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CONSUMER ASSURANCE OF RADIOLOGIC EXCELLENCE ACT OF 2006

DECEMBER 5, 2006.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 2322]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 2322) 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

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I. PURPOSE AND NEED FOR LEGISLATION

The Consumer Assurance of Radiologic Excellence (CARE) Act would establish national standards for the education, training, and credentialing of those technical providers who work directly with patients to obtain diagnostic medical images or deliver therapeutic radiation. Patients and providers alike will benefit from more efficient and accurate diagnoses and safer, more appropriate therapies, all afforded at a substantially decreased cost to the taxpayer.

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Cancer of many different types has become much more common; behind only heart disease, cancer is the second leading cause of death in America. Medical imaging tests play an increasingly important role in diagnosing a wide variety of malignant diseases and in determining the results of treatment. Radiation therapy is a common form of cancer therapy and used in more than half of all cancer cases. As the population ages, we should anticipate that such procedures and therapies will be performed with greater frequency on older Americans, with the cost borne more and more often by federally financed health care programs. For example, in 2004, Medicare paid over $1 billion for radiation therapy.

Improvements in healthcare often occur through technological innovations. For example, today's providers depend much more on diagnostic medical imaging than they did in the past, which has led to explosive number of procedures performed, procedures that are not limited just to patients with cancer. Over 300 million radiologic procedures are performed annually in the United States, with 70 percent of Americans undergoing some type of medical imaging exam or radiation therapy treatment annually. These innovations, while of undeniable potential benefit, come with substantial costs. Radiology costs are reaching over $100 billion annually; diagnostic imaging is one of the fastest growing cost areas in American healthcare.

Congress has already taken some steps to assure the public that those who provide these services meet sufficient standards of technical proficiency. The Mammography Quality Standards Act of 1992 established standards for technologists performing one crucial diagnostic test; substantial quality improvement has been the result. The Consumer-Patient Radiation Health and Safety Act of 1981 encouraged the States to set standards for the technical competence of those who provide diagnostic imaging or radiation therapy services to patients, but left compliance with those standards optional. Unfortunately, to date, nine States and the District of Columbia have enacted no regulatory statutes at all while, in a further six States, those regulations remain incomplete. Some provider disciplines have no specified standards of education, training and experience at all. In fact, a provider with only a few hours of course work or a couple of weeks of on-the-job training may be responsible for obtaining the image a physician uses to diagnose your cancer or to deliver the radiation that is crucial to the treatment of a tumor.

In a June 2005 report to Congress, MedPAC—the Medicare Payment and Advisory Commission—recognized that, while the issue is complex, technical excellence in diagnostic imaging and radiation therapy plays a central role in improving the public health and lowering costs of care. The CARE Act seeks to implement those recommendations that speak to credentialing of technical providers and brings to completion work begun with the Consumer-Patient Radiation Health and Safety Act.

II. SUMMARY

Consumer Assurance of Radiologic Excellence Act of 2006—Amends the Public Health Service Act to direct the Secretary of Health and Human Services to establish standards to assure the safety and accuracy of medical imaging or radiation therapy. 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 the equipment they use.

III. History of Legislation and Votes in Committee

On February 17, 2006, Senators ENZI and KENNEDY introduced S. 2322, the "Consumer Assurance of Radiologic Excellence Act of 2006." On September 20, 2006, the committee held an executive session to consider S. 2322. The committee approved by unanimous consent a manager's amendment to S. 2322. Senators KENNEDY and ISAKSON cosponsored the manager's amendment.

During the 107th Congress, Senators ENZI and KENNEDY introduced S. 1197, the Consumer Assurance of Radiologic Excellence Act of 2003 on June 5, 2003. The bill was referred to the Senate Health, Education, Labor, and Pensions Committee. No further action was taken.

IV. Explanation of Bill and Committee Views

The Centers for Medicare and Medicaid Services (CMS) and private payers alike have documented that imaging utilization and spending are growing at a rate faster than other health care expenditures. Demand grows for medical imaging as the "Baby Boom" generation continues to age and dramatic scientific and technical advances are made.

