

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Healthcare Facility Sanctions (LAC 48:I.Chapter 46)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.Chapter 46 as authorized by R.S. 36:254, 40:2009.11, 40:2009.23, 40:2199, and 40:2199.1. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 461 of the 2022 Regular Session of the Louisiana Legislature requires Department of Health to promulgate rules for licensed healthcare facilities to establish duties and requirements addressing and preventing workplace violence. The Department of Health, Bureau of Health Services Financing promulgated a Notice of Intent which amended LAC 48:I.Chapter 46 governing healthcare facility sanctions in order to comply with the requirements of Act 461 and to add and update definitions (*Louisiana Register*, Volume 48, Number 11). As a result of additional communication with stakeholders, the department determined it was necessary to abandon the November 20, 2022 Notice of Intent.

In compliance with Act 461, the department now proposes to amend the provisions governing healthcare facility sanctions in

order to establish duties and requirements addressing workplace violence and to add and update definitions.

Title 48

PUBLIC HEALTH-MEDICAL ASSISTANCE

Part I. Administration

Subpart 3. Licensing and Certification

Chapter 46. ~~Health-Care~~Healthcare Facility Sanctions

Subchapter A. General Provisions

§4601. Introduction

A. The purpose of this Chapter is to:

1. provide for the development, establishment, and enforcement of statewide standards for the imposition of sanctions pursuant to state statutes against ~~health care~~healthcare facilities in the state of Louisiana ~~which~~that have violations of federal or state law or statutes, licensure standards and requirements, certification requirements, or Medicaid requirements;

2. - 6. ...

B. This Chapter shall not apply to any individual ~~health care~~healthcare provider who is licensed or certified by one of the boards under ~~the Department of Health and Hospitals~~LDH.

These boards include, but are not limited to:

1. - 6. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3077 (November 2013), LR 49:

§4603. Definitions

Administrative Reconsideration—for purposes of this Chapter, also known as an informal reconsideration.

Class A Violation—a violation of a rule or regulation that creates a condition or occurrence relating to the maintenance and/or operation of a facility which results in death or serious harm to a-client the resident(s), patient(s), or client(s).

Examples of class A violations include, but are not limited to:

1. acts or omissions by an employee or employees of a facility that either knowingly or negligently resulted in the death of a-client the resident(s), patient(s), or client(s); or
2. acts or omissions by an employee or employees of a facility that either knowingly or negligently resulted in serious harm to a-client the resident(s), patient(s), or client(s).

Class B Violation—a violation of a rule or regulation in which a condition or occurrence relating to the maintenance and/or operation of a facility is created which results in the substantial probability of death or serious physical or mental

harm to ~~a client~~ the resident(s), patient(s), or client(s).

Examples of class B violations include, but are not limited to:

1. - 3 ...

4. failure to employ a sufficient number of adequately trained staff to care for ~~clients~~ resident(s), patient(s), or client(s); or

5. ...

Class C Violation—a violation of a rule or regulation in which a condition or occurrence relating to the maintenance and/or operation of a facility creates a potential for harm by directly threatening the health, safety, ~~rights,~~ or welfare of ~~a client~~ the resident(s), patient(s) or client(s). Examples of class C violations include, but are not limited to:

1. - 5 ...

6. lack of adequately trained staff necessary to meet ~~a patient's or client's~~ the resident(s), patient(s), or client(s)' needs; ~~or~~

7. failure of a regulated entity to ~~protect patients or clients from personal exploitation including, but~~ display on its premises at least one sign, which is at least 18 inches tall by 18 inches wide and written in the English language with letters that are not ~~limited to, sexual conduct involving facility staff and a patient or client.~~ less than one-square-inch

in size, in a conspicuous location in a publically-accessible area;

8. failure by a regulated entity to develop a workplace violence prevention plan that includes, as a minimum, all of the following resources:

a. resources for ongoing education on the issue of workplace violence;

b. resources for prevention of workplace violence; and

c. resources on responding to incidents of workplace violence and debriefing with respect to such incidents and responses thereto;

