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## Regulatory Changes RE: Independent Diagnostic Testing Facilities

The recent changes to regulations relating to which entities must enroll as independent diagnostic testing facilities ("IDTFs") were finalized in the Final 2009 Physician Fee Schedule published on November 19, 2008 (the "Final Rule").

Question 1: Does a physician practice performing diagnostic testing services need to enroll with Medicare as an IDTF?

No. Physician practices performing diagnostic tests do not need to enroll as IDTFs and can bill for the technical component of such diagnostic tests as long as the facility:

- Is a physician practice owned directly by one or more physicians or a hospital;
- Is a facility that primarily bills for physician services and not for diagnostic tests;
- Furnishes diagnostic tests primarily to patients whose medical conditions are being treated or managed on an ongoing basis by one or more physicians in the practice; and
- Performs and interprets diagnostic tests at the same location where the practice physicians treat patients.



# Question 2: Do entities furnishing mobile diagnostic testing need to enroll with Medicare as IDTFs?

Yes. All entities that furnish mobile diagnostic tests to Medicare beneficiaries must (i) enroll in the Medicare program as IDTFs and (ii) directly bill the Medicare program for all mobile diagnostic services they furnish. The only exception is for any entity performing mobile diagnostic services "under arrangements" with a hospital. While such a mobile company must still enroll in the Medicare program as an IDTF, it is not required to comply with the direct billing requirement. Instead, it must provide CMS with documentation of the arrangement when it submits a CMS Form 855B during its initial or revalidation enrollment application or change in enrollment application.

Note that CMS made clear in the preamble to the Final Rule that an entity that leases equipment and provides technologists who conduct diagnostic tests in the office of a physician or physician organization is deemed to furnish diagnostic imaging services and must enroll as an IDTF and directly bill for its services (regardless of who supervises such services).

Question 3: Are there any other new requirements that apply to entities furnishing diagnostic testing services?

Yes. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires the Secretary of Health and Human Services

to establish an accreditation process for non-hospital entities (including, without limitation physician practices) furnishing diagnostic testing services which include MRI, CT and certain other diagnostic procedures by January 1, 2012. The accrediting bodies for such process are expected to be selected by 2010.

To the extent that providers are able to prepare for accreditation, they definitely should. Many providers already apply for and obtain accreditation, and those who may not understand the process should at least begin to do so.

# Question 4: When do the new IDTF enrollment rules go into effect?

January 1, 2009. The Final Rule does not specify when enrollment applications must be submitted. CMS representatives have informally indicated that they are developing new manual instructions on these issues. However, as of this date, no formal guidelines exist on when such applications must be submitted and approved. In addition, CMS does not address how the IDTF criteria generally designed for freestanding providers would apply in the hospital under arrangements context.

Question 5: Did the Final Rule contain any other developments in this area?

Prior to the enactment of the Final Rule, IDTFs whose billing numbers were revoked



could bill for services already provided for up to 27 months after the effective date of such revocation. Effective January 1, 2009, all such outstanding claims must be billed within 60 days of the effective date of revocation.

Question 6: Were any significant proposals contained in the 2009 Proposed Physician Fee Schedule not adopted in the Final Rule?

Yes. You may have heard that it was proposed that all entities providing diagnostic testing

services to Medicare beneficiaries (including, without limitation, physician practices) be required to enroll with Medicare as IDTFs. As discussed above, this proposal was not included in the Final Rule at least in part due to the accreditation process required under MIPPA described above.

As stated above, the changes described above went into effect on January 1, 2009. If you have any questions on this Health Law Checkup, please contact your Snell & Wilmer attorney or one of the attorneys listed.

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