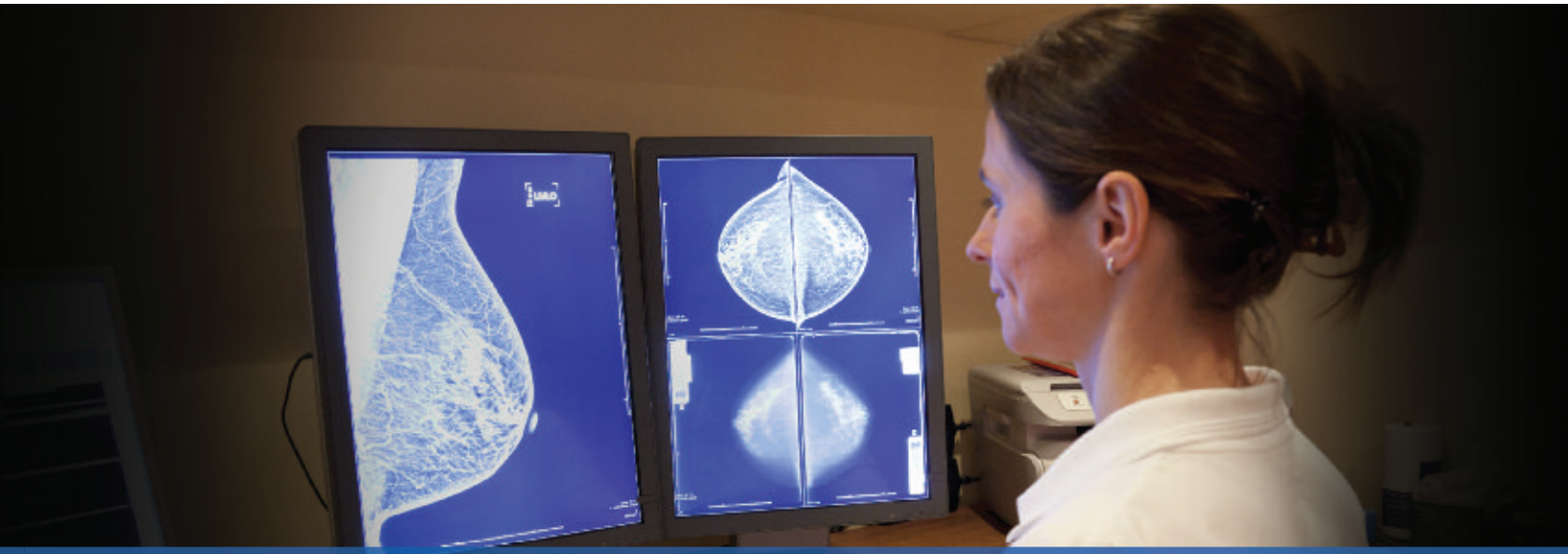

Is It Time to Scrap Your IDTF Enrollment Status?

New Bundled Breast Biopsy Codes Wreak Havoc on IDTFs Performing Women's Imaging Services.

BY THOMAS W. GREESON AND PAUL PITTS

Imaging centers enrolled in the Medicare program as Independent Diagnostic Testing Facilities, or IDTFs, face a growing number of challenges. For years IDTFs have been subject to a specific set of rules that are more restrictive than those applied to similar imaging centers enrolled in the Medicare program as physician offices (which are sometimes referred to as radiology clinics). For example, IDTFs are prohibited from sharing space with another Medicare provider, subject to compliance surveys, and required to disclose and update details of their operations in the Medicare enrollment applications (the CMS 855B form). Important to women's imaging, IDTFs are only permitted to perform and bill a subset of testing services within the 70000 series CPT codes.

IDTFs are often unable to bill the Medicare program for services important to women, such as percutaneous needle breast biopsies or interventional procedures, because the codes for these procedures are not included in the list of diagnostic tests Medicare expressly permits in the IDTF setting. Even for the minority of IDTFs that were previously able to bill for breast biopsies, changes in the 2014 Medicare Physician Fee Schedule have limited their ability to continue to do so. The 2014 update to the Medicare Physician Fee Schedule deleted codes 77031 and 77032 for stereotactic and mammographic guidance for breast biopsies. In place of these codes CMS added new 19000 series surgical codes for breast biopsy procedures and imaging guidance, none of which are billable by an IDTF. Although the RBMA and others have asked CMS to permit IDTFs to perform and bill breast biopsy procedures, CMS officials have not yet indicated whether they are willing to revise these policies. The new breast biopsy codes have not impacted those imaging centers enrolled in the Medicare program as physician offices or clinics. Because these offices or clinics are exempt from the IDTF rules, they may provide both breast biopsies and interventional procedures. Furthermore, imaging centers enrolled as physician offices or clinics are paid the same rates under the Medicare Physician Fee Schedule as imaging centers enrolled as IDTFs, despite the additional regulatory requirements and limitations placed on IDTFs.

