

112TH CONGRESS
1ST SESSION

H. R. 2104

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.

IN THE HOUSE OF REPRESENTATIVES

JUNE 2, 2011

Mr. WHITFIELD (for himself, Mr. BARROW, Mr. BOSWELL, Mr. COHEN, Mr. CONNOLLY of Virginia, Mr. DUNCAN of Tennessee, Mr. GUTHRIE, Mr. HALL, Mr. HARPER, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. JONES, Mr. KILDEE, Mr. KIND, Mr. LANCE, Mr. HEINRICH, Mr. MCINTYRE, Mrs. MYRICK, Ms. RICHARDSON, and Mr. RUSH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Consistency, Accuracy,
3 Responsibility, and Excellence in Medical Imaging and
4 Radiation Therapy Act of 2011”.

5 **SEC. 2. PURPOSE.**

6 The purpose of this Act is to improve the quality and
7 value of health care by increasing the safety and accuracy
8 of medical imaging examinations and radiation therapy
9 procedures, thereby reducing duplication of services and
10 decreasing costs.

11 **SEC. 3. QUALITY OF MEDICAL IMAGING AND RADIATION**
12 **THERAPY.**

13 Part F of title III of the Public Health Service Act
14 (42 U.S.C. 262 et seq.) is amended by adding at the end
15 the following:

16 **“Subpart 4—Medical Imaging and Radiation Therapy**
17 **“SEC. 355. QUALITY OF MEDICAL IMAGING AND RADIATION**
18 **THERAPY.**

19 “(a) **QUALIFIED PERSONNEL.—**

20 “(1) **IN GENERAL.—**Effective January 1, 2014,
21 personnel who perform or plan the technical compo-
22 nent of either medical imaging examinations or radi-
23 ation therapy procedures for medical purposes shall
24 be qualified under this section to perform or plan
25 such services.

1 “(2) QUALIFICATIONS.—Individuals qualified to
2 perform or plan the technical component of medical
3 imaging examinations or radiation therapy proce-
4 dures shall—

5 “(A) possess current certification in the
6 medical imaging or radiation therapy modality
7 or service they plan or perform from a certifi-
8 cation organization designated by the Secretary
9 pursuant to subsection (c); or

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

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

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

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

21 “(A) IN GENERAL.—Nothing in this sec-
22 tion shall be construed to diminish the author-
23 ity of a State to define requirements for licen-
24 sure, certification, or registration, the require-

1 ments for practice, or the scope of practice of
2 personnel.

3 “(B) LIMITATION.—The Secretary shall
4 not take any action under this section that
5 would require licensure by a State of personnel
6 who perform or plan the technical component of
7 medical imaging examinations or radiation ther-
8 apy procedures.

9 “(4) EXEMPTIONS.—The qualification stand-
10 ards described in this subsection and the payment
11 provisions in section 1848(b)(4)(C) of the Social Se-
12 curity Act shall not apply to physicians (as defined
13 in section 1861(r) of the Social Security Act (42
14 U.S.C. 1395x(r))) or to nurse practitioners and phy-
15 sician assistants (each as defined in section
16 1861(aa)(5) of the Social Security Act (42 U.S.C.
17 1395x(aa)(5))). Such practitioners shall not be in-
18 cluded under the terms ‘personnel’ or ‘qualified per-
19 sonnel’ for purposes of this section.

20 “(b) ESTABLISHMENT OF STANDARDS.—

21 “(1) IN GENERAL.—For the purposes of deter-
22 mining compliance with subsection (a), the Sec-
23 retary, in consultation with recognized experts in the
24 technical provision of medical imaging or radiation
25 therapy services, shall establish minimum standards

1 for personnel who perform, plan, evaluate, or verify
2 patient dose for medical imaging examinations or ra-
3 diation therapy procedures. Such standards shall not
4 apply to the equipment used.

5 “(2) RECOGNIZED EXPERTS.—

6 “(A) IN GENERAL.—For the purposes of
7 this subsection, the Secretary shall select recog-
8 nized expert advisers to reflect a broad and bal-
9 anced input from all sectors of the health care
10 community that are involved in the provision of
11 services of the type described in paragraph (1)
12 to avoid undue influence from any single sector
13 of practice relating to the content of such
14 standards.

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

17 “(i) representatives of all medical spe-
18 cialties and providers that perform or plan
19 medical imaging procedures;

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

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

1 “(iv) other experts determined appro-
2 priate by the Secretary.

3 “(3) MINIMUM STANDARDS.—Minimum stand-
4 ards established under this subsection shall reflect
5 the unique or specialized nature of the technical
6 services provided, and shall represent expert con-
7 sensus from those practicing in each of the covered
8 imaging modalities and radiation therapy procedures
9 as to what constitutes excellence in practice and be
10 appropriate to the particular scope of care involved.

11 “(4) ALLOWANCE FOR ADDITIONAL STAND-
12 ARDS.—Nothing in this subsection shall be con-
13 strued to prohibit a State or certification organiza-
14 tion from requiring compliance with standards that
15 exceed the minimum standards specified by the Sec-
16 retary pursuant to this subsection.

