

United States Government Accountability Office Report to Congressional Committees

April 2014

MEDICARE IMAGING ACCREDITATION

Effect on Access to Advanced Diagnostic Imaging Is Unclear amid Other Policy Changes

GAO Highlights

Highlights of GAO-14-378, a report to congressional committees

Why GAO Did This Study

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required that beginning January 1, 2012, suppliers that produce the images for Medicarecovered ADI services in office settings, such as physician offices, be accredited by an organization approved by CMS. MIPPA mandated that GAO issue two reports on the effect of the accreditation requirement. The first report, issued in 2013. assessed CMS's standards for the accreditation of ADI suppliers and its oversight of the accreditation requirement.

In this report, GAO examined the effect the accreditation requirement may have had on beneficiary access to ADI services provided in the office setting. To do this, GAO examined trends in the use of the three ADI modalities-CT; MRI; and NM, including PETprovided to Medicare beneficiaries from 2009 through 2012 that were subject to the ADI accreditation requirement. GAO also interviewed CMS officials, representatives of the Intersocietal Accreditation Commission and the American College of Radiology-the two CMS-approved accrediting organizations that accounted for about 99 percent of all accredited suppliers as of January 2013; and 19 accredited ADI suppliers that reflected a range of geographic areas, imaging services provided, and accrediting organizations used. In addition, GAO reviewed relevant literature to understand the context of any observed changes in ADI services throughout the period studied.

View GAO-14-378. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

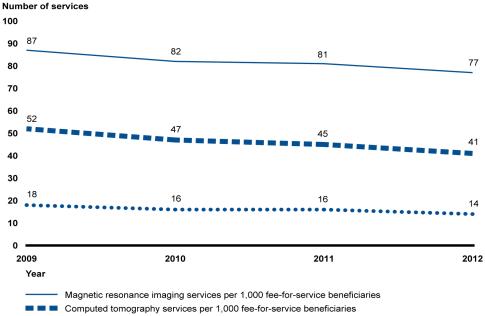
MEDICARE IMAGING ACCREDITATION

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What GAO Found

GAO found that the number of advanced diagnostic imaging (ADI) services provided to Medicare beneficiaries in the office setting—an indicator of access to those services—began declining before and continued declining after the accreditation requirement went into effect on January 1, 2012. In particular, the rate of decline from 2009 to 2010 was similar to the rate from 2011 to 2012 for magnetic resonance imaging (MRI); computed tomography (CT); and nuclear medicine (NM), including positron emission tomography (PET) services. These results suggest that the overall decline was driven, at least in part, by factors other than accreditation. The percentage decline in the number of ADI services provided in the office setting was generally similar in both urban and rural areas during the period GAO studied.

Number of Advanced Diagnostic Imaging Services in the Office Setting per 1,000 Medicare Fee-for-Service Beneficiaries, by Modality, 2009-2012



••••• Nuclear medicine services per 1,000 fee-for-service beneficiaries

Source: GAO analysis of CMS data

The effect of accreditation on access is unclear in the context of recent policy and payment changes implemented by Medicare and private payers. For example, the Centers for Medicare & Medicaid Services (CMS) reduced Medicare payment for certain CT and MRI services, which could have contributed to the decline in the number of these services. Officials from CMS, representatives from the accrediting organizations, and accredited ADI suppliers GAO interviewed suggested that any effect of the accreditation requirement on access was likely limited.

The Department of Health and Human Services stated that it had no comments on a draft of this report.

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Abbreviations

ACR	American College of Radiology
ADI	advanced diagnostic imaging
ATRA	American Tax Relief Act of 2012
CMS	Centers for Medicare & Medicaid Services
СТ	computed tomography
CPT	Current Procedural Terminology
FFS	fee-for-service
HCERA	Health Care and Education Reconciliation Act of 2010
IAC	Intersocietal Accreditation Commission
IDTF	independent diagnostic testing facility
MedPAC	Medicare Payment Advisory Commission
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MPPR	multiple procedure payment reduction
NM	nuclear medicine
OPPS	outpatient prospective payment system
PET	positron emission tomography
PPACA	Patient Protection and Affordable Care Act