So why, then, be enrolled as an IDTF? For some imaging centers there is no alternative. Imaging centers owned by non-physicians or operated independently of a physician practice must enroll as an IDTF and comply with the limits imposed on IDTFs. For other imaging centers, particularly those owned by radiologists, there is a choice of enrollment between an IDTF and a physician office or clinic. For imaging centers currently enrolled as an IDTF, but not operating separately from a physician office or clinic, the enrollment status may be changed if permitted by the imaging center's Medicare Administrative Contractor. The central factor in determining whether IDTF enrollment is required for any particular imaging center is whether the center is truly "independent" from a physician office or hospital.

IDTF Enrollment

IDTFs are a regulatory creation of the Centers for Medicare & Medicaid Services (CMS) that initially developed in 1998. According to the rules adopted by CMS, an IDTF is a free-standing entity, independent of a hospital or physician's office, in which diagnostic tests are performed by licensed, certified non-physician personnel under appropriate physician supervision. An IDTF does not directly use the test results to treat a beneficiary. The sole purpose of an IDTF is to furnish a diagnostic test. The IDTF designation was originally intended to resolve confusion surrounding the structure of entities Medicare previously classified as Independent Physiological Laboratories or IPLs. In adopting the IDTF rules, CMS also sought to define the scope of services IDTFs furnished and to address the potential quality and safety concerns raised by the lack of federal and state licensure and certification requirements.

Medicare regulations now provide that Medicare will only make payment for diagnostic testing procedures performed outside the hospital setting by one of the following provider-types: (1) a physician, (2) a physician group, (3) an approved supplier of portable x-ray services, or (4) an IDTF. Diagnostic testing procedures performed by IPLs are no longer covered.

When Is IDTF Enrollment Required?

For a long period of time the Medicare Program Integrity Manual included specific criteria for determining whether an imaging center is required to enroll as an IDTF and comply with the IDTF rules. However, in 2007, CMS issued a transmittal revising the manual instructions, which inadvertently or not, removed the criteria for determining when an entity must enroll as an IDTF. Prior to this change, Section 4.19.1 of Chapter 10 of the Program Integrity Manual provided the following instruction:

> "As a general rule, an applicant that is considered to be: (1) a physician's office or (2) a part of a hospital can bill for diagnostic tests without having to enroll as an IDTF.
>
> Conversely, an applicant that operates independently from a physician's office or a hospital must enroll as an IDTF. Hence, one of the key tests in determining whether IDTF enrollment is warranted is whether the supplier is independent."

While this language no longer appears in the Manual instructions, CMS and its Medicare Administrative Contractors continue to apply these same principles. As a result, imaging centers owned by a radiologist or a group of radiologists are not required to enroll as an IDTF. CMS and its contractors consider an imaging center exempt from IDTF status if it has the following features:

- The practice is owned by radiologists, a hospital, or both;
- The owning radiologists and any employed or contractual radiologists regularly perform physician services (e.g., test interpretations) at the location where the diagnostic tests are performed;
- The entity's billing patterns indicate that it is not primarily a testing facility, and that it was organized to provide the professional services of radiologists. (To illustrate, the enrolled entity (1) should not bill for a significant number of purchased interpretations, (2) should rarely bill only for the technical component of a diagnostic test, and (3) should bill for a substantial percentage of all of the interpretations of the diagnostic tests performed by the practice); and
- A substantial majority of the radiological interpretations are performed at the practice location where the diagnostic tests are performed.

Several Medicare Administrative Contractors include specific instructions on this enrollment choice on their websites. For example, Noridian, the contractor that administers Medicare Part B in California, provides guidance on its website that is nearly identical to the features described above.

Changing Medicare Enrollment Status

In our experience, CMS and its contractors will permit imaging centers owned by radiologists or by radiology-hospital joint ventures to change their status from IDTF to physician office or clinic. In order to change an imaging center's Medicare enrollment, the owner must file a change of information form known as the CMS-855B with its Medicare Administrative Contractor and complete the applicable sections, including Section 2.A—check box for "Clinic/Group Practice." In addition, the Company should enclose with the CMS-855B a cover letter describing the purpose for filing the CMS-855B as changing the Company's "type of supplier" enrolled in the Medicare program from IDTF to "Clinic/Group Practice." It is always a good idea to work directly with an IDTF's Medicare Administrative Contractor prior to submitting the CMS-855B to confirm that the a change in enrollment status is appropriate for the circumstances and to confirm that the contractor will accept and process the change of information form.

THOMAS W. GREESON
is a partner in the Falls Church, Va., office of Reed Smith LLP. His practice focuses on the regulatory and transactional needs of diagnostic imaging providers. He served as general counsel of the American College of Radiology for many years before entering private practice in 1998. Thomas serves as chair of the Virginia Bar Association Health Law Section. *Thomas can be reached at 703.641.4242 or tgreeson@reedsmith.com.*

PAUL PITTS
is a partner in the firm's San Francisco office. *Paul can be reached at ppitts@reedsmith.com.*