H. R. 1426

To amend title XIX of the Social Security Act to provide public access to quality medical imaging procedures and radiation therapy procedures.

IN THE HOUSE OF REPRESENTATIVES

March 17, 2005

Mr. Pickering (for himself, Mr. Doyle, Mr. Taylor of Mississippi, Mr. Larson of Connecticut, Mr. Lynch, Mr. Tanner, Mr. Duncan, Mr. Kildee, Mr. McCotter, Mr. Abercrombie, Mr. Wicker, Mr. Ryun of Kansas, Mr. Payne, Mr. Hyde, Mr. Hinchey, Mr. Walsh, Mr. Terry, Mrs. Wilson of New Mexico, Mr. Shimkus, and Mrs. Blackburn) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XIX of the Social Security Act to provide public access to quality medical imaging procedures and radiation therapy procedures.

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 “Consumer Assurance
5 of Radiologic Excellence Act”.

SEC. 2. STATE LICENSES REGARDING PRACTITIONERS OF MEDICAL IMAGING AND RADIATION THERAPY; LIMITATION ON MEDICAID PAYMENTS FOR PROCEDURES.

Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended—

(1) in section 1903(i) (42 U.S.C. 1396b(i))—

(A) in paragraph (20), by striking the period at the end and inserting “; or”; and

(B) by inserting after paragraph (20) the following paragraph:

“(21) with respect to any amount expended on medical imaging procedures or radiation therapy procedures unless the State meets the requirements of section 1930A (relating to State medical radiation licenses).”; and

(2) by inserting after section 1930 the following section:

“STATE MEDICAL RADIATION LICENSES

“Sec. 1930A. (a) State Licenses Regarding Medical Imaging and Radiation Therapy.—For purposes of section 1903(i)(21), a State meets the requirements of this section if the State demonstrates to the satisfaction of the Secretary that the law of the State has in effect the following policies:
“(1) Subject to paragraphs (2) and (3), it is unlawful for an individual in the State to intentionally administer or plan medical imaging procedures or radiation therapy procedures to or for a patient for medical or chiropractic purposes unless the individual has obtained from the State a license, certificate, or other document that authorizes the individual to administer such procedures in the State (referred to in this section as a ‘medical radiation license’).

“(2) Notwithstanding any other provision of this section, the State deems an individual as holding a medical radiation license if the individual is licensed in the State as a doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic.

“(3) The State requires an individual who administers or plans medical imaging procedures or radiation therapy procedures to obtain a medical radiation license from the State, unless—

“(A) the individual exclusively performs medical ultrasound or echocardiography; or

“(B) the individual is a student enrolled in an educational institution or program that is accredited pursuant to subsection (b)(2)(B) and, as a student, intentionally administers
medical imaging procedures or radiation therapy procedures for medical or chiropractic purposes under the supervision of an individual who holds a medical radiation license obtained from the State.

“(4) The State does not provide a medical radiation license to an individual unless the individual meets—

“(A) the criteria established under subsection (b) by the Secretary; and

“(B) such additional criteria as the State may establish.

“(b) Issuance by Secretary of Minimum Licensing Criteria.—

“(1) In general.—Not later than 18 months after the date of the enactment of the Consumer Assurance of Radiologic Excellence Act, the Secretary shall by regulation issue criteria that, for purposes of subsection (a)(4)(A), establish the minimum standards for an individual to obtain a medical radiation license from a State. In carrying out the preceding sentence, the Secretary shall—

“(A) establish such standards as the Secretary determines to be appropriate for ensuring the quality performance of medical imaging
procedures and radiation therapy procedures;
and

“(B) ensure that the standards are at least as protective of the public health as standards issued under the Consumer-Patient Radiation Health and Safety Act of 1981.

“(2) CERTAIN STANDARDS.—The Secretary shall ensure that standards under paragraph (1) are in accordance with the following:

“(A) The standards shall specify the educational requirements for an individual to obtain a medical radiation license, including, if applicable, requirements regarding practical experience.

“(B) The standards shall provide that an educational requirement under subparagraph (A) is that the education involved be provided by an educational institution or program that is accredited by a nonprofit private entity recognized by the Secretary for purposes of this subsection.

