

Regular Session, 2010

SENATE BILL NO. 794 (Substitute of Senate Bill No. 355 by Senator Mount)

BY SENATOR MOUNT

HEALTH CARE. Provides for an equipment utilization review for proton beam radiotherapy equipment. (2/3-CA7s2.1(A))(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 2200.16, relative to proton beam
4 radiotherapy; to provide for the registration of all proton beam radiotherapy
5 equipment; to provide for an equipment utilization review process for proton beam
6 radiotherapy equipment; to provide for definitions; to provide for rules and
7 regulations and penalties; and to provide for related matters.

8 Be it enacted by the Legislature of Louisiana:

9 Section 1. Part XV of Chapter 11 of Title 40 of the Louisiana Revised Statutes of
10 1950, comprised of R.S. 40:2200.11 through 2200.16, is hereby enacted to read as follows:

11 **PART XV. EQUIPMENT UTILIZATION REVIEW FOR PROTON**
12 **BEAM RADIOTHERAPY FACILITIES**

13 **§2200.11. Definitions**

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

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

17 **(2) "Proton beam radiotherapy equipment" means any equipment which**

1 generates and uses protons or heavy charged particles to irradiate diseased
2 tissue.

3 (3) "Proton beam radiotherapy facility" means any facility which
4 provides proton beam radiotherapy treatments.

5 §2200.12. Registration of providers

6 Prior to the operation of any proton beam radiotherapy equipment, such
7 equipment shall be registered with the department. The department shall
8 promulgate all rules and regulations, in accordance with the Administrative
9 Procedure Act, which are necessary to perform this registration requirement.

10 §2200.13. Equipment utilization review

11 A. The department, in accordance with the Administrative Procedure
12 Act, shall establish by promulgation of rules and regulations an equipment
13 utilization review process for proton beam radiotherapy equipment. Except as
14 provided in R.S. 40:2200.16, an approval under this equipment utilization
15 review process shall be required to be obtained by a provider from the
16 department prior to the operation of the provider's proton beam radiotherapy
17 equipment.

18 B. The rules and regulations promulgated by the department shall
19 include but not be limited to the following:

20 (1) Criteria for the review of proton beam radiotherapy equipment
21 pursuant to the equipment utilization review process.

22 (2) Specific duties of the department to review proposals for new proton
23 beam radiotherapy equipment.

24 (3) The collection of data necessary for the administration of the
25 program.

26 (4) Procedures to grant and revoke approvals.

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

28 (6) Procedures to request a fair hearing from a determination made by
29 the department.

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

3 **§2200.14. Equipment utilization review procedure**

4 **A. Each application for approval under the equipment utilization review**
5 **process for proton beam radiotherapy equipment shall be made to the**
6 **department on forms prescribed by the department and shall contain such**
7 **information as the department may require. Additional information required**
8 **by the department shall be provided by the applicant as requested.**

9 **B. Following receipt of the application, the department shall perform an**
10 **equipment utilization review analysis, and if the department finds that new**
11 **equipment is warranted under the equipment utilization review process an**
12 **approval shall be issued.**

13 **§2200.15. Operation without equipment utilization review approval; penalty**

14 **A. Any provider operating proton beam radiotherapy equipment without**
15 **registering the equipment or the required equipment utilization review**
16 **approval shall be guilty of a misdemeanor and upon conviction shall be fined**
17 **no less than two hundred fifty dollars nor more than one thousand dollars for**
18 **each violation. It shall be the responsibility of the department to inform the**
19 **appropriate district attorney of the alleged violation to assure enforcement.**

20 **B. If a public or private proton beam radiotherapy facility is operating**
21 **without the required registration or the required equipment utilization review**
22 **approval issued by the department, the department shall have the authority to**
23 **issue an immediate cease and desist order to that facility. Any such facility or**
24 **provider receiving such a cease and desist order from the department shall**
25 **immediately cease operations until such time as that provider is issued an**
26 **approval by the department.**

27 **C. The department shall seek an injunction in the Nineteenth Judicial**
28 **District Court against any facility or provider who receives a cease and desist**
29 **order from the department under Subsection B of this Section and who does not**

1 cease operations immediately. Any such facility or provider against whom an
2 injunction is granted shall be liable to the department for attorney fees, costs,
3 and damages.

