



**STATEMENT OF**

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**ON**

**ADVANCED DIAGNOSTIC IMAGING ACCREDITATION**

**BEFORE THE**

**U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE**

**SUBCOMMITTEE ON HEALTH**

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U.S. House of Representatives Committee on Energy and Commerce  
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Chairman Pitts, Ranking Member Pallone and Members of the Subcommittee, I am pleased to be here today to discuss the role of the Centers for Medicare & Medicaid Services (CMS) in accrediting suppliers of advanced imaging services. The Department of Health and Human Services takes very seriously our role in ensuring the health and well-being of all Medicare beneficiaries and CMS in particular is working to ensure that Medicare beneficiaries receive advanced diagnostic imaging services from suppliers that meet quality and safety standards.

Medicare Improvements for Patients and Providers Act Requirements

Congress, in section 135 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275), amended the Social Security Act to include a new section 1834(e) in response to concerns about the quality and safety of imaging services provided under Medicare. This new imaging accreditation provision specifies that beginning January 1, 2012 Medicare can only make payments to the supplier of the technical component of advanced diagnostic imaging services if the supplier is accredited by an accreditation organization designated by the Department of Health and Human Services (HHS). The technical component is the taking of the images (as contrasted with the professional component comprised of a physician's interpretation of the images).

Per the statute, this requirement applies to all physicians, non-physician practitioners, as well as other entities that are paid under the Medicare Physician Fee Schedule for furnishing the technical component of advanced diagnostic imaging services. The accreditation requirement applies only to the physician, practitioner, facility, or entity that furnishes the technical component of advanced diagnostic imaging services, not to the professional component of the service.

The statute requires that the imaging accreditation requirement apply to the following advanced diagnostic imaging procedures: Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and nuclear medicine imaging, including positron emission

tomography (PET). The law also gives the Secretary flexibility to expand the scope of diagnostic imaging services to which the imaging accreditation could apply, but the statute specifically excludes X-ray, ultrasound and fluoroscopy procedures. Diagnostic and screening mammography, which is subject to quality oversight by the Food and Drug Administration (FDA) under the Mammography Quality Standards Act, is not covered under the MIPPA provision. The imaging accreditation requirement has been in place since January 2012, and the Secretary has not expanded the requirement to other diagnostic imaging services.

MIPPA requires the Secretary to approve organizations that then accredit advanced diagnostic imaging suppliers. The law requires that the accrediting organizations establish standards in six specified areas covering:

- Qualifications of non-physician personnel furnishing the technical component of advanced imaging services;
- Qualifications and responsibilities of medical directors and supervising physicians;
- Procedures to ensure that the equipment used in furnishing the technical component of imaging service meets performance specifications;
- Standards that require the supplier to have procedures in place to ensure the safety of both persons who furnish the technical component of the test and beneficiaries who receive the test;
- Establishment and maintenance of a quality assurance and quality control program to ensure the reliability, clarity, and accuracy of the technical quality of the diagnostic images produced by the supplier; and
- Other factors as the Secretary determines appropriate.

While this statute does not explicitly require it, the personnel standards that were established by the accrediting organizations include State licensure or State certification requirements where they exist. In addition, where there is no State licensure or certification requirement, only technicians/technologists that meet the education and experience requirements established by the accrediting organizations are considered qualified personnel.

CMS believes that the MIPPA accreditation provisions strike a careful balance by focusing new oversight and attention on areas of imaging that pose the greatest risk to patients in a manner that minimizes the burden imposed on physicians and others who furnish imaging services. The exclusion of X-rays and ultrasound from the accreditation requirement limits burdens on individual physician practices, especially primary care physicians who may perform some X-rays or other imaging services in their offices, yet do not provide more advanced diagnostic imaging services.

In MIPPA, Congress adopted a private sector approach to imaging accreditation. Instead of prescribing requirements for imaging facilities or tasking the Secretary of HHS with developing specific standards of care, the statute called for CMS to evaluate and approve accrediting organizations that establish specific health and safety standards and that ensure these standards are met by imaging suppliers. This approach enhances patient safety without the need for additional direct Federal government oversight of every supplier of advanced diagnostic imaging that serves Medicare beneficiaries.