“(C) The standards shall specify the criteria that an entity is required to meet in order to be recognized by the Secretary as an accrediting entity under subparagraph (B). Such cri-
riteria shall provide that an entity will not be so recognized unless the entity establishes accred-
itig criteria satisfactory to the Secretary with respect to the quality of educational institutions and programs in the areas of administrative policies and procedures, curricula, record-
keeping, faculty, administrative support, and such other areas as the Secretary determines to be appropriate.

“(3) CONSULTATION.—In developing standards under paragraph (1), the Secretary shall consult with organizations that are nationally recognized for their expertise in education and credentialing in medical imaging procedures and radiation therapy procedures.

“(c) DEFINITIONS.—For purposes of this section:

“(1) The term ‘administer’, with respect to medical imaging procedures or radiation therapy procedures, means—

“(A) the act of directly exposing a patient to radiation via ionizing or RF radiation for purposes of medical imaging or for purposes of radiation therapy; and

“(B) the act of positioning a patient to receive such an exposure.
“(2) The term ‘medical imaging procedure’ means any procedure or article, excluding medical ultrasound procedures or articles, intended for use in the diagnosis of disease or other medical or chiropractic conditions in humans, including diagnostic X-rays, nuclear medicine, and magnetic resonance procedures.

“(3) The term ‘medical radiation license’ has the meaning indicated for such term in subsection (a)(1).

“(4) The term ‘plan’, with respect to medical imaging procedures or radiation therapy procedures, means the act of preparing for the administering of such a procedure to a patient by evaluating patient-specific or site-specific information, based on computer analysis or direct measurement of dose, in order to customize the procedure for the patient and verifying appropriate dose administrations.

“(5) The term ‘radiation therapy procedure’ means any radiation procedure or article intended for the cure, mitigation, or prevention of diseases or disorders in humans.”.
SEC. 3. APPLICABILITY.

With respect to the condition described in paragraph (21) of section 1903(i) of the Social Security Act (as inserted by section 2 of this Act):

(1) Except as provided in paragraph (2), such condition applies to the States on and after the first day of the first calendar quarter that begins after the date on which the Secretary of Health and Human Services promulgates the final rule under section 1930A(b)(1) of the Social Security Act (as added by section 2 of this Act).

(2) If the Secretary determines that meeting such condition requires State legislation (other than legislation appropriating funds), the condition applies to the State involved on and after the first day of the first calendar quarter that begins after the close of the relevant session of the State legislature.

For purposes of the preceding sentence:

(A) The relevant session is the first regular session of the State legislature that begins after the date on which such final rule is promulgated by the Secretary, subject to subparagraph (B).

(B) If the State has a two-year legislative session, each year of the session is deemed to
be a separate regular session of the State legislature for purposes of subparagraph (A).
MedPAC recommendations on imaging services

March 17, 2005

Statement of
Mark E. Miller, Ph.D.
Executive Director
Medicare Payment Advisory Commission

Before the
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Chairman Johnson, Congressman Stark, distinguished Subcommittee members. I am Mark Miller, Executive Director of the Medicare Payment Advisory Commission (MedPAC). I appreciate the opportunity to be here with you this morning to discuss ways to improve imaging services for Medicare beneficiaries.

The Commission has concluded that it is time for the Medicare program to start to differentiate among providers when making payments. Currently, Medicare pays providers the same regardless of their quality. In its March report to the Congress MedPAC discusses several important steps towards differentiation which, taken together, will improve the quality of care for beneficiaries and lay the groundwork for obtaining better value in the Medicare program. For example, MedPAC recommends pay for performance linked to quality. As requested, this testimony focuses on the Commission’s recommendations for imaging services contained in the March report.

Technological progress in imaging over the past years, and its promise for improving diagnosis, treatments, and health outcomes are impressive. In addition, improvements in technology have made those services available outside the hospital in settings such as imaging centers and doctors’ offices—with concomitant improvements in convenience for patients. However, at the same time there has been rapid and sustained growth in the volume of imaging services for Medicare beneficiaries; and there are concerns about potential overuse of imaging services, possible poor quality, and that Medicare payment policy has not kept up with technological changes. As an example of the rapid growth in imaging, according to the Wall Street Journal, there are now more magnetic resonance imaging (MRI) scanners in the Pittsburgh area than in all of Canada and, in 2003, there were over 13 computed tomography (CT) scans provided for every 100 members of the largest health plan in the area.

