

109TH CONGRESS
2^D SESSION

S. 2322

To amend the Public Health Service Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 17, 2006

Mr. ENZI (for himself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Consumer Assurance
5 of Radiologic Excellence Act of 2006”.

6 **SEC. 2. PURPOSE.**

7 The purpose of this Act is to improve the quality and
8 value of healthcare by increasing the safety and accuracy

1 of medical imaging examinations and radiation therapy
2 treatments, thereby reducing duplication of services and
3 decreasing costs.

4 **SEC. 3. QUALITY OF MEDICAL IMAGING AND RADIATION**
5 **THERAPY.**

6 Part F of title III of the Public Health Service Act
7 (42 U.S.C. 262 et seq.) is amended by adding at the end
8 the following:

9 **“Subpart 4—Medical Imaging and Radiation Therapy**
10 **“SEC. 355. QUALITY OF MEDICAL IMAGING AND RADIATION**
11 **THERAPY.**

12 “(a) ESTABLISHMENT OF STANDARDS.—

13 “(1) IN GENERAL.—The Secretary, in consulta-
14 tion with recognized experts in the technical provi-
15 sion of medical imaging and radiation therapy serv-
16 ices, shall establish standards to ensure the safety
17 and accuracy of medical imaging studies and radi-
18 ation therapy treatments. Such standards shall per-
19 tain to the personnel who perform, plan, evaluate, or
20 verify patient dose for medical imaging studies and
21 radiation therapy procedures and not to the equip-
22 ment used.

23 “(2) EXPERTS.—The Secretary shall select ex-
24 pert advisers under paragraph (1) to reflect a broad
25 and balanced input from all sectors of the health

1 care community that are involved in the provision of
2 such services to avoid undue influence from any sin-
3 gular sector of practice on the content of such stand-
4 ards.

5 “(3) LIMITATION.—The Secretary shall not
6 take any action under this subsection that would re-
7 quire licensure by a State of those who provide the
8 technical services referred to in this subsection.

9 “(b) EXEMPTIONS.—The standards established
10 under subsection (a) shall not apply to physicians (as de-
11 fined in section 1861(r) of the Social Security Act (42
12 U.S.C. 1395x(r))), nurse practitioners and physician as-
13 sistants (as defined in section 1861(aa)(5) of the Social
14 Security Act (42 U.S.C. 1395x(aa)(5))).

15 “(c) REQUIREMENTS.—

16 “(1) IN GENERAL.—Under the standards estab-
17 lished under subsection (a), the Secretary shall en-
18 sure that individuals, prior to performing or plan-
19 ning medical imaging and radiation therapy services,
20 demonstrate compliance with the standards estab-
21 lished under subsection (a) through successful com-
22 pletion of certification by a professional organiza-
23 tion, licensure, completion of an examination, perti-
24 nent coursework or degree program, verified perti-
25 nent experience, or through other ways determined

1 appropriate by the Secretary, or through some com-
2 bination thereof.

3 “(2) MISCELLANEOUS PROVISIONS.—The
4 standards established under subsection (a)—

5 “(A) may vary from discipline to discipline,
6 reflecting the unique and specialized nature of
7 the technical services provided, and shall rep-
8 resent expert consensus as to what constitutes
9 excellence in practice and be appropriate to the
10 particular scope of care involved;

11 “(B) may vary in form for each of the cov-
12 ered disciplines; and

13 “(C) may exempt individual providers from
14 meeting certain standards based on their scope
15 of practice.

16 “(3) RECOGNITION OF INDIVIDUALS WITH EX-
17 TENSIVE PRACTICAL EXPERIENCE.—For purposes of
18 this section, the Secretary shall, through regulation,
19 provide a method for the recognition of individuals
20 whose training or experience are determined to be
21 equal to, or in excess of, those of a graduate of an
22 accredited educational program in that specialty, or
23 of an individual who is regularly eligible to take the
24 licensure or certification examination for that dis-
25 cipline.