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W. Washington, DC 20548

April 18, 2014

Congressional Committees

Advanced diagnostic imaging (ADI) services, such as computed tomography (CT), magnetic resonance imaging (MRI), and nuclear medicine (NM), allow physicians to diagnose life-threatening diseases like cancer and heart disease with greater speed and precision.¹ However, problems such as inadequately trained technologists or poorly functioning equipment can lead to duplicative or inaccurate imaging tests, unnecessary exposure to radiation, missed or inaccurate diagnoses, and inappropriate treatment. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required that beginning January 1, 2012, suppliers of the technical component of ADI services-specifically CT, MRI, and NM, including positron emission tomography (PET)²—be accredited by a designated accrediting organization in order to receive Medicare payment for these services.³ The requirement applies to ADI services provided in office settings, including physician offices and independent diagnostic testing facilities (IDTF), which are paid under the physician fee schedule.⁴ MIPPA accreditation does not apply to ADI services provided in institutional settings, including hospital inpatient or outpatient departments, which are not paid under the physician fee schedule.⁵ MIPPA outlined broad criteria that accrediting organizations should use to evaluate ADI suppliers, such as standards for qualifications

⁴IDTFs are facilities that are independent of a hospital and physician office and provide only outpatient diagnostic services.

¹There are six types of medical imaging capabilities, referred to as modalities: CT; MRI; NM; ultrasound; X-ray and other standard imaging; and procedures that use imaging, such as using ultrasound to localize a needle when performing a biopsy.

²MIPPA also provided for the inclusion of certain other diagnostic imaging services as specified by CMS in consultation with physician specialty organizations and other stakeholders.

³Pub. L. No. 110-275, § 135(a), 122 Stat. 2494, 2532 (codified at 42 U.S.C. § 1395m(e)). Medicare divides payment for ADI services into two components: the technical component, which is the production of the image, and the professional component, which is a physician's interpretation of the image and report on the findings.

⁵For this report, we use the term "institutional settings" to refer to services provided in settings such as hospital inpatient departments, hospital outpatient departments, and emergency rooms.

of personnel and standards to ensure the safety of beneficiaries and staff. The Centers for Medicare & Medicaid Services (CMS) administers and oversees the MIPPA accreditation requirement on behalf of the Secretary of Health and Human Services and has selected four organizations to serve as designated accrediting organizations—the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), The Joint Commission, and RadSite. In order to become accredited, ADI suppliers must select one of the accrediting organizations and undergo an accreditation review process to demonstrate that they meet the organization's standards. Although the accreditation requirement has the potential to improve the quality and safety of ADI services, it could potentially disrupt Medicare beneficiaries' access to ADI services if some suppliers are unwilling or unable to become accredited and, as a result, stop furnishing ADI services to Medicare beneficiaries.

MIPPA mandated that we issue a preliminary report in 2013 and a final report in 2014 on the effect of the accreditation requirement administered by CMS. Our first report, issued in May 2013, assessed CMS's standards for the accreditation of ADI suppliers as well as its oversight of the accreditation requirement.⁶ We found that CMS did not establish minimum national standards for the accreditation of suppliers of ADI services, but rather relied on its selected accrediting organizations to establish their own standards for quality and safety. We also found that CMS's oversight of the accreditation requirement was limited, as the agency focused its initial oversight efforts on ensuring that claims were paid only to accredited suppliers. We recommended, among other things, that the Administrator of CMS determine the content of and publish minimum national standards for the accreditation of ADI suppliers and develop an oversight framework for evaluating accrediting organization performance. The Department of Health and Human Services, which oversees CMS, concurred with our recommendations. This final report examines the effect, if any, of the accreditation requirement on beneficiary access to ADI services provided in the office setting.

To examine the effect the accreditation requirement may have had on beneficiary access to ADI services in the office setting, we identified trends in the number of these services provided to Medicare

⁶See GAO, *Medicare Imaging Accreditation: Establishing Minimum National Standards and an Oversight Framework Would Help Ensure Quality and Safety of Advanced Diagnostic Imaging Services*, GAO-13-246 (Washington, D.C.: May 31, 2013).