The Commission has investigated these issues through data analysis, consultations with private sector experts in management of imaging services, discussions with specialty medical societies, and a review of the available literature. After public discussion and deliberation the Commission, by a unanimous vote among those present, has recommended that:

- the Secretary of HHS improve Medicare’s coding edits for imaging studies,
- the Congress direct the Secretary to set standards for all providers who bill Medicare for performing and interpreting diagnostic imaging studies,
- the Secretary measure physicians’ use of imaging services so that physicians can compare their practice patterns with those of their peers, and
- the Secretary strengthen the rules that govern physician investment in imaging centers to which they refer patients.

Taken together, these actions should help add value to the imaging services Medicare buys.

**Growth has been dramatic**

Diagnostic imaging services paid under Medicare’s physician fee schedule grew more rapidly than any other type of physician service between 1999 and 2003. While the sum of all physician
services grew 22 percent in those years, imaging services grew twice as fast, by 45 percent (see figure 1). This measure is the growth in the volume and intensity of services per beneficiary; we have removed changes resulting from increases in the number of beneficiaries and changes in prices during those years. Not all imaging services grew at this rate; some grew even faster. Advanced imaging services and nuclear medicine led the way: MRI of parts of the body other than the brain grew by 99 percent; nuclear medicine grew 85 percent; and CT of parts of the body other than the head grew 82 percent (see figure 2).

In dollar terms, Medicare spending for imaging services paid under the physician fee schedule grew over 60 percent, from $5.7 billion in 1999 to $9.3 billion in 2003. Beneficiaries’ spending on these services has also increased, both directly through copayments and indirectly through increased part B premiums.

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**Figure 1**

*Imaging shows highest cumulative growth in services per beneficiary (1999–2003)*

Some argue that much of this increase was attributable to the movement of imaging from the outpatient setting to settings where the technical charge is included in the physician fee schedule. However, of the $1.6 billion increase in fee schedule imaging spending from 2001 to 2003, only $300 million was offset by the decrease in imaging provided in hospital outpatient departments. In addition, the movement of imaging from outpatient departments to physician offices raises another concern: the institutional standards that govern the performance and interpretation of studies in hospitals are usually absent in physician offices.
The growth in imaging services could be driven by various factors, among them:
- technological innovation that has improved physicians’ ability to diagnose disease and made it more feasible to provide imaging procedures in physician offices,
- patients’ desire to receive diagnostic tests in more convenient settings,
- physicians practicing defensive medicine,
- possible misalignment of fee schedule payment rates and costs, and
- physicians’ interest in supplementing their professional fees with revenues from ancillary services.

Some of these factors raise concerns that not all of the growth in the use of imaging services may be appropriate, and that quality safeguards may need to be put in place.

**Variation in use not linked to quality**

The use of imaging services varies widely across the country. In fact, the average use of imaging services in one area can be three times the average use in another area. This variation is twice that seen in the use of major procedures. This finding raises a concern about the value of some of those services because geographic areas with a disproportionate use of health services in general do not have better health outcomes, according to Dartmouth researchers Fisher and
Wennberg. Those researchers also find that wide variations in the use of discretionary services, such as imaging and diagnostic tests, are sensitive to the supply of physician and hospital resources rather than to the health status of the population.

In a separate study, Dartmouth researchers have found that regions providing more imaging services do not have higher survival rates among Medicare beneficiaries. Their study examined whether long-term survival in three cohorts—patients with heart attacks, colon cancer, and hip fractures—was better in regions with higher versus lower imaging use. They found that increased use of imaging services was not associated with improved survival in any of the three study populations.

