

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  
USFDA/ORR/OPQO Division III  
550 W. Jackson Blvd. 15th floor  
Chicago, IL 60661  
312-353-5863

DATE(S) OF INSPECTION  
1/17, 1/18, 1/19, 1/24, 1/25, 1/29, 2/06, and  
2/08/2018  
FEI NUMBER  
3012188090

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bruce A. Harper, Senior Director of Operations

FIRM NAME  
Option Care Enterprises Inc. dba Option Care

STREET ADDRESS  
1226 Michael Drive, Suite A

CITY, STATE AND ZIP CODE  
Wood Dale, IL 60191

TYPE OF ESTABLISHMENT INSPECTED  
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 WE OBSERVED:

1. Poor aseptic practices were observed.

Specifically, on the morning of 01/25/18 while watching a Technician perform the sterile production manipulations to make the (b) (4) bags for Rx (b) (6) SN (b) (4) TPN (b) (4) mL I observed:

- A. During the required (b) (4) addition of the drug component sodium acetate 2 meq/mL to the (b) (4) bag of TPN sterile drug product, the technician placed a finger directly on the junction between the uncapped injection port of the TPN bag and the syringe hub of the syringe being used to make the addition in such a manner as to both contact the unprotected junction with the gloved finger and impede first air to this junction during the addition.
- B. While placing the uncapped syringe back onto the ISO 5 cabinet working surface after removing the air from bag (b) (4) I observed that the syringe needle touched the surface of the ISO 5 cabinet. The same syringe and needle was used to remove air from bag (b) (4) of the same formulation.

2. Disinfecting agents, cleaning pads, and cleaning wipes used for sterile drug production were not always sterile or controlled in a manner as to maintain sterility.

Specifically,

- A. Your firm uses (b) (4) wipes labeled in part (b) (4) (b) (4) to disinfect the exterior of equipment, components, and container/closures before placing into the ISO 5 cabinets during aseptic processing. The wipes are not labeled as sterile. The wipe manufacturers technical data sheet for these wipes indicates that (b) (4) are intended for non-sterile products.
- B. On 02/06/18 I observed that sterile lint free wipes used to sanitize the ISO 5 classified aseptic processing areas are removed from the manufacturers packaging and stored uncovered in

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Brian D. Nicholson</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Brian D. Nicholson, C.S.O.	DATE ISSUED 02/08/2018
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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

plastic bins in the ISO 7 area.

3. Your facility design allows the influx of poor quality air into a higher classified area.

Specifically, I observed that the uncontrolled refrigerated pass through that separates the ISO 7 buffer room from the uncontrolled pharmacy processing area has a refrigeration fan blowing unfiltered chilled air into this space. The refrigerated space is used to pass finished sterile drug product from the ISO 7 buffer room into the uncontrolled pharmacy processing room. I observed that when the door is opened from the ISO 7 buffer room, significant air can be felt coming from this space into the ISO 7 Buffer Room. The firm is not monitoring differential pressures from the buffer room to this space. The firm does not include this uncontrolled refrigerated pass through in its environmental monitoring.

4. Media fills were not performed under the most challenging or stressful conditions.

Specifically, your procedures for media fills do not fully emulate the number and type of connections used to produce all parenteral nutrition drug products using the (b) (4)

(b) (4). Option Care utilizes an (b) (4) (b) (4) to produce Total Parenteral Nutrition drug products such as Rx (b) (6) compounded on 12/28/2017. The (b) (4) requires the (b) (4) (b) (4) during initial set-up and operation. (b) (4)

(b) (4). Aseptic connections are also made (b) (4) (b) (4). In addition, up to (b) (4) of solution can (b) (4) during TPN drug production. In contrast, the firm's procedures for media fills in support of TPN production, SOP Pharmacy P-164 "Personnel Training and Evaluation in Aseptic Manipulation Skills" effective 12/15/2017 and its attachment "Process Validation (b) (4) Risk Guideline", requires (b) (4) and transfers only (b) (4) of (b) (4).

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PAGE

EMPLOYEE(S) SIGNATURE

*Brian D. Nicholson*

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Brian D. Nicholson, C.S.O.

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02/08/2018