Technical providers are an integral part of medical imaging and radiation therapy treatments. An imaging procedure may be performed at the request of a physician if a physician feels it necessary to aid in the patient's diagnosis. There are two components to the procedure—the exam itself and the radiologist's interpretation. The imaging exam is referred to as the technical component. Nine States and the District of Columbia do not have any standards for the technical competence of those who provide diagnostic imaging or radiation therapy, while in six States, those regulations remain incomplete. The committee believes standards for the health care professionals will only add to the overall quality of care of patients. The intent of the legislation is not to overturn effective State standards already in place but rather to see that the benefits of having effective standards are extended to those States in which such standards are not currently in effect. To ensure that effective State standards are not improperly overturned by the legislation, the bill provides for an appeal process through which a State may respond to any contention by the Secretary of Health and Human Services that such State lacks standards that meet the Federal minimum established by the act.

The committee recognizes many technicians already undergo some type of credentialing through specialty society or are required by the State. To complement and not interfere with credentialing already required in some States, the committee views it necessary that the standards set by the HHS Secretary aim to establish the minimum standards for each type of technical provider for radiologic imaging or radiation therapist. The committee also recognizes the varying disciplines that require medical imaging. Thus the legislation is flexible to ensure each scope of practice has recognized experts who are consulted by the Secretary about the min-

imum standards that will be established. By doing so, the unique aspects of various radiologic procedures will be considered.

There are five different ways the technical providers can attain the standards promulgated by the Secretary including the "recognition of verified pertinent work experience." The committee does not want to disenfranchise individuals currently practicing as medical imaging professionals or Radiation Therapists who have experience that could reasonably be substituted for the credentialing standards called for in this legislation. For this reason, the bill includes language authorizing the Secretary to develop a process by which individuals, who are practicing at the time of the enactment of this legislation, can be grandfathered into the standards the Secretary is charged with developing. The years of experience these individuals have developed can be reasonably substituted for the credentialing standards anticipated by this bill. However, that work experience should be relatively current. By this we mean that individuals should be practicing as medical imaging professionals or Radiation Therapists for a minimum of 3 of the previous 5 years prior to enactment of this bill.

We note that the process for developing the standards and implementing the standards will afford individuals not currently credentialed as medical imaging professionals or Radiation Therapists several years to become credentialed prior to enforcement of these standards. Therefore, individuals who are unable to obtain the necessary credential, but who meet the experience requirements, should seek recognition under the grandfather clause within a reasonable time period after enactment of the legislation. We recommend that the Secretary only consider requests for recognition under the grandfathering process for 2 years after the date when enforcement of the standards begins.

Under this arrangement, individuals not credentialed at the time of enactment of the legislation will have 4 years to obtain the necessary credential prior to enforcement and an additional 2 years to apply for recognition based upon the experience requirements set by the Secretary.

The committee expects the Secretary to establish standards in consultation with experts in the medical imaging field within 18 months of enactment. Within 24 months, the standards of certification of approved bodies shall be set, and such regulations shall be promulgated within 36 months. The Secretary may withhold Federal Assistance if standards are not met by a State within 48 months of enactment.

It is the committee's intent that individuals who provide medical imaging services relating to mammograms will continue to meet standards enacted by the Mammography Quality Standards Act of 1992.

V. Congressional Budget Office Cost Estimate

S. 2322—Consumer Assurance of Radiologic Excellence Act of 2006

Summary: S. 2322 would amend the Public Health Service Act to require that the Secretary of Health and Human Services (HHS) establish national educational and credentialing standards for technologists who perform certain medical-imaging studies and procedures involving radiation therapy. The new federal standards

would not pertain to equipment or to physicians, nurse practitioners, or physician assistants. All standards established under the bill would expire on September 30, 2016.

CBO estimates that implementing S. 2322 would result in additional discretionary spending of $2 million in 2007 and about $20 million over the 2007–2011 period, assuming the appropriation of the necessary amounts. CBO estimates that establishing national standards for technologists would have a negligible effect on direct spending. Enacting S. 2322 would not affect revenues.

