

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.

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## 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

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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,*

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 **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.

○