

Advanced Diagnostic Imaging: Policy Options

Advanced diagnostic imaging can benefit patients when used appropriately - it detects diseases and conditions early and accurately, allows health care practitioners to direct patients to the health care services they need, and improves patient outcomes. But, when used inappropriately, advanced diagnostic imaging provides practitioners and patients with minimal clinical benefits, wastes scarce health care resources and can even jeopardize patient safety.

As a profitable service with growing demand and low barriers to entry, advanced diagnostic imaging has attracted many new providers. The growing volume of diagnostic medical imaging services prescribed by practitioners, including non-radiologists, raises potential concerns about patient safety, costs and implications for the health care industry.

Current Federal and NYS Regulations

There are regulations regarding radiation at both the federal and state levels. The United States Food and Drug Administration regulations cover the manufacture of radiation producing equipment; however, they do not regulate the use of this equipment. The use is generally under professional practice (i.e. medicine, dentistry etc) which are regulated by the states. The federal Atomic Energy Act of 1954 authorizes the Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. New York State (NYS), under this law, is an “agreement state” and as such the state agrees to adopt and enforce standards that are comparable or exceed the federal rules. Radiation producing equipment (all x-ray machines, fluoroscopy, computed tomography services (CT) and linear accelerators are registered with either the New York State Department of Health (NYS DOH) or the New York City Department of Health and Mental Hygiene (NYC DOHMH). All radioactive materials used in medicine are licensed as well by those same entities. Licensure is more restrictive than registration; however, both require the facility operator to maintain minimum quality and safety standards. The NYS DOH and NYC DOHMH inspect all these facilities periodically (every 1-4 years for medical use facilities) depending on their size and scope. The Departments’ regulations only authorize the review of quality and safety issues. There is no assessment or review of “need” or of appropriateness or other issues that do not relate to the quality of imaging, treatment or radiation safety.

Within the State, the Bureau of Environmental Radiation Protection (BERP) oversees the requirements of 10 NYCRR Part 16, the state regulations that are at least as stringent as the federal standards in 10 CFR 20-35. The Department of Health (BERP) has proposed an amendment to Part 16 that will require facilities operating computed tomography (CT) equipment to be accredited by the American College of Radiology (ACR) or the The Joint Commission or the Intersocietal Accreditation Commission (IAC, formerly ICACTL), within 12 months of the passage of that amendment. Approximately 75% of the facilities operating CT in NYS already meet this requirement, as it is identical to the Medicare Improvements for Patients and Providers Act

(MIPPA) requirement (discussed later in this report). Currently this draft rule is being reviewed by the Governor's Office. The draft rule would only apply to CT and not magnetic resonance imaging (MRI) or other aspects of advanced imaging.

Options

1. Define in Statute or Regulation Advanced Diagnostic Imaging

Most definitions of advanced medical imaging include magnetic resonance imaging service (MRI), computed tomography services (CT), positron emission tomography services (PET). The federal government's Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 defines advanced medical imaging as:

Section 135 (B) ADVANCED DIAGNOSTIC IMAGING SERVICES DEFINED- In this subsection, the term 'advanced diagnostic imaging services' includes--

'(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

'(ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

Pros:

- A standard definition would provide clarity as to what is included/excluded.
- Currently there is no statutory authority in New York State to regulate MRI, only ionizing radiation (x-ray and nuclear medicine).

Cons:

- Definition could soon become outdated.

State Models:

- Several states, including Minnesota, have already adopted a definition identical or very similar to the MIPPA definition.
- The state of Washington, defines it to mean "magnetic resonance imaging service, computed tomography services, positron emission tomography services, cardiac nuclear medicine services, and similar new imaging services."

2. Require Certificate of Need

Pros:

- Addresses the issue of supply and potential overutilization
- Creates barrier to market entry that can protect essential providers that serve Medicaid, uninsured or geographically underserved populations.
- Assist in preventing widespread penetration of expensive and potentially unnecessary technologies

Cons:

- Existing CON methodology would need to be extended to settings other than Article 28 facilities.
- This option may meet considerable resistance from physicians and other interested parties concerned about revenue loss, however this could be mitigated by grandfathering in existing facilities.
- If existing facilities are grandfathered in, the impact of CON on areas with excess supply will be minimized.

