01/2016 and 06/2016 showed that the recordings were not always made (b) (4). Differential pressure readings are (b) (4) through observation of the magnahelic gauges located outside of the sterile drug processing area. There is no alarm system to notify employees on site that a pressure excursion has occurred.

OBSERVATION 3

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, the gowning components worn for the preparation of sterile drugs are non-sterile with the exception of the sterile gloves.

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- On 06-20-2016 I observed technician (b) (6), (b) (7)(C) prepare Naficillin 12GM/24hr bag for (b) (4) pursuant to Rx (b) (4), (b) (6) Technician (b) (6), (b) (7)(C) had donned a non-sterile hairnet, face mask, and gown (jump suit) with a hood that was not n. The gowning left the skin of the technician's forehead, cheeks, and neck exposed. During drug preparation, the technician's arms extended inside the ISO 5 (b) (4) laminar flow hood. At times the technician's head would also be inside the ISO 5 hood.

- On 06-20-2016 I observed technician (b) (6), (b) (7)(C) prepare Gamunex 10% pursuant to Rx (b) (4), (b) (6). Technician (b) (6), (b) (7)(C) had donned a non-sterile hairnet, face mask, and gown (disposable lab coat). The gowning left the skin of the technician's forehead, cheeks, and neck exposed. During drug preparation, the technician's arms extended inside the ISO 5 (b) (4) laminar flow hood. At times the technician's head would also be inside the ISO 5 hood.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

1. On 06-20-2016, during the preparation of Naficillin 12GM/24hr bags for (b) (4) pursuant to Rx (b) (4), (b) (6) by technician (b) (6), (b) (7)(C) I observed:

A. When technician (b) (6), (b) (7)(C) was attempting to pick up supplies in the cart adjacent to (b) (6), (b) (7)(C) some of the packaged sterile needles fell on to the floor. Technician (b) (6), (b) (7)(C) asked Pharmacist (b) (6), (b) (7)(C) to pick them up from the floor. Pharmacist (b) (6), (b) (7)(C) placed the needles back on the cart. Technician (b) (6), (b) (7)(C) touched the needles, and then collected other supplies and placed them inside the hood (Serial No. (b) (4)) without spraying (b) (6), (b) (7)(C) gloves with sterile (b) (4)

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B. Technician (b) (6), (b) (7)(C) rested (b) (6), (b) (7)(C) left hand on the sleeve of (b) (6), (b) (7)(C) non-sterile gown and then performed the necessary manipulations to proceed with the drug preparation without spraying (b) (6), (b) (7)(C) gloves with sterile (b) (4) I observed the technician performing manipulations (b) (4) without sanitizing (b) (6), (b) (7)(C) gloves for a period of at least 20 minutes.

C. I observed Technician (b) (6), (b) (7)(C) leave the ISO 7 clean room (IV room) and enter the ISO 8 anteroom. (b) (6), (b) (7)(C) returned to the clean room (IV room) carrying a bag of (b) (4) which was placed inside the ISO 5 LAF hood without being sprayed with sterile (b) (4)

D. I observed Technician (b) (6), (b) (7)(C) pull a non-sterile wipe from a package on top of the laminar flow hood and place the dry wipe on the work surface. (b) (6), (b) (7)(C) proceeded to perform drug manipulations over the wipe and placed a syringe and bottles of Naficillin on the non-sterile wipe.

E. Once preparation of the Naficillin was complete, technician (b) (6), (b) (7)(C) began to prepare for a different drug order and started to unpackage bags containing (b) (4) that were packaged in plastic liners. The plastic liners surrounding the (b) (4) bags contained moisture on the interior. I observed technician (b) (6), (b) (7)(C) discard the plastic liners into the trash can and then push the trash down so that (b) (6), (b) (7)(C) gown was inside the trash can up to the elbow. The gowns are not sanitized with sterile (b) (4) (b) (4) and the gowns are not changed before preparing the next drug order. During drug preparation the technician's arms and sometimes head are inside the ISO5 hood.

F. I also observed a formulation sheet printed on regular paper that was placed on a cart in the ISO 7 clean room (IV room). The paper formulation sheet was not protected in a plastic sheet.

2. The media fill procedure designed to simulate (b) (4) is deficient in that a (b) (4) (b) (4) that does not simulate the most challenging (b) (4) conditions or the number of manipulations made during a normal (b) (4) operation. During (b) (4) production (b) (4) The (b) (4) containers may be bags, bottles, vials, or in some cases syringes are used. On 06/20/2016 I observed (b) (4) were used to (b) (4) production.

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OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

There are (b) (4) air return vents located near the floor in the ISO 7 clean room (IV room). Four of the (b) (4) vents were partially obstructed by carts, a garbage can, a hood, and a chair.

*DATES OF INSPECTION

6/20/2016(Mon),6/22/2016(Wed),6/28/2016(Tue)

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