beneficiaries—an indicator of access—before and after the accreditation requirement went into effect. We examined these trends for each of the three ADI modalities—CT; MRI; and NM, including PET—using Medicare Part B Carrier claims from 2009 through 2012, which were the most recent data available at the time of our analysis.⁷ We limited our analysis to the technical component of those services that were provided in the office setting, as the professional component is not subject to the accreditation requirement. We further limited the ADI services in our study to those Current Procedural Terminology (CPT) codes that are subject to ADI accreditation, according to CMS.⁸ We excluded certain codes to ensure that our results reflected trends in the number of ADI services rather than changes in billing practices. Specifically, because CPT codes can change over time, we excluded any codes from CMS's list that were not billed at least once each year from 2009 to 2012. We also excluded CPT codes for any services that were combined, or "bundled," with another service at any time during our study period. After these exclusions, the codes we analyzed represented 171 of the 219 CPT codes (78 percent) subject to the ADI accreditation requirement and 75 percent of Medicare-covered ADI services in 2012 that were subject to the requirement.⁹ Using claims data for these CPT codes, we analyzed trends in the number of ADI services provided to Medicare beneficiaries. both at the national level and separately for urban and rural areas nationwide, before and after January 1, 2012, the date the accreditation requirement went into effect.¹⁰ Specifically, we examined the total number

⁹Of the 171 CPT codes for ADI services in our analysis, 37 codes were for CT services, 55 codes were for MRI services, and 79 codes were for NM/PET services.

¹⁰We defined urban areas as those within a Metropolitan Statistical Area (MSA). An MSA consists of one or more counties that contain a core urban area with a population of 50,000 or more as well as adjacent counties that have a high degree of social and economic integration with the urban core, as measured by commuting ties. We defined rural areas as those that were not located within an MSA.

⁷PET is a nuclear imaging technique in which radioactive substances are administered to a patient and tracked by a radiation detector to render time-lapse images of the substance as it moves through the body. We have combined both NM and PET for the purposes of this report.

⁸CPT codes and their definitions are developed by the American Medical Association and used by physicians and other providers to identify health care services for billing purposes. According to CMS officials, the list of CPT codes subject to ADI accreditation was developed with input from a CMS staff radiologist and radiologic technicians, and is updated annually to incorporate coding changes. At the time of our study, the most current list available of CPT codes subject to ADI accreditation was published in May 2012.

of CT, MRI, and NM/PET services in the office setting per 1,000 Medicare fee-for-service (FFS) beneficiaries each year from 2009 to 2012.¹¹ In 2012, approximately 21 percent of ADI services included in our study were provided in the office setting, while the remaining 79 percent were provided in the institutional setting. Although our analyses provide insight into the extent to which the accreditation requirement may have affected access to ADI services in the office setting, we did not determine whether a given level of utilization indicated sufficient access or whether changes in ADI service use were medically appropriate. We assessed the reliability of the data from CMS that we analyzed by reviewing relevant documentation and examining the data for obvious errors. We determined that the data were sufficiently reliable for the purposes of our study.

We also interviewed CMS officials, representatives of IAC and ACR—the two CMS-approved accrediting organizations that accounted for about 99 percent of all accredited suppliers as of January 2013,¹² and 19 accredited ADI suppliers to obtain their perspectives on the effect of accreditation on beneficiary access to ADI services.¹³ In addition, we reviewed relevant literature on trends in imaging to better understand the context of any observed changes in ADI services throughout the time period we studied.

We conducted this performance audit from July 2013 to April 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our

¹¹Examining the number of services per 1,000 Medicare FFS beneficiaries allows us to account for changes in the Medicare population, such as baby boomers who age into Medicare and/or beneficiaries who enroll in Medicare Advantage plans. To calculate the number of Medicare FFS beneficiaries from 2009 through 2012, we used the Master Beneficiary Summary File, a database that contains enrollment information for all Medicare beneficiaries enrolled in a given year.

¹²We did not interview suppliers accredited by The Joint Commission because of the small number of suppliers accredited by the organization as of January 2013. In addition, we did not include suppliers accredited by RadSite as it had not been designated as a CMS-approved accrediting organization when we interviewed suppliers.