State Models:

FACILITIES AND SERVICES REGULATED BY CON

| Regulated Services | No. of States | States, Districts & Commonwealth |
|---|----------------------|--|
| Computed Tomography (CT) Scanners | 13 | AK, CT, HI, ME, MI, MO, NY, NC, RI, VT, VA, WV, DC |
| Magnetic Resonance Imaging (MRI) Scanners | 19 | AK, CT, HI, KY, ME, MA, MI, MS, MO, NH, NY, NC, RI, SC, TN, VT, VA, WV, DC |
| Mobile Hi Technology (CT / MRI / PET, etc) | 16 | AK, CT, HI, KY, ME, MI, MO, NH, NY, NC, RI, SC, VT, VA, WV, DC |
| Positron Emission Tomography (PET) Scanners | 20 | AK, CT, DE, GA, HI, KY, ME, MA, MI, MS, MO, NH, NC, RI, SC, TN, VT, VA, WV, DC |
| Ultrasound | 4 | HI, ME, VT, DC |

Source: AHPA, 2011; as found on the website of the NCSL – National Conference of State Legislatures

3. Require Licensure. (Refers to operating license. Professional and radioactive materials license already required).

Options:

- Require licensure as an Article 28
- Establish a new licensure category
- Require access for Medicaid and uninsured patients to be eligible for a license
- Require utilization of certified electronic health records that are connected to the Statewide Health Information Network for New York (SHIN-NY) and Regional Health Information Organizations (RHIOs).
- Require compliance with Statewide Policy Guidance for sharing of electronic patient health information.

Pros:

- Provides state oversight of quality/safety
- Creates barrier to market entry that can protect essential providers
- Can be used to create a lever to promote Medicaid/uninsured access
- Creates a barrier to prevent the widespread penetration of expensive and unnecessary technologies
- Patient imaging studies will be available to the patient's primary care provider, and any specialists involved in their care. Additionally, all providers involved in a patient's care will have information on the cumulative radiation exposure for the patient.
- Licensed facilities can command higher payments.

Cons:

- Licensed facilities can command higher payments.
- Licensure requirements may meet with resistance from physicians and other interested parties.

State Models:

- No states identified that license medical imaging facilities. X-ray equipment is registered, however, for safety and QA issues by almost all states, and the clinical uses by physicians is not generally restricted.
- New Mexico first state in 2009 to license medical imaging *professionals* that requires licensure for persons who perform ultrasound testing and other medical imaging procedures.
- Oregon has legislation that expanded medical imaging licensure requirements. With few exceptions, the practice of diagnostic medical imaging in Oregon requires a current state license; this requirement applies to radiography, radiation therapy, MRI, sonography and nuclear medicine technologists. Limited x-ray machine operators are required to have a current state permit.

- 41 states have licensure laws for radiologic technologists. NYS has licensed radiologic Technologists since 1965 and was one of the first states to do so. Only a few sparsely populated states do not require licensure.

4. Require Registration and Data Collection (e.g. practice size; services; payer mix)

Pros:

- Provides state with information on the marketplace
- Least burdensome for providers
- Less resource intensive for DOH
- Incremental approach that would permit collection of information relevant to regulatory strategy
- Would benefit future proposal on this topic to proceed with more accurate information on the NYS marketplace

Cons:

- Does not address risks associated with excess supply
- Does not address access for Medicaid beneficiaries or destabilization of essential providers.

State Models:

- No states identified that require registration of medical imaging providers.

5. Require accreditation by a nationally approved organization in order to be eligible for reimbursement from any source.

Options:

- Explore accrediting bodies providing data on providers that is collected as part of the accreditation process.

Pros:

- Ensure appropriate staffing patterns and quality and safety standards. Accreditation standards include: (1) provisions establishing qualifications of the physician; (2) standards for quality control and routine monitoring by a medical physicist; (3) qualifications of the technologist; (4) guidelines for personnel and patient safety; and (5) standards for initial and ongoing quality control using clinical image review and quantitative testing.
- Provides consumer protections to ensure consumers can obtain imaging records.
- May prevent providers from using equipment that is below current standards of care.
- Less burdensome for providers.
- Less DOH resources to license and survey sites.
- Consistent with CMS MIPPA requirements (see below).

- This will be required for CT in proposed DOH regulations. (Draft is currently with Governor’s Office, may get published by the end of 2013).
- May provide additional data on advanced imaging providers to the state.

Cons:

- Does not directly address overutilization.
- Does not address access for Medicaid beneficiaries or destabilization of essential providers.
- Cost to providers for accreditation.

Federal/State Models:

- The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 requires freestanding advanced diagnostic imaging facilities (performing CT, MRI, and nuclear medicine) that seek Medicare reimbursement to be accredited by January 1, 2012, by an organization designated by the U.S. Department of Health and Human Services. Approved accreditation organizations include: the Joint Commission; American College of Radiology; and Intersocietal Accreditation Commission.

