

113TH CONGRESS
1ST SESSION

S. 642

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

MARCH 21, 2013

Mr. ENZI 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 2013”.

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 furnish the technical component of medical imaging
19 examinations or radiation therapy procedures for
20 medical purposes (except exempt individuals and
21 suppliers as described in paragraph (4)) shall be
22 fully qualified under this section to furnish such
23 services.

24 “(2) QUALIFICATIONS.—Individuals qualified to
25 furnish the technical component of medical imaging

1 examinations or radiation therapy procedures
2 shall—

3 “(A) possess current certification in the
4 medical imaging or radiation therapy modality
5 or service they furnish from a certification or-
6 ganization designated under subsection (b); and

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

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

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

21 “(B) LIMITATION.—The Secretary shall
22 not take any action under this section that
23 would require licensure by a State of personnel
24 who furnish the technical component of medical

1 imaging examinations or radiation therapy pro-
 2 cedures.

3 “(4) EXEMPTIONS.—

4 “(A) IN GENERAL.—The qualification
 5 standards described in this subsection and the
 6 limitation on payment in section 1848(b)(4)(E)
 7 of the Social Security Act (42 U.S.C. 1395w-
 8 4(b)(4)(E)) shall not apply to any of the fol-
 9 lowing:

10 “(i) Items and services furnished by a
 11 physician (as defined in section 1861(r) of
 12 such Act (42 U.S.C. 1395x(r))), a nurse
 13 practitioner or a physician assistant (each
 14 as defined in section 1861(aa)(5) of such
 15 Act (42 U.S.C. 1395x(aa)(5))). Such phy-
 16 sicians and practitioners shall not be in-
 17 cluded under the terms ‘personnel’ or
 18 ‘qualified personnel’ for purposes of this
 19 section.

20 “(ii) Advanced diagnostic imaging
 21 services (as defined in paragraph (1)(B) of
 22 section 1834(e) of such Act) furnished by
 23 a supplier (as defined in paragraph (1)(C)
 24 of such Act) for which the accreditation re-
 25 quirement under such section is applicable.

1 “(B) INDIVIDUALS CURRENTLY EN-
2 ROLLED.—Individuals enrolled in a nuclear
3 medicine, radiation therapy, or medical physi-
4 cist training or certification program as of the
5 date the Secretary publishes the list of ap-
6 proved certification organizations shall have 6
7 months from the date of completion of the
8 training program to become fully qualified as
9 required under paragraph (1).

10 “(b) DESIGNATION OF CERTIFICATION ORGANIZA-
11 TIONS.—

12 “(1) IN GENERAL.—The Secretary shall estab-
13 lish a program for designating medical imaging or
14 radiation therapy certification organizations that the
15 Secretary determines have established appropriate
16 procedures and programs for certifying personnel as
17 qualified to furnish medical imaging or radiation
18 therapy services. In establishing such program, the
19 Secretary shall consult with professional organiza-
20 tions and recognized experts in the technical compo-
21 nent of medical imaging and radiation therapy serv-
22 ices.

23 “(2) FACTORS.—

24 “(A) IN GENERAL.—When designating cer-
25 tification organizations under this subsection,

1 and when reviewing or modifying the list of des-
2 ignated organizations for the purposes of para-
3 graph (4)(B), the Secretary—

4 “(i) shall consider—

5 “(I) whether the certification or-
6 ganization has established a process
7 for the timely integration of new med-
8 ical imaging or radiation therapy serv-
9 ices into the organization’s certifi-
10 cation program;

11 “(II) whether the certification or-
12 ganization has established education
13 and continuing education require-
14 ments for individuals certified by the
15 organization;

16 “(III) whether the certification
17 organization is a nonprofit organiza-
18 tion;

19 “(IV) whether the certification
20 organization requires completion of a
21 certification examination as a pre-
22 requisite for certification; and

23 “(V) whether the certification or-
24 ganization has been accredited by an
25 accrediting body (as defined in sub-

1 paragraph (B)) that is approved by
 2 the Secretary; and

3 “(ii) may consider—

4 “(I) whether the certification or-
 5 ganization has established reasonable
 6 fees to be charged to those applying
 7 for certification; and

8 “(II) the ability of the certifi-
 9 cation organization to review applica-
 10 tions for certification in a timely man-
 11 ner.

12 “(B) ACCREDITING BODY.—For purposes
 13 of this section, the term ‘accrediting body’
 14 means an organization that—

15 “(i) is a nonprofit organization;

16 “(ii) is a national or international or-
 17 ganization with accreditation programs for
 18 examinations leading to certification by
 19 certification organizations; and

20 “(iii) has established standards for
 21 recordkeeping and to minimize the possi-
 22 bility of conflicts of interest.