9. failure by a regulated entity to have a healthcare workplace violence prevention plan that addresses and encompasses all of the following:

a. personnel education and policies requiring all healthcare workers who provide direct care to resident(s), patient(s), or client(s) to receive, at least annually, education and training in a format that provides an opportunity for interactive questions and answers with a person knowledgeable about the workplace violence prevention plan. The education and training delivered pursuant to a workplace violence prevention plan that covers topics including but not limited to all of the following:

i. how to recognize the potential for violence to occur;

ii. when and how to seek assistance to prevent or respond to violence;

iii. how to report violent incidents to law enforcement; and

iv. resources available to employee or employees for coping with incidents of workplace violence.

b. a system for responding to and investigating violent incidents and situations involving violence; and

c. a system for regularly, and not less than annually, assessing and improving upon factors that may contribute to or help in preventing workplace violence. The system must address, without limitation, all of the following aspects of the workplace:

i. staffing, including staffing patterns that may contribute to, or be insufficient to address, the risk of violence;

ii. sufficiency of security systems including alarms, emergency response systems, and availability of security personnel;

iii. job design, equipment, and facilities; and

iv. security risks associated with particular units of the workplace, areas of the regulated entity's facility with uncontrolled access, late night, or early morning shifts, and areas surrounding the facility such as employee or employees' parking areas;

10. failure by a regulated entity to orient all permanent and temporary employee or employees of the entity's workplace violence prevention plan;

11. failure by a regulated entity to maintain its workplace violence prevention plan in effect at all times; or

12. failure by a regulated entity to protect resident(s), patient(s), or client(s) from personal exploitation including, but not limited to, sexual conduct involving facility staff and the resident(s), patient(s), or client(s).

Class D Violation—a violation of a rule or regulation related to administrative and reporting requirements that do not directly threaten the health, safety, ~~rights,~~ or welfare of ~~a client~~the resident(s), patient(s), or client(s), or the safety of its employee or employees through workplace violence.

Examples of *class D violations* include, but are not limited to:

1. - 2. ...

3. falsification of a record; ~~or~~

4. failure to maintain ~~a patient's or client's~~the
resident(s), patient(s), or client(s)' financial records as
required by rules and regulations-i

5. failure by a regulated entity to maintain and
make available to its employee or employees, a written safety
and security plan; or

6. a regulated entity taking retaliatory action
against a person who, in good faith:

a. reports an allegation or instance of
workplace violence;

b. seeks assistance and intervention from local
emergency services or law enforcement when a violent incident
occurs; or

c. reports to law enforcement a crime or
allegation involving workplace violence at the regulated
entity's facility.

Department or ~~DHH~~LDH—the Louisiana Department of Health—~~and~~
~~Hospitals~~.

Employee—for purposes of this Chapter, a person who
performs a job or task for the healthcare provider. An employed
person may be permanent, temporary, or contracted.

~~Health-Care~~Healthcare Facility or Facility—any ~~health care~~healthcare provider or entity licensed or certified by ~~DHH~~LDH, including all regulated entities, as defined by R.S. 40:2199.12, under the regulatory jurisdiction of LDH. In other laws, ~~statues~~statutes and regulations, this entity may be referred to as a provider, agency, clinic, residential unit, or home. A ~~health-care~~healthcare facility shall include, but not be limited to a/an:

1. - 11. ...
12. ~~supplier of portable x-ray services~~free-standing birth center;
13. ~~home and community-based~~supplier of portable x-ray services—~~(HCBS) provider~~;
14. home ~~health agency~~and community-based services (HCBS) provider;
15. ~~hospice~~home health agency;
16. ~~hospital~~hospice agency;
17. ~~intermediate care facility for persons with developmental disabilities (ICF-DD)~~hospital;
18. ~~mental health clinic~~intermediate care facility for persons with developmental disabilities (ICF-DD);
19. mental health ~~center~~clinic;
20. mental health ~~rehabilitation agency~~center;

