

112TH CONGRESS
2D SESSION

S. 3338

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 SENATE OF THE UNITED STATES

JUNE 25, 2012

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

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 2012”.

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 42 months after
17 the date of enactment of this section, personnel who
18 perform or plan the technical component of either
19 medical imaging examinations or radiation therapy
20 procedures for medical purposes shall be fully quali-
21 fied under this section to perform or plan such serv-
22 ices.

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

1 “(A) possess current certification in the
2 medical imaging or radiation therapy modality
3 or service they plan or perform from a certifi-
4 cation organization designated under subsection
5 (b); and

6 “(B) if a State requires the possession of
7 licensure, certification, or registration, possess
8 current State licensure or certifications where
9 such services and modalities are within the
10 scope of practice as defined by the State for
11 such profession.

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

14 “(A) IN GENERAL.—Nothing in this sec-
15 tion shall be construed to diminish the author-
16 ity of a State to define requirements for licen-
17 sure, certification, or registration, the require-
18 ments for practice, or the scope of practice of
19 personnel.

20 “(B) LIMITATION.—The Secretary shall
21 not take any action under this section that
22 would require licensure by a State of personnel
23 who perform or plan the technical component of
24 medical imaging examinations or radiation ther-
25 apy procedures.

1 “(4) EXEMPTIONS.—

2 “(A) IN GENERAL.—The qualification
3 standards described in this subsection and the
4 payment provisions in section 1848(b)(4)(E) of
5 the Social Security Act shall not apply to physi-
6 cians (as defined in section 1861(r) of the So-
7 cial Security Act (42 U.S.C. 1395x(r))) or to
8 nurse practitioners and physician assistants
9 (each as defined in section 1861(aa)(5) of the
10 Social Security Act (42 U.S.C. 1395x(aa)(5))).
11 Such practitioners shall not be included under
12 the terms ‘personnel’ or ‘qualified personnel’ for
13 purposes of this section.

14 “(B) INDIVIDUALS CURRENTLY EN-
15 ROLLED.—Individuals currently enrolled in a
16 nuclear medicine, radiation therapy, or medical
17 physicist training or certification program as of
18 the date the Secretary publishes the list of ap-
19 proved certification organizations shall have 6
20 months from the date of completion of the
21 training program to become fully qualified as
22 required under subsection (a).

23 “(b) DESIGNATION OF CERTIFICATION ORGANIZA-
24 TIONS.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish a program for designating medical imaging or
3 radiation therapy certification organizations that the
4 Secretary determines have established appropriate
5 procedures and programs for certifying personnel as
6 qualified to furnish medical imaging or radiation
7 therapy services. In establishing such program, the
8 Secretary shall consult with professional organiza-
9 tions and recognized experts in the technical compo-
10 nent of medical imaging and radiation therapy serv-
11 ices.

12 “(2) FACTORS.—

13 “(A) IN GENERAL.—When designating cer-
14 tification organizations under this subsection,
15 and when reviewing or modifying the list of des-
16 ignated organizations for the purposes of para-
17 graph (4)(B), the Secretary—

18 “(i) shall consider—

19 “(I) whether the certification or-
20 ganization has established a process
21 for the timely integration of new med-
22 ical imaging or radiation therapy serv-
23 ices into the organization’s certifi-
24 cation program;

1 “(II) whether the certification or-
2 ganization has established education
3 and continuing education require-
4 ments for individuals certified by the
5 organization;

6 “(III) whether the certification
7 organization is a nonprofit organiza-
8 tion;

9 “(IV) whether the certification
10 organization requires completion of a
11 certification examination as a pre-
12 requisite for certification; and

13 “(V) whether the certification or-
14 ganization has been accredited by an
15 accrediting body (as defined in sub-
16 paragraph (B)) that is approved by
17 the Secretary; and

18 “(ii) may consider—

19 “(I) whether the certification or-
20 ganization has established reasonable
21 fees to be charged to those applying
22 for certification; and

23 “(II) the ability of the certifi-
24 cation organization to review applica-

1 tions for certification in a timely man-
2 ner.

3 “(B) ACCREDITING BODY.—For purposes
4 of this section, the term ‘accrediting body’
5 means and organization that—

6 “(i) is a nonprofit organization;

7 “(ii) is a national or international or-
8 ganization with accreditation programs for
9 examinations leading to certification by
10 certification organizations; and

11 “(iii) has established standards for
12 recordkeeping and to minimize the possi-
13 bility of conflicts of interest.

14 “(3) EQUIVALENT EDUCATION, TRAINING, AND
15 EXPERIENCE.—

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

procedures. Such process may include documentation of items such as—

“(i) years and type of experience;

“(ii) a list of settings where experience was obtained; and

“(iii) verification of experience by supervising physicians or clinically qualified hospital personnel.

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

“(4) PROCESS.—

“(A) REGULATIONS.—Not later than 12 months after the date of enactment of this section, the Secretary shall promulgate regulations for designating certification organizations pursuant to this subsection.

“(B) DESIGNATIONS AND LIST.—Not later than 18 months after the date of enactment of

1 this section, the Secretary shall make deter-
2 minations regarding all certification organiza-
3 tions that have applied for designation pursuant
4 to the regulations promulgated under subpara-
5 graph (A), and shall publish a list of all certifi-
6 cation organizations that have received a des-
7 ignation.

