Imaging Policies

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Medicare Policies Affecting Diagnostic Imaging Services

Over the past decade, Congress and the Centers for Medicare & Medicaid Services (CMS) have instituted a range of policies affecting diagnostic imaging services, especially "advanced diagnostic imaging services," such as MRI, CT, PET/CT, and other nuclear procedures (including SPECT).

In general, these policies have been adopted in response to the growth in utilization prior to 2006 and the perception that some of the procedures were medically unnecessary. Although utilization has leveled-off or declined since then, this perception has persisted among many policy leaders. The result has been continued efforts to reduce or otherwise limit payment and utilization. This issue brief summarizes the most significant changes affecting Medicare reimbursement for diagnostic imaging.

Background

Medicare pays for imaging services through several different payment systems.

	**Physician Fee Schedule (PFS)**	CMS uses this system to reimburse providers for interpreting diagnostic imaging tests **in all delivery settings and facilities**. It also uses this system to reimburse providers for the cost of equipment, non-physician clinical personnel (such as RTs), supplies, and overhead in **non-hospital facilities**, which include physicians' offices and diagnostic imaging centers. In Medicare parlance, such equipment, staff, and services are referred to as "Technical Component" (or "TC") Physician Fee Schedule services.
	**Hospital Outpatient Prospective Payment System (HOPPS)**	Medicare uses this system to pay for the equipment, non-physician clinical staff, supplies, and overhead associated with diagnostic imaging services that are provided in **hospital outpatient departments and certain "provider based" facilities**.
	**Inpatient Prospective Payment System**	Medicare pays for diagnostic imaging services for **hospital inpatients** as part of the payment made for the hospital admission.

The imaging policies that follow are organized by whether they influence care in non-hospital, hospital, or physician office settings.

Imaging Policy Changes in Non-Hospital Settings

Cap on Technical Component Payments

The Deficit Reduction Act of 2005 set a cap on the technical component (TC) of diagnostic imaging services performed in physician offices and diagnostic imaging centers (often referred to by Medicare as "independent diagnostic testing facilities" (IDTFs). The law limits the TC in these settings to the amount paid for comparable services provided in hospital outpatient facilities. The cap applies to virtually all radiology services, including MRI and CT.

- ✓ Effective Date: January 1, 2007.

- ✓ Impact: Initially, the cap primarily affected MRI, CT, PET and certain ultrasound services (especially vascular ultrasound), but not myocardial perfusion (SPECT) imaging. Although the cap is still in place, over time the TC allowances for many of the services that were initially affected decreased to an amount that is below the hospital outpatient rate for comparable services, making the cap inapplicable. Thus, the impact of this cap on Medicare allowances for imaging services overall has diminished.

Mandatory Accreditation for MRI, CT, and Nuclear Facilities

All non-hospital providers of MRI, CT, PET, and other nuclear procedures (including PET/CT and nuclear cardiology procedures) are required to be accredited by the Joint Commission, the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), or another accreditation organization approved by CMS. All of these accreditation organizations maintain quality standards that address the safety of the equipment as well as the safety of the patients and staff.

- ✓ Effective Date: January 1, 2012.

- ✓ Impact: The accreditation requirements vary depending on which of the three approved accreditation organizations is used, but the accreditation process may include:
  - Unannounced, random site visits;
  - Review of phantom images;
  - Review of staff credentialing records and maintenance records;
  - Review of beneficiary complaints and patient records;
  - Review of quality data and ongoing data monitoring; and
  - Triennial surveys

  For additional Q & A, see http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/CompilationOfE-NewsMessagesADIAccred.pdf.

Multiple Procedure Payment Reductions on Technical Component Services

Medicare reduces payment for the second and subsequent TC of MRI, CT, and certain (non-cardiology) ultrasound services by 50% when two or more of these services are provided to the same patient during a single session. This reduction applies even if the two procedures do not use the same modality (e.g., when an ultrasound and an MRI are performed in the same session).

For certain ophthalmic and cardiology procedures (including SPECT and echocardiography procedures), the TC for the second and subsequent TC is reduced by 25%, rather than 50%.

