

109TH CONGRESS
2^D SESSION

S. 2322

AN ACT

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”.

1 **SEC. 2. PURPOSE.**

2 The purpose of this Act is to improve the quality and
3 value of healthcare by increasing the safety and accuracy
4 of medical imaging examinations and radiation therapy
5 treatments, thereby reducing duplication of services and
6 decreasing costs.

7 **SEC. 3. QUALITY OF MEDICAL IMAGING AND RADIATION**
8 **THERAPY.**

9 Part F of title III of the Public Health Service Act
10 (42 U.S.C. 262 et seq.) is amended by adding at the end
11 the following:

12 **“Subpart 4—Medical Imaging and Radiation Therapy**
13 **“SEC. 355. QUALITY OF MEDICAL IMAGING AND RADIATION**
14 **THERAPY.**

15 “(a) ESTABLISHMENT OF STANDARDS.—

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

1 “(2) EXPERTS.—The Secretary shall select ex-
2 pert advisers under paragraph (1) to reflect a broad
3 and balanced input from all sectors of the health
4 care community that are involved in the provision of
5 such services to avoid undue influence from any sin-
6 gle sector of practice on the content of such stand-
7 ards.

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

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

18 “(c) REQUIREMENTS.—

19 “(1) IN GENERAL.—Under the standards estab-
20 lished under subsection (a), the Secretary shall en-
21 sure that individuals, prior to performing or plan-
22 ning medical imaging and radiation therapy services,
23 demonstrate compliance with the standards estab-
24 lished under subsection (a) through successful com-
25 pletion of certification by a professional organiza-

1 tion, licensure, completion of an examination, perti-
2 nent coursework or degree program, verified perti-
3 nent experience, or through other ways determined
4 appropriate by the Secretary, or through some com-
5 bination thereof.

6 “(2) MISCELLANEOUS PROVISIONS.—The
7 standards established under subsection (a)—

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

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

16 “(C) may exempt individual providers from
17 meeting certain standards based on their scope
18 of practice.

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

1 of an individual who is regularly eligible to take the
2 licensure or certification examination for that dis-
3 cipline.

4 “(d) APPROVED BODIES.—

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

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

24 “(3) ASSURANCES.—To be certified as an ap-
25 proved body under paragraph (1), an organization or

1 agency shall provide the Secretary satisfactory as-
2 surances that the body will—

3 “(A) be a nonprofit organization;

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

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

9 “(D) provide such other information as the
10 Secretary may require.

11 “(4) WITHDRAWAL OF APPROVAL.—

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

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

22 “(e) EXISTING STATE STANDARDS.—Standards es-
23 tablished by a State for the licensure or certification of
24 personnel, accreditation of educational programs, or ad-
25 ministration of examinations shall be deemed to be in com-

1 pliance with the standards of this section unless the Sec-
2 retary determines that such State standards do not meet
3 the minimum standards prescribed by the Secretary or are
4 inconsistent with the purposes of this section. The Sec-
5 retary shall establish a process by which a State may re-
6 spond to or appeal a determination made by the Secretary
7 under the preceding sentence.

8 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
9 tion shall be construed to prohibit a State or other ap-
10 proved body from requiring compliance with a higher
11 standard of education and training than that specified by
12 this section. Notwithstanding any other provision of this
13 section, individuals who provide medical imaging services
14 relating to mammograms shall continue to meet the stand-
15 ards applicable under the Mammography Quality Stand-
16 ards Act of 1992.

17 “(g) EVALUATION AND REPORT.—The Secretary
18 shall periodically evaluate the performance of each ap-
19 proved body under subsection (d) at an interval deter-
20 mined appropriate by the Secretary. The results of such
21 evaluations shall be included as part of the report sub-
22 mitted to the Committee on Health, Education, Labor,
23 and Pensions of the Senate and the Committee on Energy
24 and Commerce of the House of Representatives in accord-
25 ance with 354(e)(6)(B).

1 “(h) DELIVERY OF AND PAYMENT FOR SERVICES.—

2 Not later than the date described in subsection (j)(3), the
3 Secretary shall promulgate regulations to ensure that all
4 programs under the authority of the Secretary that involve
5 the performance of or payment for medical imaging or ra-
6 diation therapy, are performed in accordance with the
7 standards established under this section.

8 “(i) ALTERNATIVE STANDARDS FOR RURAL AND UN-
9 DERSERVED AREAS.—

10 “(1) IN GENERAL.—The Secretary shall deter-
11 mine whether the standards established under sub-
12 section (a) must be met in their entirety for medical
13 imaging or radiation therapy that is performed in a
14 geographic area that is determined by the Medicare
15 Geographic Classification Review Board to be a
16 ‘rural area’ or that is designated as a health profes-
17 sional shortage area. If the Secretary determines
18 that alternative standards for such rural areas or
19 health professional shortage areas are appropriate to
20 assure access to quality medical imaging, the Sec-
21 retary is authorized to develop such alternative
22 standards.

23 “(2) STATE DISCRETION.—The chief executive
24 officer of a State may submit to the Secretary a
25 statement declaring that an alternative standard de-

1 developed under paragraph (1) is inappropriate for ap-
2 plication to such State, and such alternative stand-
3 ard shall not apply in such submitting State. The
4 chief executive officer of a State may rescind a
5 statement described in this paragraph following the
6 provision of appropriate notice to the Secretary.

7 “(j) APPLICABLE TIMELINES.—

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

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

21 “(3) REGULATIONS FOR DELIVERY OF OR PAY-
22 MENT FOR SERVICES.—Not later than 36 months
23 after the date of enactment of this section, the Sec-
24 retary shall promulgate the regulations described in
25 subsection (h). The Secretary may withhold the pro-

1 vision of Federal assistance as provided for in sub-
2 section (h) beginning on the date that is 48 months
3 after the date of enactment of this section.

4 “(k) DEFINITIONS.—In this section:

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

13 “(2) MEDICAL IMAGING.—The term ‘medical
14 imaging’ means any procedure used to visualize tis-
15 sues, organs, or physiologic processes in humans for
16 the purpose of diagnosing illness or following the
17 progression of disease. Images may be produced uti-
18 lizing ionizing radiation, radiopharmaceuticals, mag-
19 netic resonance, or ultrasound and image production
20 may include the use of contrast media or computer
21 processing. For purposes of this section, such term
22 does not include routine dental diagnostic proce-
23 dures.

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

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

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

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

19 “(5) **RADIATION THERAPY.**—The term ‘radi-
20 ation therapy’ means any procedure or article in-
21 tended for use in the cure, mitigation, treatment, or
22 prevention of disease in humans that achieves its in-
23 tended purpose through the emission of radiation.

24 “(1) **SUNSET.**—This section shall have no force or ef-
25 fect after September 30, 2016.”.

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

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

Passed the Senate December 6, 2006.

Attest:

Secretary.

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