MIPPA specifically excludes from the accreditation requirements imaging services such as X-rays, ultrasound, fluoroscopy, and diagnostic and screening mammography, with the later subject to quality oversight by the Food and Drug Administration under the Mammography Quality Standards Act.

The accreditation requirements only apply to the “supplier” of technical components (TC) of diagnostic imaging and not a physician's interpretation. The term supplier includes physicians (whether a sole-practitioner or a physician group practice), non-physician practitioners and facilities or other entities that are paid under the Medicare Physician Fee Schedule, including independent diagnostic testing facilities. The accreditation requirement does not apply to radiologists, per se. However, the interpreting physicians must meet the accreditation organization’s published standards for training and residency.

Hospitals are exempt from MIPPA requirements, since hospitals generally are not paid under the MPFS. Hospitals are subject to separate Medicare Conditions of Participation at 42 CFR 482.26 and 42 CFR 482.53, governing the provision of radiologic and nuclear medicine services.

MIPPA requires that the accreditation criteria address the following elements:

- Qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services.
- Qualifications and responsibilities of medical directors and supervising physicians, such as training in advanced diagnostic imaging services in a residency program, expertise obtained through experience or continuing medical education courses.

- Procedures to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished.
- Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier.
- Procedures to assist the Medicare beneficiary in obtaining the beneficiary's imaging records on request.
- Procedures to notify CMS of any changes to the modalities subsequent to the organization's accreditation decision.

The accreditation costs vary by accreditation organization. The average cost for one location and one modality is approximately \$3,500 every 3 years. The accrediting organizations are required to develop a plan for reducing the burden and costs of accreditation to small and rural suppliers.

- Minnesota laws require accreditation for reimbursement including health insurance, worker compensation insurance, automobile insurance, the state employee group insurance program, and other state health care programs. Must also demonstrate holding accreditation annually in reports to the Commissioner of Health. The requirement applies to nonhospital, physician, non-physician practitioners, surgical centers, and freestanding and mobile diagnostic imaging facilities. The accreditation will apply only to facility billing for the production of the images themselves (Technical Component (TC) of the services), and not to the physician's interpretation of the image.
- Proposed regulations amending 10 NYCRR 16 include an accreditation requirement similar to MIPPA for all CT facilities. These regulations are currently being reviewed by the Governor's Office. Currently MRI (non-ionizing radiation) is not regulated. Regulation of MRI and the operators of the equipment has been proposed in the past but with current DOH resources it would be difficult to accomplish.

6. Require Use of Evidence-Based Practice Guidelines

There are only a few bodies that have any significant guidelines on imaging. The American College of Radiology (ACR) has "Appropriateness Criteria" and is the primary reference. The ACR imaging guidelines are developed in consultation with dozens of other medical colleges to attain consensus on what exam is appropriate to confirm a diagnoses. The ACC (American College of Cardiology) has some specific guidelines dealing with interventional fluoroscopy studies and other cardiac imaging. Most other medical specialties refer to the ACR with respect to imaging.

The *Choosing Wisely* campaign, an initiative of the ABIM Foundation, developed in concert with many national organizations representing medical specialists, is encouraging physicians, patients and other health care stakeholders to discuss medical tests and procedures that may be unnecessary and even cause harm. Lists of tests or procedures commonly used that should be discussed or questioned have been created based on evidence-based recommendations.

Pros:

- Consistent with the policy direction of standardizing clinical care by using evidence- based medicine and consensus processes.
- Improve clinical benefit of diagnostic tests and improve patient safety by reducing patient exposure to unnecessary, potentially cancer-causing radiation. Potential alternative if accreditation is not an alternative.
- Reduce/eliminate unnecessary testing related costs.

Cons:

- The “in office ancillary service exemption” allows many other physicians who operate advanced imaging equipment to self-refer and bypass radiologists who may use these guidelines.
- Potential disagreement in the literature (or among physicians) regarding best practices/diagnostic tools.
- Guidelines change frequently which makes adoption of them in the regulatory process by incorporation by reference complicated.

State Models:

- The American College of Radiology that provide guidance on the use of diagnostic imaging and interventional radiology procedures. These recommendations are evidence based guidelines that are available for all physicians.
- The State of Washington has implemented evidence-based best practice guidelines or protocols that require all state-funded health care programs and services to implement evidence-based best practice guidelines or protocols applicable to advanced diagnostic imaging services, as well as the decision support tools to implement the guidelines or protocols.
- There are several pending revisions to Part 16 regulations are in progress including quality assurance updates on CT and radiation therapy.