- ✓ Effective Date: The 50% reduction in the TC of the second and subsequent CT, MRI, and certain ultrasound services became effective on January 1, 2011. The 25% reduction in the TC of the second and subsequent cardiology and ophthalmic procedures became effective on January 1, 2013.

- ✓ Impact: This "multiple procedure payment reduction" or "MPPR" discourages the performance of more than one study on the same date of service in non-hospital settings. The initial impact was especially harsh for CT services. However, some of that has been mitigated by the creation of new codes that include procedures commonly performed together (e.g. abdominal and pelvic CTs), thus making the MPPR inapplicable.

  As for cardiology procedures, the primary service combination affected by this limitation appears to be myocardial perfusion (SPECT) and transthoracic echocardiography (TTE) performed on the same date of service. In addition, other relatively common service combinations affected by the MPPR include vascular and other ultrasound services performed on the same date as echocardiography.

Restrictions on Physician Self-Referral

The federal physician self-referral law (commonly called the "Stark Law") precludes a physician from sending patients who need diagnostic imaging and radiation therapy services to facilities in which the physician has a financial relationship. An exception to the law allows physicians in bona fide group practices to provide these services, but special provisions require group practices that self-refer for MRI, CT or PET to:

- inform the patient *in writing* that the patient may obtain the service from a clinician other than the referring physician, and
- provide the patient with a *list of suppliers* that furnish the service in the area.

- ✓ Effective Date: Disclosure of alternative facility requirements became effective on January 1, 2011.

- ✓ Impact: To date, no formal studies have been done on the impact of the disclosure policy on physician practices. However, the Stark Law generally remains a constraint on the types of ventures that can provide diagnostic imaging, radiation therapy, and many other services.

Equipment Utilization Rate Assumption

The formula for determining the TC for MRI and CT services in non-hospital settings assumes that such equipment is used 90% of the time—an increase from 75% which had been used in the formula for many years. The net effect of this change is a substantial decrease in Medicare reimbursement for the TC for MRI and CT in non-hospital settings.

- ✓ Effective Date: January 1, 2014
- ✓ Impact: Implementation of the 90% utilization assumption reduced Medicare payment for the TC of MRI and CT procedures by approximately $800 million in 2014, according to Congressional Budget Office. The 90% equipment utilization rate assumption is not used in determining Medicare payment for CT or MRI services provided by hospital outpatient departments.

Imaging Policy Changes in Hospital and Non-Hospital Settings

National Coverage Determination for FDG PET and FDG CT/PET

Although Medicare coverage policy for FDG PET and FDG PET/CT services was initially limited, CMS decided in 2009 to expand it for Medicare beneficiaries diagnosed with cancer. The ruling covered PET scans used in the initial evaluation of patients with most types of solid tumors and allowed for PET in subsequent evaluations for several cancer types. However, the 2009 coverage decision also required providers to participate in a device registry—the National Oncologic PET Registry (NOPR)—as a condition of coverage for a number of different cancer types and for subsequent evaluations.

In 2013, CMS eliminated the NOPR participation requirements. It also determined that it would allow PET scans under specific circumstances for certain cancer types that had not been included in its 2009 expansion of coverage. Specifically, it determined that Medicare would cover three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy. Coverage of any additional FDG PET scans (that is, beyond three) used in this way would have to be determined by local Medicare administrative contractors.

- ✓ Effective Date: Effective for claims with dates of service on and after June 11, 2013, the chart below summarizes national FDG PET coverage for oncologic conditions:

FDG PET for Solid Tumors and Myeloma Tumor Type	Initial Treatment Strategy (formerly "diagnosis" & "staging")	Subsequent Treatment Strategy (formerly "restaging" and "monitoring response to treatment")
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head and Neck (not thyroid or CNS)	Cover	Cover

FDG PET for Solid Tumors and Myeloma Tumor Type	Initial Treatment Strategy (formerly "diagnosis" & "staging")	Subsequent Treatment Strategy (formerly "restaging" and "monitoring response to treatment")
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover
Cervix	Cover with exceptions *	Cover
Small cell lung	Cover	Cover
Soft tissue sarcoma	Cover	Cover
Pancreas	Cover	Cover
Testes	Cover	Cover
Prostate	**Non-cover**	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions *	Cover
Melanoma	Cover with exceptions *	Cover
All other solid tumors	Cover	Cover
Myeloma	Cover	Cover
All other cancers not listed	Cover	Cover

*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.
*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.
*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.

