

Amendment No. _____

Signature of Sponsor

FILED

Date _____

Time _____

Clerk _____

Comm. Amdt. _____

AMEND Senate Bill No. 195

House Bill No. 184*

by deleting all language after the enacting clause and substituting the following:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, Part 23, is amended by adding the following new section:

(a) This section shall be known and may be cited as the "Proton Therapy Access Act."

(b) As used in this section:

(1) "Aggregate amount" means the total amount paid under the state group insurance program for the applicable radiation treatment delivery CPT codes to deliver a biological effective dose;

(2) "Biological effective dose" means the total prescribed radiation dose delivered in a course of radiation therapy treatments to induce tumor cell death;

(3) "CPT code" means the unique numerical designations established by the American Medical Association for various medical, surgical, and diagnostic services used in billing healthcare services;

(4) "Eligible patient" means a cancer patient who is approved for a standard radiation therapy protocol delivered with IMRT by the state group insurance program's third-party administrator and prescribed a hypofractionated proton therapy protocol for the treatment of the same cancer;

(5) "Hypofractionated radiation therapy protocol" means a cancer treatment protocol that involves the delivery of fewer, larger radiation therapy



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treatment doses than a standard radiation therapy protocol to deliver a biological effective dose;

(6) "Intensity modulated radiation therapy" or "IMRT" means a type of conformal radiation therapy that delivers x-ray radiation beams of different intensities from many angles for the treatment of tumors;

(7) "Proton therapy" means the advanced form of radiation therapy that utilizes protons as the radiation delivery method for the treatment of tumors;

(8) "Radiation therapy" means the delivery of a biological effective dose with proton therapy, IMRT, brachytherapy, stereotactic body radiation therapy, three-dimensional conformal radiation therapy, or other forms of therapy using radiation;

(9) "Registry" means an organized system that uses observational study methods to collect uniform clinical data to evaluate specified outcomes for a population defined by a particular disease and is compliant with the principles established by the U.S. department of health and human services through their *Agency for Healthcare Research and Quality's Registries for Evaluating Patient Outcomes: A User's Guide – Third Edition*;

(10) "Standard radiation therapy protocol" means a cancer treatment protocol that involves the delivery of radiation therapy treatment doses over an extended period of time to deliver a biological effective dose;

(11) "State group insurance program" means health insurance provided under title 8, chapter 27; and

(12) "Treatment dose" means the amount of radiation delivered in a single treatment or fraction of radiation therapy.

(c) The state group insurance program shall cover a physician prescribed hypofractionated proton therapy protocol to deliver a biological effective dose by paying the same aggregate amount as would be paid for the delivery of the same biological

effective dose with a standard radiation therapy treatment protocol delivered with IMRT for the same indication if the following conditions are satisfied:

(1) Coverage is provided to an eligible patient who is being treated as part of a clinical trial or registry;

(2) The eligible patient is diagnosed with a cancer type or indication that can be treated with a hypofractionated proton therapy protocol;

(3) The radiation oncologist prescribing the hypofractionated proton therapy protocol is board certified or board eligible in the specialty of radiation oncology; and

(4) The hypofractionated proton therapy protocol is administered in a facility in this state.

(d) If coverage of the hypofractionated proton therapy protocol is required pursuant to subsection (c), then:

(1) The aggregate amount must be equal to the average cost actually paid by the state group insurance program for a standard IMRT treatment radiation therapy protocol required to deliver the prescribed biological effective dose for the particular indication. For purposes of this subdivision (d)(1), aggregate amounts must be established by reference to the amount paid for a course of IMRT treatment under a standard IMRT radiation therapy protocol for the indication under the state group insurance program; and

(2) Coverage is subject to annual deductible and co-insurance established for radiation therapy and other similar benefits within the policy or contract of insurance. The annual deductible and co-insurance for any radiation therapy delivery method permitted by this section must be no greater than the annual deductible and co-insurance established for all other similar benefits within a policy or contract of insurance.

(e) Notwithstanding any other provision of this section to the contrary, the aggregate amount:

(1) Reimbursed for the hypofractionated proton therapy protocol must not exceed the average aggregate amount paid by the state group insurance program for a course of IMRT treatment under a standard IMRT radiation therapy protocol to deliver the prescribed biological effective dose for the same indication;

(2) Chargeable to or payable by an eligible patient for a covered course of hypofractionated proton therapy by an in-network provider must not exceed the aggregate amount that would otherwise be chargeable to or payable by the eligible patient for a course of IMRT treatment under a standard IMRT radiation therapy protocol that is covered by the state group insurance program for the delivery of the same biological effective dose by an in-network provider; and

(3) Chargeable to or payable by an eligible patient for a covered course of hypofractionated proton therapy by an out-of-network provider must not exceed the aggregate amount that would otherwise be chargeable to or payable by the eligible patient for a course of treatment under a standard IMRT radiation therapy protocol that is covered by the state group insurance program for the delivery of the same biological dose by an out-of-network provider. However, the patient is not responsible for amounts above the allowable maximum charge.

(f) Notwithstanding § 56-7-1005, this section applies only to the state group insurance program.

(g) This section supplements the requirements of 42 U.S.C. § 300gg-8.

SECTION 2. This act shall take effect January 1, 2020, the public welfare requiring it.