1 “(d) APPROVED BODIES.—

2 “(1) IN GENERAL.—Not later than the date de-
3 scribed in subsection (j)(2), the Secretary shall begin
4 to certify qualified entities as approved bodies with
5 respect to the accreditation of the various mecha-
6 nisms by which an individual can demonstrate com-
7 pliance with the standards promulgated under sub-
8 section (a), if such organizations or agencies meet
9 the standards established by the Secretary under
10 paragraph (2) and provide the assurances required
11 under paragraph (3).

12 “(2) STANDARDS.—The Secretary shall estab-
13 lish minimum standards for the certification of ap-
14 proved bodies under paragraph (1) (including stand-
15 ards for recordkeeping, the approval of curricula and
16 instructors, the charging of reasonable fees for cer-
17 tification or for undertaking examinations, and
18 standards to minimize the possibility of conflicts of
19 interest), and other additional standards as the Sec-
20 retary may require.

21 “(3) ASSURANCES.—To be certified as an ap-
22 proved body under paragraph (1), an organization or
23 agency shall provide the Secretary satisfactory as-
24 surances that the body will—

25 “(A) be a nonprofit organization;

1 “(B) comply with the standards described
2 in paragraph (2);

3 “(C) notify the Secretary in a timely man-
4 ner if the body fails to comply with the stand-
5 ards described in paragraph (2); and

6 “(D) provide such other information as the
7 Secretary may require.

8 “(4) WITHDRAWAL OF APPROVAL.—

9 “(A) IN GENERAL.—The Secretary may
10 withdraw the certification of an approved body
11 if the Secretary determines the body does not
12 meet the standards under paragraph (2).

13 “(B) EFFECT OF WITHDRAWAL.—The
14 withdrawal of the certification of an approved
15 body under subparagraph (A) shall have no ef-
16 fect on the certification status of any individual
17 or person that was certified by that approved
18 body prior to the date of such withdrawal.

19 “(e) EXISTING STATE STANDARDS.—Standards es-
20 tablished by a State for the licensure or certification of
21 personnel, accreditation of educational programs, or ad-
22 ministration of examinations shall be deemed to be in com-
23 pliance with the standards of this section unless the Sec-
24 retary determines that such State standards do not meet

1 the minimum standards prescribed by the Secretary or are
2 inconsistent with the purposes of this section.

3 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion shall be construed to prohibit a State or other ap-
5 proved body from requiring compliance with a higher
6 standard of education and training than that specified by
7 this section.

8 “(g) EVALUATION AND REPORT.—The Secretary
9 shall periodically evaluate the performance of each ap-
10 proved body under subsection (d) at an interval deter-
11 mined appropriate by the Secretary. The results of such
12 evaluations shall be included as part of the report sub-
13 mitted to the Committee on Health, Education, Labor,
14 and Pensions of the Senate and the Committee on Energy
15 and Commerce of the House of Representatives in accord-
16 ance with 354(e)(6)(B).

17 “(h) DELIVERY OF AND PAYMENT FOR SERVICES.—
18 Not later than the date described in subsection (j)(3), the
19 Secretary shall promulgate regulations to ensure that all
20 programs under the authority of the Secretary that involve
21 the performance of or payment for medical imaging or ra-
22 diation therapy, are performed in accordance with the
23 standards established under this section.

24 “(i) ALTERNATIVE STANDARDS FOR RURAL AND UN-
25 DESERVED AREAS.—The Secretary shall determine

1 whether the standards established under subsection (a)
2 must be met in their entirety for medical imaging or radi-
3 ation therapy that is performed in a geographic area that
4 is determined by the Medicare Geographic Classification
5 Review Board to be a ‘rural area’ or that is designated
6 as a health professional shortage area. If the Secretary
7 determines that alternative standards for such rural areas
8 or health professional shortage areas are appropriate to
9 assure access to quality medical imaging, the Secretary
10 is authorized to develop such alternative standards.