4 §2200.16. Exemptions

5 Proton beam radiotherapy equipment which is obtained and operated
6 by the following shall be exempt from having to obtain approval under the
7 equipment utilization review process:

8 (1) A major Louisiana cancer center which functions as the primary
9 sponsoring institution for any of the following accredited graduate medical
10 education programs related to oncology including radiation oncology, medical
11 oncology, hematology/oncology, radiation biology or radiation therapy
12 technology, and maintains an accredited Institutional Review Board for
13 Research.

14 (2) A National Cancer Institute designated Comprehensive Cancer
15 Center.

16 (3) A nonprofit organization which maintains a joint accreditation with
17 a state university by the Commission on Accreditation of Medical Physics
18 Educational Programs, Inc., (CAMPEP) for a graduate medical physics
19 program and which provides facilities and personnel for use for a joint
20 CAMPEP-accredited graduate medical physics program for research, teaching,
21 and clinical training for graduate students.

22 (4) Any facility who has executed a contract, secured by a deposit, for
23 proton radiotherapy equipment prior to January 1, 2010.

24 Section 2. The Department of Health and Hospitals shall promulgate all rules and
25 regulations necessary to carry out the provisions of this Act by August 20, 2011; however,
26 failure by the department to promulgate rules and regulations by that date shall not affect the
27 validity of any rules and regulations promulgated pursuant to this Act.

28 Section 3. This Act shall become effective upon signature by the governor or, if not
29 signed by the governor, upon expiration of the time for bills to become law without signature

1 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If
2 vetoed by the governor and subsequently approved by the legislature, this Act shall become
3 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

Mount (SB 794)

Proposed law provides that prior to the operation of any proton beam radiotherapy equipment, such equipment shall be registered with DHH.

Proposed law provides that DHH shall establish an equipment utilization review process for proton beam radiotherapy equipment and further provides that an approval under this equipment utilization review process shall be required to be obtained by a provider from the department prior to the operation of the provider's proton beam radiotherapy equipment.

Proposed law provides that DHH shall promulgate rules and regulations in accordance with the APA to provide for an equipment utilization review process. The rules and regulations shall include but not be limited to the following:

- (1) Criteria for the review of proton beam radiotherapy equipment pursuant to the equipment utilization review process.
- (2) Specific duties of the department to review proposals for new proton beam radiotherapy equipment.
- (3) 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 approval under the equipment utilization review process for proton beam radiotherapy equipment shall be made to DHH on forms prescribed by DHH and shall contain such information as DHH may require.

Proposed law provides that upon the receipt of the application, DHH shall perform an equipment utilization review analysis, and if DHH finds that new equipment is warranted under the equipment utilization review process an approval shall be issued.

Proposed law provides that any provider operating proton beam radiotherapy equipment without registering the equipment or the required equipment utilization review approval shall be guilty of a misdemeanor and upon conviction shall be fined no less than \$250 nor more than \$1000. It shall be the responsibility of DHH to inform the appropriate district attorney of the alleged violation to assure enforcement.

Proposed law provides that if a public or private proton beam radiotherapy facility is operating without the required registration or the required equipment utilization review approval issued by DHH, then DHH shall have the authority to issue an immediate cease and

desist order to that facility. 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.

Proposed law provides that DHH shall seek an injunction in the Nineteenth Judicial District Court against any facility or provider who receives a cease and desist order from DHH under proposed law and who does not cease operations immediately. Any such facility or provider against whom an injunction is granted shall be liable to DHH for attorney fees, costs, and damages.

Proposed law provides that proton beam radiotherapy equipment which is obtained and operated by the following shall be exempt from having to obtain approval under the equipment utilization review process:

- (1) A major Louisiana cancer center which functions as the primary sponsoring institution for any of the following accredited graduate medical education programs related to oncology including radiation oncology, medical oncology, hematology/oncology, radiation biology or radiation therapy technology, and maintains an accredited Institutional Review Board for research.
- (2) A National Cancer Institute designated Comprehensive Cancer Center.
- (3) A nonprofit organization which maintains a joint accreditation with a state university by the Commission on Accreditation of Medical Physics Educational Programs, Inc. (CAMPEP) for a graduate medical physics program and which provides facilities and personnel for use for a joint CAMPEP-accredited graduate medical physics program for research, teaching, and clinical training for graduate students.
- (4) Any facility who has executed a contract, secured by a deposit, for proton radiotherapy equipment prior to January 1, 2010.

Proposed law provides that DHH shall promulgate all rules and regulations necessary to carry out the provisions of this Act by August 20, 2011; however, failure by the department to promulgate rules and regulations by that 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 - 2200.16)