23 “(3) EQUIVALENT EDUCATION, TRAINING, AND
 24 EXPERIENCE.—

“(A) IN GENERAL.—For purposes of this section, the Secretary shall, through regulation, provide a process for individuals whose training or experience are determined to be equal to, or in excess of, those of a graduate of an accredited educational program in that specialty to demonstrate their experience meets the educational standards for qualified personnel in 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 furnishing the technical component of medical imaging examinations or radiation

1 therapy treatments prior to the date of enact-
2 ment of this section.

3 “(4) PROCESS.—

4 “(A) REGULATIONS.—Not later than 12
5 months after the date of enactment of this sec-
6 tion, the Secretary shall promulgate regulations
7 for designating certification organizations pur-
8 suant to this subsection.

9 “(B) DESIGNATIONS AND LIST.—Not later
10 than 18 months after the date of enactment of
11 this section, the Secretary shall make deter-
12 minations regarding all certification organiza-
13 tions that have applied for designation pursuant
14 to the regulations promulgated under subpara-
15 graph (A), and shall publish a list of all certifi-
16 cation organizations that have received a des-
17 ignation.

18 “(C) PERIODIC REVIEW AND REVISION.—
19 The Secretary shall periodically review the list
20 under subparagraph (B), taking into account
21 the factors under paragraph (2). After such re-
22 view, the Secretary may, by regulation, modify
23 the list of certification organizations that have
24 received such designation.

1 “(D) WITHDRAWAL OF APPROVAL.—The
2 Secretary may withdraw the approval of a cer-
3 tification organization listed under subpara-
4 graph (B) if the Secretary determines that the
5 body no longer meets the requirements of sub-
6 section (b).

7 “(E) CERTIFICATIONS PRIOR TO REMOVAL
8 FROM LIST.—If the Secretary removes a certifi-
9 cation organization from the list of certification
10 organizations designated under subparagraph
11 (B), any individual who was certified by the
12 certification organization during or before the
13 period beginning on the date on which the cer-
14 tification organization was designated as a cer-
15 tification organization under such subpara-
16 graph, and ending 12 months from the date on
17 which the certification organization is removed
18 from such list, shall be considered to have been
19 certified by a certification organization des-
20 ignated by the Secretary under such subpara-
21 graph for the remaining period that such cer-
22 tification is in effect.

23 “(c) ALTERNATIVE STANDARDS FOR RURAL AND
24 UNDERSERVED AREAS.—The chief executive officer of a
25 State may submit to the Secretary a statement declaring

1 that the requirements described in subsection (a) are inap-
 2 propriate for application for medical imaging examinations
 3 or radiation therapy procedures that are furnished in a
 4 geographic area that is determined to be a ‘rural area’
 5 (as such term is defined for purposes of section
 6 1886(d)(2)(D) of the Social Security Act) or that is des-
 7 ignated as a health professional shortage area (as defined
 8 in section 332 of this Act). Upon receipt of such state-
 9 ment, if the Secretary deems it appropriate, the Secretary
 10 may waive the standards described in subsection (a) or
 11 develop alternative standards for such rural areas or
 12 health professional shortage areas.

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

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

19 “(1) MEDICAL IMAGING.—The term ‘medical
 20 imaging’ means any examination or procedure used
 21 to visualize tissues, organs, or physiologic processes
 22 in humans for the purpose of detecting, diagnosing,
 23 treating, or impacting the progression of disease or
 24 illness. For purposes of this section, such term does
 25 not include routine dental or ophthalmologic diag-

1 nostic procedures or ultrasound guidance of vascular
2 access procedures.

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

9 **SEC. 4. STANDARDS FOR MEDICAL IMAGING AND RADI-**
10 **ATION THERAPY.**

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

14 “(E) STANDARDS FOR MEDICAL IMAGING
15 AND RADIATION THERAPY.—With respect to ex-
16 penses incurred in the furnishing of the tech-
17 nical component of medical imaging examina-
18 tions or radiation therapy procedures for med-
19 ical purposes (as defined in subsection (e) of
20 section 355 of the Public Health Service Act)
21 on or after 42 months after the date of enact-
22 ment of the Consistency, Accuracy, Responsi-
23 bility, and Excellence in Medical Imaging and
24 Radiation Therapy Act of 2013, payment shall
25 be made under this section only if the examina-

1 tion or procedure is furnished by an individual
 2 who meets the standards established by the
 3 Secretary under such section 355 (other than
 4 an individual described in subsection (a)(4)(A)
 5 of such section).”.

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

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

14 (b) REQUIREMENTS.—The report under subsection
 15 (a) shall include the types and numbers of individuals
 16 qualified to furnish the technical component of medical im-
 17 aging or radiation therapy services for whom standards
 18 have been developed, the impact of such standards on di-
 19 agnostic accuracy and patient safety, and the availability
 20 and cost of services. Entities reimbursed for technical
 21 services through programs operating under the authority
 22 of the Secretary of Health and Human Services shall be
 23 required to contribute data to such report.

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