I

109TH CONGRESS
2D SESSION

S. 2322

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 7, 2006
Referred to the Committee on Energy and Commerce

AN ACT

To amend the Public Health Service 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 ''Consumer Assurance of Radiologic Excellence Act of 2006''.

SEC. 2. PURPOSE.

The purpose of this Act is to improve the quality and value of healthcare by increasing the safety and accuracy of medical imaging examinations and radiation therapy treatments, 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) ESTABLISHMENT OF STANDARDS.—

''(1) IN GENERAL.—The Secretary, in consultation with recognized experts in the technical provision of medical imaging and radiation therapy services, shall establish standards to ensure the safety and accuracy of medical imaging studies and radiation therapy treatments. Such standards shall pertain to the personnel who perform, plan, evaluate, or verify patient dose for medical imaging studies and radiation therapy procedures and not to the equipment used.

''(2) EXPERTS.—The Secretary shall select expert advisers under paragraph (1) to reflect a broad and balanced input from all sectors of the health care community that are involved in the provision of such services to avoid undue influence from any single sector of practice on the content of such standards.

''(3) LIMITATION.—The Secretary shall not take any action under this subsection that would require licensure by a State of those who provide the technical services referred to in this subsection.

''(b) EXEMPTIONS.—The standards established under subsection (a) shall not apply to physicians (as defined in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r))), nurse practitioners and physician assistants (as defined in section 1861(aa)(5) of the Social Security Act (42 U.S.C. 1395x(aa)(5))).

''(c) REQUIREMENTS.—

''(1) IN GENERAL.—Under the standards established under subsection (a), the Secretary shall ensure that individuals, prior to performing or planning medical imaging and radiation therapy services, demonstrate compliance with the standards established under subsection (a) through successful completion of certification by a professional organiza-

tion, licensure, completion of an examination, pertinent coursework or degree program, verified pertinent experience, or through other ways determined appropriate by the Secretary, or through some combination thereof.

''(2) MISCELLANEOUS PROVISIONS.—The standards established under subsection (a)—

''(A) may vary from discipline to discipline, reflecting the unique and specialized nature of the technical services provided, and shall represent expert consensus as to what constitutes excellence in practice and be appropriate to the particular scope of care involved;

''(B) may vary in form for each of the covered disciplines; and

''(C) may exempt individual providers from meeting certain standards based on their scope of practice.

''(3) RECOGNITION OF INDIVIDUALS WITH EXTENSIVE PRACTICAL EXPERIENCE.—For purposes of this section, the Secretary shall, through regulation, provide a method for the recognition of 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, or

of an individual who is regularly eligible to take the licensure or certification examination for that discipline.

''(d) APPROVED BODIES.—

''(1) IN GENERAL.—Not later than the date described in subsection (j)(2), the Secretary shall begin to certify qualified entities as approved bodies with respect to the accreditation of the various mechanisms by which an individual can demonstrate compliance with the standards promulgated under subsection (a), if such organizations or agencies meet the standards established by the Secretary under paragraph (2) and provide the assurances required under paragraph (3).

''(2) STANDARDS.—The Secretary shall establish minimum standards for the certification of approved bodies under paragraph (1) (including standards for recordkeeping, the approval of curricula and instructors, the charging of reasonable fees for certification or for undertaking examinations, and standards to minimize the possibility of conflicts of interest), and other additional standards as the Secretary may require.

''(3) ASSURANCES.—To be certified as an approved body under paragraph (1), an organization or

agency shall provide the Secretary satisfactory assurances that the body will—

"(A) be a nonprofit organization;

"(B) comply with the standards described in paragraph (2);

"(C) notify the Secretary in a timely manner if the body fails to comply with the standards described in paragraph (2); and

"(D) provide such other information as the Secretary may require.

"(4) WITHDRAWAL OF APPROVAL.—

"(A) IN GENERAL.—The Secretary may withdraw the certification of an approved body if the Secretary determines the body does not meet the standards under paragraph (2).

