

Georgia Drugs and Narcotics Agency
 Washington Street SW - G2000
 Atlanta, Georgia 30334

OPIOID TREATMENT PROGRAM CLINIC

Pharmacy Inspection Report

Board Office: 404-651-8000
 Board Fax: 470-386-6137
 GDNA Office: 404-656-5100
 GDNA Fax: 404-651-8210
 GDNA Toll Free: 800-656-6568

Pharmacy Information

| | | | |
|---|-------------------------------|---|---|
| Inspection Type: Routine | | | |
| Name: The Genesis Center of Winder LLC | | | County: Barrow |
| DCH Narcotic Treatment Programs Permit #: NTP001104 | | | Date: 8/8/2023 |
| Permit #: PHOP000103 | Exp: 6/30/2025 | DEA Registration #: RT/ZT0569600 | Exp: 11/30/2023 |
| Street Address: 206 E Broad Street | | | |
| City: Winder | State: GA | ZIP Code: 30680 | Website: www.thegenesiscenterofwinder.com |
| Phone: 678-900-1579 | Fax: 678-900-1593 | Administrator: Deborah Bradley (Owner) | |
| Pharmacy Hours: Tuesday/Thursday: 5:30AM - 12PM | | Clinic Hours: T,R,S: 5:30AM - 12PM | |
| Director of Pharmacy: Charles L Davenport, Jr | | License #: RPH017948 | Exp: 12/31/2024 Full Time <input type="checkbox"/> Part Time <input checked="" type="checkbox"/> |
| PIC Email: grrcwinder@gmail.com | PIC Cell: 678-575-8701 | PIC Alternate Phone | |
| Medical Director: Robert Van Gallera | | GA License #: 37717 | Exp Date: 12/31/2023 |
| Pharmacist Director's DEA Registration# AV3277185 | | Exp Date: 5/31/2026 | |
| Other Pharmacists, Interns, Technicians, Nurses: | | | |
| Name: Jeffery Michael Millon | | License/Registration #: RPH015520 | Exp: 12/31/2024 |
| Name: Lacey Starr Webster | | License/Registration #: PHTC023832 | Exp: 6/30/2025 |
| Name: | | License/Registration #: | Exp: |
| Name: | | License/Registration #: | Exp: |
| Name: | | License/Registration #: | Exp: |
| Name: | | License/Registration #: | Exp: |
| Name: | | License/Registration #: | Exp: |
| Name: | | License/Registration #: | Exp: |
| Last GDNA Inspection Date: 9/12/2020 | | Inspected by: Poblet | |
| DEA Biennial Inventory Date: 12/26/2022 | | DEA Biennial Inv conducted at the: <input type="checkbox"/> Beginning of Business <input checked="" type="checkbox"/> Close of Business | |
| List of drug suppliers and reverse distributors: Hikma; Reverse distributor: Rx Exchange | | | |

| 480-18-.03 Personnel | Satisfactory |
|---|--------------|
| 1. The pharmacy has a sufficient number of trained supportive personnel (b) | 1. Yes |
| 2. Supportive personnel are properly supervised (c) | 2. Yes |

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480-18-.04 Absence of a Pharmacist

Satisfactory

| | |
|--|--------------|
| 3. Only specifically authorized, licensed medical personnel, have access to drugs in the absence of the pharmacist (1) | 3. Yes |
| 4. Emergency Kits / Crash Carts (3): | 4a. Comments |
| a. Sealed and stored in a limited access area | 4b. Yes |
| b. Properly labeled for both interior and exterior | 4c. N/A |
| c. Removed pursuant to a valid physician's order or by a pharmacist | 4d. Yes |
| d. The pharmacy is properly notified when an emergency kit is used | 4e. Yes |
| e. Emergency kits are inspected at least once every ninety (90) days | |
| 5. After-hours access to the pharmacy (4) | 5a. Yes |
| a. Only licensed healthcare professionals have after-hours access to the pharmacy | 5b. Yes |
| b. The licensed healthcare professionals have been trained | 5c. N/A |
| c. Required documentation is performed for drugs removed from the pharmacy | 5d. N/A |
| d. A pharmacist promptly reviews drugs removed from the pharmacy | |

480-18-.05 Physical Requirements and Equipment

Satisfactory

| | |
|--|---------|
| 6. The pharmacy has sufficient space - a minimum of 150 ft ² (1) | 6. Yes |
| 7. The pharmacy has access to current reference materials related to OTP (2)(a) | 7. Yes |
| 8. Current antidote information and the poison control phone number are readily available(2)(b) | 8. Yes |
| 9. The pharmacy has access to O.C.G.A. 26-4; 26-3; 16-3; and the official rules of the GA Georgia State Board of Pharmacy (2)(c) | 9. Yes |
| 10. The pharmacy has the minimum equipment required (2)(d-e) | 10. Yes |
| Approved variances are posted (if applicable) (3) | 11. N/A |

