

111TH CONGRESS  
2D SESSION

# S. 3737

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

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## IN THE SENATE OF THE UNITED STATES

AUGUST 5, 2010

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

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## A BILL

To amend the Public Health Service Act and title XVIII of the Social Security 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 “Consistency, Accuracy,  
5 Responsibility, and Excellence in Medical Imaging and  
6 Radiation Therapy Act of 2010”.

1 **SEC. 2. PURPOSE.**

2       The purpose of this Act is to improve the quality and  
3 value of health care by increasing the safety and accuracy  
4 of medical imaging examinations and radiation therapy  
5 procedures, 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) QUALIFIED PERSONNEL.—

16           “(1) IN GENERAL.—Effective January 1, 2013,  
17 personnel who perform or plan the technical compo-  
18 nent of either medical imaging examinations or radi-  
19 ation therapy procedures for medical purposes shall  
20 be qualified under this section to perform or plan  
21 such services.

22           “(2) QUALIFICATIONS.—Individuals qualified to  
23 perform or plan the technical component of medical  
24 imaging examinations or radiation therapy proce-  
25 dures shall—

“(A) possess current certification in the medical imaging or radiation therapy modality or service they plan or perform from a certification organization designated by the Secretary pursuant to subsection (c); or

“(B) possess current State licensure or certification, where—

“(i) such services and modalities are within the scope of practice as defined by the State for such profession; and

“(ii) the requirements for licensure, certification, or registration meet or exceed the standards established by the Secretary pursuant to this section.

“(3) STATE LICENSURE, CERTIFICATION, OR REGISTRATION.—

“(A) IN GENERAL.—Nothing in this section shall be construed to diminish the authority of a State to define requirements for licensure, certification, or registration, the requirements for practice, or the scope of practice of personnel.

“(B) LIMITATION.—The Secretary shall not take any action under this section that would require licensure by a State of personnel

1           who perform or plan the technical component of  
2           medical imaging examinations or radiation ther-  
3           apy procedures.

4           “(4) EXEMPTIONS.—The qualification stand-  
5           ards described in this subsection and the payment  
6           provisions in section 1848(b)(4)(C) of the Social Se-  
7           curity Act shall not apply to physicians (as defined  
8           in section 1861(r) of the Social Security Act (42  
9           U.S.C. 1395x(r))) or to nurse practitioners and phy-  
10          sician assistants (each as defined in section  
11          1861(aa)(5) of the Social Security Act (42 U.S.C.  
12          1395x(aa)(5))). Such practitioners shall not be in-  
13          cluded under the terms ‘personnel’ or ‘qualified per-  
14          sonnel’ for purposes of this section.

15          “(b) ESTABLISHMENT OF STANDARDS.—

16               “(1) IN GENERAL.—For the purposes of deter-  
17               mining compliance with subsection (a), the Sec-  
18               retary, in consultation with recognized experts in the  
19               technical provision of medical imaging or radiation  
20               therapy services, shall establish minimum standards  
21               for personnel who perform, plan, evaluate, or verify  
22               patient dose for medical imaging examinations or ra-  
23               diation therapy procedures. Such standards shall not  
24               apply to the equipment used.

25               “(2) RECOGNIZED EXPERTS.—

“(A) IN GENERAL.—For the purposes of this subsection, the Secretary shall select recognized expert advisers to reflect a broad and balanced input from all sectors of the health care community that are involved in the provision of services of the type described in paragraph (1) to avoid undue influence from any single sector of practice relating to the content of such standards.

“(B) DEFINITION.—In this paragraph, the term ‘recognized experts’ includes—

“(i) representatives of all medical specialties and providers that perform or plan medical imaging procedures;

“(ii) representatives of all medical specialties and providers that perform or plan radiation therapy procedures;

“(iii) medical imaging and radiation therapy technology experts; and

“(iv) other experts determined appropriate by the Secretary.

