DECLARATION OF EMERGENCY

Department of Health Health Standards Section

Behavioral Health Service Providers Licensing Standards (LAC 48:I.Chapter 56)

The Department of Health, Health Standards Section amends LAC 48:I.Chapter 56 and adopts §5612 and §5735 as authorized by R.S. 36:254 and R.S. 40:2151-2161. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:962, and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health, Health Standards Section amends the provisions governing the licensing of behavioral health service providers of opioid treatment programs in order to remove outdated eligibility criteria, expand the types of eligible practitioners, adjust the provisions related to take-home doses of medication, and include provisions for mobile dosing units. These updates align with recently updated federal standards.

This action is being taken due to the drastic increase in the number of fatal opioid overdoses in Louisiana. To prevent the imminent peril to the health, safety, and welfare of the public, access to critical medications for the treatment of opioid use disorder will be expanded. It is anticipated that implementation of this Emergency Rule will have no fiscal impact for state fiscal year 2024-2025. This action is effective November 13, 2024.

Title 48 PUBLIC HEALTH—GENERAL Part I. General Administration Subpart 3. Licensing and Certification

Chapter 56. Behavioral Health Service Providers Subchapter A. General Provisions §5603. Definitions

* * *

Mobile Dosing Unit—a mobile unit that is established as part of, but geographically separate from, an opioid treatment program (OTP) parent facility from which appropriately licensed practitioners may dispense or administer medications for opioid use disorder or collect samples for drug testing or analysis.

* * *

OTP Practitioner—a physician, advanced practice registered nurse, nurse practitioner, or physician assistant who is currently licensed and in good standing to prescribe and/or dispense medications for opioid use disorders, and who is acting within the scope of all applicable state and federal laws and the individual's professional license.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:1682 (September 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1380 (July 2017), LR 46:587 (April 2020), LR 48:1277 (May 2022), LR 48:2755 (November 2022), LR 50:394 (March 2024), amended by the Department of Health, Health Standards Section, LR 51:

Subchapter B. Licensing

§5612. Change in License by Addition or Deletion of Services

- A. Addition of Services to an Existing Behavioral Health Service Provider (BHSP) License
- 1. A BHSP with an active BHSP license, current and in good standing, may submit a request to add a service. The following information shall be submitted for consideration of this request:
 - a. letter of intent;
- b. a completed BHSP license application that has add a service clearly marked;
- c. a facility need review approval letter, if applicable; and
- d. applicable nonrefundable fee for issuance of the new BHSP license.
 - B. Deletion of Services from an Existing BHSP License
- 1. A BHSP with an active BHSP license may submit a request to delete a service. The following documentation shall be submitted for consideration of this request:
 - a. letter of intent:
- b. a completed BHSP license application that has delete a service clearly marked; and
- c. applicable nonrefundable fee for issuance of the new BHSP license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health, Health Standards Section, LR 51:

Subchapter I. Physical Environment §5670. Mobile Units

 $A.-D. \ \dots$

NOTE: Repealed.

E. Only local governing entities (LGEs) and OTPs shall be authorized to be licensed as mobile units.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:1284 (May 2022), amended by the Department of Health, Health Standards Section, LR 51:

Subchapter O. Additional Requirements for Opioid Treatment Programs

§5725. Treatment

- A. Client Admission Criteria. The program shall only admit clients that:
 - 1. ...
- 2. meet the federal requirements regarding the determination that the client is currently addicted to opiates;
- 3. are verified by an OTP practitioner that treatment is medically necessary:
- 4. have had a complete physical evaluation by the client's or program's OTP practitioner before admission to the opioid treatment program; and
- 5. have had a full medical exam, including results of serology and other tests, completed within 14 days of admission.
 - 6. Repealed.
 - B. C.5....
- D. Physical Evaluations/Examinations. The provider shall ensure that each client has a documented physical evaluation and examination by an OTP practitioner as follows:

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:1721 (September 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 48:1288 (May 2022), amended by the Department of Health, Health Standards Section, LR 51:

§5727. Additional Staffing Requirements

A. – A.4.e.iii. ...

- 5. OTP Practitioner. There shall be an OTP practitioner who is on-site as needed or on-call as needed during hours of operation.
- a. the OTP practitioner shall have a current, valid unrestricted license to practice in the state of Louisiana. The OTP practitioner shall be on-site or on-call as needed during the hours of operation to provide the following services:
 - i. examine member for admission;
 - ii. prescribe medications;

iii. - ix.

6. Medical Director

a. ...

b. the medical director shall provide the following services:

i. – ii. ...

- iii. participate in the documentation of reviews of treatment plan every 90 days in the first two years of treatment; and
 - iv. participate in discharge planning.
 - v. Repealed.

