DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 913-495-5100	07/13/2026 – 07/28/2026
	FEI NUMBER 3013927023
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED James M. Krogman, CEO	
FIRM NAME Apollo Care, LLC	STREET ADDRESS 3801 Mojave Ct Ste 101
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65202-4042, USA	TYPE ESTABLISHMENT INSPECTED 503B Outsourcing Facility

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:

OBSERVATION 1

There is a failure of the quality control unit to secure their responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

Specifically,

A) You do not have procedures for documented review of retain samples. On 07/21/2026 and 07/22/2026 the inspection team reviewed retain samples of Semaglutide Injection and Semaglutide with Glycine Injection drug product vials and observed approximately 59 vials across [redacted] (b)(4) lots contained white particles of varying size and quantity, of which you were previously unaware.

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	Tyler S Matt Schuckmann, CSO Kelly B	Tyler M. Peterson, CSO Kelly M. Bromley, CSO Matthew M. Schuckmann, CSO	07/28/2026

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Lot #	Product	# of Vials with Observed Particulate	# of Vials Free of Particulate
AC-017115	Semaglutide 4.5mg/mL Injection	12	(b)(4)
AC-017163	Semaglutide 4.5mg/mL Injection	2	
AC-017167	Semaglutide 2.5mg/mL Injection	12	
AC-017170	Semaglutide 4.5mg/mL Injection	8	
AC-017204	Semaglutide 0.9mg/mL Injection	1	
AC-017225	Semaglutide 2.5mg/mL Injection	12	
AC-017274	Semaglutide 10mg/mL Injection	5	
AC-017275	Semaglutide 5mg/mL&Glycine 5mg/mL Injection	7	

B) Stickers used as the primary status identification control to label finished products, raw materials, and components as rejected, accepted, and quarantined were observed unsecured in the warehouse on 07/13/2026.

OBSERVATION 2 (Repeat)

Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes.

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Specifically,

A) On 01/15/26 during aseptic filling operations for Semaglutide 4.5 mg/ml Injection Lot AC-017147 the particle counter used in the ISO 5 filling zone was paused during a manual intervention performed to adjust the (b)(4) height on the (b)(4) aseptic filler in response to a jam. There was no notation in your batch record's Exception Handling Log describing the events leading to, during, and after the intervention. You relied on an after-the-fact incident report to release the batch despite the missing particle count data. You released this batch on 01/23/2026.

B) Smoke studies conducted to visualize airflow within the Product Finishing Lab (b)(4) automated filling line ISO 5 environment indicate turbulent airflow over open (b)(4) sterile vials and interrupted first air over (b)(4) sterile stoppers.

C) A glass (b)(4) bulk solution formulation beaker with a cracked base was observed stored among the "clean" glassware. You use (b)(4) glass formulation beakers to compound bulk solutions for sterile injectable human drug products.

OBSERVATION 3 (Repeat)

There is a failure to thoroughly review any unexplained discrepancy, the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

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A) Your visual inspection procedure INST001 Visual Inspection Revision 14 Effective Date 02/05/2026 is inadequate in that:

i) Lot tolerance percent defect criteria is inadequate in that you allow for less than or equal to (b)(4) of rejected units regardless of defect risk classification for all your sterile injectable drug products. You also allow for a greater than (b)(4) visual inspection rejection rate if a subsequent reinspection of the remaining unrejected units results in a rejection rate of less than (b)(4) again regardless of defect risk classification.

ii) "Reflective", "non-reflective", and "agglomeration" particles in the sterile injectable drug products are classified as Minor defects with "no safety/CCI risk".

B) You failed to investigate multiple differential pressure excursions for classified cleanrooms where aseptic operations are performed. For example:

i) On 11/25/2025 in in ISO 7 room Product Finishing Lab (b)(4) during aseptic filling operations for Semaglutide 4.5mg/mL Injection Lot AC-017115 four uninvestigated differential pressure excursions of -0.01 to -0.03 inches water column (specification no less than (b)(4) inches water column) were recorded by the facility's differential pressure monitors.

ii) On 04/29/2026 in ISO 7 room Product Finishing Lab (b)(4) during aseptic filling operations for Semaglutide 2.5mg/mL Injection Lot AC-017225 two uninvestigated differential pressure excursions of -0.03 inches water column were recorded by the facility's differential pressure monitors.

