

Advanced Diagnostic Imaging: Background on Use, Patient Safety, Costs and Implications for the Health Care Industry

Advanced diagnostic imaging can benefit patients when used appropriately - it detects diseases and conditions early and it allows health care practitioners to direct patients to the health care services they need. 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, defined for the purposes of this report to include diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine imaging such as positron emission tomography (PET), has attracted many new providers. There has been a dramatic proliferation in the volume of diagnostic medical imaging services prescribed by practitioners, including non-radiologists, raising concerns about patient safety, costs and implications for the health care industry.

Definition of Advanced Medical Imaging

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.

For the purposes of this report, the MIPPA definition will be used.

Concerns about Inappropriate Use and Overuse

The rapid pace of advances in the field of advanced medical imaging and a lack of knowledge on how best to leverage these technologies to appropriately serve the needs of each patient have created challenges to ensuring the most efficient diagnostic pathways and optimal outcomes for patients. Many providers, organizations and individual physicians argue that much of the utilization of advanced diagnostic imaging classified as “waste” by payers provides practitioners with information used to make early diagnoses of disease, limit complications, reduce long term costs and improve patient outcomes. Others argue that increased utilization of these services is a result of defensive medicine.

A report by John Iglehart in *The New England Journal of Medicine* (2009) indicated that, between 2000 and 2007, use of imaging studies grew faster than that of any other medical service in the Medicare population. A 2008 report, “Ensuring Quality through Appropriate Use of Diagnostic Imaging,” by America’s Health Insurance Plans claimed that 20% to 50% of all “high-tech” imaging provide no useful information and may be unnecessary.

A 2012 study published in *The Journal of the American Medical Association* by lead author Dr. Smith-Bindman, a radiologist and epidemiologist, looked at data on one million to two million patients a year from 1996 to 2010 in six health maintenance organizations across the United States, only some of whom had imaging. The number of CT scans tripled over the study period, to 149 per 1,000 patients in 2010, while the number of MRI’s quadrupled, to 65 per 1,000 patients in 2010. Since the health maintenance plans were part of integrated health care delivery systems that are clinically and fiscally accountable for the outcomes and health status of the population served, financial incentives did not seem to drive the increase. Rather, the changes seemed to derive from improvements in scanning technologies that made them more widely applicable, along with the fact that patients more often requested the scans. Also, the authors said, some doctors practiced “defensive medicine,” ordering tests to guard against malpractice lawsuits.

Multiple independent studies have concluded that as many as one-third of all advanced imaging services are either clinically inappropriate or they do not contribute to a physician's diagnosis or the ultimate health outcomes for the patient (National Imaging Associates). Often, traditional technology can be utilized, rather than an advanced imaging procedure, as a more efficient and economical diagnostic tool for physicians and other practitioners.

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 test 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. The *Choosing Wisely* Web site (www.choosingwisely.org) lists the tests and treatments that doctors should perform less often, with imaging prominent among them.

There are only a few professional societies that have 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 when an imaging technology is appropriate to confirm a diagnoses. The American College of Cardiology (ACC) has some specific guidelines addressing interventional fluoroscopy studies and other cardiac imaging. Most other medical specialties refer to the ACR with respect to imaging.

Patient Safety Issues

The overuse of imaging services poses a risk to patient safety. CT and PET scans use ionizing radiation that may expose people to potentially cancer-causing radiation. Because ionizing

radiation exposure is cumulative over a person's lifetime, excessive and unnecessary use of advanced imaging is cause for concern.

CT scans deliver high quality imaging and are becoming the dominant imaging modality. CTs, however, also represents the largest contributor to an increase in population radiation exposure based on reports from the National Council on Radiation Protection and Measurements. The usage of CT scans has more than tripled in the past decade and currently there are about 80 million CT scans performed in the United States each year.

MRI's do not use ionizing radiation but are not without risks. MRI risks are mainly due to the use of contrast agents, risks also associated with CT and other imaging methods involving administration of contrast.

The Smith-Bindman study published in *The Journal of the American Medical Association* states that while advanced medical imaging has undoubted benefits, allowing problems to be diagnosed earlier and more accurately, its value needs to be weighed against potential harms, which include a small cancer risk from the radiation.

Growth in Physician Offices and Physician Self-Referrals

Much of the growth in advanced diagnostic imaging has been concentrated in physician offices. This growth is partly attributed to physician self-referrals - defined as the referral of a patient by a physician to medical facilities in which the physician has a financial interest, or by patient self-referral. Physician self-referrals not only pose a conflict of interest, but also, in the case of diagnostic medical imaging, encourages inappropriate utilization of those services, and drives up health care costs. These types of arrangements may also limit competition and patient choice because patients may not be advised of other venues for obtaining imaging services, and adversely affect the practice of other health care providers.

A 2012 report on Medicare Part B Imaging Services from the Government Accountability Office (GAO) showed that between 2004 and 2010, the number of self-referred and non-self-referred advanced imaging services for MRI and CT services both increased, with the larger increase among self-referred services. Provider referrals substantially increased the year after they began to self-refer – that is, they purchased or leased imaging equipment, or joined a group practice that already self-referred, as opposed to doctors who refer patients to hospital and clinics. Providers that began self-referring in 2009 – referred to as switchers – increased MRI and CT referrals on average about 67 percent in 2010 compared to 2008.

Unnecessary Costs

GAO estimates that in 2010, providers who self-referred likely made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring. These additional referrals cost Medicare about \$109 million. The \$109 million is just the effect from Medicare patients.

