

Georgia Drugs and Narcotics Agency
254 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: **Bainbridge Treatment Center**

County: **Decatur**

GDCH Narcotic Treatment Programs Permit #: **NTP001006**

Date: **9/8/2021**

Permit #: **PHOP000011**

Exp: **6/30/2023**

DEA Registration #: **RP0356130**

Exp: **3/31/2022**

Street Address: **931 South West Street**

City: **Bainbridge**

State: **GA**

ZIP Code: **39818**

Website: **N/A**

Phone: **229-248-4220**

Fax: **229-248-4221**

Administrator: **Jewana Lowe**

Pharmacy Hours: **Tues 8:30-2**

Clinic Hours: **M-F 6:00-2:00, Sat 6:30-9:00**

Director of Pharmacy: **Edward Franklin Reynolds**

License #: **RPH016169** Exp: **12/31/2022** Full Time ☒ Part Time ☐

PIC Email: **reynoldsef@gmail.com**

PIC Cell: **229-400-0313**

PIC Alternate Phone

229-246-7200

Medical Director: **Henry Almazan Eugenio**

GA License #: **32379**

Exp Date: **7/31/2023**

Medical Director's DEA Registration# **BE1434579**

Exp Date: **8/31/2024**

Other Pharmacists, Interns, Technicians, Nurses:

Name: **Kelsey Rice Holt**

License/Registration #: **RPH028757** Exp: **12/31/2022**

Name: **Dianne Hunter Fagg**

License/Registration #: **LPN047595** Exp: **3/31/2023**

Name: **Carolyn Mills**

License/Registration #: **LPN054697** Exp: **3/31/2023**

Name:

License/Registration #:

Exp:

Name:

License/Registration #:

Exp:

Name:

License/Registration #:

Exp:

Name:

License/Registration #:

Exp:

Name:

License/Registration #:

Exp:

Last GDNA Inspection Date: **1/31/2017**

Inspected by: **Tinsley**

DEA Biennial Inventory Date: **12/1/2020**

DEA Biennial Inv conducted at the: ☐ Beginning of Business ☒ Close of Business

List of drug suppliers and reverse distributors: **Hikma, no reverse distributor currently being used**

480-18-.03 Personnel

Satisfactory

1. The pharmacy has a sufficient number of trained supportive personnel (b)
2. Supportive personnel are properly supervised (c)

1. Yes

2. Yes

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

Satisfactory

480-18-.04 Absence of a Pharmacist

Only specifically authorized, licensed medical personnel, have access to drugs in the absence of the pharmacist (1)

3. Yes

Emergency Kits / Crash Carts (3):

- Sealed and stored in a limited access area
- Properly labeled for both interior and exterior
- Removed pursuant to a valid physician's order or by a pharmacist
- The pharmacy is properly notified when an emergency kit is used
- Emergency kits are inspected at least once every ninety (90) days

4a. Yes

4b. Yes

4c. Yes

4d. Yes

4e. Yes

After-hours access to the pharmacy (4)

- Only licensed healthcare professionals have after-hours access to the pharmacy
- The licensed healthcare professionals have been trained
- Required documentation is performed for drugs removed from the pharmacy
- A pharmacist promptly reviews drugs removed from the pharmacy

5a. Yes

5b. No

5c. Yes

5d. Yes

Satisfactory

480-18-.05 Physical Requirements and Equipment

The pharmacy has sufficient space - a minimum of 150 ft² (1)

6. Yes

The pharmacy has access to current reference materials related to OTP (2)(a)

7. Yes

Current antidote information and the poison control phone number are readily available (2)(b)

8. Yes

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

The pharmacy has the minimum equipment required (2)(d-e)

10. No

Approved variances are posted (if applicable) (3)

11. Yes

480-18-.06 Drug Distribution and Control

Satisfactory

No drugs are dispensed or administered without a physician's written medication drug order (1)

12. Yes

Drugs are identified up to the point of administration (2)(a)(1)

13. Yes

The pharmacy receives a valid drug order prior to dispensing the first dose (2)(a)(2)

14. Yes

The pharmacy maintains a patient profile for each OTP clinic patient (2)(a)(3)

15. Yes

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. No

The pharmacy participates in the patient care evaluation program (2)(d)

17. Yes

Records of all transactions of the OTP clinic are maintained for two (2) years (2)(b)