7. Require radiation doses for CT scans be recorded in every patient’s medical record.

Pros:

- Electronic medical records could help doctors and patients keep track of radiation exposures.
- Increase practitioner consciousness about patient exposure to radiation and provide further incentive to avoid unnecessary imaging or at least monitor radiation doses.
- Reporting data on dose level and accidental overuse can prevent future radiation accidents and enhance scientific and biomedical research.
- NYS DOH regulations require x-ray facilities to maintain information on patient exposures already (non patient specific). Dose approximations are based on “reference man” and are not actual patient doses but are reasonable approximations that can give the practitioners interpreting the exam information with respect to relative patient dose.

- All modern CT systems are capable of doing this already, but some very old systems may have to be exempted or grandfathered. (Note: NYSDOH Center for Environmental Health staff expects that there are very few such systems in actual use).

Cons:

- EMRs may have to be modified to display this information from the PACS systems.
- Smaller institutions/practice may not have the resources.
- Statutory authority would need to be established to extend this to non-Article 28 providers. This could probably be achieved by tying it to Quality Assurance (QA) requirements in the existing radiation safety regulations.

State Models:

- California law requires radiation doses for CT scans be recorded in patient’s medical records and inadvertent overdoses be reported to the state immediately.
- The Conference of Radiation Control Program Directors (CRCPD) publishes Suggested State Regulations for the Control of Radiation, which may be voluntarily adopted by states. FDA will continue to engage CRCPD to update its Suggested State Regulations to address facility quality assurance and operator qualifications.
- Several updates to NYS regulations are in progress including quality assurance updates on CT and radiation therapy. These will improve overall quality assurance and may help to reduce patient doses.

8. Prohibit in-office self-referrals by amending federal or New York State Stark laws.

Pros:

- Directly addresses the issue of overutilization
- Reduces unnecessary costs

Cons:

- May meet considerable resistance from physicians and other interested parties concerned about revenue loss.

Federal/State Models:

- Congress passed “Stark I” in the Omnibus Budget Reconciliation Act of 1989 and expanded the scope in “Stark II” of the Omnibus Budget Reconciliation Act of 1993 in order to stop the practice of physician self-referrals. Physician self-referrals are defined as the referral of a patient by a physician to medical facilities in which the physician has a financial interest. There is an exception, however, to Stark II for in-office ancillary services. This exception is designed to protect physicians who provide certain designated health services that are generally ancillary to the medical service provided by their practice.

Because of the exception for in-office ancillary services in the Stark provisions, physicians can either open their own diagnostic imaging centers featuring highly utilized imaging modalities, such as MRI and CT, or purchase such equipment for their office. These types of arrangements allow physicians to bill insurance providers and Medicare for both the technical and professional components of these expensive scans and studies.

H.R. 1476 introduced on April 12, 2011, by Representative Jackie Speier (D-CA), the Integrity in Medicare Advanced Diagnostic Imaging Act of 2011, which would remove advanced diagnostic imaging services (MRI, CT, and PET) from the in-office ancillary services exception within the Stark self-referral law.

9. Change Medicaid Reimbursement Structure/Oversight to Control Costs

Pros:

- Potentially address excess supply
- Reduce unnecessary utilization
- Cause consolidation in the industry

Cons:

- May impact patient access and decrease benefits of early detection
- May meet considerable resistance from physicians and other interested parties concerned about revenue loss.

Federal/State Models:

- The federal Deficit Reduction Act of 2005 (DRA) capped the technical component of nonhospital Medicare payments at the hospital rate. The GAO estimates that the DRA saved \$1.7 billion in imaging expenses in 2007 and produced the first annual drop in Medicare spending on imaging since 2000. Its goal was to reduce imaging spending by \$2.8 billion by 2011.

Medical Imaging and Technology Alliance (MITA) analysis of Medicare claims data demonstrated that spending on imaging services for each Medicare beneficiary has dropped 13.2 percent since 2006, when significant imaging-specific reimbursement cuts from the Deficit Reduction Act began to be implemented, and imaging utilization per beneficiary declined by 3 percent in 2010. Contrary to the decline in imaging, spending for non-imaging Medicare services has grown by 20 percent since 2006 and non-imaging utilization increased 2 percent in 2010. The analysis also found that imaging is now a smaller portion of Medicare spending than it was in 2000.

- Commercial insurers have effectively employed radiology benefit management programs to avoid inappropriate use of advanced imaging. These programs generally apply only to outpatient services and frequently target nonhospital providers. Private insurers who use

the programs have recorded drops in imaging utilization from over 20 percent growth to single-digit growth—a result so effective that the GAO is considering recommending the same prescreening technique for Medicare.