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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2012''.

SEC. 2. PURPOSE.

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

SEC. 3. QUALITY OF MEDICAL IMAGING AND RADIATION THERAPY.

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

"Subpart 4—Medical Imaging and Radiation Therapy

"SEC. 355. QUALITY OF MEDICAL IMAGING AND RADIATION THERAPY.

"(a) QUALIFIED PERSONNEL.—

"(1) IN GENERAL.—Effective 42 months after the date of enactment of this section, personnel who perform or plan the technical component of either medical imaging examinations or radiation therapy procedures for medical purposes shall be fully qualified under this section to perform or plan such services.

"(2) QUALIFICATIONS.—Individuals qualified to perform or plan the technical component of medical imaging examinations or radiation therapy procedures shall—

"(A) possess current certification in the medical imaging or radiation therapy modality or service they plan or perform from a certification organization designated under subsection (b); and

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

"(3) STATE LICENSURE, CERTIFICATION, OR REGISTRATION.—

"(A) IN GENERAL.—Nothing in this section shall be construed to diminish the authority of a State to define requirements for licensure, certification, or registration, the requirements for practice, or the scope of practice of personnel.

"(B) LIMITATION.—The Secretary shall not take any action under this section that would require licensure by a State of personnel who perform or plan the technical component of medical imaging examinations or radiation therapy procedures.

"(4) EXEMPTIONS.—

"(A) IN GENERAL.—The qualification standards described in this subsection and the payment provisions in section 1848(b)(4)(E) of the Social Security Act shall not apply to physicians (as defined in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r))) or to nurse practitioners and physician assistants (each as defined in section 1861(aa)(5) of the Social Security Act (42 U.S.C. 1395x(aa)(5))). Such practitioners shall not be included under the terms 'personnel' or 'qualified personnel' for purposes of this section.

"(B) INDIVIDUALS CURRENTLY ENROLLED.—Individuals currently enrolled in a nuclear medicine, radiation therapy, or medical physicist training or certification program as of the date the Secretary publishes the list of approved certification organizations shall have 6 months from the date of completion of the training program to become fully qualified as required under subsection (a).

"(b) DESIGNATION OF CERTIFICATION ORGANIZATIONS.—

"(1) IN GENERAL.—The Secretary shall establish a program for designating medical imaging or radiation therapy certification organizations that the Secretary determines have established appropriate procedures and programs for certifying personnel as qualified to furnish medical imaging or radiation therapy services. In establishing such program, the Secretary shall consult with professional organizations and recognized experts in the technical component of medical imaging and radiation therapy services.

"(2) FACTORS.—

"(A) IN GENERAL.—When designating certification organizations under this subsection, and when reviewing or modifying the list of designated organizations for the purposes of paragraph (4)(B), the Secretary—

"(i) shall consider—

"(I) whether the certification organization has established a process for the timely integration of new medical imaging or radiation therapy services into the organization's certification program;

"(II) whether the certification organization has established education and continuing education requirements for individuals certified by the organization;

"(III) whether the certification organization is a nonprofit organization;

"(IV) whether the certification organization requires completion of a certification examination as a prerequisite for certification; and

"(V) whether the certification organization has been accredited by an accrediting body (as defined in subparagraph (B)) that is approved by the Secretary; and

"(ii) may consider—

"(I) whether the certification organization has established reasonable fees to be charged to those applying for certification; and

"(II) the ability of the certification organization to review applica-

tions for certification in a timely manner.

"(B) ACCREDITING BODY.—For purposes of this section, the term 'accrediting body' means and organization that—

"(i) is a nonprofit organization;

"(ii) is a national or international organization with accreditation programs for examinations leading to certification by certification organizations; and

"(iii) has established standards for recordkeeping and to minimize the possibility of conflicts of interest.