21. ~~non-emergency medical transportation~~mental health rehabilitation agency;
22. ~~nursing facility~~non-emergency medical transportation agency;
23. ~~rural health clinic~~nursing facility;
24. ~~pain management clinic~~nurse staffing agency;
25. ~~pediatric day health care (PDHC) facility~~rural health clinic;
26. ~~psychiatric rehabilitation treatment facility (PRTF)~~pain management clinic;
27. ~~substance abuse/addiction treatment~~pediatric day healthcare (PDHC) facility; ~~and~~
28. ~~therapeutic group home (TGH)~~psychiatric residential treatment facility (PRTF);
29. substance use/addiction treatment facility;
30. therapeutic group home (TGH); and
31. any other program licensed or certified by LDH.

~~HSS—the Department of Health and Hospitals, Office of Management and Finance,~~ LDH Health Standards Section.

Regulated Entity—any licensed healthcare facility as defined by R.S. 40:2199.12.

Secretary—the ~~secretary~~secretary of ~~DHHL~~LDH or his/her designee.

Workplace Violence—violent acts, including battery or the intentional placing of another person in reasonable apprehension of sustaining battery, directed toward persons at work or on duty with their employment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3077 (November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

Subchapter B. Sanctions and Standards for the Imposition of Sanctions

§4611. General Provisions

A. - B.12.c. ...

C. Considerations. When determining whether to impose a sanction, the department may consider some or all of the following factors:

1. whether the violations pose an immediate threat to the health, ~~or~~ safety, or welfare of the resident(s), patient(s), or client(s);

C.2. - E ...

F. Any facility sanctioned under this Rule and found to have a violation that poses a threat to the health, safety, ~~rights,~~ or welfare of ~~a client~~ the resident(s), patient(s), or

client(s) may have additional actions, such as criminal charges, brought against it under another applicable law, statute or regulation.

G. Unless otherwise provided for in state law or statute, if the secretary determines that the violations committed by the facility pose an imminent or immediate threat to the health, safety, or welfare ~~or safety~~ of any ~~client~~resident(s), patient(s), or client(s) receiving services, the imposition of the sanction may be immediate and may be enforced during the pendency of the administrative appeal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3078 (November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

§4613. Civil Fines

A. - B.2. ...

C. Class C Violations

1. ...

2. A facility may elect to pay 50 percent of the civil fine imposed for a class C violation in exchange for waiving its right to an administrative reconsideration and

appeal if it submits, and HSS receives, the following within 30 days of the facility's receipt of the civil fine notice:

a. ...

b. the facility's written waiver of the right to an administrative reconsideration and appeal on the form provided by ~~DHHL~~LDH.

D. - E.1. ...

F. Determination of the Amount of Civil Fines

1. In establishing the amount of civil fines to be imposed against the provider, the department may consider:

a. all relevant aggravating circumstances, including, but not limited to:

i. - iii. ...

iv. the extent of actual or potential harm to ~~clients~~resident(s), patient(s), or client(s); and

b. - F.2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3079 (November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

§4619. Removal from the Freedom of Choice List

A. The department may impose the sanction of ~~“~~removal from the freedom of choice list~~”~~ to a facility placed on a freedom of choice list. ~~DHH~~LDH may impose this sanction for any violation including, but not limited to:

A.1. - C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3080 (November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

§4621. Transfer of ~~Clients~~Resident(s), Patient(s), or Client(s) Receiving Services

A. The department may impose the sanction of ~~“~~transfer of ~~clients~~resident(s), patient(s), or client(s) receiving services~~”~~ provided by a facility. This sanction may be imposed for any violation of statute, rule or regulation including but not limited to:

A.1. - F.3. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3080

(November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

§4623. License Suspension

A. Unless otherwise provided by federal or state law, the department may impose a suspension of a license if the department determines that the violations committed by the facility pose an imminent or immediate threat to the health, welfare or safety of its ~~clients~~resident(s), patient(s), or client(s).

