



HEALTH LAW ALERT

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CMS PROPOSED ADDITIONAL RULES RESTRICTING THE ABILITY OF GROUP PRACTICES TO BILL FOR CT, MRI, ULTRASOUND, AND OTHER DIAGNOSTIC TESTING SERVICES

CMS has proposed new rules in an effort to improve the quality of diagnostic testing services provided to Medicare beneficiaries by physician group practices and other physician entities. If enacted, these rules will require group practices that provide diagnostic testing services to Medicare beneficiaries to enroll as independent diagnostic testing facilities (IDTF's) and to comply with many of the standards in effect for other IDTF's. This will severely affect physician practices who presently furnish these services.

The current rules allow group practices and other physician entities to enroll as a "physician office" in order to avoid having to comply with the IDTF standards. If required to enroll as an IDTF, physician practices, including sole proprietorships, clinics and physician group practices, will be required to enroll as an IDTF for each practice location that furnishes diagnostic testing services. This may severely impact those physician groups who currently provide the services because they will be required to comply with most of the IDTF standards, including very restrictive supervision standards and other rigorous quality and performance standards. They will also be prohibited from sharing space with other Medicare suppliers.

IDTF Supervision, Performance, and Quality Standards

Just last year, CMS imposed performance and quality standards for IDTF's in order to improve the quality of diagnostic testing services furnished to Medicare beneficiaries. These standards, in addition to the supervision requirements, are found at 42 CFR § 410.33, and are similar to standards previously in place for durable medical equipment suppliers. A list of CMS' IDTF standards can be found below.

Public Comments

During the comment period for the 2008 Physician Fee Schedule, CMS received a number of comments requesting that it apply IDTF performance standards to physician practices. CMS, as a result of these comments, expressed concern that physician practices were allowed to provide the

full range of diagnostic testing services without the benefit of qualified personnel. Further, CMS was concerned that a number of entities purposely enrolled as physician practices in order to "circumvent the performance standards found in the IDTF requirements." Accordingly, CMS proposed these new rules to close the loopholes, and to ensure that "[Medicare] beneficiaries receive the quality of care that can only be administered by appropriately licensed or credentialed personnel." Once adopted, the new rules will require group practices to comply with the same regulations to which other entities enrolled as IDTF's must comply.

Exemptions

Recognizing that physician groups already meet or exceed some of the IDTF standards, CMS has proposed to exempt physician groups from the following IDTF standards:

- Maintaining additional comprehensive liability insurance for each practice location
- Posting IDTF standards.
- Maintaining a formal clinical complaint process
- Maintaining a visible sign posting business hours.
- Separately enrolling each practice location as required by 42 CFR 410.33(g)(15)(i)

Thus, enrolled physician groups will have to comply with the remaining IDTF standards, including the somewhat onerous supervision requirements which may require, for example, that some practices engage or employ a board certified radiologist as a member of the group practice to be on-site whenever diagnostic testing services are being performed. Physician IDTF's will also be required to employ appropriately credentialed technologists.

Presently, the proposed rules apply to all diagnostic testing services including a number of services that are frequently furnished in primary care practices, including electrocardiograms. CMS is requesting comments about whether the IDTF enrollment requirement should be applied only to more advanced or costly testing services, such as MRIs, CT's, and nuclear medi-

cine services. We will have to wait and see if CMS changes its policy, but for now, group practices which provide any diagnostic testing services can expect to be required to enroll as an IDTF.

If adopted, these proposed rules would become effective September 30, 2009 for physician entities already enrolled in Medicare. Newly enrolling practices would be subject to the rule effective January 1, 2009.

Conclusion

Physician groups who currently provide testing services should be aware of these proposed changes and the possible effects on their practices. Although the possibility exists that certain types of testing may eventually be exempted from these registration requirements, one should assume for now that these rules will go into effect with little variation. It is important that physician entities take these proposed regulations seriously because after adoption, a failure to enroll as an IDTF could result in claims denial and, if a claim is submitted, potential liability under the Federal False Claims Act.



Summary of IDTF Standards

Supervision standards:

- Each supervising physician must be limited to providing general supervision to no more than three IDTF sites.
- Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State authorities. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body.
- The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by board certification in specific medical specialties or by criteria established by the applicable carrier.

Performance and quality standards:

- Complying with all applicable Federal and State licensure and regulatory requirements.
- Providing complete and accurate information on enrollment applications.
- Maintaining a physical facility at an appropriate site.
- Having all applicable non-portable diagnostic testing equipment available at the physical site.
- Maintaining a primary business phone under the name of the designated business.

- Having a comprehensive liability insurance policy of at least \$300,000 per location that covers both the place of business and all customers and employees of the IDTF. [Will not apply to physician entities under proposed rules.]
- Maintaining a patient complaint process. [Will not apply to physician entities under proposed rules.]
- Posting IDTF standards. [Will not apply to physician entities under proposed rules.]
- Disclosing to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.
- Agreeing not to directly solicit patients.
- Having a technical staff on duty with appropriate credentials to perform tests.
- Having testing equipment appropriately calibrated and maintained in compliance with instructions and standards.
- Having proper record storage to be able to retrieve medical records upon request from CMS.
- Agreeing to unannounced onsite inspections by or on behalf of CMS. The IDTF must -- (i) Be accessible during regular business hours to CMS and beneficiaries; and (ii) Maintain a visible sign posting its normal business hours.
- An IDTF is prohibited from: (i) Sharing a practice location with another Medicare-enrolled individual or organization; (ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or (iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

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