¹³As a group, these suppliers represented both urban and rural locations, a range of states nationwide, and each of the three ADI modalities. Of the 19 suppliers we selected, 12 were located in urban areas, 3 were in rural areas, and 4 were in both rural and urban areas; these 19 suppliers were located in 14 states. The suppliers we interviewed were accredited by ACR (11 suppliers), IAC (5 suppliers), or both (3 suppliers).

findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Imaging Modalities	CT uses ionizing radiation and computers to produce cross-sectional images of internal organs and body structures. MRI uses powerful magnets, radio waves, and computers to create cross-sectional images of internal body tissues. NM uses radioactive materials in conjunction with an imaging modality to produce images that show both structure and function within the body. During an NM service, such as a PET scan, a patient is administered a small amount of radioactive substance, called a radiopharmaceutical or radiotracer, which is subsequently tracked by a radiation detector outside the body to render time-lapse images of the radioactive material as it moves through the body. Imaging equipment that uses ionizing radiation—such as CT and NM—poses greater potential short- and long-term health risks to patients than other imaging modalities, such as ultrasound. This is because ionizing radiation has enough energy to potentially damage DNA and thus increase a person's lifetime risk of developing cancer. In addition, exposure to very high doses of this radiation can cause short-term injuries, such as burns or hair loss.
ADI Accreditation Process and CMS Oversight	To become accredited, ADI suppliers must select a CMS-designated accrediting organization, pay the organization an accreditation fee, and demonstrate that they meet the organization's standards. As we noted in our May 2013 report, the accrediting organization fees vary. ¹⁴ For example, as of January 2013, ACR's accreditation fees ranged from \$1,800 to \$2,400 per unit of imaging equipment, while IAC's fees ranged

¹⁴See GAO-13-246.

from \$2,600 to \$3,800 per application.¹⁵ While the specific standards used by accrediting organizations vary, MIPPA requires all accrediting organizations to have standards in five areas: (1) qualifications of medical personnel who are not physicians and who furnish the technical component of ADI services, (2) qualifications and responsibilities of medical directors and supervising physicians, (3) procedures to ensure that equipment used in furnishing the technical component of ADI services meets performance specifications, (4) procedures to ensure the safety of beneficiaries and staff, and (5) establishment and maintenance of a quality-assurance and quality control program.¹⁶ To demonstrate that they meet their chosen accrediting organization's standards, ADI suppliers must submit an online application as well as required documents, which could include information on qualifications of personnel or a sample of patient images.¹⁷

MIPPA requires CMS to oversee the accrediting organizations and authorizes CMS to modify the list of selected accrediting organizations, if necessary. Federal regulations specify that CMS may conduct "validation audits" of accredited ADI suppliers and provide for the withdrawal of CMS approval of an accrediting organization at any time if CMS determines that the organization no longer adequately ensures that ADI suppliers meet or exceed Medicare requirements.¹⁸ CMS also has requirements for accrediting organizations. For example, accrediting organizations are responsible for using mid-cycle audit procedures, such as unannounced site visits, to ensure that accredited suppliers maintain compliance with

¹⁶MIPPA also provided for the inclusion of any additional standards CMS determines appropriate.

¹⁷Depending on their chosen accrediting organization, suppliers may also be subject to an on-site visit prior to accreditation.

¹⁸42 C.F.R. § 414.68(h).

¹⁵ACR's fees vary by modality, and discounted fees are available for facilities with more than one imaging unit and multiple modalities. IAC's fees vary by modality and cover the first unit of imaging equipment for MRI and CT; the fee for NM and PET covers all of the equipment. For MRI and CT, IAC offers discounted fees for each additional unit for facilities with more than one imaging unit. For all modalities, IAC offers a discount for facilities with more than one site. Neither organization's fees include additional costs that suppliers may incur to obtain accreditation, such as fees paid to a consultant or for the purchase of a phantom, which is a solid object designed to mimic critical imaging characteristics of patients, such as bone and tissue, that is imaged using suppliers' equipment to help assess performance parameters such as resolution and image uniformity.

	MIPPA's requirements for the duration of the 3-year accreditation cycle. According to CMS officials, five full-time staff are budgeted to oversee and develop standards for the ADI accreditation requirement. ¹⁹ Since our report was issued in May 2013, CMS has begun to gather input from stakeholders on the development of national standards for the accreditation of ADI suppliers, which it intends to develop by the end of 2014.
Medicare Payment and Billing Policies for ADI Services	Medicare payment for the technical component of ADI services is intended to cover the cost of the equipment, supplies, and nonphysician staff and is generally significantly higher than the payment for the professional component. The payment for the professional component is intended to cover the physician's time in interpreting the image and writing a report on the findings. Medicare reimburses providers through different payment systems depending on where an ADI service is performed. When an ADI service is performed in an office setting such as a physician's office or IDTF, both the professional and technical component are billed under the Medicare physician fee schedule. Alternatively, when the ADI service is performed in an institutional setting, the physician can only bill the Medicare physician fee schedule for the professional component, while the payment for the technical component is covered under a different Medicare payment system, according to the setting in which the service is provided. For example, the technical component of an ADI service provided in a hospital outpatient department is paid under the hospital outpatient prospective payment system (OPPS).