S. 2322 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Although it would add new requirements for individuals who provide medical-imaging or radiation-therapy services in federally supported medical programs, S. 2322 would not preempt state laws that require individuals to be licensed or certified. Because the requirements of S. 2322 on individuals are only enforceable under government programs in which participation is voluntary, such requirements are considered conditions of participation in those programs.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 2322 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—				
	2007	2008	2009	2010	2011
CHANGES IN SPENDING SUBJECT TO APPROPRIATION [1]					
Estimated Authorization Level	2	3	5	5	6
Estimated Outlays	2	3	4	5	6

[1] Enacting S. 2322 also could affect direct spending, but CBO expects that any such changes would be negligible.

Basis of estimate

Spending subject to appropriation

For this estimate, CBO assumes that S. 2322 will be enacted near the start of fiscal year 2007 and that the amounts necessary to implement the bill will be appropriated for each year.

National Standards for Selected Technologists Under S. 2322. S. 2322 would require the Secretary of HHS to establish educational and credentialing standards for technical personnel who perform, plan, evaluate, or verify dosing for medical imaging services and procedures involving radiation therapy. Medical imaging refers to any procedure used to visualize tissues, organs, or physiologic processes in humans for diagnosing illness or monitoring the progression of disease. Radiation therapy uses the emission of radiation for treating or preventing disease. (The new standards would not apply to certain routine dental procedures, and they would not pertain to equipment or to physicians, nurse practitioners, or physician assistants.)

S. 2322 also would require the Secretary to certify qualified entities as approved bodies for administering standards and accrediting the various ways a technologist could demonstrate compliance. All of the standards established under this legislation would expire on September 30, 2016.

Enforcement Authority. S. 2322 would require the Secretary to ensure that individuals, prior to performing or planning specified

services, demonstrate compliance with the new standards. The bill would require all HHS programs that perform or pay for medical imaging services or radiation therapy to comply with such standards. It also would give the Secretary discretion to withhold payment by HHS programs for services furnished by technologists who are not certified.

Other Provisions. The bill would authorize the Secretary to develop alternative standards for rural areas or other underserved areas if necessary to assure access to quality health care. It would also require the Agency for Healthcare Research and Quality to conduct a study on the effect of the new federal standards on diagnostic accuracy, patient safety, and the availability and cost of services.

Administrative Costs to Implement S. 2322. S. 2322 does not specify which agency within HHS would administer the new standards. CBO assumes that the Food and Drug Administration (FDA) would coordinate with the Centers for Medicare & Medicaid Services (CMS) and the Health Services and Resources Administration to implement the bill. Given the uncertainty surrounding how the Secretary would develop and enforce the new standards, it is difficult to estimate the total resources necessary to administer such activities.

Within a few years of enactment, CBO expects that the total costs to administer the new standards for technologists could reach between one-third and one-half of FDA's estimated costs to operate its existing quality assurance program for mammography (excluding costs funded through user fees primarily for activities related to the inspections of facilities). We estimate that implementing S. 2322 would result in additional discretionary outlays of $2 million in 2007 and about $20 million over the 2007–2011 period, assuming the appropriation of the necessary amounts. Although S. 2322 would apply standards to a broader array of technical personnel than does the mammography program, CBO expects that FDA's costs would be lower for the new program because the new standards would apply only to technologists and not to equipment, facilities, or other practitioners as does the mammography program.

Direct spending

S. 2322 would allow the Secretary of HHS to withhold "federal assistance" from noncompliant providers who participate in health programs under the Secretary's jurisdiction. Vigorous enforcement of educational and credentialing standards for certain technologists under the bill could reduce spending by health programs such as Medicare and Medicaid.

Expanding federal standards for such personnel could improve the diagnostic accuracy of imaging tests and reduce the number of images services paid by those programs. However, based on information provided by CMS, CBO expects that it is unlikely that the Secretary would choose to withhold payments to enforce compliance. Therefore, CBO expects that expanding national standards would not substantially change how Medicare and Medicaid operate, and as a result, probably would not have a significant effect on spending in those programs.

