Excerpt from CMS Proposed Rule 1403-P

Below is the relevant section of the proposed CMS Rule that would impose new requirements on physicians performing imaging services in their offices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services (CMS)

I. Independent Diagnostic Testing Facility (IDTF) Issues

[If you choose to comment on issues in this section, please include the caption ``INDEPENDENT DIAGNOSTIC TESTING FACILITIES'' at the beginning of your comments.]

In the CY 2007 and 2008 PFS final rules with comment period, we established performance standards for suppliers enrolled in the Medicare program as an IDTF (71 FR 69695 and 72 FR 66285). These standards were established to improve the quality of care for diagnostic testing furnished to Medicare beneficiaries by a Medicare enrolled IDTF and to improve our ability to verify that these suppliers meet minimum enrollment criteria to enroll or maintain enrollment in the Medicare program. These performance standards were established at Sec. 410.33. In this proposed rule, we are again proposing to expand on the quality and program safeguard activities that we implemented previously.

1. Improving Quality of Diagnostic Testing Services Furnished by Physician and Nonphysician Practitioner Organizations

During the CY 2008 PFS proposed rule comment period, we received comments requesting that we require that the IDTF performance standards adopted in Sec. 410.33, including prohibitions regarding the sharing of space and leasing/sharing arrangements, apply to physicians and nonphysician practitioners (NPPs) who are performing diagnostic testing services for Medicare beneficiaries, and who have enrolled in the Medicare program as a clinic, group practice, or physician office. The commenters stated that standards for imaging services were not applied consistently for all imaging centers and that two distinct compliance and regulatory standards would emerge depending on how the similarly situated imaging centers were enrolled. In addition, one commenter stated that we should not prohibit space sharing when done with an adjoining physician practice or radiology group that is an owner of an IDTF.

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In response to the public comments, we are concerned that--

Certain physician entities, including physician group practices, and clinics, can enroll as a group practice or clinic and provide diagnostic testing services without the benefit of qualified nonphysician personnel, as defined in Sec. 410.33(c), to conduct diagnostic testing.

Some physician entities expect to furnish diagnostic testing services for their own patients and the general public and are making the decision to enroll as a group or clinic thereby circumventing the performance standards found in the IDTF requirements in Sec. 410.33.

Some physician organizations are furnishing diagnostic

tests using mobile equipment provided by an entity that furnishes mobile diagnostic services.

We are proposing certain exceptions to the established performance standards found in Sec. 410.33(g) because we believe that physician organizations already meet or exceed some of these standards. For example, their liability insurance coverage usually far exceeds the $300,000 per incident threshold, and there are a host of ways in which patient may issue clinical complaints concerning their physicians. In addition, we believe that compliance with some of the performance standards would be costly and burdensome and possibly limit beneficiary access, particularly in rural or medically underserved areas. For these reasons, we propose not to require physician entities to comply with the following standards:

Maintaining additional comprehensive liability insurance for each practice location as required under Sec. 410.33(g)(6).

Maintaining a formal clinical complaint process as required under Sec. 410.33(g)(8).

Posting IDTF standards as required under Sec. 410.33(g)(9).

Maintaining a visible sign posting business hours as required under Sec. 410.33(g)(14)(ii).

Separately enrolling each practice location as required under Sec. 410.33(g)(15)(i).

Accordingly, we are proposing to add Sec. 410.33(j) which states that, ``A physician or NPP organization (as defined in Sec. 424.502) furnishing diagnostic testing services, except diagnostic mammography services: (1) Must enroll as an independent diagnostic testing facility for each practice location furnishing these services; and (2) is subject to the provisions found in Sec. 410.33, except for Sec. 410.33(g)(6), Sec. 410.33(g)(8), Sec. 410.33(g)(9), Sec. 410.33(g)(14)(ii), and Sec. 410.33(g)(15)(i). As discussed in section II.J. of this preamble, we propose to define a ``physician or nonphysician practitioner organization'' as any physician or NPP entity that enrolls in the Medicare program as a sole proprietorship or organizational entity such as a clinic or group practice.