¹⁹CMS officials stated that these budgeted staff do not include staff involved with the processing of payments for ADI services.

Laws and Policies Designed to Control Imaging Utilization and Expenditures

The use of imaging services grew rapidly during the decade starting in 2000—MedPAC reported that cumulative growth between 2000 and 2009 totaled 85 percent²⁰—although the rate of growth has declined in recent years.²¹ Growth in imaging utilization and expenditures—including those for ADI services—prompted action from Congress, CMS, and private payers. Congress has enacted legislation to help ensure appropriate Medicare payment for ADI services; in some cases, this legislation has had the effect of reducing Medicare payment for the technical component of certain imaging services, such as the following:

- The Deficit Reduction Act of 2005 required that, beginning January 1, 2007, Medicare payment for certain imaging services under the physician fee schedule not exceed the amount Medicare pays under the OPPS.²²
- The Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA) and the American Tax Relief Act of 2012 (ATRA), reduced payment for the technical component of ADI services by adjusting assumptions, known as utilization rates, related to the rate at which certain imaging equipment is used.²³ These changes had the effect of reducing payments for the technical component of ADI

²²Pub. L. No. 109-171, § 5102(b), 120 Stat. 4, 39-40 (2006) (codified at 42 U.S.C. § 1395w-4).

²⁰MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 2013). See also GAO, *Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices*, GAO-08-452 (Washington, D.C.: June 13, 2008).

²¹A recent study found that the use of MRI in Medicare slowed from an annual growth rate of 14 percent during 2000 through 2005 to an average of 2.6 percent per year from 2006 through 2009. See D.W. Lee and F. Levy, "The Sharp Slowdown in Growth of Medical Imaging: An Early Analysis Suggests Combination of Policies was the Cause," *Health Affairs*, vol. 31, no. 8 (2012).

²³Pub. L. No. 111-148, § 3135(a), 124 Stat. 119, 436 (2010), as amended by Pub. L. No, 111-152, § 1107, 124 Stat. 1029, 1050, which we refer to collectively as PPACA; Pub. L. No. 112-240, § 635, 126 Stat. 2313, 2356. Utilization rates are taken into account when calculating technical component payments for ADI services. Higher utilization rates correspond to lower technical component payments. CMS used a 50 percent utilization rate in 2009. In 2010, CMS began transitioning to a 90 percent utilization rate, with the intent of completing the transition over a 4-year period, for equipment priced at over \$1 million—primarily affecting CT and MRI services. However, PPACA, as amended by HCERA, changed the rate to 75 percent beginning in January 2011. ATRA increased the utilization rate for this equipment to 90 percent beginning in January 2014.

services beginning in January 2011, with additional reductions scheduled to take effect in 2014.

CMS implemented additional changes to Medicare payment policy to help ensure appropriate payment for ADI services, which had the effect of reducing Medicare payment for certain imaging services. In January 2006 CMS began applying a multiple procedure payment reduction (MPPR) policy to the technical component of certain CT and MRI services, which reduces payments for these services when they are furnished together by the same physician, to the same patient, on the same day.²⁴ Beginning in January 2012, CMS expanded the MPPR by reducing payments for the lower-priced professional component of certain CT and MRI services by 25 percent when two or more services are furnished by the same physician to the same patient, in the same session, on the same day.