Estimated impact on state, local, and tribal governments: Although it would add new requirements for individuals who provide

medical imaging or radiation therapy services through medical programs that are federally supported, S. 2322 would not preempt state laws that require individuals to be licensed or certified. Consequently, the bill does not contain an intergovernmental mandate as defined in the UMRA. State procedures for licensing or certifying those individuals may be deemed sufficient for meeting the new federal standards. If they are not, states may appeal the decision. Nothing in the bill would require states to implement higher standards in their own law, but in order for individuals to be qualified to act as medical imaging or radiation therapy personnel in most cases, they would have to meet the new federal standards as well—possibly through an accredited nonprofit organization.

Estimated impact on the private sector: S. 2322 also contains no private-sector mandates as defined in UMRA. The Secretary of the Department of Health and Human Services would be given authority to enforce the requirements of S. 2322 by withholding federal assistance. The requirements created are considered conditions of participation, because they are only enforceable under government programs in which participation is voluntary.

Estimate prepared by: Federal Costs: Julia Christensen, Geoff Gerhardt, and Camile Williams. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Peter Richmond.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. Regulatory Impact Statement

Pursuant to the requirements of paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has determined that the bill will not have a significant regulatory impact.

VII. Application of Law to the Legislative Branch

The committee has determined that there is not impact of this law on the legislative branch.

VIII. Section-by-Section Analysis

Section 1. Short title

The Short Title of the bill is the Consumer Assurance of Radiologic Excellence Act of 2006.

Section 2. Purpose

The purpose of the bill is to improve the quality and value of healthcare by increasing the safety and accuracy of medical imaging examination and radiation therapy treatments.

Section 3. Quality of medical imaging and radiation therapy

Section 3 authorizes the Secretary, in consultation with recognized experts in the technical provision of medical imaging and radiation therapy services, to establish standards for personnel who perform, plan, evaluate or verify patient dose for medical imaging studies and radiation therapy procedures.

Standards do not pertain to equipment used or physicians, nurse practitioners or physician assistants.

The Secretary shall ensure that individuals, prior to performing or planning medical imaging and radiation therapy services, demonstrate compliance with the standards established through various mechanisms:

- successful completion of certification by a professional organization,
- licensure,
- completion of an examination,
- pertinent coursework or degree program, and
- verified pertinent experience.

The Secretary shall certify qualified entities as approved bodies for accreditation and establish minimum standards for certification of approved bodies. Periodic evaluation of their performance will be submitted as part of a report to the Health, Education, Labor, and Pensions Committee and the Committee on Energy and Commerce.

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 compliance with the standards of this section unless the Secretary determines that such State standards do not meet the minimum standards. A State may appeal the Secretary's determination that it does not meet the minimum standards. Alternative standards for rural and health professional shortage areas will be set by the Secretary that will assure access to quality medical imaging. A chief-elected official may decide whether or not the use of alternatives standards is appropriate.

This section provides a timeline for implementation after enactment:

- Establish standards within 18 months.
- Establish standards of Certification of approved bodies within 24 months.
- Promulgate regulations within 36 months.
- Secretary may withhold the provision of Federal assistance within 48 months.

A sunset provision requires the legislation to expire on September 30, 2016.

Section 4. Report on the effects of this act

This section requires the Secretary acting through the Director of the Agency for Healthcare Research and Quality to submit a report to the Committee on Health, Education, Labor, and Pensions and the Energy and Commerce Committee through the Agency not later than 5 years after the date of enactment. The report shall include the types and number of providers who have developed standards and an update of standards on diagnosis accuracy, patient safety, availability and costs of services.

IX. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

* * * * * * *

PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS [2]

SEC. 351. (a)(1) * * *

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Subpart 3—Mammography Facilities

SEC. 354. CERTIFICATION OF MAMMOGRAPHY FACILITIES.

(a) DEFINITIONS.—* * *

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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 organization, 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 not effect on the certification status of any individual or person that was certified by the 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 compliance 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 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.

(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) MINUMUM 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) REGULATONS 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 provision 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) DEFINITIONIS.—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.

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