We maintain that this enrollment requirement is necessary to ensure that beneficiaries are receiving the quality of care that can only be administered by appropriately licensed or credentialed nonphysician personnel as described in Sec. 410.33(c). Moreover, we propose that physician or NPP organizations that do not enroll as an IDTF and meet the provisions at Sec. 410.33 may be subject to claims denial for diagnostic testing services or a revocation of their billing privileges.

We are soliciting comments on whether we should consider establishing additional exceptions to the established performance standards in Sec. 410.33(g) for physician and NPP organizations furnishing diagnostic testing services.

While we believe that most physician and NPP organizations utilize nonphysician personnel described in Sec. 410.33(c) to furnish diagnostic testing services, we are also soliciting comments on whether physician or NPPs conduct diagnostic tests without benefit of qualified nonphysician personnel and under what circumstances the testing occurs.

While we are proposing to apply the IDTF requirement to all diagnostic testing services furnished in physicians' offices, we are considering whether to limit this enrollment requirement to less than the full range of diagnostic testing services, such as to procedures that generally involve more costly testing and equipment. We seek

comment about whether the policy should apply only to imaging services or whether it should also include other diagnostic testing services such as electrocardiograms or other diagnostic testing services frequently furnished by primary care physicians. Within the scope of imaging services, we seek comment about whether the policy should be limited to advanced diagnostic testing procedures which could include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography), and other such diagnostic testing procedures described in section 1848(b)(4)(B) of the Act (excluding X-ray, ultrasound, and fluoroscopy). We are also soliciting comments on what would be appropriate criteria to limit this provision.

Finally, since this change, if adopted, would take time to implement for suppliers that have enrolled in the Medicare program, we are proposing an effective date of September 30, 2009, rather than the effective date of the final rule. For newly enrolling suppliers, the effective date of this rule would be January 1, 2009.

2. Mobile Entity Billing Requirements

To ensure that entities furnishing mobile services are providing quality services and are billing for the diagnostic testing services they furnish to Medicare beneficiaries, we are proposing a new performance standard for mobile entities at Sec. 410.33(g)(16), which would require that entities furnishing mobile diagnostic services enroll in Medicare and bill directly for the mobile diagnostic services that they furnish, regardless of where the services are performed. We believe that entities furnishing mobile diagnostic services to Medicare beneficiaries must be enrolled in the Medicare program, comply with the IDTF performance standards, and directly bill Medicare for the services they render.

While we understand that a mobile entity can furnish diagnostic testing services in various types of locations, we believe that it is essential that mobile entities use qualified physicians or nonphysician personnel to perform diagnostic testing procedures and that the enrolled mobile supplier bill for the services rendered. We maintain that it is essential to our program integrity and quality improvement efforts that an entity furnishing mobile diagnostic testing services comply with the performance standards for IDTFs and bill the Medicare program directly for the services provided to Medicare beneficiaries.

Since we believe that most mobile entities are already billing for the services they furnish, whether the service was provided in a fixed-based location or in a mobile facility, this proposed provision, if adopted, would be effective with the effective date of the final rule.

3. Revocation of Enrollment and Billing Privileges of IDTFs in the Medicare Program

Historically, we have allowed IDTFs whose Medicare billing numbers have been revoked to continue billing for services furnished prior to revocation for up to 27 months after the effective date of the revocation. Since we believe that permitting this extensive billing period poses a significant risk to the Medicare program, we are proposing to limit the claims submission timeframe

after revocation. In Sec. 424.535(g), we are proposing that a revoked IDTF must submit all outstanding claims for not previously submitted items and services furnished within 30 calendar days of the revocation effective date. We maintain that this change is necessary to limit the

Medicare program exposure to future vulnerabilities from physician and NPP organizations and individual practitioners that have had their billing privileges revoked. Accordingly, this proposed change would allow a Medicare contractor to conduct focused medical review on the claims submitted during the claims filing period to ensure that each claim is supported by medical documentation that the contractor can verify. We maintain that focused medical review of these claims will ensure that Medicare only pays for services furnished by a physician or NPP organization or individual practitioner and that these entities and individuals receive payment in a timely manner. In addition, we are also proposing to amend Sec. 424.44(a)(3) to account for this provision related to the requirements for the timely filing of claims. The timely filing requirements in Sec. 424.44(a)(1) and (a)(2) will no longer apply to physician and NPP organizations, physicians, NPPs and IDTFs whose billing privileges have been revoked by CMS.