#### Implementation of Medicare Improvements for Patients and Providers Act Provisions

To implement these provisions, CMS issued a Notice of Proposed Rulemaking (NPRM) on July 13, 2009.<sup>1</sup> Several stakeholders submitted comments in response to the NPRM, with most affirming their support for the requirement. The rule was finalized on November 25, 2009, as a part of the Medicare Physician Fee Schedule final rule with comment period for calendar year 2010 (74 FR 62189) and provided a more detailed description of the application requirements that CMS would consider in selecting accreditation organizations.

CMS also issued a Request for Proposals (RFP) on November 25, 2009, requesting applications for organizations interested in applying to be an accrediting body. CMS received three applications from this solicitation, which were reviewed by an internal professional panel. MIPPA established a number of criteria for consideration in the selection of accreditation organizations including:

- The ability of the organization to conduct timely reviews of accreditation applications;

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<sup>1</sup> <http://www.gpo.gov/fdsys/pkg/FR-2009-07-13/pdf/E9-15835.pdf>

- Whether the organization has established a process for the timely integration of new advanced imaging services into the organization's accreditation program;
- Whether the organization uses random site visits, site audits or other strategies for ensuring accredited suppliers maintain adherence to the accreditation standards;
- The ability of the organization to take into account the capacities of suppliers' location in rural areas; and
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

Based on these criteria for selecting accrediting organizations, and an assessment of how well the specific accreditation requirements met the statutory criteria, on January 26, 2010, CMS announced the selection of three national accreditation organizations that met all MIPPA standards and requirements: the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and The Joint Commission (TJC). Imaging suppliers work directly with one of the three accrediting organizations to demonstrate that they meet quality standards and receive accreditation. The accreditation process may include several different components, including: an unannounced site visit; review of staff credentialing and records of equipment maintenance; review of quality data, patient health records, and beneficiary complaints; and ongoing data monitoring. CMS launched a variety of outreach initiatives to help educate suppliers about the accreditation requirements. Efforts included national provider calls, Medicare Learning Network articles, outreach messages on CMS' provider listservs, and online resources with additional information on the requirements.<sup>2</sup>

The accreditation requirements became effective on January 1, 2012. CMS is not aware of any disruptions in beneficiary access to diagnostic imaging services that resulted from the implementation of the MIPPA requirements. MIPPA also grandfathered facilities that were previously accredited by one of the selected accreditation organizations; as a result, previously-accredited suppliers did not need to seek new accreditation to comply with MIPPA. However, these suppliers must continue to maintain their accreditation. As of May 25, 2012, there are

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<sup>2</sup> <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/AdvancedDiagnosticImagingAccreditation.html>

15,821 accredited suppliers, with a total of 61,434 locations, with a majority of locations (41,019) accredited by the ACR.

As part of our commitment to safeguarding Medicare beneficiaries and ensuring they maintain access to quality care, CMS routinely verifies that only accredited suppliers are eligible to receive Medicare payments for advanced diagnostic imaging services. By verifying accreditation status before paying claims, CMS can quickly identify any supplier that may have had their accreditation revoked for any violation and take appropriate action to stop Medicare payment.

### Conclusion

Since the beginning of this year, the advanced diagnostic imaging accreditation requirements included in MIPPA have helped CMS ensure that all Medicare beneficiaries are receiving high quality, safe diagnostic advanced imaging services. As physicians increasingly rely on advanced imaging services to diagnose complex medical conditions, this requirement provides beneficiaries with assurance that imaging facilities have well-trained staff using safe machines and procedures to conduct diagnostic imaging tests. CMS will continue to work to fulfill our statutory requirements to oversee this accreditation process and ensure that accreditation organizations, suppliers and beneficiaries continue to have the information they need on these requirements.

Thank you for the opportunity to testify today; I would be pleased to answer any questions you may have.