Physician Fee Schedule Value-Based Modifier

The Affordable Care Act (ACA) required CMS to implement a system that adjusts physician payment to reflect the value of services they provide patients. The agency did this, beginning in 2015, through a "Value-Based Modifier" (VBM) in the Physician Fee Schedule that factors-in the cost and quality of services. It will be fully implemented to affect all physicians in 2017. However, the VBM will sunset on January 1, 2019, as many of the cost measurements used in the program, along with the fundamental focus of linking payment to performance, were incorporated into the Quality Payment Program mandated by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

- ✓ Effective Date: The VBM started implementation on January 1, 2015, for groups of 100 or more eligible professionals (with adjustments based on 2013 performance); January 1, 2016, for groups of 10 or more eligible professionals (based on 2014 performance); January 1, 2017 for solo practitioners and groups of fewer than 10

eligible professionals (based on 2015 performance). Sunset effective January 1, 2019.

- ✓ Impact: Under the VBM, practices are generally held harmless from negative reductions if they meet certain quality reporting requirements. Practices are evaluated in part on a "Cost Composite Score" that generally incentivizes practices to minimize the Medicare costs (including imaging costs) of beneficiaries.

New Quality Payment Program for Physician Services (including TC services)

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) mandates adoption of a new system, now being referred to by CMS as the "Quality Payment Program," for updating and adjusting payment rates for physicians' services (including TC services). The MACRA rule implements two paths to Medicare payment for physicians' services:

- ✓ The Merit-based Incentive Payment System (MIPS) and
- ✓ The Advanced Alternative Payment Models (AAPMs).

While the MACRA changes are often referred to as a "new" payment system for physicians services, this description is not entirely accurate. In fact, physicians' basic payment rates will continue to be based on the Physician Fee Schedule, and the basic methodology for determining the "relative value units" of particular services will remain substantially unchanged by MACRA. The new law focuses on updating and adjusting rates to reflect changes in costs and to reward physicians for better, more efficient care.

Under the MIPS part of the new system, Medicare will adjust the Physician Fee Schedule payment for physicians and certain other clinicians either up or down based on how they perform with respect to four performance categories: Quality, Advancing Care Information (currently Meaningful Use of Certified Electronic Health Records), Clinical Practice Improvement Activities, and Cost (currently the Value-Based Modifier noted earlier). Under the AAPM track, physicians can qualify for a 5% bonus from 2019 – 2024 on top their normal PFS reimbursement, and these physicians will be entitled to higher annual adjustments in later years. But in either case—MIPS or AAPM—the basis for these adjustments is still determined under the basic PFS methodology.

- ✓ Effective Date: January 1, 2019 (based on 2017 performance).

- ✓ Impact: It is anticipated that the vast majority of physicians will be paid under the MIPS rather than the AAPM track. For the first two years of the MIPS program, special transition rules will apply and, at least for the first year, it is anticipated that these special transition rules will result in most physicians receiving either neutral or slightly positive adjustments. Thereafter, it is anticipated that implementation of MIPS will work to the advantage of hospital-based practices and large group practices that have the resources to meet the MIPS program's formidable administrative and IT requirements. For this reason, some speculate that the new program will reinforce the already accelerating trend toward hospital employment of physicians, including many physicians who provide or refer for diagnostic imaging services.

Appropriate Use Criteria

The 2014 Protecting Access to Medicare Act directs CMS to require appropriate use criteria (AUC) for advanced diagnostic imaging services, which include MRI, CT, PET, and other nuclear medicine procedures (including nuclear cardiology). Beginning January 1, 2017, physicians and other health care professionals who order an advanced diagnostic imaging test must consult with AUC established by an approved Provider-Led Entity (PLE) using a qualified decision support (CDS) mechanism. To be paid for a test, the physician or other professional ordering it must document that they consulted with AUC. The law also directs CMS to require prior authorization beginning in 2020 for those professionals ordering a test who have shown especially low adherence to appropriate use criteria.

