I. Independent Diagnostic Testing Facility (IDTF) Issues

[If you choose to comment on issues in this section, please include the caption "IDTF ISSUES" at the beginning of your comments.]

In the CY 2007 PFS final rule with comment period, we established 14 performance standards and several other provisions at §410.33(g) associated with independent diagnostic testing facilities (IDTFs). In this proposed rule, we are clarifying our interpretation of several of the performance standards at §410.33(g) to assist the public in understanding how we expect our designated contractors to implement these standards. In addition, we are proposing several new performance standards and other provisions associated with IDTFs.

1. Proposed Revisions of Existing IDTF Performance Standards

a. §410.33(g)(6)

The supplier standard at §410.33(g)(6) states, "Has a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. The policy must be carried by a nonrelative-owned company." We are proposing to revise this standard to read, "Has a comprehensive liability insurance policy in the amount of

at least $300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier and ensures that this insurance policy must remain in force at all times. The policy must be carried by a nonrelative-owned company. The IDTF must list the Medicare contractor as a Certificate Holder on the policy and promptly notify the Medicare contractor in writing of any policy changes or cancellations. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter." This proposed rule clarifies how we will verify whether an IDTF meets this standard to include the provision that IDTF suppliers are responsible for providing the contact information of an individual employed with the underwriter, who can verify coverage. This proposed revision will not preclude the use of self insurance to demonstrate compliance with the comprehensive liability insurance policy as long as CMS or our designated contractor can verify the policy and its coverage provisions with an independent underwriter.

We believe that we should be able verify the issuance

of a comprehensive liability insurance policy with an underwriter, as well as an insurance agent. This approach will allow our designated contractors to verify that a comprehensive liability insurance policy has been issued and is in effect at the time of enrollment and throughout the enrollment period. Moreover, since 90 days may pass before the underwriter receives notification the policy has been issued by the insurance agent or broker, we encourage IDTFs to obtain comprehensive liability insurance at least 90 days prior to filing its Medicare enrollment application. This will prevent delays in the enrollment process and will allow our designated contractors to verify the issuance of an IDTF's comprehensive liability insurance policy on the day an application is submitted for review.

As a result, at §410.33(g)(6), we are proposing to revise this performance standard to include the requirement that an IDTF must list our designated contractor as a Certificate Holder on the policy. By listing our designated contractor as a Certificate Holder on the policy, our contractor will be able to verify coverage with the underwriter at the time of enrollment and as the need arises throughout the year.

Therefore, we are also proposing to revise §410.33(g)(6) to state that it is the IDTF supplier's

responsibility to: (1) ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and (2) promptly notify the CMS designated contractor in writing of any policy changes and cancellations.

b. §410.33(g)(2)

Based on feedback that we received after the implementation of §410.33(g)(2), we believe that several changes are necessary to ensure timely reporting of certain events and less frequent reporting of reportable events. Accordingly, we are proposing to change §410.33(g)(2) from, "Provides complete and accurate information on its enrollment application. Any change in enrollment information must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change," to "Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported within 30 calendar days of the change. All other reportable changes must be reported within 90 days."

c. §410.33(g)(8)

We are proposing to revise §410.33(g)(8) from "Answer beneficiaries' questions and respond to their complaints," to , "Answer, document, and maintain documentation of beneficiaries' questions and responses to their complaints at the physical site of the IDTF." This change corrects an oversight in drafting of the initial performance standards for IDTFs. In the CY 2007 PFS final rule with comment period, we did not include a requirement for the documentation of the complaint process. Thus, by making this proposed change, we are proposing to require an IDTF to document its complaint process. We believe that this change is consistent with the established practice for durable medical equipment, prosthetics orthotics and supplies (DMEPOS) suppliers found in §424.57(c)(19). To meet this revised standard, an IDTF would be responsible for maintaining the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

- The name, address, telephone number, and health insurance claim number of the beneficiary.
- A summary of the complaint; the date it was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

- If an investigation was not conducted, the name of the person making the decision and the reason for the decision. For mobile IDTFs, this documentation would be stored at their home office.

d. §410.33(b)(1)

At §410.33(b)(1), we are proposing to delete, "The IDTF supervising physician is responsible for the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations". We believe that our earlier rulemaking effort had the unintended consequence of appearing to shift the overall administrative responsibility from owners or administrative staff employed by an IDTF to the supervising physician. This was not our intent. Moreover, we believe that this requirement can be interpreted as being too restrictive as it is currently written and may convey responsibilities to a general supervising physician who may not have the administrative authority or knowledge to make these decisions. We are proposing to clarify and expand on our meaning of what constitutes three IDTF sites found at §410.33(b)(1). We believe that limitation on sites applies to both fixed

sites and mobile units. Accordingly, we believe that a physician providing general supervision as defined in §410.32(b)(3)(i) can oversee a maximum of three sites (that is, fixed or mobile) where concurrent operations can be performed. For example, we believe that a physician providing general supervision could oversee up to three individual IDTF mobile units or three individual fixed location IDTFs, or a combination of both that total up to three separate places which can concurrently run diagnostic tests. This does not change the requirements found at §410.32(b)(3) for direct and personal supervision.