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iii) On 01/15/2026 in ISO 7 room Product Finishing Lab (b)(4) during operations for aseptic filling of Semaglutide 4.5mg/mL Injection Lot AC-017147 two uninvestigated differential pressure excursions of -0.07 and -0.03 inches water column was recorded by the facility's differential pressure monitors.

OBSERVATION 4 (Repeat)

Your firm failed to perform operations within specifically defined areas of adequate size and to have separate or defined areas or such other control systems necessary to prevent contamination or mix-ups in aseptic processing areas.

Specifically,

A) The design of your (b)(4) sterile IV bag filling process lacks adequate aseptic and in-process material controls. This process was observed on 07/17/2026 during the compounding of Vancomycin 1.5g added to 250mL of 0.9% Sodium Chloride (Injection For Intravenous Use Only) Lot AC-017291.

i) Unfinished in-process Sodium Chloride IV bags were observed to be unnecessarily moved into and through the ISO 5 aseptic filling environment without aseptic manipulation, only to be removed back into the adjacent ISO 7 environment for intermittent in-process weight checks before being re-introduced into the ISO 5 hood.

ii) A support compounding operator was observed repeatedly handling both unfinished Sodium Chloride IV bags and finished Vancomycin in Sodium Chloride IV bags during in process weight checks, without adequate control over identification of finished and unfinished IV bags.

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B) On 07/15/2026 during bulk solution formulation used to compound Vancomycin 1.5g added to 250mL of 0.9% Sodium Chloride Injection Lot AC-017291, your facility's classified cleanroom (b)(4) system was observed not functioning as intended. The door separating Anteroom (b)(4) from the locker room did not register as open on the visual light panel indicator and did not result in the locking classified cleanroom Anteroom (b)(4) as intended.

OBSERVATION 5

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

A) You do not test all received containers of at-risk API raw material (b)(4) for potential contamination with (b)(4) and (b)(4) You release raw material (b)(4) for compounding sterile human injectable drugs based upon review of the supplier CoA. You use (b)(4) as a raw material in Semaglutide Injection products, including but not limited lot AC-017165.

B) Your firm releases critical raw materials for use in compounding before a specific identity test. Performance and review of identity testing occur after quality release. You neither require batches to be made exclusively with materials after a completed identity test nor have a process to ensure that compounded lots are withheld from distribution until all component raw materials have a completed identity test. For example, you released semaglutide (b)(4) ITN: (b)(4), for use in

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compounding on 01/12/2026. You began the compounding of lot AC-017165, Semaglutide 2.5mg/mL Stock Solution, on 02/17/2026, however you did not receive material identity test results from your contract lab on 02/23/2026.

OBSERVATION 6 (Repeat)

Buildings used in the manufacture, processing, packing, or holding of a drug do not have the suitable construction and location to facilitate cleaning, maintenance, and proper operations.

Specifically,

A) On 07/13/2026 the inspection team observed you storing bagged sterile gowning and opened boxes of bagged components and materials used for aseptic compounding including sterile vials, vial stoppers, syringes, sterile (b)(4) (b)(4) bag, and IV bags of Sodium Chloride Injection USP in a warehouse constructed with exposed wood and (b)(4) -coated wall insulation. On 07/17/2026, the inspection team observed a non-integral package of sterile coveralls in the facility's prep room amongst sterile garb staged for use in production.

B) A textured wall panel, approximately 4' x 18" in size, was observed on the wall in ISO 8 room Anteroom(b)(4) where all bulk formulation is performed.

OBSERVATION 7

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Your outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B because they (a) are not used to compound drug products that appear on the drug shortage list in effect under section 506E of the Act and (b) do not appear on a list developed by FDA of bulk drug substances for which there is a clinical need.

Specifically,

Your facility compounded human drug products using semaglutide and tirzepatide bulk drug substance.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."