

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax: (913) 495-5115	<small>DATE(S) OF INSPECTION</small> 9/10/2018-9/19/2018*	
		<small>FEI NUMBER</small> 3014088548
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Joshua R. Clinard, General Manager		
<small>FIRM NAME</small> HomeChoice Partners, Inc. dba Bioscrip Infusion Services	<small>STREET ADDRESS</small> 528 Trade Center Blvd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Chesterfield, MO 63005-1253	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Sterile Drug Products	
<p>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.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1</p> <p>You produced beta-lactam drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.</p> <p>Specifically,</p> <p>You aseptically process beta-lactam drug products, such as Ceftriaxone and Cefazolin, in the same ISO 5 area of the IV Room as non-beta-lactam drug products. Your cleaning procedure does not identify the use of appropriate cleaning agents to reduce the risk of cross-contamination.</p>		
<p>OBSERVATION 2</p> <p>Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.</p> <p>Specifically,</p> <p>On September 10, 2018, during the production of Tigecycline 50mg in NS 0.9% 100ml eclipse, Vancomycin 1.5g/ 300mL NS eclipse, Ceftriaxone 1g/10mL SW syringe, and Cefazolin 2g/100mL NS easypump, I observed,</p>		
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Tiara N Brown-Crosen, Investigator	<small>DATE ISSUED</small> 9/19/2018 <small>Tiara N Brown-Crosen Investigator Signed By: Tiara N. Brown-crosen S Date Signed: 09-19-2018 08:11:28</small> X

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<p>A technician touch a supply cart and operate the repeater fluid dispensing pump located in the ISO 7 IV Room and continue to perform aseptic processing in the ISO 5 LFH without changing or sanitizing gloves.</p>			
<p>*DATES OF INSPECTION 9/10/2018(Mon), 9/11/2018(Tue), 9/12/2018(Wed), 9/14/2018(Fri), 9/19/2018(Wed)</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tiara N Brown-Crosen, Investigator		DATE ISSUED 9/19/2018
	<div style="border-top: 1px solid black; width: 100%; margin-bottom: 5px;"></div> <small>Tiara N Brown-Crosen</small>		