U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

December 20, 2019

VIA UPS

John Kirtley, Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, Arkansas 72201

Mr. Kirtley:

The purpose of this letter is to refer to the Arkansas State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Arkansas BOP, Option Care Enterprises, Inc. dba Option Care, located at 9601 Baptist Health Drive, Suite 330, Little Rock, Arkansas 72205-6323 (two active retail pharmacy licenses #AR20883 and #AR20885; expires 12/31/2019).

FDA inspected the firm from March 5, 2019, to March 12, 2019. The FDA investigator was accompanied by an Arkansas state inspector for 2 days. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/122716/download, with any nonpublic information redacted . Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Option Care and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

Additionally, during the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm did not always disinfect materials or supplies before entering the aseptic

processing areas. We observed operators place supplies in two ISO 5 hoods without first disinfecting them. The operators then engaged in sterile drug production within the ISO 5 hoods.

2. The facility design allowed an influx of poor quality air into a higher classified area. While aseptic drug production was taking place, we observed the door from the non-classified area to the ISO 7 ante room open at the same time the door from the ISO 7 ante room to the ISO 7 buffer room was open.
3. We found that aseptic process simulation (media fill) studies were not adequate. The firm's media fills were not representative of actual maximum batch sizes.

Option Care committed to FDA in its response to the Form FDA 483, received April 2, 2019, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Arkansas State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Rebecca A. Asente, Compliance Officer, via (504) 846-8104, or Rebecca.asente@fda.hhs.gov.

Sincerely,

John W. Diehl -S3

Digitally signed by John W. Diehl -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S3, 0.9.2342.19200300.100.1.1=2000099727
Date: 2019.12.20 16:56:14 -06'00'

John W. Diehl, M.S
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: Ms. Kimberly I. Young
Director of Operations
Option Care Enterprises, Inc.
dba Option Care
9601 Baptist Health Drive, Suite 330
Little Rock, Arkansas 72205-6323
(Previously known as Baptist Health Medical Towers Pharmacy and Infusion Services)