2. Proposed New IDTF Standards

At §410.33(i), we are proposing to add a provision to state that Medicare will establish an initial enrollment date for IDTFs. Currently, IDTFs can retroactively bill Medicare for services that are rendered before they submitted a Medicare enrollment application or were approved to participate in the Medicare program. This means an IDTF is allowed to bill Medicare for services rendered on dates prior to the date the IDTF was enrolled in the Medicare program. For example, if an IDTF submits a Medicare enrollment application in November 2007 and is enrolled in the Medicare program in December 2007, then a physician or supplier could retrospectively bill for

services furnished to Medicare beneficiaries as far back as October 1, 2005; indeed, an IDTF may bill Medicare for services rendered up to 27 months prior to their Medicare enrollment date. This means that an IDTF in the example that is enrolled as meeting our program requirements in December 2007 may not have met those same requirements prior to the date of enrollment, even though the IDTF could bill Medicare and receive payments for services rendered up to 27 months prior to their enrolling in the Medicare program.

We are concerned that some IDTFs may bill Medicare for services when they do not meet all of the program requirements, including compliance with the performance standards at §410.33(g). Allowing an IDTF to bill Medicare for services furnished prior to being enrolled in the Medicare program, creates a significant risk for the Medicare program and its beneficiaries. Specifically, we believe that allowing an IDTF to bill for services furnished prior to enrolling in the Medicare program allows these facilities to potentially be reimbursed for services they are not qualified to perform or for which they otherwise may be precluded from billing to the Medicare program.

Since Medicare FFS contractors verify enrollment information at the time an enrollment application is filed, not for prior periods, we do not believe that it is appropriate to continue the practice of allowing IDTFs to bill the Medicare program for services rendered in periods prior to their enrollment in the Medicare program. Therefore, we are proposing to add §410.33(i) to state that Medicare will establish an initial enrollment date for an IDTF that would be the later of: (1) the date of filing of a Medicare enrollment application that was subsequently approved by FFS contractor; or (2) the date an IDTF first started rendering services at its new practice location. We also propose to define the "date of filing" as the date that the Medicare FFS contractor receives a signed provider enrollment application that the Medicare FFS contractor is able to process for approval. If the contractor rejects or denies and enrollment application, the new date of filing would be established when an IDTF submits a new enrollment application that the contractor is able to process for approval. Please note that we expect to implement a Web-based enrollment process known as the Provider Enrollment, Chain, and Ownership System (PECOS) process, to be known as PECOS Web, in most States during the 2007 calendar year. This internet enrollment process will

permit IDTFs to complete and submit enrollment applications online. The date of filing for applications submitted through PECOS Web will be the date the Medicare FFS contractor receives all of the following: (1) a signed Certification Statement; (2) an electronic version of the enrollment application; and (3) a signature page that the Medicare FFS contractor processes to approval. Further, our proposed policy is consistent with current Medicare payment policy of precluding payment for services until the provider or supplier of service establishes that they meet enrollment and certification requirements prior to being eligible to bill the Medicare program.

While this change limits the retrospective payments that an IDTF may obtain from Medicare program, we believe that this approach is consistent with our existing requirements for those providers that require a State survey prior to being enrolled as specified in §489.13 and the requirements followed by DMEPOS suppliers as established in section 1834(j)(1) of the Act and §424.57(b)(2). Moreover, this change would ensure that we are able to verify that an IDTF meets all program requirements at the time of filing, including the performance standards outlined in §410.33(g) before payment for service occurs.

We are also proposing a new performance standard at §410.33(g)(15), which states, "Does not share space, equipment, or staff or sublease its operations to another individual or organization." We believe that it is inappropriate for a fixed-base (physical site) IDTF to commingle office space, staff, and equipment, and that commingling office space, staff and equipment or subleases its fixed-base (physical site) operation to another individual or organization constitutes a significant risk to the Medicare program because it prohibits CMS or our contractors from ensuring that each fixed-base (physical site) IDTF establishes and maintains Medicare billing privileges consistent with the provisions at §424.500 and each IDTF meets and maintains all performance standards and other requirements under §410.33. While we believe that this new performance standard should only apply to fixed-base (physical site) IDTF locations, we are seeking public comments on establishing a similar requirement for mobile IDTFs. This proposed standard, in conjunction with the existing IDTF performance standard three (concerning appropriate sites for an IDTF), expands the interpretation of these standards to state that a motel, or hotel is not an appropriate site for an IDTF. While we initially believed that this new performance standard should apply to

only fixed-based (physical site) locations, we also believe it should apply to mobile IDTFs, but we are seeking public comment on establishing this requirement.

We believe that allowing fixed-base (physical site) IDTFs to commingle office space (including waiting rooms), staff (including supervising physicians, nonphysician personnel, or receptionists), or equipment through subleasing agreements may allow an IDTF to circumvent Medicare enrollment and billing requirements. These types of arrangements also raise concerns because they may implicate the physician self-referral prohibition and the anti-kickback prohibition.

J. Expiration of MMA Section 413 Provisions for Physician Scarcity Areas (PSAs)

[If you choose to comment on issues in this section, please include the caption "PHYSICIAN SCARCITY AREAS" at the beginning of your comments.]

Section 413(a) of the MMA added a new section 1833(u) to the Act. That section provided a 5 percent incentive payment to physicians furnishing services in physician scarcity areas (PSAs) for physicians' services furnished on or after January 1, 2005, and before January 1, 2008. Specifically, section 1833(u) of the Act provided for payment of an additional 5 percent of the payment amount