A.7. - B.6...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:1721 (September 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 48:1288 (May 2022), amended by the Department of Health, Health Standards Section, LR 51:

§5729. Medications

A. ...

- B. Take-Home Dose(s)
 - 1. The provider shall ensure that:
- a. determinations for take-home dose(s), the factors considered, and the rationale to provide unsupervised doses of methadone are made by the client's OTP practitioner, and are documented in the client's record when each take-home dose is authorized;
- b. date and recommended dosage are documented in the client's record and the methadone central registry; and
- c. take-home dose(s) are ordered by the OTP practitioner operating within the scope of his/her license.
- 2. In determining which clients may receive unsupervised doses, the OTP practitioner shall consider, among other pertinent factors that indicate whether the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:
- a. absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of client harm as it relates to the potential for overdose, or the ability to function safely;
- b. regularity of attendance for supervised medication administration;
- c. absence of serious behavioral problems that endanger the client, the public, or others;

- d. absence of known recent diversion activity;
- e. whether take-home medication can be safely transported and stored; and;
- f. any other criteria that the OTP practitioner considers relevant to the client's safety and the public's health.

 $g.-h. \qquad Repealed. \\$

- 3. If it is determined that a client is safely able to manage unsupervised doses of methadone, the OTP practitioner operating within the scope of his/her license shall determine the number of take-home doses authorized within the following dispensing restrictions.
- a. During the first 14 days of treatment, the takehome supply shall be limited to 7 days of take home doses.
- b. From 15 days of treatment, the take-home supply shall be limited to 14 days of take home doses.
- c. From 31 days of treatment, the take-home supply provided to a client shall not exceed 28 days of take home doses at a time.
 - d. f. Repealed.
- 4. Loss of Privilege. Positive drug screens at any time for any drug other than those prescribed shall require a new determination to be made by the OTP practitioner regarding take-home doses. Operating within the scope of his/her license, the OTP practitioner shall determine the actual number of take-home doses and whether the client is allowed to maintain take-home medication.
- 5. Exceptions. The provider shall request and obtain approval for a federally identified exception to the takehome dispensing restrictions from the State Opioid Treatment Authority (SOTA). Any exception shall be for an emergency or severe travel hardship.

C. - C.3...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:1722 (September 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1388 (July 2017), LR 48:1289 (May 2022), amended by the Department of Health, Health Standards Section, LR 51:

§5731. Client Records

A. In addition to the general requirements for client records, each client record shall contain:

1.-5. ...

6. documentation of approval of any exception to the dispensing restrictions of take-home doses and the OTP practitioner's justification for such exception; and

7. ..

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:1723 (September 2015), amended by the Department of Health, Health Standards Section, LR 51:

§5735. Mobile Dosing Unit (MDU) Services

- A. Prior to providing MDU services, an OTP shall apply to HSS to add MDU services to an existing BHSP license.
- B. OTPs with a current, valid license in accordance with Subchapter O, a current, valid certification by the Substance Abuse and Mental Health Services Administration in accordance with 42 CFR §8.11, and SOTA approval may establish a MDU that shall be authorized to dispense Federal Drug Administration-approved medications for opioid use

disorder (MOUD), and to collect samples for drug testing or analysis for the purpose of treatment.

- 1. SOTA approval shall be required for the following criteria:
 - a. floor plan;
 - b. policies and procedures;
 - c. location;
 - d. schedule;
 - e. staffing; and
 - f. training.
 - 2. HSS shall receive directly from SOTA:
 - a. evidence of approval to establish a MDU; and
- b. a copy of a SOTA-approved MDU location schedule.
- C. The MDU shall be established as part of, but geographically separate from, the OTP's parent facility, and the MDU shall maintain all state and federal confidentiality requirements.
 - D. Location
- 1. MDUs shall dispense MOUD from a location within the same LDH region as the OTP's parent facility.
- 2. The MDU location shall be limited to one location each day that shall be approved by the SOTA.
- 3. The MDU shall be returned and secured at the OTP's parent facility upon completion of all MDU services each day.
 - E. Storage and Maintenance
- 1. All medication shall be transported and removed directly from the MDU upon completion of all MDU services each day, and stored at the OTP's parent facility.
- 2. OTPs shall notify the SOTA in advance of any scheduled maintenance of the MDU, and within 24 hours of any incidents.
- F. OTPs shall have a Drug Enforcement Administration (DEA) and SOTA-approved contingency plan for MDUs as follows:
- 1. safeguarding MDU controlled substances in the event the MDU breaks down or is disabled for any reason (e.g., mechanical failure, accident, fire); and
- 2. ensuring that the controlled substances are removed, secured, and accounted for at the OTP's parent facility.
- G. OTPs shall maintain all DEA-mandated reports and records at the parent facility, and shall provide copies to the SOTA upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2151-2161.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 48:2758 (November 2022), amended by the Department of Health, Health Standards Section, LR 51:

Tasheka Dukes, RN, Health Standards Section, is responsible for responding to inquiries regarding this Emergency Rule.

Michael Harrington, MBA, MA Secretary