“(3) MINIMUM STANDARDS.—Minimum standards established under this subsection shall reflect the unique or specialized nature of the technical services provided, and shall represent expert con-

1       sensus from those practicing in each of the covered  
2       imaging modalities and radiation therapy procedures  
3       as to what constitutes excellence in practice and be  
4       appropriate to the particular scope of care involved.

5       “(4) ALLOWANCE FOR ADDITIONAL STAND-  
6       ARDS.—Nothing in this subsection shall be con-  
7       strued to prohibit a State or certification organiza-  
8       tion from requiring compliance with standards that  
9       exceed the minimum standards specified by the Sec-  
10      retary pursuant to this subsection.

11      “(5) TIMELINE.—Not later than 12 months  
12      after the date of enactment of this section, the Sec-  
13      retary shall promulgate regulations for the purposes  
14      of carrying out this subsection.

15      “(c) DESIGNATION OF CERTIFICATION ORGANIZA-  
16      TIONS.—

17      “(1) IN GENERAL.—The Secretary shall estab-  
18      lish a program for designating certification organiza-  
19      tions that the Secretary determines have established  
20      appropriate procedures and programs for certifying  
21      personnel as qualified to furnish medical imaging or  
22      radiation therapy services.

23      “(2) FACTORS.—When designating certification  
24      organizations under this subsection, and when re-  
25      viewing or modifying the list of designated organiza-

1        tions for the purposes of paragraph (4)(B), the Sec-  
2        retary shall consider—

3                “(A) whether the certification organization  
4                has established certification requirements for  
5                individuals that are consistent with or exceed  
6                the minimum standards established in sub-  
7                section (b);

8                “(B) whether the certification organization  
9                has established a process for the timely integra-  
10               tion of new medical imaging or radiation ther-  
11               apy services into the organization’s certification  
12               program;

13               “(C) whether the certification organization  
14               has established education and continuing edu-  
15               cation requirements for individuals certified by  
16               the organization;

17               “(D) whether the organization has estab-  
18               lished reasonable fees to be charged to those  
19               applying for certification;

20               “(E) whether the examinations leading to  
21               certification by the certification organization  
22               are accredited by an appropriate accrediting  
23               body as defined in subsection (d);

1           “(F) the ability of the certification organi-  
 2           zation to review applications for certification in  
 3           a timely manner; and

4           “(G) such other factors as the Secretary  
 5           determines appropriate.

6           “(3) EQUIVALENT EDUCATION, TRAINING, AND  
 7           EXPERIENCE.—

8           “(A) IN GENERAL.—For purposes of this  
 9           section, the Secretary shall, through regulation,  
 10          provide a process for individuals whose training  
 11          or experience are determined to be equal to, or  
 12          in excess of, those of a graduate of an accred-  
 13          ited educational program in that specialty to  
 14          demonstrate their experience meets the edu-  
 15          cational standards for qualified personnel in  
 16          their imaging modality or radiation therapy  
 17          procedures. Such process may include docu-  
 18          mentation of items such as—

19                   “(i) years and type of experience;

20                   “(ii) a list of settings where experi-  
 21                   ence was obtained; and

22                   “(iii) verification of experience by su-  
 23                   pervising physicians or clinically qualified  
 24                   hospital personnel.



1           “(B) ELIGIBILITY.—The Secretary shall  
2 not recognize any individual as having met the  
3 educational standards applicable under this  
4 paragraph based on experience pursuant to the  
5 authority of subparagraph (A) unless such indi-  
6 vidual was performing or planning the technical  
7 component of medical imaging examinations or  
8 radiation therapy treatments prior to the date  
9 of enactment of this section

10           “(C) CERTIFICATION TEST REQUIRE-  
11 MENT.—To be eligible to be certified under this  
12 subsection an individual shall, not later than 18  
13 months after the date on which the list of des-  
14 ignated certification organizations is published  
15 under paragraph (4), successfully complete a  
16 certification examination administered by a des-  
17 ignated certification organization. During such  
18 18-month period, the penalties provided for  
19 under section 1848(b)(4)(C) of the Social Secu-  
20 rity Act (as added by section 4 of the Consist-  
21 ency, Accuracy, Responsibility, and Excellence  
22 in Medical Imaging and Radiation Therapy Act  
23 of 2010) shall not apply to such individuals.