**Quality varies**
According to published studies, health plans, and experts we consulted, providers vary in their ability to perform quality imaging procedures. In one study, published in *Radiology*, BlueCross BlueShield of Massachusetts inspected 1,000 imaging providers to evaluate the quality of their equipment, technical staff, and other features. Nearly one-third of the providers had at least one serious deficiency, such as film processing problems, failure to monitor radiation exposure, poor image quality, or lack of an equipment calibration report. Eleven percent of the providers had severe problems that could not be easily remedied, while 20 percent had deficiencies that could be remedied. Chiropractic and podiatric offices were the most likely to have deficiencies; cardiology, radiology, and surgical specialty offices were the least likely. According to a study in the *American Journal of Roentgenology*, another health plan that inspected almost 100 nonradiologist offices that provided radiography services identified serious problems in 78 percent of the offices. These problems included lack of proper image identification (e.g., noting left or right) and use of equipment that had not been inspected during the previous year.

In our March 2004 public meeting a panel of health plans and imaging benefit managers informed us that some providers fail to meet standards because their imaging equipment is old or not working properly. Physician offices sometimes acquire used equipment from a hospital and continue to use that equipment beyond its useful life.

Problems identified by purchasers may lead to inaccurate studies, missed or inaccurate diagnoses, and inappropriate treatment. A recent study published in the *Journal of Vascular Surgery* found that vascular ultrasound providers that were not accredited often produced inaccurate carotid ultrasound examinations. In that study, carotid ultrasound tests performed by nonaccredited labs were repeated by an accredited lab that follows standards for diagnostic criteria, testing protocols, and technician training. For 61 percent of the patients, findings by this lab contradicted findings by the nonaccredited providers in a clinically significant way.

There may also be problems with the quality of interpretation of imaging. For example, in one study published in the *Annals of Emergency Medicine*, over 500 CT scans that were interpreted by emergency physicians were also read by radiologists. Radiologists disagreed with the emergency physicians’ interpretations in 39 percent of the cases, most of which were potentially clinically significant misinterpretations (e.g., major false negatives or positives). Another study by an imaging benefit company found interpretation reports, which are an integral part of a
diagnostic examination, to be incomplete. The study found half of the reports examined lacked information on the indication for the study and many lacked information on the views taken.

**Setting standards for imaging providers and interpreters**
The lack of quality oversight for imaging tests provided in physician offices, concerns about use of imaging studies, and rapid volume growth lead to our first recommendation: The Congress should direct the Secretary to set standards for providers who bill Medicare for performing and/or interpreting diagnostic imaging studies. The Secretary should select private sector organizations to administer the standards. As many physicians integrate imaging services into their office practices, ensuring that these studies are done by skilled technicians using appropriate equipment and interpreted by qualified physicians should improve the accuracy of diagnostic tests and reduce the need to repeat studies, thus enhancing quality of care and helping to control spending.

Requiring physicians to meet quality standards as a condition of payment for imaging services provided in their offices represents a major change in Medicare’s payment policy. Traditionally, Medicare has paid for all medically necessary services provided by physicians operating within the scope of practice for the state in which they are licensed. We believe that this policy change is warranted by the growth of imaging studies provided in physician offices and the lack of comprehensive standards for this setting. There are some limited precedents for this policy in imaging, but they are not comprehensive.

**Current standards**
Aside from a physician supervision requirement, no national Medicare standards for imaging apply to physician offices, and many imaging modalities, such as MRI, are not covered by any government standards. CMS has developed national standards for imaging provided in hospitals and independent diagnostic testing facilities. For example, hospitals that treat Medicare beneficiaries must comply with Medicare’s conditions of participation, which include standards for radiology services. In addition, several Medicare carriers have minimum standards for the technical quality of some types of ultrasound studies performed in physician offices, but these standards have not been adopted nationally. Even when standards exist for an imaging modality, they may not be comprehensive or well enforced.

There are also two limited cases where standards are set for imaging interpretation. First, the Medicare carrier for New York (Empire) sets standards for physicians who wish to bill for interpreting an echocardiography study. Another exception is contained in CMS’s recent decision to cover positron emission tomography (PET) scans for the diagnosis of patients with mild cognitive impairment and early dementia. The coverage decision specifies that tests be interpreted by physicians only in certain specialties, such as nuclear medicine and radiology, who have expertise in reading these scans.

