Georgia Drugs and Narcotics Agency 4 Washington Street SW - G2000 Atlanta, Georgia 30334

# OPIOID TREATMENT PROGRAM CLINIC

Pharmacy Inspection Report

Board Office: Board Fax: GDNA Office: GDNA Fax: GDNA Toll Free:

404-651-8000 470-386-6137 404-656-5100 404-651-8210 800-656-6568

	Pharmac	y Information		
Inspection Type Routine				
Name: Dallas Comprehensive Treatment Center			County: Paulding	
DCH-HFRD License #: NTP001090			Date: 09/11/2024	
Permit #: PHOP000117	Exp: 6/30/2025	DEA Registration #: RG064	3189, ZG0643189 Exp: 09/30/2025	
Street Address: 311 White Ingran			03/30/2023	
City: Dallas	State: GA		site: www.ctcprograms.com	
Phone: 770-615-0951 Fax: N/A	4	Administrator: Demetrice		
Pharmacy Hours: T,W,F: 6AM-2P	М	Clinic Hours: M-F: 5A-		
Director of Pharmacy: Sheetal Shal	n	License #: RPH020902 Ex	p: 12/31/2024 Full Time □: Part Time ☑	
PIC Email: sheetal.shah@ctcprograms	s.com PIC Cell: 404-	822-5682 PIC Alternate	Phone 770-615-0951	
Medical Director: Dawn Ferguson		GA License #: 35	5179 Exp Date: 12/31/2025	
al Director's DEA Registration# BF	3168297	Exp Date: 09/30	/2025	
Other Pharmacists, Interns, Technicians, Nurses:				
Name:		License/Registration #:	Exp:	
Name:		License/Registration #:	Exp:	
Name:		License/Registration #:	Exp;	
Name:		License/Registration #:	Exp:	
Name:		License/Registration #:	Exp:	
Name:		License/Registration #:	Exp:	
Name:		License/Registration #:	Exp:	
Name:		License/Registration #:	Exp:	
ast GDNA Inspection Date: 10/19/2022	J	Inspected by: Kaptain		
PEA Biennial Inventory Date: 06/14/2024	DEA Biennial In	v conducted at the: ☐ Begin	ning of Business 🗹 Close of Business	
ist of drug suppliers and reverse distributo	rs: SPECGX LLC	, (PHWH004353), Inmar		
Hikma Pharmaceuticals USA Inc, PH	WH004103			
480-1803 Personnel			Satisfactory	
e pharmacy has a sufficient number of trained supportive personnel (b)			1. Yes	
. Supportive personnel are properly super	vised (d)		2. N/A	

Georgia Drugs and Narcotics Agency 354 Washington Street SW - G2000 Atlanta, Georgia 30334

### OPIOID TREATMENT PROGRAM CLINIC

Pharmacy Inspection Report

Board Office: Board Fax: GDNA Office: GDNA Fax: GDNA Toll Free:

404-651-8000 470-386-6137 404-656-5100 404-651-8210 800-656-6568

Recommendations / Comments (continued)

- 2. Comment: There are no supportive personnel only PIC Shah works in the pharmacy.
- 4. Comment: Pharmacy does not supply the emergency kit, which only contains Narcan. Narcan is OTC.
- 5. Comment: No after hours access to pharmacy.
- 22. Comment: Clinic will complete an incident report Nurse/Pharmacist and Program Director sign off on report.

#### 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: Emilie Lobeck

Printed Name: Sheetal Shah

Gustal Ila

Signature: Pharmacy Representative

(D<sub>N</sub>)

Special Agent, Georgia Drugs and Narcotics Agency

Date\_\_09/11/2024

### Georgia Drugs and Narcotics Agency 254 Washington Street SW - G2000 Atlanta, Georgia 30334

## OPIOID TREATMENT PROGRAM CLINIC

Pharmacy Inspection Report

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

	480-1804 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):  a. Sealed and stored in a limited access area  b. Properly labeled for both interior and exterior  c. Removed pursuant to a valid physician's order or by a pharmacist  d. The pharmacy is properly notified when an emergency kit is used  e. Emergency kits are inspected at least once every ninety (90) days	4a. N/A 4b. N/A 4c. N/A 4d. N/A 4e. N/A
5.	After-hours access to the pharmacy (4)  a. Only licensed healthcare professionals have after-hours access to the pharmacy  b. The licensed healthcare professionals have been trained  c. Required documentation is performed for drugs removed from the pharmacy  d. A pharmacist promptly reviews drugs removed from the pharmacy	5a. N/A 5b. N/A 5c. N/A 5d. N/A
	480-1805 Physical Requirements and Equipment	Satisfactory
6.	The pharmacy has sufficient space - a minimum of 150 ft <sup>2</sup> (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
1(	pproved variances are posted (if applicable) (3)	11. N/A
_	480-1806 Drug Distribution and Control	Satisfactory
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 $(2)(a)(5-7)$	16. Yes
17.	The pharmacy participates in the patient care evaluation program $(2)(a)(8)$	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 an an after-hours safe or emergency kit are labeled with the following at a minimum (3)(a):  a. Brand name or generic name of the drug b. Drug strength c. Lot number d. Expiration date	19a. Yes 19b. Yes 19c. Yes 19d. Yes
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):  a. Patient name b. Name of physician c. Name, address, and telephone number of the OTP clinic pharmacy d. Drug name e. Drug strength f. Date of dispensing g. Expiration date h. "Federal Caution" for controlled substances i. Clinic pharmacy serial number	20a. Yes 20b. Yes 20c. Yes 20d. Yes 20e. Yes 20f. Yes 20g. Yes 20h. Yes 20i. Yes

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

### OPIOID TREATMENT PROGRAM CLINIC

Pharmacy Inspection Report

Board Office: Board Fax: GDNA Office: GDNA Fax: GDNA Toll Free:

404-651-8000 470-386-6137 404-656-5100 404-651-8210 800-656-6568

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)		Yes
<ol> <li>Drug storage areas are locked or otherwise secured when licensed health care professionals are not present (10)</li> </ol>	25.	Yes
6. Required records & reports are maintained for 2 years and are readily available during inspection (11)	26.	Yes

480-1807 Delivery of Drugs, General	Satisfactory	
<ul><li>27. Drugs are dispensed or administered upon receipt of a medication drug order (1):</li><li>a. A practitioner must write an initial dosing medication order for each patient prior to dispensing</li></ul>	27a. Yes	
<ul> <li>In emergency situations a 72 hour supply verbal order is permitted which is signed within 72 hours</li> </ul>	27b. Yes	
<ul> <li>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.</li> </ul>	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 480-1809(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 (480-1810)	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 480-1803(d)(4)	<ul> <li>Access to drugs in the absence of the pharmacist 480-1804(2)</li> </ul>	
• Emergency Kits 480-1804(1)(e)	Distribution of medications 480-1806(2)(a)	
• Drug recalls 480-1808	Drugs from outside sources 480-1808	
Discontinued Drugs 480-1806(4)	Recalls of prescription medication 480-1806(8)	
After-hours access to the pharmacy 480-1804(e)	Drug administration 480-1807	

Date of last policy and procedure manual revision: ongoing (various dates including 11/2023)

#### 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 30<sup>th</sup> 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: <u>WWW.GBP.Georgia.GOV</u>;
- Georgia Drugs & Narcotics Agency Website: <u>WWW.GDNA.Georgia.GOV</u>

#### Recommendations / Comments

Comment: Facility utilizes Methasoft software