

Regular Session, 2010

SENATE BILL NO. 355

BY SENATOR MOUNT

HEALTH CARE. Provides for a facility need process for proton radiotherapy facilities.
(gov sig)

1 AN ACT

2 To enact Part XV of Chapter 11 of Title 40 of the Louisiana Revised Statutes of 1950, to be
3 comprised of R.S. 40:2200.11 through 2200.14, relative to proton beam
4 radiotherapy; to provide for a facility need review process for proton beam
5 radiotherapy facilities; to provide for definitions; to provide for rules and regulations
6 and penalties; and to provide for related matters.

7 Be it enacted by the Legislature of Louisiana:

8 Section 1. Part XV of Chapter 11 of Title 40 of the Louisiana Revised Statutes,
9 comprised of R.S. 40:2200.11 through 2200.14, is hereby enacted to read as follows:

10 **PART XV. FACILITY NEED REVIEW OF PROTON BEAM RADIOTHERAPY**
11 **FACILITIES**

12 **§2200.11. Definitions**

13 **As used in this Part, the following terms shall have the following**
14 **meanings, except when the context clearly indicates otherwise:**

15 **(1) "Department" means the Department of Health and Hospitals.**

16 **(2) "Proton beam radiotherapy facility" means any facility which**
17 **provides proton beam radiotherapy treatments.**

1 **§2200.12. Facility need review**

2 **A. The Department of Health and Hospitals, in accordance with the**
3 **Administrative Procedure Act, shall establish a facility need review process for**
4 **proton beam radiotherapy facilities.**

5 **B. The department shall promulgate rules and regulations in accordance**
6 **with the Administrative Procedure Act to provide for facility need review. The**
7 **rules and regulations shall include but not be limited to the following:**

8 **(1) Criteria for review of a proton beam radiotherapy facility to**
9 **determine if there is a need for additional facilities to provide proton beam**
10 **radiotherapy services and treatments.**

11 **(2) Specific duties of the department to review proposals for new**
12 **facilities and determine the need therefor.**

13 **(3) Appropriate methodology for the collection of data necessary for the**
14 **administration of the program.**

15 **(4) Procedures to grant and revoke approvals.**

16 **(5) Procedures for review of applications by the department.**

17 **(6) Procedures to request a fair hearing from a determination made by**
18 **the department.**

19 **(7) Provisions for judicial review from the decision rendered after a fair**
20 **hearing.**

21 **§2200.13. Facility need review procedure**

22 **A. Each application for approval under the facility need review process**
23 **for a proton beam radiotherapy facility shall be made to the department on**
24 **forms prescribed by the department and shall contain such information as the**
25 **department may require. Additional information required by the department**
26 **shall be provided by the applicant as requested.**

27 **B. Following receipt of the application, the department shall perform a**
28 **facility need review analysis and if the department finds a new facility is**
29 **warranted under the facility need review process an approval shall be issued.**

1 **§2200.14. Operation without facility need review approval; penalty**

2 **A. No public or private proton beam radiotherapy facility shall operate**
3 **without approval from the department under the facility need review process**
4 **pursuant to this Part. Any such facility or provider operating without such**
5 **approval shall be guilty of a misdemeanor and upon conviction shall be fined**
6 **no less than two hundred fifty dollars nor more than one thousand dollars. It**
7 **shall be the responsibility of the department to inform the appropriate district**
8 **attorney of the alleged violation to assure enforcement.**

9 **B. If a public or private proton beam radiotherapy facility is operating**
10 **without an approval issued by the department, the department shall have the**
11 **authority to issue an immediate cease and desist order to that facility. Any such**
12 **facility or provider receiving such a cease and desist order from the department**
13 **shall immediately cease operations until such time as that provider is issued an**
14 **approval by the department.**

15 **C. The department shall seek an injunction in the Nineteenth Judicial**
16 **District Court against any facility or provider who receives a cease and desist**
17 **order from the department under Subsection B of this Section and who does not**
18 **cease operations immediately. Any such facility or provider against whom an**
19 **injunction is granted shall be liable to the department for attorney fees, costs,**
20 **and damages.**

21 Section 2. The Department of Health and Hospitals shall promulgate all rules and
22 regulations necessary to carry out the provisions of this Act by October 1, 2010; however,
23 failure by the department to promulgate rules and regulations by that date shall not affect the
24 validity of any rules and regulations promulgated pursuant to this Act.

25 Section 3. This Act shall become effective upon signature by the governor or, if not
26 signed by the governor, upon expiration of the time for bills to become law without signature
27 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If
28 vetoed by the governor and subsequently approved by the legislature, this Act shall become
29 effective on the day following such approval.

The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Greg Waddell.

DIGEST

Proposed law provides that DHH, in accordance with the APA, shall establish a facility need review process for proton beam radiotherapy facilities.

Proposed law provides that DHH shall promulgate rules and regulations relative to a facility need review process which shall include but not be limited to the following:

- (1) Criteria for review of a proton beam radiotherapy facility to determine if there is a need for additional facilities to provide proton beam radiotherapy services and treatments.
- (2) Specific duties of the department to review proposals for new facilities and determine the need therefor.
- (3) Appropriate methodology for the collection of data necessary for the administration of the program.
- (4) Procedures to grant and revoke approvals.
- (5) Procedures for review of applications by the department.
- (6) Procedures to request a fair hearing from a determination made by the department.
- (7) Provisions for judicial review from the decision rendered after a fair hearing.

Proposed law provides that each application for a facility need review for a proton beam radiotherapy facility shall be made to DHH on forms prescribed by DHH and shall contain such information as may be required.

Proposed law provides that following receipt of the application, DHH shall perform a facility need review analysis and if DHH finds a new facility is warranted under the facility need review process an approval shall be issued.

Proposed law provides that no public or private proton beam radiotherapy facility shall operate without an approval issued by DHH.

Proposed law provides that any such facility or provider operating without an approval shall be guilty of a misdemeanor and upon conviction shall be fined no less than \$250 nor more than \$1000.

Proposed law provides that if a public or private proton beam radiotherapy facility is operating without an approval, DHH has the authority to issue an immediate cease and desist order to that facility. Proposed law further provides that any such facility or provider receiving such a cease and desist order from DHH shall immediately cease operations until such time as that provider is issued an approval by DHH pursuant to the facility need review process.

Proposed law provides that DHH shall promulgate all rules and regulations necessary to carry out the provisions of proposed law by October 1, 2010; however, failure by the department to promulgate rules and regulations by this date shall not affect the validity of any rules and regulations promulgated pursuant to proposed law.

Effective upon signature of the governor or lapse of time for gubernatorial action.

(Adds R.S. 40:2200.11 - 2200.14)