B. - D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3081 (November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

§4627. Special Staffing Requirements

A. - B.5. ...

C. The department may impose the sanction of special staffing for any violation of statute, rule or regulation including, but not limited to:

1. a violation of a rule or regulation that creates a condition or occurrence relating to the maintenance and/or operation of a facility which results in death or serious harm

to ~~a resident, patient~~the resident(s), patient(s), or
~~elient~~client(s);

2. a violation of a rule or regulation in which a condition or occurrence relating to the maintenance and/or operation of a facility is created and results in the substantial probability of death or serious physical or mental harm to ~~a resident, patient~~the resident(s), patient(s) or ~~elient~~client(s) will result from the violation;

3. a repeat violation of a rule or regulation in which a condition or occurrence relating to the maintenance and/or operation of a facility creates a potential for harm by directly threatening the health, safety, ~~rights,~~ or welfare of ~~a elient~~the resident(s), patient(s), or client(s);

4. ...

5. when there is an imminent threat to the health, safety~~-and-~~, or welfare of the facility's ~~clients~~resident(s), patient(s), or client(s).

D. - E.2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3081 (November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

§4629. Temporary Management

A. The department may require the immediate appointment of a temporary manager, at the facility's expense, to:

1. ...

2. ~~assure~~ensure the health, ~~and~~-safety, and welfare of the facility's ~~elient~~resident(s), patient(s), or client(s).

B. Temporary management may be imposed for any violation of statute, rule or regulation including, but not limited to:

1. a violation of a rule or regulation that creates a condition or occurrence relating to the maintenance and/or operation of a facility which results in death or serious harm to ~~a resident, patient~~the resident(s), patient(s) or ~~elient~~client(s);

2. a violation of a rule or regulation in which a condition or occurrence relating to the maintenance and/or operation of a facility is created and results in the substantial probability of death, serious physical harm or mental harm to ~~a resident, patient~~the resident(s), patient(s) or ~~elient~~client(s);

3. a repeat violation of a rule or regulation in which a condition or occurrence relating to the maintenance and/or operation of a facility creates a potential for harm by directly threatening the health, safety, ~~rights,~~ or welfare of ~~a elient~~the resident(s), patient(s), or client(s);

B.4. - G. ...

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Bureau of Health Services Financing, LR 39:3082
(November 2013), amended by the Department of Health, Bureau of
Health Services Financing, LR 49:

Subchapter C. Notice and Appeals

§4643. Administrative Appeal Process

A. - C.5. ...

D. Hearings

1. - 2.b.v. ...

c. The [administrative law judge \(ALJ\)](#) may
question any party or witness and may admit any relevant and
material evidence.

2.d. - 7. ...

8. The ALJ does not have the authority to:

a. rescind or amend any violation of federal
law, statute, or regulation found by ~~DHH~~[LDH](#) on behalf of CMS; or

D.8.b. - F. ...

AUTHORITY NOTE: Promulgated in accordance with R.S.
40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health
and Hospitals, Bureau of Health Services Financing, LR 39:3083

(November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

Subchapter D. Enforcement of Sanctions

§4651. Enforcement of Sanctions/Collection of Fines

A. - D.2. ...

E. The facility is prohibited from:

1. ...

2. increasing charges to ~~clients~~resident(s), patient(s), or client(s) as a result of civil fines and/or interest imposed by ~~DHH~~LDH.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.11, 40:2009.23, 40:2199 and 40:2199.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3085 (November 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 49:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

Small Business Analysis

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule may have an indeterminable impact on small businesses that fail to comply with the requirements for addressing workplace violence and may be sanctioned.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Public Comments

Interested persons may submit written comments to Tasheka Dukes, RN, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821. Ms. Dukes is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on May 30, 2023.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on May 10, 2023. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on May 25, 2023 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after May 10, 2023. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez

Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Stephen R. Russo

LDH Secretary