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

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.

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,
SECTION 1. SHORT TITLE.

This Act may be cited as the “Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2011”.

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 January 1, 2014, personnel who perform or plan the technical component of either medical imaging examinations or radiation therapy procedures for medical purposes shall be 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 by the Secretary pursuant to subsection (c); or

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

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

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

“(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 require-
ments 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.—The qualification standards described in this subsection and the payment provisions in section 1848(b)(4)(C) 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) ESTABLISHMENT OF STANDARDS.—

“(1) IN GENERAL.—For the purposes of determining compliance with subsection (a), the Secretary, in consultation with recognized experts in the technical provision of medical imaging or radiation therapy services, shall establish minimum standards
for personnel who perform, plan, evaluate, or verify patient dose for medical imaging examinations or radiation therapy procedures. Such standards shall not apply to the equipment used.

“(2) Recognized experts.—

“(A) In general.—For the purposes of this subsection, the Secretary shall select recognized expert advisers to reflect a broad and balanced input from all sectors of the health care community that are involved in the provision of services of the type described in paragraph (1) to avoid undue influence from any single sector of practice relating to the content of such standards.

“(B) Definition.—In this paragraph, the term ‘recognized experts’ includes—

“(i) representatives of all medical specialties and providers that perform or plan medical imaging procedures;

“(ii) representatives of all medical specialties and providers that perform or plan radiation therapy procedures;

“(iii) medical imaging and radiation therapy technology experts; and
“(iv) other experts determined appropriate by the Secretary.

“(3) **MINIMUM STANDARDS.**—Minimum standards established under this subsection shall reflect the unique or specialized nature of the technical services provided, and shall represent expert consensus from those practicing in each of the covered imaging modalities and radiation therapy procedures as to what constitutes excellence in practice and be appropriate to the particular scope of care involved.

“(4) **ALLOWANCE FOR ADDITIONAL STANDARDS.**—Nothing in this subsection shall be construed to prohibit a State or certification organization from requiring compliance with standards that exceed the minimum standards specified by the Secretary pursuant to this subsection.

“(5) **TIMELINE.**—Not later than 12 months after the date of enactment of this section, the Secretary shall promulgate regulations for the purposes of carrying out this subsection.

“(c) **DESIGNATION OF CERTIFICATION ORGANIZATIONS.**—

“(1) **IN GENERAL.**—The Secretary shall establish a program for designating 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.

“(2) FACTORS.—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 shall consider—

“(A) whether the certification organization has established certification requirements for individuals that are consistent with or exceed the minimum standards established in subsection (b);

“(B) 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;

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

“(D) whether the organization has established reasonable fees to be charged to those applying for certification;
“(E) whether the examinations leading to certification by the certification organization are accredited by an appropriate accrediting body as defined in subsection (d);

“(F) the ability of the certification organization to review applications for certification in a timely manner; and

“(G) such other factors as the Secretary determines appropriate.

“(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.

“(C) CERTIFICATION TEST REQUIREMENT.—To be eligible to be certified under this subsection an individual shall, not later than 18 months after the date on which the list of designated certification organizations is published under paragraph (4), successfully complete a certification examination administered by a designated certification organization. During such 18-month period, the penalties provided for under section 1848(b)(4)(C) of the Social Security Act (as added by section 4 of the Consistency, Accuracy, Responsibility, and Excellence VerDate Mar 15 2010 03:08 Jun 08, 2011 Jkt 099200 PO 00000 Frm 00009 Fmt 6652 Sfmt 6201 E:\BILLS\H2104.IH H2104jbell on DSKDVH8Z91PROD with BILLS
in Medical Imaging and Radiation Therapy Act of 2011) shall not apply to such individuals.

“(4) Process.—

“(A) Regulations.—Not later than July 1, 2013, the Secretary shall promulgate regulations for designating certification organizations pursuant to this subsection.

“(B) Designations and List.—Not later than January 1, 2014, 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) 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 on 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.

“(d) APPROVED ACCREDITING BODIES.—

“(1) IN GENERAL.—Not later than 24 months after the date of enactment of this section, the Secretary shall publish a list of entities that are approved accrediting bodies for certification organizations for purposes of subsection (c)(2)(E). The Secretary shall revise such list as appropriate.

“(2) REQUIREMENTS FOR APPROVAL.—The Secretary shall not approve an accrediting body for certification organizations under this subsection unless the Secretary determines that such accrediting body—
“(A) is a nonprofit organization;

“(B) is a national or international organization with accreditation programs for examinations leading to certification by certification organizations;

“(C) has established standards for record-keeping and to minimize the possibility of conflicts of interest; and

“(D) demonstrates compliance with any other requirements established by the Secretary.

“(3) WITHDRAWAL OF APPROVAL.—The Secretary may withdraw the approval of an accrediting body under this paragraph if the Secretary determines that the body does not meet the requirements of paragraph (2).

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

“(1) IN GENERAL.—The Secretary shall determine whether the standards established under subsection (a) must be met in their entirety 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. If the Secretary determines that alternative standards for such rural areas or health professional shortage areas are appropriate to ensure access to quality medical imaging examinations or radiation therapy procedures, the Secretary is authorized to develop such alternative standards.

“(2) State Discretion.—The chief executive officer of a State may submit to the Secretary a statement declaring that an alternative standard developed under paragraph (1) is inappropriate for application to such State, and such alternative standard shall not apply in such submitting State. The chief executive officer of a State may rescind a statement described in this paragraph following the provision of appropriate notice to the Secretary.

“(f) 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 (as amended).

“(g) 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 diag-
nostic procedures or ultrasound guidance of vascular
access procedures.

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

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

“(B) the act of positioning a patient to re-
ceive 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 proce-
dure on a patient by evaluating site-specific informa-
tion, based on measurement and verification of radi-
ation dose distribution, computer analysis, or direct
measurement of dose, in order to customize the pro-
cedure 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. REQUIRED 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) REQUIRED STANDARDS FOR MEDICAL IMAGING AND RADIATION THERAPY SERVICES.—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 (g) of section 355 of the Public Health Service Act) furnished on or after January 1, 2014, payment shall be made under this section only if the examination or procedure is planned or performed by an individual who meets the requirements 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 the enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the Agency for Healthcare Research and Quality, 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 authority of the Secretary of Health and Human Services shall be required to contribute data to such report.