8 “(C) PERIODIC REVIEW AND REVISION.—

9 The Secretary shall periodically review the list
10 under subparagraph (B), taking into account
11 the factors established under paragraph (2).
12 After such review, the Secretary may, by regu-
13 lation, modify the list of certification organiza-
14 tions that have received such designation.

15 “(D) WITHDRAWAL OF APPROVAL.—The

16 Secretary may withdraw the approval of a cer-
17 tification organization listed under subpara-
18 graph (B) if the Secretary determines that the
19 body no longer meets the requirements of sub-
20 section (b).

21 “(E) CERTIFICATIONS PRIOR TO REMOVAL

22 FROM LIST.—If the Secretary removes a certifi-
23 cation organization from the list of certification
24 organizations designated under subparagraph
25 (B), any individual who was certified by the

1 certification organization during or before the
2 period beginning on the date on which the cer-
3 tification organization was designated as a cer-
4 tification organization under such subpara-
5 graph, and ending 12 months from the date on
6 which the certification organization is removed
7 from such list, shall be considered to have been
8 certified by a certification organization des-
9 ignated by the Secretary under such subpara-
10 graph for the remaining period that such cer-
11 tification is in effect.

12 “(c) ALTERNATIVE STANDARDS FOR RURAL AND
13 UNDERSERVED AREAS.—The chief executive officer of a
14 State may submit to the Secretary a statement declaring
15 that the requirements described in subsection (a) are inap-
16 propriate for application for medical imaging examinations
17 or radiation therapy procedures that are performed and
18 planned in a geographic area that is determined by the
19 Medicare Geographic Classification Review Board to be a
20 ‘rural area’ or that is designated as a health professional
21 shortage area. Upon receipt of such statement, if the Sec-
22 retary deems it appropriate, the Secretary may waive the
23 standards described in subsection (a) or develop alter-
24 native standards for such rural areas or health profes-
25 sional shortage areas.

1 “(d) RULE OF CONSTRUCTION.—Notwithstanding
2 any other provision of this section, individuals who provide
3 medical imaging examinations relating to mammograms
4 shall continue to meet the regulations applicable under the
5 Mammography Quality Standards Act of 1992.

6 “(e) DEFINITION.—As used in this section:

7 “(1) MEDICAL IMAGING.—The term ‘medical
8 imaging’ means any examination or procedure used
9 to visualize tissues, organs, or physiologic processes
10 in humans for the purpose of detecting, diagnosing,
11 treating, or impacting the progression of disease or
12 illness. For purposes of this section, such term does
13 not include routine dental or ophthalmologic diag-
14 nostic procedures or ultrasound guidance of vascular
15 access procedures.

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

19 “(A) the act of directly exposing a patient
20 to radiation, including ionizing or radio fre-
21 quency radiation, to ultrasound, or to a mag-
22 netic field for purposes of medical imaging or
23 for purposes of radiation therapy; and

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

1 “(3) PLAN.—The term ‘plan’, with respect to
 2 medical imaging or radiation therapy, means the act
 3 of preparing for the performance of such a proce-
 4 dure on a patient by evaluating site-specific informa-
 5 tion, based on measurement and verification of radi-
 6 ation dose distribution, computer analysis, or direct
 7 measurement of dose, in order to customize the pro-
 8 cedure for the patient.

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

15 **SEC. 4. STANDARDS FOR MEDICAL IMAGING AND RADI-**
 16 **ATION THERAPY.**

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

20 “(E) STANDARDS FOR MEDICAL IMAGING
 21 AND RADIATION THERAPY.—With respect to ex-
 22 penses incurred for the planning and per-
 23 forming of the technical component of medical
 24 imaging examinations or radiation therapy pro-
 25 cedures (as defined in subsection (f) of section

1 355 of the Public Health Service Act) furnished
2 on or after 42 months after date of enactment
3 of the Consistency, Accuracy, Responsibility,
4 and Excellence in Medical Imaging and Radi-
5 ation Therapy Act of 2012, payment shall be
6 made under this section only if the examination
7 or procedure is planned or performed by an in-
8 dividual who meets the standards established by
9 the Secretary under such section 355.”.

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

11 (a) IN GENERAL.—Not later than 5 years after the
12 date of enactment of this Act, the Secretary of Health and
13 Human Services, shall submit to the Committee on
14 Health, Education, Labor, and Pensions of the Senate, the
15 Committee on Finance of the Senate, and the Committee
16 on Energy and Commerce of the House of Representa-
17 tives, a report on the effects of this Act.

18 (b) REQUIREMENTS.—The report under subsection
19 (a) shall include the types and numbers of individuals
20 qualified to perform or plan the technical component of
21 medical imaging or radiation therapy services for whom
22 standards have been developed, the impact of such stand-
23 ards on diagnostic accuracy and patient safety, and the
24 availability and cost of services. Entities reimbursed for
25 technical services through programs operating under the

- 1 authority of the Secretary of Health and Human Services
- 2 shall be required to contribute data to such report.