24           “(4) PROCESS.—

1           “(A) REGULATIONS.—Not later than July  
2           1, 2012, the Secretary shall promulgate regula-  
3           tions for designating certification organizations  
4           pursuant to this subsection.

5           “(B) DESIGNATIONS AND LIST.—Not later  
6           than January 1, 2013, the Secretary shall make  
7           determinations regarding all certification orga-  
8           nizations that have applied for designation pur-  
9           suant to the regulations promulgated under  
10          subparagraph (A), and shall publish a list of all  
11          certification organizations that have received a  
12          designation.

13          “(C) PERIODIC REVIEW AND REVISION.—  
14          The Secretary shall periodically review the list  
15          under subparagraph (B), taking into account  
16          the factors established under paragraph (2).  
17          After such review, the Secretary may, by regu-  
18          lation, modify the list of certification organiza-  
19          tions that have received such designation.

20          “(D) CERTIFICATIONS PRIOR TO REMOVAL  
21          FROM LIST.—If the Secretary removes a certifi-  
22          cation organization from the list of certification  
23          organizations designated under subparagraph  
24          (B), any individual who was certified by the  
25          certification organization during or before the

1 period beginning on the date on which the cer-  
2 tification organization was designated as a cer-  
3 tification organization under such subpara-  
4 graph, and ending on the date on which the cer-  
5 tification organization is removed from such  
6 list, shall be considered to have been certified  
7 by a certification organization designated by the  
8 Secretary under such subparagraph for the re-  
9 maining period that such certification is in ef-  
10 fect.

11 “(d) APPROVED ACCREDITING BODIES.—

12 “(1) IN GENERAL.—Not later than 24 months  
13 after the date of enactment of this section, the Sec-  
14 retary shall publish a list of entities that are ap-  
15 proved accrediting bodies for certification organiza-  
16 tions for purposes of subsection (c)(2)(E). The Sec-  
17 retary shall revise such list as appropriate.

18 “(2) REQUIREMENTS FOR APPROVAL.—The  
19 Secretary shall not approve an accrediting body for  
20 certification organizations under this subsection un-  
21 less the Secretary determines that such accrediting  
22 body—

23 “(A) is a nonprofit organization;

24 “(B) is a national or international organi-  
25 zation with accreditation programs for examina-

1           tions leading to certification by certification or-  
2           ganizations;

3           “(C) has established standards for record-  
4           keeping and to minimize the possibility of con-  
5           flicts of interest; and

6           “(D) demonstrates compliance with any  
7           other requirements established by the Sec-  
8           retary.

9           “(3) WITHDRAWAL OF APPROVAL.—The Sec-  
10          retary may withdraw the approval of an accrediting  
11          body under this paragraph if the Secretary deter-  
12          mines that the body does not meet the requirements  
13          of paragraph (2).

14          “(e) ALTERNATIVE STANDARDS FOR RURAL AND  
15          UNDERSERVED AREAS.—

16          “(1) IN GENERAL.—The Secretary shall deter-  
17          mine whether the standards established under sub-  
18          section (a) must be met in their entirety for medical  
19          imaging examinations or radiation therapy proce-  
20          dures that are performed and planned in a geo-  
21          graphic area that is determined by the Medicare Ge-  
22          ographic Classification Review Board to be a ‘rural  
23          area’ or that is designated as a health professional  
24          shortage area. If the Secretary determines that al-  
25          ternative standards for such rural areas or health

1 professional shortage areas are appropriate to en-  
2 sure access to quality medical imaging examinations  
3 or radiation therapy procedures, the Secretary is au-  
4 thorized to develop such alternative standards.