"(3) EQUIVALENT EDUCATION, TRAINING, AND 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 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

this section, the Secretary shall make determinations regarding all certification organizations that have applied for designation pursuant to the regulations promulgated under subparagraph (A), and shall publish a list of all certification organizations that have received a designation.

"(C) PERIODIC REVIEW AND REVISION.—The Secretary shall periodically review the list under subparagraph (B), taking into account the factors established under paragraph (2). After such review, the Secretary may, by regulation, modify the list of certification organizations that have received such designation.

"(D) WITHDRAWAL OF APPROVAL.—The Secretary may withdraw the approval of a certification organization listed under subparagraph (B) if the Secretary determines that the body no longer meets the requirements of subsection (b).

"(E) CERTIFICATIONS PRIOR TO REMOVAL FROM LIST.—If the Secretary removes a certification organization from the list of certification organizations designated under subparagraph (B), any individual who was certified by the

certification organization during or before the period beginning on the date on which the certification organization was designated as a certification organization under such subparagraph, and ending 12 months from the date on which the certification organization is removed from such list, shall be considered to have been certified by a certification organization designated by the Secretary under such subparagraph for the remaining period that such certification is in effect.

''(c) ALTERNATIVE STANDARDS FOR RURAL AND UNDERSERVED AREAS.—The chief executive officer of a State may submit to the Secretary a statement declaring that the requirements described in subsection (a) are inappropriate for application for medical imaging examinations or radiation therapy procedures that are performed and planned in a geographic area that is determined by the Medicare Geographic Classification Review Board to be a 'rural area' or that is designated as a health professional shortage area. Upon receipt of such statement, if the Secretary deems it appropriate, the Secretary may waive the standards described in subsection (a) or develop alternative standards for such rural areas or health professional shortage areas.

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

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

"(1) MEDICAL IMAGING.—The term 'medical imaging' means any examination or procedure used to visualize tissues, organs, or physiologic processes in humans for the purpose of detecting, diagnosing, treating, or impacting the progression of disease or illness. For purposes of this section, such term does not include routine dental or ophthalmologic diagnostic procedures or ultrasound guidance of vascular access procedures.

"(2) PERFORM.—The term 'perform', with respect to medical imaging or radiation therapy, means—

"(A) the act of directly exposing a patient to radiation, including ionizing or radio frequency radiation, to ultrasound, or to a magnetic field for purposes of medical imaging or for purposes of radiation therapy; and

"(B) the act of positioning a patient to receive such an exposure.

"(3) PLAN.—The term 'plan', with respect to medical imaging or radiation therapy, means the act of preparing for the performance of such a procedure on a patient by evaluating site-specific information, based on measurement and verification of radiation dose distribution, computer analysis, or direct measurement of dose, in order to customize the procedure for the patient.

"(4) RADIATION THERAPY.—The term 'radiation therapy' means any procedure or article intended for use in the cure, mitigation, treatment, or prevention of disease in humans that achieves its intended purpose through the emission of ionizing or non-ionizing radiation.".

SEC. 4. STANDARDS FOR MEDICAL IMAGING AND RADIATION THERAPY.

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

"(E) STANDARDS FOR MEDICAL IMAGING AND RADIATION THERAPY.—With respect to expenses incurred for the planning and performing of the technical component of medical imaging examinations or radiation therapy procedures (as defined in subsection (f) of section

355 of the Public Health Service Act) furnished on or after 42 months after date of enactment of the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2012, payment shall be made under this section only if the examination or procedure is planned or performed by an individual who meets the standards established by the Secretary under such section 355.''.

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

(a) IN GENERAL.—Not later than 5 years after the date of enactment of this Act, the Secretary of Health and Human Services, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Finance of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report on the effects of this Act.

(b) REQUIREMENTS.—The report under subsection (a) shall include the types and numbers of individuals qualified to perform or plan the technical component of medical imaging or radiation therapy services for whom standards have been developed, the impact of such standards on diagnostic accuracy and patient safety, and the availability and cost of services. Entities reimbursed for 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.

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