If it is assumed that one-third of advanced imaging tests performed across the nation are unnecessary, the data strongly suggests that efficient radiology benefits management could cut America's radiology expenditures by \$20 billion to \$30 billion annually (National Imaging Associates).

Federal Omnibus Reconciliation Acts: Stark I and II

Congress included a provision known as “Stark I” in the Omnibus Budget Reconciliation Act of 1989 in order to stop the practice of physician self-referrals for clinical laboratory services under the Medicare program. The Stark Law prohibits a physician (or an immediate family member of such physician) who has a “financial relationship” (including compensation and investment / ownership interests) with an entity from referring (broadly defined) patients to the entity for clinical laboratory services covered by the Medicare program. The Centers for Medicare & Medicaid Services (CMS) regulate the Stark Law and issue regulations, guidance and advisory opinions.

Congress expanded the scope of Stark I and passed subsequent legislation known as “Stark II,” which was included in the Omnibus Budget Reconciliation Act of 1993. Stark II includes additional health services for which physician self-referral is prohibited and also applies the limitation to both Medicare and Medicaid.

In-office Ancillary Services Loophole. There is an exception, however, to Stark laws 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 advanced imaging centers or lease 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.

Following the enactment of Stark II, the Government Accountability Office (“GAO”), formerly the General Accounting Office, released a study specifically illustrating the inappropriate utilization of diagnostic medical imaging resulting from self-referral. Its data clearly indicated that physician owners of diagnostic imaging devices referred their patients more frequently, for more expensive services, than non-owners, including 54% more MRI scans, and 27% more CT scans. Despite the GAO study that essentially concurred with a significant portion of overutilization is due to the loophole, HHS has not been willing to alter the in-office ancillary service provision.

Federal Government Efforts to Control Quality

The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, required freestanding advanced diagnostic imaging facilities (performing CT, MRI, nuclear medicine) that seek Medicare reimbursement to be accredited by January 1, 2012. In addition to impacting

costs, MIPPA also sought to ensure the quality of advanced diagnostic imaging procedures. as discussed more fully below.

MIPPA defines advanced diagnostic imaging procedures as including diagnostic MRI, CT, and nuclear medicine imaging such as positron emission tomography (PET). The statute specifically excludes from the accreditation requirements imaging services such as X-rays, ultrasound, fluoroscopy, and diagnostic and screening mammography. Screening mammography is subject to quality oversight by the Food and Drug Administration under the Mammography Quality Standards Act.

MIPPA states that all suppliers of the technical component (TC) of advanced diagnostic imaging procedures must be accredited by an organization designated by the U.S. Department of Health and Human Services (the American College of Radiology, the Intersocietal Accreditation Commission, or The Joint Commission). The accreditation requirements apply to any "supplier" of advanced diagnostic imaging service. 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 requirements only apply to the technical component of diagnostic imaging and not a physician's interpretation. Therefore, 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.

Oral surgeons and dentists must be accredited if they perform the Technical Component of MRI, CT, or Nuclear Medicine for the Technical Component of the codes that require ADI accreditation. If a facility uses an accredited mobile facility, the Medicare supplier billing for the TC of ADI, must also be accredited. The accreditation requirement is attached to the biller of the services.

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.

Federal Government and Private Sector Efforts to Control Costs

Both public and private sector payers are taking action to slow the growth in imaging costs, particularly in the physician office sector.

The Deficit Reduction Act of 2005 (DRA) was the first major regulatory action to directly address imaging costs for the federal government. Its goal was to reduce imaging spending by \$2.8 billion by 2011. The main provision affecting imaging capped the technical component of nonhospital 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.

MIPPA was enacted by Congress in July 2008. This act increases regulatory oversight for physician office imaging by requiring all advanced imaging providers to be accredited by 2012 and calling for a demonstration program to ensure that advanced imaging is not overused as a diagnostic tool.

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. As a result, the GAO is reported to be considering recommending the same prescreening technique for Medicare. Some observers argue that payers are acting as nonclinician gatekeepers and that their decisions may often lack a firm foundation within the medical literature.

Industry Changes as a Result of Public and Private Acts

The two federal acts and changes on the commercial insurer side have significantly impacted physician office imaging. It is predicted that the net effect is likely to be a reduction in the number of physician offices offering advanced imaging.

In 2012, the Medicare Payment Advisory Commission (MedPAC) reported the recent downward trend in Medicare spending and utilization on medical imaging procedures by physicians (non-hospital imaging centers and physician offices) in its annual March Report to Congress.

MedPAC's annual report stated that imaging services declined by 2.5 percent in 2010. The data is consistent with a Medical Imaging and Technology Alliance (MITA) analysis of Medicare claims data. The MITA analysis 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 was 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.

MITA has noted that Congress and the Administration have cut imaging reimbursements eight times in six years, with payments for some services being reduced by over 60 percent, including bone density screenings, arm and leg artery x-rays, and MRIs of the brain. MITA further stated: "These cuts hurt patient access and undercut the benefits of early detection, making it harder for doctors to access these life-saving technologies."

In December 2011, researchers Levin, Rao and Parker of Thomas Jefferson University, found that from 2007 through 2009, there was significant curtailment of growth in CT and MRI, and the rate of nuclear medicine utilization actually decreased. The researchers indicate that the leveling was more pronounced in hospital outpatient facilities than in physicians' offices. They postulate that the slowdown is likely because that there has been a change in physicians' ordering patterns, possibly due to the influence of radiology business management companies and imaging guidelines promulgated by specialty societies.

These changes have begun to drive consolidation in the industry. It is reported that large national and regional imaging companies have been acquiring smaller multiunit players while local health systems have been buying independent diagnostic testing facility and imaging departments in physician practices.