11 “(j) APPLICABLE TIMELINES.—

12 “(1) GENERAL IMPLEMENTATION REGULA-
13 TIONS.—Not later than 18 months after the date of
14 enactment of this section, the Secretary shall pro-
15 mulgate such regulations as may be necessary to im-
16 plement all standards in this section except those
17 provided for in subsection (d)(2).

18 “(2) MINIMUM STANDARDS FOR CERTIFICATION
19 OF APPROVED BODIES.—Not later than 24 months
20 after the date of enactment of this section, the Sec-
21 retary shall establish the standards regarding ap-
22 proved bodies referred to in subsection (d)(2) and
23 begin certifying approved bodies under such sub-
24 section.

1 “(3) REGULATIONS FOR DELIVERY OF OR PAY-
2 MENT FOR SERVICES.—Not later than 36 months
3 after the date of enactment of this section, the Sec-
4 retary shall promulgate the regulations described in
5 subsection (h). The Secretary may withhold the pro-
6 vision of Federal assistance as provided for in sub-
7 section (h) beginning on the date that is 48 months
8 after the date of enactment of this section.

9 “(k) DEFINITIONS.—In this section:

10 “(1) APPROVED BODY.—The term ‘approved
11 body’ means an entity that has been certified by the
12 Secretary under subsection (d)(1) to accredit the
13 various mechanisms by which an individual can dem-
14 onstrate compliance with the standards promulgated
15 under subsection (a) with respect to performing,
16 planning, evaluating, or verifying patient dose for
17 medical imaging or radiation therapy.

18 “(2) MEDICAL IMAGING.—The term ‘medical
19 imaging’ means any procedure used to visualize tis-
20 sues, organs, or physiologic processes in humans for
21 the purpose of diagnosing illness or following the
22 progression of disease. Images may be produced uti-
23 lizing ionizing radiation, radiopharmaceuticals, mag-
24 netic resonance, or ultrasound and image production
25 may include the use of contrast media or computer

1 processing. For purposes of this section, such term
2 does not include routine dental diagnostic proce-
3 dures.

4 “(3) PERFORM.—The term ‘perform’, with re-
5 spect to medical imaging or radiation therapy,
6 means—

7 “(A) the act of directly exposing a patient
8 to radiation via ionizing or radio frequency ra-
9 diation, to ultrasound, or to a magnetic field for
10 purposes of medical imaging or for purposes of
11 radiation therapy; and

12 “(B) the act of positioning a patient to re-
13 ceive such an exposure.

14 “(4) PLAN.—The term ‘plan’, with respect to
15 medical imaging or radiation therapy, means the act
16 of preparing for the performance of such a proce-
17 dure to a patient by evaluating site-specific informa-
18 tion, based on measurement and verification of radi-
19 ation dose distribution, computer analysis, or direct
20 measurement of dose, in order to customize the pro-
21 cedure for the patient.

22 “(5) RADIATION THERAPY.—The term ‘radi-
23 ation therapy’ means any procedure or article in-
24 tended for use in the cure, mitigation, treatment, or

1 prevention of disease in humans that achieves its in-
2 tended purpose through the emission of radiation.”.

3 **SEC. 4. REPORT ON THE EFFECTS OF THIS ACT.**

4 (a) Not later than 5 years after the date of enactment
5 of this Act, the Secretary of Health and Human Services,
6 acting through the Director of the Agency for Healthcare
7 Research and Quality, shall submit to the Committee on
8 Health, Education, Labor, and Pensions of the Senate and
9 the Committee on Energy and Commerce of the House
10 of Representatives a report on the effects of this Act. Such
11 report shall include the types and numbers of providers
12 for whom standards have been developed, the impact of
13 such standards on diagnostic accuracy and patient safety,
14 and the availability and cost of services. Entities reim-
15 bursed for technical services through programs operating
16 under the authority of the Secretary of Health and
17 Human Services shall be required to contribute data to
18 such report.

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