Despite the statutory mandate, CMS has announced that the program will not be launched until January 1, 2018. It is applicable to all advanced imaging services provided in non-hospital settings (e.g. diagnostic imaging centers and physician offices), hospital outpatient departments, and ambulatory surgical centers, but not in inpatient or emergency room settings.

- ✓ Effective Date: January 1, 2018

- ✓ Impact: Implementation of the AUC program could potentially dissuade referring physicians from ordering advanced diagnostic imaging procedures in outpatient settings.

Payment Reduction for Certain X-ray Imaging Procedures that Use Film

The Consolidated Appropriations Act of 2016 requires a 20% payment reduction in the PFS and HOPPs payment levels for x-rays that use film rather than digital technology. The reductions would apply to the technical component (and the technical component of the global fee) under the PFS and to the Ambulatory Payment Classification (APC) rate under HOPPS.

To implement this provision, CMS has created modifiers that providers must use to identify x-ray procedures using film. The same legislation mandates similar reductions for "an X-ray taken using computed radiography technology"(7% reduction in 2018-2022 and 10% thereafter).

- ✓ Effective Date: January 1, 2017 (x-ray using film); January 1, 2018 (x-ray using computed radiography).

- ✓ Impact: It is anticipated that the 20% reduction in Medicare payment for x-ray procedures that use film rather than digital technology will not have a significant impact because most x-ray services are already provided by digital technology.

Imaging Policy Changes in Hospital Settings

Packaging Imaging-Related Services in Hospital Outpatient Payment System

In 2008, Medicare decided to "package" payment for seven categories of ancillary items and services into the hospital outpatient payment classifications they support. The seven categories are:

- guidance services;
- image processing services;
- intraoperative services;
- imaging supervision and interpretation services;
- diagnostic radiopharmaceuticals;
- contrast media; and
- observation services.

Many of these are imaging services or items used in conjunction with imaging procedures, such as diagnostic radiopharmaceuticals and other drugs. For 2014, Medicare expanded the list of packaged items to include additional drugs and biologicals, certain clinical laboratory tests, and certain add-on and ancillary services, such as stress tests and stress agents used in conjunction with stress imaging procedures.

✓ Effective Date: Calendar year 2014 for stress tests, stress agents, additional drugs, and biologicals.

✓ Impact: Medicare's policies are intended to eliminate the financial incentive for providing ancillary and supportive services except as necessary for patient care. It is unclear whether these policies have affected utilization of such services.

Composite APCs for Multiple Imaging Procedures

Medicare makes a single, composite payment when a hospital performs more than one imaging procedure on the same day from an "imaging family" of services. The intent is to promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The five multiple imaging composite APCs established in 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

✓ Effective Date: January 2009

✓ Impact: While this policy is intended to encourage efficiency in providing multiple imaging services on the same date of service, it may have the effect of encouraging hospitals to refrain from scheduling necessary multiple imaging services on the same date of service.

Comprehensive APCs

First adopted in 2015, the Comprehensive Ambulatory Payment Classification (C-APC) can be viewed as the outpatient version of the diagnosis-related group (DRG) payment system, with one payment to cover all services provided during an outpatient encounter. This is part of a continuing movement toward packaging payments for services instead of paying "per service." The initial C-APCs included predominantly invasive procedures such as cardiac catheterization and stenting, pacemaker and defibrillator placement, and general, gynecologic, and orthopedic procedures. As a result of C-APCs, many imaging services performed in conjunction with common surgical procedures are not separately paid. Moreover, in the 2016 Hospital Outpatient Prospective Payment System Final Rule, CMS adopted a new C-APC for observation services, which generally eliminates separate payment for diagnostic imaging services performed in conjunction with many ER visits that include observation stays.

