

111TH CONGRESS
1ST SESSION

H. R. 3652

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

SEPTEMBER 25, 2009

Mr. BARROW 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,*

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 2009”.

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 must
20 be qualified under this section to perform or plan
21 such services.

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

1 “(A) possess current certification in each
2 medical imaging or radiation therapy modality
3 and service provided from a certification organi-
4 zation designated by the Secretary pursuant to
5 subsection (c); or

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

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

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

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

17 “(A) Nothing in this section diminishes the
18 authority of a State to define requirements for
19 licensure, certification, or registration, the re-
20 quirements for practice, or the scope of practice
21 of personnel.

22 “(B) The Secretary shall not take any ac-
23 tion under this section that would require licen-
24 sure by a State of those who perform or plan

1 the technical component of medical imaging ex-
2 aminations or radiation therapy procedures.

3 “(4) EXEMPTIONS.—The qualification stand-
4 ards described in this subsection shall not apply to
5 physicians (as defined in section 1861(r) of the So-
6 cial Security Act (42 U.S.C. 1395x(r))) or to nurse
7 practitioners and physician assistants (each as de-
8 fined in section 1861(aa)(5) of the Social Security
9 Act (42 U.S.C. 1395x(aa)(5))).

10 “(b) ESTABLISHMENT OF STANDARDS.—

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

20 “(2) EXPERTS.—For the purposes of this sub-
21 section, the Secretary shall select expert advisers to
22 reflect a broad and balanced input from all sectors
23 of the health care community that are involved in
24 the provision of such services to avoid undue influ-

1 ence from any single sector of practice on the con-
2 tent of such standards.

3 “(3) MINIMUM STANDARDS.—Minimum stand-
4 ards may vary in form for each of the covered dis-
5 ciplines, reflecting the unique or specialized nature
6 of the technical services provided, and shall rep-
7 resent expert consensus from those practicing in
8 each of the covered disciplines as to what constitutes
9 excellence in practice and be appropriate to the par-
10 ticular 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 higher stand-
15 ards than the minimum standards specified by the
16 Secretary pursuant to this subsection.

17 “(5) TIMELINE.—The Secretary shall promul-
18 gate regulations for the purposes of carrying out this
19 subsection no later than 18 months after the date on
20 which this section is enacted.

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, and when reviewing or modifying the
6 list of designated organizations for the purposes of
7 paragraph (4)(B), the Secretary shall consider—

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

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

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

22 “(D) whether the organization has estab-
23 lished reasonable fees to be charged to those
24 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 method for the recognition of individ-
15 uals whose training or experience are deter-
16 mined to be equal to, or in excess of, those of
17 a graduate of an accredited educational pro-
18 gram in that specialty. Such authority shall ex-
19 pire seven years after the enactment of this sec-
20 tion.

21 “(B) ELIGIBILITY.—The Secretary shall
22 not recognize any individual pursuant to the au-
23 thority of subparagraph (A) unless such indi-
24 vidual—

1 “(i) was performing or planning the
2 technical component of medical imaging
3 examinations or radiation therapy treat-
4 ments prior to enactment of this section;
5 and

6 “(ii) is ineligible to take the licensure
7 or certification examination for that dis-
8 cipline.

9 “(4) PROCESS.—

10 “(A) REGULATIONS.—The Secretary shall,
11 by July 1, 2012, promulgate regulations for
12 designating certification organizations pursuant
13 to this paragraph.

14 “(B) DESIGNATIONS AND LIST.—The Sec-
15 retary shall, by January 1, 2013, make deter-
16 minations regarding all certification organiza-
17 tions that have applied for designation pursuant
18 to the regulations promulgated under subpara-
19 graph (A), and shall publish a list of all certifi-
20 cation organizations that have received designa-
21 tion.

22 “(C) PERIODIC REVIEW AND REVISION.—
23 The Secretary shall periodically review the list,
24 taking into account the factors established
25 under paragraph (2). After such review, the

1 Secretary may, by regulation, modify the list of
2 certification organizations that have received
3 designation.

4 “(D) CERTIFICATIONS PRIOR TO REMOVAL
5 FROM LIST.—If the Secretary removes a certifi-
6 cation organization from the list of certification
7 organizations designated under subparagraph
8 (B), any individual who was certified by the
9 certification organization during or before the
10 period beginning on the date on which the cer-
11 tification organization was designated as a cer-
12 tification organization under subparagraph (B)
13 and ending on the date on which the certifi-
14 cation organization is removed from such list
15 shall be considered to have been certified by a
16 certification organization designated by the Sec-
17 retary under subparagraph (B) for the remain-
18 ing period that such certification is in effect.