Private payers have also implemented policies designed to help control imaging utilization and expenditures. One such policy is the use of prior authorization, which can involve requirements that physician orders of imaging services meet certain guidelines in order to qualify for payment.²⁵ Further, best practice guidelines, such as ACR's Appropriateness Criteria, as well as efforts to educate physicians and patients about radiation exposure associated with imaging, have been used to promote the appropriate use of imaging services.²⁶

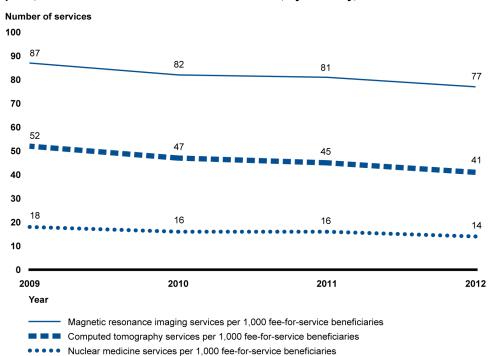
²⁴In calendar year 2006, CMS began reducing the payment for the technical component of the lower-priced imaging service by 25 percent when multiple CT or MRI services are performed on contiguous body parts during the same session. See Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, 70 Fed. Reg. 70116 (Nov. 21, 2005). In addition, PPACA increased the payment reduction from 25 percent to 50 percent beginning July 1, 2010. See Pub. L. No. 111-148, § 3135(b), 124 Stat. 119, 437.

²⁵Although as of August 2013 FFS Medicare did not require prior authorization, we recommended in 2008 that, to address the rapid growth in Medicare Part B imaging expenditures, CMS consider adopting prior authorization and privileging (that is, limiting the authority to order certain services to only providers in certain specialties). See GAO-08-452.

²⁶The ACR Appropriateness Criteria are evidence-based guidelines intended to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition.

Effect of Accreditation Requirement on Access to Advanced Diagnostic Imaging in Office Settings Is Unclear in Context of Other Policy Changes We found that the number of ADI services provided to Medicare beneficiaries in the office setting—an indicator of access to those services—began declining before and continued declining after the accreditation requirement went into effect on January 1, 2012 (see fig. 1). In particular, the rate of decline from 2009 to 2010 was similar to the rate from 2011 to 2012 for the CT; MRI; and NM, including PET, services in our analysis. These results suggest that the overall decline was driven, at least in part, by factors other than accreditation. For example, the number of CT services per 1,000 FFS beneficiaries declined by 9 percent between 2009 and 2010, 4 percent between 2010 and 2011, and 9 percent between 2011 and 2012.

Figure 1: Number of Advanced Diagnostic Imaging Services in the Office Setting per 1,000 Medicare Fee-for-Service Beneficiaries, by Modality, 2009-2012



Source: GAO analysis of CMS data.

Notes: To examine the total number of advanced diagnostic imaging (ADI) services provided in the office setting per 1,000 Medicare fee-for-service beneficiaries, we calculated the number of claims for the technical component of computed tomography; magnetic resonance imaging; and nuclear medicine, including positron emission tomography services each year. Our results were limited to selected services subject to the ADI accreditation requirement. We excluded services that were not billed at least once each year between 2009 and 2012 as well as those services that were combined, or "bundled," with another service during this time period. The codes we analyzed represented 171 of the 219 Current Procedural Terminology codes (78 percent) subject to the ADI accreditation requirement and provided to Medicare beneficiaries in 2012.

The percentage decline in the number of ADI services provided in the office setting was generally similar in both urban and rural areas during the period we studied, although we found that substantially more services were provided in urban areas than in rural areas (see fig. 2). The number of ADI services per 1,000 FFS beneficiaries provided in urban areas declined by 7 percent between 2011 and 2012, while the number of services provided in rural areas declined by 8 percent. In addition, 148 services were provided per 1,000 FFS beneficiaries in urban areas in 2012, as compared to 81 services per 1,000 beneficiaries in rural areas. One reason the use of ADI services in the office setting was relatively low in rural areas was that a smaller percentage of ADI services in these areas were provided in the office setting. Specifically, in 2012, about 14 percent of ADI services in rural areas were provided in the office setting, compared to 23 percent of ADI services in urban areas. See appendix I for trends in the number of urban and rural ADI services by modality.

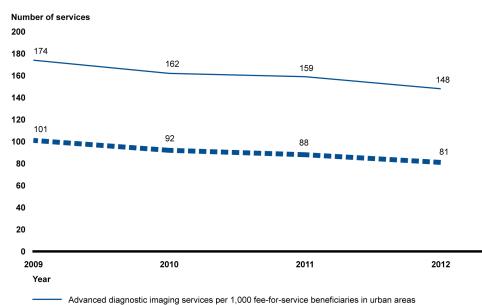


Figure 2: Number of Advanced Diagnostic Imaging Services in the Office Setting per 1,000 Medicare Fee-for-Service Beneficiaries, by Urban/Rural Location, 2009-2012

Advanced diagnostic imaging services per 1,000 fee-for-service beneficiaries in rural areas

Source: GAO analysis of CMS data.