There is a national standard for mammography. Under the Mammography Quality Standards Act, the Food and Drug Administration (FDA) develops and enforces quality assurance standards for mammography equipment, technical staff, and the physicians who interpret mammograms. The GAO has credited the FDA standards with improving the quality of
mammograms without decreasing access. Failure rates for image quality decreased from 11 percent before the act to 2 percent after.

State radiation control boards license facilities that use radiation-producing equipment, but their primary mission is to ensure patient safety rather than the quality of images, and the standards are not always comprehensive or rigorously enforced.

Several of the private insurers we interviewed require that hospital outpatient departments, freestanding facilities, and physician offices that provide imaging services meet basic standards. These standards relate to the quality of imaging equipment, the qualifications of radiology technicians, the resulting quality of the images, the procedures for ensuring patient safety, and qualifications of interpreting physicians. Plans and their vendors often require that providers become accredited by a private organization, such as the American Institute for Ultrasound in Medicine (AIUM), American College of Radiology (ACR), or the Intersocietal Accreditation Commission (IAC).

**Developing standards**
The Congress should grant the Secretary authority to develop standards. The Secretary could review the criteria used by private plans and accreditation organizations, and consult with imaging accreditation organizations, physician specialty groups, and manufacturers when developing these requirements. CMS should strongly consider setting standards for at least the following areas: the imaging equipment, qualifications of technicians, qualifications and responsibilities of the supervising physician, technical quality of the images produced, procedures for ensuring patient safety, and the professional training, experience, and education of the physicians who interpret studies.

Although private plans sometimes base permission to bill for imaging procedures on the physician’s specialty, the Commission has not recommended this approach. The practice of medicine is evolving quickly, and specialty training may change over time. Thus, CMS should develop criteria that allow physicians of different specialties to receive payment for interpreting imaging studies. Similar to the requirements set by private accreditation organizations for interpreting physicians, Medicare’s standards should be based on some combination of physician training, experience, and continuing education. Standards will vary for each major imaging modality.

Several private accreditation programs and one government agency have already developed standards for physicians who interpret certain types of imaging studies and prepare the reports. Accreditation organizations, such as the AIUM, ACR, or IAC, generally set minimum standards for some combination of professional training, experience, and education of the physicians who interpret studies at accredited providers. The IAC has forged agreement among different specialties on common standards. The IAC has had representatives of several specialty groups jointly develop facility and physician standards for: echocardiography, nuclear medicine, and vascular ultrasound.

To reduce CMS’s administrative burden, the agency should authorize private accreditation
organizations to verify that providers meet the quality standards set by the Secretary. CMS should also have the authority to change the roster of organizations that verify compliance. Private insurers often rely on accreditation programs to certify that their providers meet quality standards.

To allow CMS to implement national standards in all settings, the Congress should provide the Secretary with specific statutory authority to do so. Although CMS has set quality standards for various types of providers (such as hospitals and skilled nursing facilities), there are very few examples of federal standards for physician offices (the primary exceptions are mammography and clinical laboratory services, which are authorized by statute).

**Measuring physicians’ use of imaging services**
The Commission also recommends: The Secretary should use Medicare claims data to measure fee-for-service physicians’ resource use and share results with physicians confidentially to educate them about how they compare with aggregated peer performance. The Congress should direct the Secretary to perform this function. Educating physicians about their resource use should encourage those who practice significantly differently than their peers to reconsider their practice patterns. This initiative applies to all physicians. In regard to imaging, it should focus on the physicians who order imaging studies, because under Medicare, radiologists (with few exceptions) may only perform studies with an order from the treating physician. CMS would develop measures of imaging volume per beneficiary for patients seen by the ordering physician. Because radiologists sometimes suggest modifications to the original order, their resource use could also be measured.

**Expanding coding edits**
The Commission’s third recommendation is: The Secretary should improve Medicare’s coding edits that detect unbundled diagnostic imaging services and reduce the technical component payment for multiple imaging services performed on contiguous body parts. This action would improve Medicare’s ability to detect improper claims and help the program pay more accurately for multiple imaging services. Currently, Medicare uses edits to determine whether a claim meets the program’s payment rules.