19 “(d) APPROVED ACCREDITING BODIES.—

20 “(1) IN GENERAL.—The Secretary shall publish
21 a list of entities that are approved accrediting bodies
22 for certification organizations for purposes of sub-
23 section (c)(2)(E). The Secretary shall publish the
24 list no later than 24 months after enactment of this
25 section and shall revise the list as appropriate.

1 “(2) REQUIREMENTS FOR APPROVAL.—The
2 Secretary shall not approve an accrediting body for
3 certification organizations unless the Secretary de-
4 termines that such accrediting body—

5 “(A) is a nonprofit organization;

6 “(B) is a national or international organi-
7 zation with accreditation programs for examina-
8 tions leading to certification by certification or-
9 ganizations;

10 “(C) has established standards for record-
11 keeping and to minimize the possibility of con-
12 flicts of interest; and

13 “(D) demonstrates compliance with any
14 other requirements established by the Sec-
15 retary.

16 “(3) WITHDRAWAL OF APPROVAL.—The Sec-
17 retary may withdraw the approval of an accrediting
18 body if the Secretary determines that the body does
19 not meet the standards defined in paragraph (2).

20 “(e) ALTERNATIVE STANDARDS FOR RURAL AND
21 UNDERSERVED AREAS.—

22 “(1) IN GENERAL.—The Secretary shall deter-
23 mine whether the standards established under sub-
24 section (a) must be met in their entirety for medical
25 imaging examinations or radiation therapy proce-

1 dures that are performed and planned in a geo-
2 graphic area that is determined by the Medicare Ge-
3 ographic Classification Review Board to be a ‘rural
4 area’ or that is designated as a health professional
5 shortage area. If the Secretary determines that al-
6 ternative standards for such rural areas or health
7 professional shortage areas are appropriate to assure
8 access to quality medical imaging examinations or
9 radiation therapy procedures, the Secretary is au-
10 thorized to develop such alternative standards.

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

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

1 “(g) DEFINITIONS.—As used in this section—

2 “(1) MEDICAL IMAGING.—The term ‘medical
3 imaging’ means any examination or procedure used
4 to visualize tissues, organs, or physiologic processes
5 in humans for the purpose of detecting, diagnosing,
6 treating or impacting the progression of disease or
7 illness. For purposes of this section, such term does
8 not include routine dental diagnostic procedures or
9 advanced imaging procedures as defined in section
10 1834(e)(1)(B) of the Social Security Act.

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

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

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

21 “(3) PLAN.—The term ‘plan’, with respect to
22 medical imaging or radiation therapy, means the act
23 of preparing for the performance of such a proce-
24 dure to a patient by evaluating site-specific informa-
25 tion, based on measurement and verification of radi-

1 ation dose distribution, computer analysis, or direct
2 measurement of dose, in order to customize the pro-
3 cedure for the patient.

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

10 **SEC. 4. PAYMENT AND STANDARDS FOR MEDICAL IMAGING**
11 **AND RADIATION THERAPY.**

12 Section 1848(b)(4) of the Social Security Act (42
13 U.S.C. 1395w–4(b)(4)) is amended—

14 (1) in subparagraph (A), by striking the “imag-
15 ing” and inserting “medical imaging and radiation
16 therapy” and;

17 (2) by adding at the end the following new sub-
18 paragraph:

19 “(C) PAYMENT FOR MEDICAL IMAGING
20 AND RADIATION THERAPY SERVICES.—With re-
21 spect to expenses incurred for the planning and
22 performing of the technical component of med-
23 ical imaging examinations or radiation therapy
24 procedures furnished on or after January 1,
25 2013, payment shall be made under this section

1 only if the examination or procedure is planned
2 or performed by an individual who meets the
3 requirements established by the Secretary under
4 section 355 of the Public Health Service Act.”.

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

6 (a) **IN GENERAL.**—The Secretary of Health and
7 Human Services, acting through the Director of the Agen-
8 cy for Healthcare Research and Quality, shall submit to
9 the Committee on Health, Education, Labor, and Pen-
10 sions of the Senate, the Committee on Finance of the Sen-
11 ate, and the Committee on Energy and Commerce of the
12 House of Representatives, a report on the effects of this
13 Act no later than 5 years after the date of the enactment
14 of this Act.

15 (b) **REQUIREMENTS.**—Such report shall include the
16 types and numbers of individuals qualified to perform or
17 plan the technical component of medical imaging or radi-
18 ation therapy services for whom standards have been de-
19 veloped, the impact of such standards on diagnostic accu-
20 racy and patient safety, and the availability and cost of
21 services. Entities reimbursed for technical services
22 through programs operating under the authority of the
23 Secretary of Health and Human Services shall be required
24 to contribute data to such report.

○