"(B) EFFECT OF WITHDRAWAL.—The withdrawal of the certification of an approved body under subparagraph (A) shall have no effect on the certification status of any individual or person that was certified by that approved body prior to the date of such withdrawal.

"(e) EXISTING STATE STANDARDS.—Standards established by a State for the licensure or certification of personnel, accreditation of educational programs, or administration of examinations shall be deemed to be in com-

pliance with the standards of this section unless the Secretary determines that such State standards do not meet the minimum standards prescribed by the Secretary or are inconsistent with the purposes of this section. The Secretary shall establish a process by which a State may respond to or appeal a determination made by the Secretary under the preceding sentence.

''(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a State or other approved body from requiring compliance with a higher standard of education and training than that specified by this section. Notwithstanding any other provision of this section, individuals who provide medical imaging services relating to mammograms shall continue to meet the standards applicable under the Mammography Quality Standards Act of 1992.

''(g) EVALUATION AND REPORT.—The Secretary shall periodically evaluate the performance of each approved body under subsection (d) at an interval determined appropriate by the Secretary. The results of such evaluations shall be included as part of the report submitted to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives in accordance with 354(e)(6)(B).

''(h) DELIVERY OF AND PAYMENT FOR SERVICES.—Not later than the date described in subsection (j)(3), the Secretary shall promulgate regulations to ensure that all programs under the authority of the Secretary that involve the performance of or payment for medical imaging or radiation therapy, are performed in accordance with the standards established under this section.

''(i) 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 or radiation therapy that is performed 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 assure access to quality medical imaging, 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 de-

veloped 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.

''(j) APPLICABLE TIMELINES.—

''(1) GENERAL IMPLEMENTATION REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall promulgate such regulations as may be necessary to implement all standards in this section except those provided for in subsection (d)(2).

''(2) MINIMUM STANDARDS FOR CERTIFICATION OF APPROVED BODIES.—Not later than 24 months after the date of enactment of this section, the Secretary shall establish the standards regarding approved bodies referred to in subsection (d)(2) and begin certifying approved bodies under such subsection.

''(3) REGULATIONS FOR DELIVERY OF OR PAYMENT FOR SERVICES.—Not later than 36 months after the date of enactment of this section, the Secretary shall promulgate the regulations described in subsection (h). The Secretary may withhold the pro-

vision of Federal assistance as provided for in subsection (h) beginning on the date that is 48 months after the date of enactment of this section.

''(k) DEFINITIONS.—In this section:

''(1) APPROVED BODY.—The term 'approved body' means an entity that has been certified by the Secretary under subsection (d)(1) to accredit the various mechanisms by which an individual can demonstrate compliance with the standards promulgated under subsection (a) with respect to performing, planning, evaluating, or verifying patient dose for medical imaging or radiation therapy.

''(2) MEDICAL IMAGING.—The term 'medical imaging' means any procedure used to visualize tissues, organs, or physiologic processes in humans for the purpose of diagnosing illness or following the progression of disease. Images may be produced utilizing ionizing radiation, radiopharmaceuticals, magnetic resonance, or ultrasound and image production may include the use of contrast media or computer processing. For purposes of this section, such term does not include routine dental diagnostic procedures.

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

''(A) the act of directly exposing a patient to radiation via 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.

''(4) PLAN.—The term 'plan', with respect to medical imaging or radiation therapy, means the act of preparing for the performance of such a procedure to 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.

''(5) 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 radiation.

''(l) SUNSET.—This section shall have no force or effect after September 30, 2016.''.

SEC. 4. REPORT ON THE EFFECTS OF THIS ACT.

(a) Not later than 5 years after the date of 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 and the Committee on Energy and Commerce of the House of Representatives a report on the effects of this Act. Such report shall include the types and numbers of providers 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.

Passed the Senate December 6, 2006.

Attest: EMILY J. REYNOLDS,

Secretary.