Notes: To examine the total number of advanced diagnostic imaging (ADI) services provided in the office setting per 1,000 Medicare fee-for-service beneficiaries, we calculated the number of claims for the technical component of computed tomography; magnetic resonance imaging; and nuclear medicine, including positron emission tomography services each year. We defined urban areas as those within a Metropolitan Statistical Area (MSA) and rural areas as those that were not located

within an MSA. Our results were limited to selected services subject to the ADI accreditation requirement. We excluded services that were not billed at least once each year between 2009 and 2012 as well as those services that were combined, or "bundled," with another service during this time period. The codes we analyzed represented 171 of the 219 Current Procedural Terminology codes (78 percent) subject to the ADI accreditation requirement and 75 percent of ADI services subject to the requirement and provided to Medicare beneficiaries in 2012.

The effect of accreditation on access—as illustrated by our analysis of the trends in ADI services in the office setting—is unclear in the context of recent policy and payment changes as well as other factors affecting the use of imaging services. In particular, the decline in ADI services occurred amid the implementation in recent years of public and private policies to slow rapid increases in imaging utilization and spending. Factors, including public and private policies, that may have played a role in the decline in ADI service utilization include the following:

- Medicare payment reductions. Reductions in Medicare payment may have contributed to the decline in ADI services between 2009 and 2012 as reduced fees may affect physicians' willingness to provide imaging services for Medicare beneficiaries.²⁷ For example, PPACA and ATRA reduced payment for the technical component of ADI services by adjusting assumptions related to the rate at which certain imaging equipment is used. In addition, CMS implemented a 25 percent payment reduction for the professional component of certain CT and MRI services under the MPPR, effective January 1, 2012—the same date the accreditation requirement went into effect.
- Prior authorization. Studies have suggested that increased use of prior authorization policies among private payers in recent years has contributed to a decrease in ADI services provided to privately insured individuals.²⁸ These policies may have had a spillover effect on Medicare, thus contributing to the decline in ADI services provided to Medicare beneficiaries from 2009 to 2012.

²⁷Some studies have also noted that payment reductions may result in providers increasing their volume of services to counter their loss in revenue from individual services. For example, see Congressional Budget Office, *Factors Underlying the Growth in Medicare's Spending for Physicians' Services* (Washington, D.C.: June 2007); and Stephen Zuckerman, Stephen A. Norton, and Diana Verrili, "Price Controls and Medicare Spending: Assessing the Volume Offset Assumption," *Medical Care Research and Review*, vol. 55, no. 4 (December 1998).

²⁸For example, see Lee and Levy, "The Sharp Slowdown in Growth of Medical Imaging," and J.M. Mitchell and R.R. LaGalia, "Controlling the Escalating Use of Advanced Imaging: The Role of Radiology Benefit Management Programs," *Medical Care Research and Review*, vol. 66, no. 3 (2009).

 Radiation awareness. Studies have suggested that increased physician and patient awareness of the risks associated with radiation exposure may have led to a decline in CT and NM services provided to Medicare beneficiaries.²⁹

Although the effect of the accreditation requirement on access to ADI services in the office setting is unclear, in part because the requirement was implemented concurrently with other policy changes, CMS officials, accrediting organization representatives, and accredited ADI suppliers we interviewed suggested that any effect on access was likely limited. Specifically, CMS officials overseeing the accreditation requirement reported that they were not aware of any access to care issues resulting from the accreditation requirement and noted that there had been no beneficiary complaints regarding a lack of access to ADI services since the requirement went into effect. According to the officials, CMS performed outreach to ADI suppliers before the accreditation requirement went into effect to help ensure that it would not limit beneficiaries' access to ADI services. In addition, most of the accredited suppliers we interviewed indicated that accreditation had not had a negative effect on beneficiary access to ADI services, with 17 out of 19 suppliers, including those located in urban and rural areas, reporting that accreditation had not affected the number of services they provided.³⁰ Similarly, IAC and ACR representatives noted that the accreditation requirement likely had not had an adverse effect on beneficiary access to ADI services, and indicated that recent declines in imaging utilization largely stemmed from factors unrelated to accreditation, including reductions in Medicare and private payer reimbursement as well as increased awareness of the risks of radiation exposure. IAC and ACR representatives noted that the accreditation requirement may create a potential barrier for certain new ADI suppliers over time because they must provide imaging services without Medicare reimbursement for up to 6 months as they obtain the images and required documentation necessary to complete the