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

21 “(c) DESIGNATION OF CERTIFICATION ORGANIZA-
22 TIONS.—

23 “(1) IN GENERAL.—The Secretary shall estab-
24 lish a program for designating certification organiza-
25 tions that the Secretary determines have established

1 appropriate procedures and programs for certifying
2 personnel as qualified to furnish medical imaging or
3 radiation therapy services.

4 “(2) FACTORS.—When designating certification
5 organizations under this subsection, and when re-
6 viewing or modifying the list of designated organiza-
7 tions for the purposes of paragraph (4)(B), the Sec-
8 retary shall consider—

9 “(A) whether the certification organization
10 has established certification requirements for
11 individuals that are consistent with or exceed
12 the minimum standards established in sub-
13 section (b);

14 “(B) whether the certification organization
15 has established a process for the timely integra-
16 tion of new medical imaging or radiation ther-
17 apy services into the organization’s certification
18 program;

19 “(C) whether the certification organization
20 has established education and continuing edu-
21 cation requirements for individuals certified by
22 the organization;

23 “(D) whether the organization has estab-
24 lished reasonable fees to be charged to those
25 applying for certification;

1 “(E) whether the examinations leading to
2 certification by the certification organization
3 are accredited by an appropriate accrediting
4 body as defined in subsection (d);

5 “(F) the ability of the certification organi-
6 zation to review applications for certification in
7 a timely manner; and

8 “(G) such other factors as the Secretary
9 determines appropriate.

10 “(3) EQUIVALENT EDUCATION, TRAINING, AND
11 EXPERIENCE.—

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

23 “(i) years and type of experience;

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

1 “(iii) verification of experience by su-
2 pervising physicians or clinically qualified
3 hospital personnel.

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

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

1 in Medical Imaging and Radiation Therapy Act
2 of 2011) shall not apply to such individuals.

3 “(4) PROCESS.—

4 “(A) REGULATIONS.—Not later than July
5 1, 2013, the Secretary shall promulgate regula-
6 tions for designating certification organizations
7 pursuant to this subsection.

8 “(B) DESIGNATIONS AND LIST.—Not later
9 than January 1, 2014, the Secretary shall make
10 determinations regarding all certification orga-
11 nizations that have applied for designation pur-
12 suant to the regulations promulgated under
13 subparagraph (A), and shall publish a list of all
14 certification organizations that have received a
15 designation.

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

23 “(D) CERTIFICATIONS PRIOR TO REMOVAL
24 FROM LIST.—If the Secretary removes a certifi-
25 cation organization from the list of certification

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

14 “(d) APPROVED ACCREDITING BODIES.—

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

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

1 “(A) is a nonprofit organization;

2 “(B) is a national or international organi-
3 zation with accreditation programs for examina-
4 tions leading to certification by certification or-
5 ganizations;

6 “(C) has established standards for record-
7 keeping and to minimize the possibility of con-
8 flicts of interest; and

9 “(D) demonstrates compliance with any
10 other requirements established by the Sec-
11 retary.

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

17 “(e) ALTERNATIVE STANDARDS FOR RURAL AND
18 UNDERSERVED AREAS.—

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

1 area' or that is designated as a health professional
2 shortage area. If the Secretary determines that al-
3 ternative standards for such rural areas or health
4 professional shortage areas are appropriate to en-
5 sure access to quality medical imaging examinations
6 or radiation therapy procedures, the Secretary is au-
7 thorized to develop such alternative standards.

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

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

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

24 “(1) MEDICAL IMAGING.—The term ‘medical
25 imaging’ means any examination or procedure used

1 to visualize tissues, organs, or physiologic processes
2 in humans for the purpose of detecting, diagnosing,
3 treating, or impacting the progression of disease or
4 illness. For purposes of this section, such term does
5 not include routine dental or ophthalmologic diag-
6 nostic procedures or ultrasound guidance of vascular
7 access procedures.

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

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

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

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

1 “(4) RADIATION THERAPY.—The term ‘radi-
 2 ation therapy’ means any procedure or article in-
 3 tended for use in the cure, mitigation, treatment, or
 4 prevention of disease in humans that achieves its in-
 5 tended purpose through the emission of ionizing or
 6 non-ionizing radiation.”.

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

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

12 “(E) REQUIRED STANDARDS FOR MEDICAL
 13 IMAGING AND RADIATION THERAPY SERV-
 14 ICES.—With respect to expenses incurred for
 15 the planning and performing of the technical
 16 component of medical imaging examinations or
 17 radiation therapy procedures (as defined in sub-
 18 section (g) of section 355 of the Public Health
 19 Service Act) furnished on or after January 1,
 20 2014, payment shall be made under this section
 21 only if the examination or procedure is planned
 22 or performed by an individual who meets the
 23 requirements established by the Secretary under
 24 such section 355.”.

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

2 (a) IN GENERAL.—Not later than 5 years after the
3 date of the enactment of this Act, the Secretary of Health
4 and Human Services, acting through the Director of the
5 Agency for Healthcare Research and Quality, shall submit
6 to the Committee on Health, Education, Labor, and Pen-
7 sions of the Senate, the Committee on Finance of the Sen-
8 ate, and the Committee on Energy and Commerce of the
9 House of Representatives, a report on the effects of this
10 Act.

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

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