480-18-.06 Drug Distribution and Control

Satisfactory

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|---|----------|
| 12. No drugs are dispensed or administered without a physician's written medication drug order (1) | 12. Yes |
| 13. Drugs are identified up to the point of administration (2)(a)(1) | 13. Yes |
| 14. The pharmacy receives a valid drug order prior to dispensing the first dose (2)(a)(2) | 14. Yes |
| 15. The pharmacy maintains a patient profile for each OTP clinic patient (2)(a)(3) | 15. Yes |
| 16. All drug invoices are attached to their accompanying DEA form 222 order form and filed separately from all other drug records - computerized records may meet these requirements (2)(a)(5-6) | 16. Yes |
| 17. The pharmacy participates in the patient care evaluation program (2)(d) | 17. Yes |
| 18. Records of all transactions of the OTP clinic are maintained for two (2) years (2)(b) | 18. Yes |
| 19. For use inside the clinic, all drugs dispensed by an OTP clinic pharmacy, including those for use in an after-hours safe or emergency kit are labeled with the following at a minimum (3)(a): | 19a. Yes |
| a. Brand name or generic name of the drug | 19b. Yes |
| b. Drug strength | 19c. Yes |
| c. Lot number | 19d. Yes |
| d. Expiration date | |
| 20. Any drug dispensed by the pharmacy for take-home use by an OTP clinic patient is labeled the following at a minimum (3)(b): | 20a. Yes |
| a. Patient name | 20b. Yes |
| b. Name of physician | 20c. Yes |
| c. Name, address, and telephone number of the OTP clinic pharmacy | 20d. Yes |
| d. Drug name | 20e. Yes |
| e. Drug strength | 20f. Yes |
| f. Date of dispensing | 20g. Yes |
| g. Expiration date | 20h. Yes |
| h. "Federal Caution" for controlled substances | 20i. Yes |
| i. Clinic pharmacy serial number | |

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| 21. The pharmacy maintains a proof of use for controlled substances and other specified drugs (5) | 21. Yes |
| 22. On-premises drug destruction is for small quantities of controlled substances that are <u>both</u> the remainder of a single-dose unit and prepared to the nearest possible size to the ordered dose (6) | 22. Yes |
| 23. The pharmacy maintains a perpetual inventory of all Schedule II medications (7) | 23. Yes |
| 24. Suspected adverse drug reactions are reported to the ordering practitioner, the pharmacy and recorded in the patient's record. (9) | 24. Yes |
| 25. Drug storage areas are locked or otherwise secured when licensed health care professionals are not present (10) | 25. Yes |
| 26. Required records & reports are maintained for 2 years and are readily available during inspection (11) | 26. Yes |

480-18-.07 Delivery of Drugs, General

Satisfactory

| | |
|--|----------------------------------|
| 27. Drugs are dispensed or administered upon receipt of a medication drug order (1): a. A practitioner must write an initial dosing medication order for each patient prior to dispensing b. In emergency situations a 72 hour supply verbal order is permitted which is signed within 72 hours c. Any adjustment to a patient dosage regimen is considered a new medication order and shall be written and signed by the medical director within 72 hours. | 27a. Yes 27b. Yes 27c. Yes |
| 28. The pharmacist-in-charge or designee conducts and documents inspections, no less than once per month. These inspections shall, at a minimum, verify items found in 480-18-.09(2)(a-f). | 28. Yes |
| 29. The BOP and GDNA are notified of patients that improperly utilize more than one OTP at the same time (480-18- 10) | 29. Yes |

Required Policies and Procedures

The following items are required to be included as part of a policy and procedure manual for an Opioid Treatment Clinic Pharmacy. By signing below the pharmacist is confirming this pharmacy has a policy and procedure that addresses each item listed here, and pharmacy personnel adhere to these policies and procedures.

- | | |
|---|--|
| • Training supportive personnel 480-18-.03(d)(4) | • Access to drugs in the absence of the pharmacist 480-18-.04(2) |
| • Emergency Kits 480-18-.04(1)(e) | • Distribution of medications 480-18-.06(2)(a) |
| • Drug recalls 480-18-.08 | • Drugs from outside sources 480-18-.08 |
| • Discontinued Drugs 480-18-.06(4) | • Recalls of prescription medication 480-18-.06(8) |
| • After-hours access to the pharmacy 480-18-.04(e) | • Drug administration 480-18-.07 |

Date of last policy and procedure manual revision: 8/2023

ADDITIONAL INFORMATION

- Licenses shall become null and void upon the sale, transfer or change of mode of operation or location of the business. (480-18-.02(5))
- Licenses are renewed for two years and expire on June 30th of each odd numbered year. (480-18-.02(3)(d))
- Any discrepancies or deficiencies noted shall be corrected within 30 days of this inspection. Written notice of such corrections shall be filed with GDNA within thirty (30) days after receipt of the inspection report. (480-18-.02(6))
- Georgia State Board of Pharmacy Website: WWW.GBP.Georgia.GOV;
- Georgia Drugs & Narcotics Agency Website: WWW.GDNA.Georgia.GOV

Recommendations / Comments

4) Injectable Narcan was observed stored in a lockable cabinet in the patient waiting area. No other drugs were included in this cabinet. According to PIC the Ekits have not been accessed over the last 2 years.
 According to PIC the no after hours access has occurred.

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Recommendations / Comments (continued)

SIGNATURE

This inspection report has been read and explained to the person whose name appears below. Explanations include any observed violations, deficiencies, or comments, and such are based on state/federal laws and rules pertaining to the practice of pharmacy in the State of Georgia. I do affirm the information I have given pursuant to this inspection is true and correct to the best of my knowledge. This inspection report is not intended to be all inclusive, and there may be deficiencies, non-compliance, or violations of the laws and rules not detected and noted in this report.

Printed Name: Jeffery Millon

Printed Name: Michael Poblet

Jeffery M. Millon
Signature: Pharmacy Representative



Michael Poblet
Special Agent, Georgia Drugs and Narcotics Agency

Today's Date 8/8/2023

GDNA considers this document confidential for use between GDNA, the Board of Pharmacy, and the registrant.