²⁹For example, see Lee and Levy, "The Sharp Slowdown in Growth of Medical Imaging," and Harvey L. Neiman Health Policy Institute, *Medical Imaging: Is the Growth Boom Over*? (Reston, Va.: American College of Radiology, 2012). CT and NM services use ionizing radiation, thus exposing patients to the potential health risks associated with radiation, while MRI services do not.

³⁰Of the remaining two suppliers, one indicated that it was unsure whether accreditation has affected the number of services it provides, while the other indicated that accreditation may have led to a slight increase in the number of services it provides.

	accreditation process. ³¹ According to the representatives, IAC and ACR requested that CMS provide a provisional accreditation period for new suppliers that would allow them to obtain reimbursement for applicable ADI services while they undergo the accreditation process. According to CMS, it does not have the authority under MIPPA to provide provisional accreditation, as the statute only allows accredited suppliers to be paid for the technical component of ADI services beginning on January 1, 2012. ³²
Agency Comments	We provided a draft of this report for review to the Department of Health and Human Services, and the agency stated that it had no comments.
	We are sending copies of this report to the Secretary of Health and Human Services and appropriate congressional committees. The report will also be available at no charge on the GAO website at http://www.gao.gov.
me at (202) 512-7114 or cosgrov Offices of Congressional Relation the last page of this report. GAO	If you or your staff have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.
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	³¹ IAC and ACR require suppliers to submit, among other items, a sample of actual patient images in order to apply for accreditation. New ADI suppliers must therefore open facilities, hire staff, purchase imaging equipment, and provide imaging services until they obtain the necessary images to undergo the accreditation process. Suppliers are unable to receive reimbursement from Medicare for ADI services that are subject to the accreditation requirement until their accreditation has been approved.

³²CMS does provide provisional accreditation for 120 days for accredited suppliers that purchase additional equipment or expand their services by adding locations or modalities.

List of Committees

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The Honorable Fred Upton Chairman The Honorable Henry A. Waxman Ranking Member Committee on Energy and Commerce House of Representatives

The Honorable Dave Camp Chairman The Honorable Sander M. Levin Ranking Member Committee on Ways and Means House of Representatives

Appendix I: Advanced Diagnostic Imaging Services in Office Settings per 1,000 Medicare FFS Beneficiaries, 2010-2012

Geographic designation	Year	Computed Tomography (CT)	Magnetic Resonance Imaging (MRI)	Nuclear Medicine (NM)/Positron Emission Tomography (PET)
Urban	2009	57.3	96.7	19.7
	2010	52.3	91.4	17.9
	2011	50.3	90.8	17.3
	2012	46.2	86.1	15.8
Rural	2009	33.4	55.2	12.0
	2010	30.3	51.3	10.5
	2011	28.8	49.5	10.0
	2012	25.4	46.2	9.4

Source: GAO analysis of CMS data.

Notes: To examine the total number of advanced diagnostic imaging (ADI) services provided in the office setting per 1,000 Medicare FFS beneficiaries, we calculated the number of claims for the technical component of CT; MRI; and NM, including PET services each year. We defined urban areas as those within a Metropolitan Statistical Area (MSA) and rural areas as those that were not located within an MSA. Our results were limited to selected services subject to the ADI accreditation requirement. We excluded services that were not billed at least once each year between 2009 and 2012 as well as those services that were combined, or "bundled," with another service during this time period. The codes we analyzed represented 171 of the 219 Current Procedural Terminology (CPT) codes (78 percent) subject to the ADI accreditation requirement and 75 percent of ADI services subject to the requirement and provided to Medicare beneficiaries in 2012.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact	James Cosgrove, (202) 512-7114 or cosgrovej@gao.gov
Staff Acknowledgments	In addition to the contact named above, Phyllis Thorburn, Assistant Director; William Black, Assistant Director; Priyanka Sethi Bansal; William A. Crafton; Richard Lipinski; Beth Morrison; Jennifer Whitworth; and Rachael Wojnowicz made key contributions to this report.

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