5 “(2) STATE DISCRETION.—The chief executive  
6 officer of a State may submit to the Secretary a  
7 statement declaring that an alternative standard de-  
8 veloped under paragraph (1) is inappropriate for ap-  
9 plication to such State, and such alternative stand-  
10 ard shall not apply in such submitting State. The  
11 chief executive officer of a State may rescind a  
12 statement described in this paragraph following the  
13 provision of appropriate notice to the Secretary.

14 “(f) RULE OF CONSTRUCTION.—Notwithstanding  
15 any other provision of this section, individuals who provide  
16 medical imaging examinations relating to mammograms  
17 shall continue to meet the regulations applicable under the  
18 Mammography Quality Standards Act of 1992 (as amend-  
19 ed).

20 “(g) DEFINITION.—As used in this section:

21 “(1) MEDICAL IMAGING.—The term ‘medical  
22 imaging’ means any examination or procedure used  
23 to visualize tissues, organs, or physiologic processes  
24 in humans for the purpose of detecting, diagnosing,  
25 treating, or impacting the progression of disease or

1 illness. For purposes of this section, such term does  
2 not include routine dental or ophthalmologic diag-  
3 nostic procedures or ultrasound guidance of vascular  
4 access procedures.

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

8 “(A) the act of directly exposing a patient  
9 to radiation, including ionizing or radio fre-  
10 quency radiation, to ultrasound, or to a mag-  
11 netic field for purposes of medical imaging or  
12 for purposes of radiation therapy; and

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

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

23 “(4) RADIATION THERAPY.—The term ‘radi-  
24 ation therapy’ means any procedure or article in-  
25 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 ionizing or  
 3 non-ionizing radiation.”.

4 **SEC. 4. REQUIRED STANDARDS FOR MEDICAL IMAGING**  
 5 **AND RADIATION THERAPY.**

6 Section 1848(b)(4) of the Social Security Act (42  
 7 U.S.C. 1395w-4(b)(4)) is amended by adding at the end  
 8 the following new subparagraph:

9 “(E) REQUIRED STANDARDS FOR MEDICAL  
 10 IMAGING AND RADIATION THERAPY SERV-  
 11 ICES.—With respect to expenses incurred for  
 12 the planning and performing of the technical  
 13 component of medical imaging examinations or  
 14 radiation therapy procedures (as defined in sub-  
 15 section (g) of section 355 of the Public Health  
 16 Service Act) furnished on or after January 1,  
 17 2013, payment shall be made under this section  
 18 only if the examination or procedure is planned  
 19 or performed by an individual who meets the  
 20 requirements established by the Secretary under  
 21 such section 355.”.

22 **SEC. 5. REPORT ON THE EFFECTS OF THIS ACT.**

23 (a) IN GENERAL.—Not later than 5 years after the  
 24 date of the enactment of this Act, the Secretary of Health  
 25 and Human Services, acting through the Director of the

1 Agency for Healthcare Research and Quality, shall submit  
2 to the Committee on Health, Education, Labor, and Pen-  
3 sions of the Senate, the Committee on Finance of the Sen-  
4 ate, and the Committee on Energy and Commerce of the  
5 House of Representatives, a report on the effects of this  
6 Act.

7 (b) REQUIREMENTS.—The report under subsection  
8 (a) shall include the types and numbers of individuals  
9 qualified to perform or plan the technical component of  
10 medical imaging or radiation therapy services for whom  
11 standards have been developed, the impact of such stand-  
12 ards on diagnostic accuracy and patient safety, and the  
13 availability and cost of services. Entities reimbursed for  
14 technical services through programs operating under the  
15 authority of the Secretary of Health and Human Services  
16 shall be required to contribute data to such report.

○