

Beginning in three and a half years, any non-hospital supplier of the technical component of “advanced” medical medical imaging procedures [magnetic resonance imaging (MRI), computed tomography (CT), and nuclear imaging including positron emission tomography (PET)] will have to be accredited for the purpose by an organization designated by the federal government if the imaging facility wishes to be paid for services to Medicare beneficiaries.

That provision and one setting standards for medical directors and supervising physicians in imaging centers was part of a larger bill, HR 6331, passed by the Congress in July to postpone the imposition of a 10.6 % cut in Medicare fees to physicians under the existing Medicare sustainable growth rate formula. The reduction is deferred to the end of 2009 and a 1.5 % increase is granted during the same period.

The bill was vetoed by President George W. Bush and his veto was overridden by the Congress. According to a White House spokesman, the President’s objection was to provisions in the bill funding the continued payment of doctors by reducing the subsidies to health maintenance organizations participating in the Medicare Advance Program. That Program was enacted in 2005, along with the Medicare Part D pharmaceutical benefit provisions. It encouraged insurance companies to offer managed-care coverage to any Medicare beneficiary regardless of the beneficiary’s health circumstances by paying the insurer more than Medicare allowed physicians on a fee-for-service basis. That extra payment allocation will be stripped from Medicare Advance providers and will be applied directly to physician fees

The provision for required competence in medical imaging was pushed by the American College of Radiology (ACR) with the cooperation of the American College of Cardiology and the National Electrical Manufacturers Association, representing the makers of x-ray equipment.

While the new program will recognize the competence of radiologists to perform the advanced imaging procedures, it also provides for other medical organizations to accredit their members to operate imaging facilities and, presumably to interpret imaging procedures performed in those facilities.

The justification for legal restraints on imaging came in part from a study by the Government Accountability Office which indicated that the volume and cost of medical imaging for Medicare beneficiaries had more than doubled in six years, increasing from \$6.9 billion in 2000 to \$14.1 billion in 2006. The volume of imaging procedures in physician offices rose from 58 to 64 % and procedures in hospitals dropped from 35 to 25 %. The volume in independent diagnostic testing facilities rose from 7 to 11 % in the same six years. The share of in-office imaging spending for radiologists decreased by 4 % from 26 to 32 %.

The other part of the justification was based on a 2006 preliminary estimate by the National Council on Radiation Protection and Measurements (NCRP) that the per capita medical radiation dose to Americans rose by 600 % from 1982 to 2006. The largest increase in dose was attributed to the expansion in CT examinations to some 67 million in 2006 accounting for half of the dose, and a dose increase in nuclear imaging, particularly heart examinations, accounting for a fourth of the total dose. NCRP observed that the population dose from medical exposures now equals natural background radiation as the largest source of exposure to Americans.

Much of the increases in both volume and exposure relate to the surge of performance of imaging procedures by physicians in disciplines other than radiology. The surge was based in part on restrictions in Medicare payment of physicians in the late 1980s and the encouragement of moving imaging procedures away from hospitals to avoid hospital planning restrictions. A study by Bruce Hillman and others in 1991 reflected that other physicians performing imaging procedures in their own offices charged more than radiologists. The Medicare Payment Advisory Commission was quoted as expressing concerns “that (imaging ownership) arrangements create financial incentives that could influence physicians’ clinical judgements, leading to unnecessary services.”

The provisions for imaging standards in the recently passed bill are to take effect on January 1, 2012. By January 2010, the government “will designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services.” The bill authorizes spending \$10 million on a two-year demonstration project to test the proposed federal

program. The bill directs the Medicare program to consult with medical organizations in developing the program.

The legislative language specifies criteria to be sought for accreditation organizations as:

1. the ability of the organization to conduct timely reviews of accreditation applications;
2. whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program;
3. whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria;
4. the ability of the organization to take into account the capacities of suppliers located in a rural area;
5. whether the organization has established reasonable fees to be charged to suppliers applying for accreditation; and
6. other such factors as the Medicare program determines appropriate.

ACR should qualify as an accrediting agency, based upon its participation of mammography facilities in cooperation with the Public Health Service and the state radiation control programs which license x-ray facilities, plus its voluntary accreditation programs for other imaging technologies. Whether ACR will qualify facilities owned by other physicians or how other medical societies will qualify to accredit facilities owned and operated by their members remains to be determined.

The new law also specifies criteria for accreditation to be used by an accreditation organization evaluating suppliers of technical components of the designated advanced imaging suppliers. The criteria are to be specific for each modality of CT, MRI and PET. The criteria are to include:

1. standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;
2. standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations defined subsequently;

3. procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;
4. standards that require the supplier to have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;
5. standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity and accuracy of diagnostic images produced by such supplier; and
6. any other standards or procedures the program determines appropriate.

The legislative standards for medical directors and supervising physicians are to include:

1. in a particular specialty receives training in advanced diagnostic imaging services in a residency program;
2. has attained, through experience, the necessary expertise to be a medical director or a supervising physician;
3. has completed any continuing medical education courses relating to such services; and
4. has met such other standards as the program determines appropriate.

During consideration of the legislation, the American Medical Association and most other medical organizations, including ACR, had devoted major effort to resisting the 10 % cut in payment of physician fees. The provisions for imaging qualifications met with little opposition from other disciplines whose members will be affected by the new requirements.

The question of which other medical specialty societies and allied health groups will respond to the federal requirements is not answered in the legislation. In a white paper on radiation exposures and needed restraints [[Amis et al. \(2007\). "American College of Radiology white paper on radiation dose in medicine," JACR 4, 272–284](#)], the ACR outlines a series of suggestions and offers to work with other medical disciplines in helping their members understand appropriateness criteria and the need for training in radiation protection.

Many aspects of the white paper recognized that ACR concerns about turf issues were not likely to dissuade or exclude any other physicians from seeking to perform imaging procedures in their own facilities. The terms of HR 6331 do not exclude other physicians, but they seek to impose standards which should improve quality and might well have the effect of deterring physicians who cannot or choose not to meet criteria for imaging developed by their own societies. The very fact that a variety of medical specialties will be required to define medical imaging as related to their own discipline is a significant change with potential effects yet to be determined.

In the mid-1990s, Congress recognized the self-referral of imaging to facilities owned by physicians as a problem and enacted two bills sponsored by Rep. Fortney Stark, (D-California) then the Chairman of the Health Subcommittee of the House Ways and Means Committee. Both bills sought to impose restrictions on self-referral of imaging procedures and other medical services. However, loopholes in the legislative language restricted the effectiveness of the legislation.

Now the law of the land recognizes that other physicians, accredited by standards set by their own organizations, will be paid for imaging services in facilities owned and operated by them. The only prior restrictions for federal programs were those set by the Stark laws. And there is no restriction in state medical licensure language. The new law applies only to MRI, CT and PET and not to basic x ray, fluoroscopy, and ultrasound, which are legally defined as radiology. Nor does it apply to angiography or any other image-guided procedure which involves sticking a needle into a patient.

Like with most laws, the creation of supporting regulations and definitions will determine the impact of the legislative intent of this one on uses of medical imaging, how much, for what and by whom. ACR made its point that the growth of volume in imaging and the added radiation exposure is not medically justified by a lack of restrictions on who can do what kinds of imaging. How effective this legislation may be will require the continued efforts of radiologists. These efforts should be worthwhile.