- ✓ Effective Date: Varies based on C-APC
- ✓ Impact: C-APCs, like other forms of "packaging," are intended to incentivize hospitals to provide only those diagnostic imaging and other "ancillary" services necessary to care for a Medicare outpatient.

Consolidation of Diagnostic Imaging APCs

Effective January 1, 2017, CMS consolidated all non-nuclear diagnostic imaging procedures into seven Ambulatory Payment Classifications (APCs), including four APCs for procedures performed without contrast and three APCs for procedures performed with contrast. The new Diagnostic Imaging APCs combine procedures using different imaging modalities (e.g. MRI, CT, x-ray, and ultrasound) and combine procedures in different medical specialty areas (e.g. radiology and cardiology). This APC consolidation is consistent with CMS' overall policy favoring fewer and broader APCs, and to make the Hospital Outpatient Prospective Payment System (HOPPS) more closely resemble the Inpatient Prospective Payment System. While the governing law requires APCs to include only procedures and services that are clinically comparable, CMS has taken the view that, at least in the context of HOPPS, diagnostic imaging procedures are all sufficiently comparable to be grouped together.

- ✓ Effective Date: January 2017
- ✓ Impact: The immediate impact of the Diagnostic Imaging APC consolidation is to reduce Medicare payment for ultrasound and MRI services while increasing it for CT and many common x-ray procedures. The swings in payment for individual procedures resulting from the consolidation is significant. Also of concern is CMS' view that diagnostic imaging procedures are fundamentally clinically interchangeable, since this viewpoint may have substantial payment and coverage implications over the long-term.

Hospital Quality Reporting Program for Outpatient Services

Medicare reduced payment for hospitals that fail to meet certain quality reporting requirements which include a wide range of quality measures for care provided in hospital outpatient departments. These may include measures of process, structure, outcome, and efficiency. As part of this, CMS has adopted a number of measures to reduce unnecessary

exposure to contrast materials and/or radiation, ensure adherence to evidence-based medicine and practice guidelines, and promote efficiency defined as "absence of waste."

- ✓ Effective Date: Varies by measure

- ✓ Impact: This policy is intended to reduce unnecessary utilization of contrast materials, multiple procedures, imaging of pre-operative patients undergoing minor surgery, and other practices that are not consistent with medical guidelines. Hospitals failing to meet these requirements are subject to a 2% reduction in hospital outpatient payment. The vast majority of hospitals meet the requirements.

Site Neutrality Reductions for Certain Off-Campus Hospital Outpatient Facilities

In many cases, Medicare payment for the services provided in physician offices and other non-hospital facilities, such as imaging centers, are substantially below the payment rates for identical services provided by hospitals through their own outpatient facilities that are located off of the hospital campus. To address this issue, in 2015 Congress enacted legislation that was intended to essentially "level the playing field" between these two categories of providers.

CMS adopted rules cutting reimbursement for hospital facilities located off the campus by some 50% of the otherwise applicable rate paid under the hospital outpatient payment system. The rules also required them to bill their services to Medicare using a new "PN" modifier. CMS did allow such facilities to be "grandfathered" if they billed for Medicare services before November 2, 2015 or if they are located with 250 yards of the main hospital campus or the remote location of a hospital. Stand-alone emergency rooms owned by hospitals are exempt as well, so any imaging done in these facilities would be paid under the hospital outpatient payment system. This payment policy will remain in effect in 2017 and 2018, but may be modified by CMS in 2019 and beyond.

Even those facilities that are "grandfathered" under these site-neutrality provisions will be impacted. For example, a change in ownership that does not involve the whole hospital or a change in location for non-emergency reasons may result in loss of "grandfather" status. On the other hand, CMS decided that grandfathered facilities will be able to increase the scope of services they provide without losing grandfather status—at least for now.

Effective Date: January 1, 2017

Impact: It appears likely that hospitals wishing to expand outpatient services will have a financial incentive to do so by adding-on to existing, grandfathered, off-campus hospital facilities or by adding capacity to on-campus facilities. To the extent that it is not possible to increase physical plant, there may be increased incentive to increase the through-put of imaging equipment located at grandfathered and on-campus imaging units.