Some private insurers have developed their own set of coding edits that go beyond Medicare’s current edits. First, some plans have implemented more rigorous policies to address unbundling of services—that is, separately billing for two procedures when one is a component of the other—and billing for mutually exclusive procedures. For example, one imaging benefit manager does not pay for both a CT of the head and CT of the maxillofacial region at the same time because the head includes the maxillofacial area.

Second, a number of plans use coding edits to adjust payments when providers bill for multiple imaging services performed on contiguous body parts. Medicare already has a similar policy for surgical services: it pays the full rate for the most expensive surgical services and a discounted rate for other services. For imaging, private insurers usually pay the full amount for the first service but a reduced amount (usually half) for the technical component of an additional study that is of the same modality (e.g., MRI or CT). This strategy is based on the premise that
savings in clerical time, technical preparation, and supplies occur when multiple studies of the same modality are performed on contiguous body parts during one patient encounter. For example, according to a panel of experts that reported at our March 2004 public meeting, a CT of the pelvis, performed immediately after a CT of the abdomen, takes much less time than if performed separately because the patient has already been prepared for the procedure.

In developing more extensive coding edits for imaging services, CMS should consult with private plans and imaging benefit managers that have developed such edits, encourage physicians to review and comment on the edits, and communicate them in advance to physicians so they can bill correctly.

**Strengthening the rules that restrict physician investment in imaging centers**

The Commission also recommends strengthening the rules restricting physician investment in imaging centers to which they refer Medicare or Medicaid patients. Specifically, it recommends the Secretary should:

- include nuclear medicine and PET procedures as designated health services under the Ethics in Patient Referrals Act, and
- expand the definition of physician ownership in the Ethics in Patient Referrals Act to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services.

These changes should reduce physicians’ financial incentives to refer patients for additional imaging services, which should help control Medicare spending on these services.

Physician ownership of health care facilities may create a financial incentive to order additional services. In addition, some argue that rather than referring patients to the facility providing the best care, physician investors might refer patients to the facilities they own. Studies by the GAO and others have found that physicians who invest in diagnostic imaging centers or who have imaging equipment in their offices refer their patients more frequently for MRI, CT, nuclear medicine, and ultrasound.

The Ethics in Patient Referrals Act (also known as the Stark law) prohibits physicians from referring Medicare or Medicaid patients for certain services to providers with which the physician has a financial relationship. It also prohibits those entities from submitting claims for services provided to patients referred by the physician-investor. The law applies to a set of “designated health services” (DHS), which includes radiology and certain other imaging services (MRI, CT, and ultrasound).

In a final rule, CMS excluded nuclear medicine from the Stark law’s prohibitions. This decision allowed physicians to invest in freestanding centers that provide nuclear medicine procedures and refer Medicare or Medicaid patients to these facilities. The Commission recommends CMS add nuclear medicine to the list of designated health services because of the recent rapid growth of these services and its similarity to other designated health services. Prohibiting physicians from referring Medicare or Medicaid patients to nuclear medicine facilities they own should reduce their financial incentives to refer patients for these services.
CMS currently permits physicians to own entities that provide services and equipment to imaging centers and other DHS providers, as long as the physicians do not own the actual entity submitting claims to Medicare or Medicaid. The rule implementing the Stark law defines “ownership” of an entity only as an interest in the entity that submits claims to Medicare or Medicaid. However, this definition allows arrangements that may be inconsistent with the intent of the law. For example, physicians can buy a MRI machine from a manufacturer, lease it to an imaging center, and be reimbursed a fixed amount per use (figure 3). This arrangement creates a financial incentive for the physicians who lease the MRI to the center to refer patients to that center.

**Impacts**

Setting standards should increase the quality of imaging services provided to Medicare beneficiaries, not decrease access, and potentially decrease spending by reducing duplication of images and eliminating unnecessary services. Physician resource measurement should educate physicians who have higher use, and has the potential to decrease spending in the long run. Improved edits should reduce inappropriate billing and thus decrease spending. Strengthening restrictions on ownership will reduce financial incentives to provide additional services. Beneficiaries will not only experience higher quality imaging services if these recommendations are implemented, but will also benefit from reduced cost sharing and part B premiums.