18. Yes

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):

- Brand name or generic name of the drug
- Drug strength
- Lot number
- Expiration date

19a. Yes

19b. Yes

19c. No

19d. Yes

Any drug dispensed by the pharmacy for take-home use by an OTP clinic patient is labeled the following at a minimum (3)(b):

- Patient name
- Name of physician
- Name, address, and telephone number of the OTP clinic pharmacy
- Drug name
- Drug strength
- Date of dispensing
- Expiration date
- "Federal Caution" for controlled substances
- Clinic pharmacy serial number

20a. Yes

20b. Yes

20c. Yes

20d. Yes

20e. Yes

20f. Yes

20g. Yes

20h. Yes

20i. Yes

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

- | | |
|---|---------|
| 1. The pharmacy maintains a proof of use for controlled substances and other specified drugs (5) | 21. Yes |
| 2. 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. N/A |
| 3. 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): | 27a. Yes |
| 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 | 27b. N/A |
| 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. | 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. No |
| 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: Ongoing

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

5b. No documentation of training found or being maintained; DOP to ensure training of personnel also addressed in pharmacy's SOPs/P&Ps.

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

Recommendations / Comments (continued)

0. No refrigerator (with thermometer) located in pharmacy. Pharmacy does not currently maintain any medications that require refrigeration. DOP to ensure pharmacy maintains all required equipment. DOP may apply for waiver/variance.

16. Invoices not currently maintained at pharmacy (with corresponding DEA form 222s); DOP maintains hardcopy invoices at 'other' pharmacy location. Recommend hardcopy invoices (or copies of such) be maintained at OTP location, coupled with corresponding DEA form 222. If online/digital access of such invoices is available, such may meet requirements as well.

19c. DOP to ensure drugs for use inside clinic are labeled with all information required in Board rules; currently lot number not listed on label.

28. No monthly inspections currently being conducted or documented.

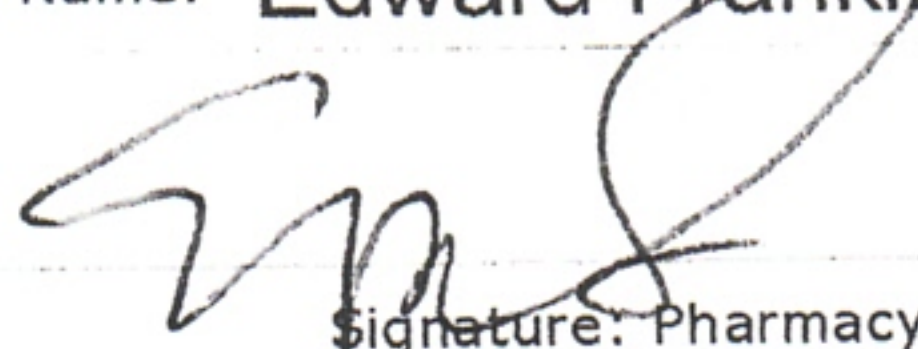
*DOP to ensure facility's SOPs/P&Ps contain all information required in Board rule 480-18.

SIGNATURE

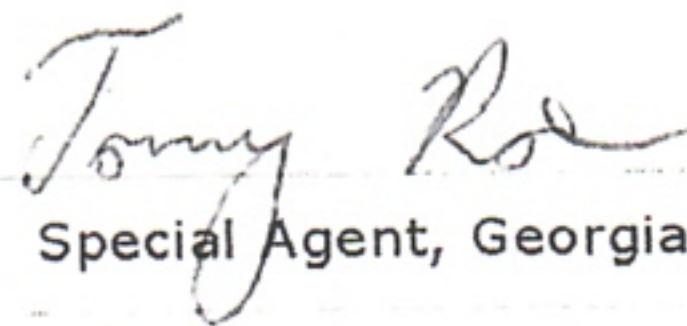
This inspection report has been read and explained to the person whose name appears below. Explanations include any observed violations, deficiencies, or comments, and such are based on state/federal laws and rules pertaining to the practice of pharmacy in the State of Georgia. I do affirm the information 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: **Edward Franklin Reynolds**

Printed Name: **Tommy Roe**



Signature: Pharmacy Representative



Special Agent, Georgia Drugs and Narcotics Agency

Today's Date 9/8/2021

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