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CMS Ranks Labs as "Moderate" Risk

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Q: Can you explain some of the new Medicare and Medicaid regulations established to prevent fraud?

A: Effective March 25, 2011, the Centers for Medicare and Medicaid Services (CMS) implemented new regulations designed to enhance enrollment procedures to protect against fraud — required by provisions in the 2010 healthcare-reform legislation. One of the key components of these new regulations is the separation of providers and suppliers into three categories ("limited," "moderate," or "high" risk), with more rigorous screening procedures as the perceived risk increases. Independent clinical laboratories have been identified as "moderate" risk, although a provider's or supplier's risk category may change over time as warranted by CMS' risk assessment.

- Screening for *limited-risk* providers and suppliers:

  Federal and state requirements satisfied: Verification that the enrollee meets federal (which would include CLIA certification) and state requirements related to the services to be rendered under a specific provider or supplier type.

  Licensure verification: Verification that the enrollee has the requisite state licenses, which would include any required state lab license.

  Database checks: Database checks include taxpayer identification verification; the Social Security Administration (including checks for deceased individuals); the National Plan and Provider Enumeration System (National Provider

Identifier data); the Office of Inspector General's list of excluded individuals/entities; and the General Services Administration's excluded-parties list.

- Additional screening for *moderate-risk* providers and suppliers:

  Site visits: Unannounced site visits to confirm that the provider or supplier is operational. These site-verification visits are *in addition* to any on-site inspection or survey required for certified providers and suppliers, such as the surveys conducted by the state survey agency for purposes of determining compliance with the federal CLIA rules.

- Additional screening for *high-risk* providers and suppliers:

  Fingerprint-based criminal history record check: Individual owners (direct or indirect ownership interest of 5% or more) of the enrolled provider or supplier will be subject to this screening.

Other significant changes occurring as a result of these regulations include:
Application fee: Each "institutional provider" is required to pay an application fee at the time of the initial Medicare enrollment, with a request to add a practice location, and when submitting revalidation forms. "Institutional provider" is defined to include all providers and suppliers who enroll in Medicare using the CMS 855A, CMS 855B (including clinical labs), or CMS 855S enrollment form, with the exception of physician and non-physician group practices. The fee is updated annually, with an initial fee for 2011 of $505. Payment must be made electronically through the Pay.gov website (www.pay.gov/). There is an ability to request a hardship exception, not only for financial reasons but also when necessary to enhance access to services, such as during a declared disaster when providers would enroll simply to respond to the emergent need. CMS will regularly send a list of providers and suppliers that have paid an application fee to the respective enrollment contractor (the "fee submitter list"); however, CMS encourages providers and suppliers to submit a receipt for the application-fee payment with an initial enrollment application, request to add a practice location, or revalidation filing. A

request to add multiple practice locations at the same time will require only payment of one application fee.

Temporary moratorium: Medicare and state Medicaid agencies will be able to impose temporary enrollment moratoria for a particular type of provider or supplier if determined to be "necessary to combat fraud, waste, or abuse." An initial six-month moratorium could be extended in six-month increments. An imposed moratorium will affect newly enrolling providers and suppliers (i.e., initial enrollment applications) and the establishment of new practice locations. The relocation of an existing practice location and change of ownerships of clinical labs should be unaffected by an existing moratorium.

Suspension of payments: Regulations allow for the suspension of payments during an investigation of a "credible allegation of fraud." To be "credible," the allegation must be from a reliable source, with a listing of such sources, and "have an indicia of reliability." There is an 18-month limit to the length of the payment suspension except in certain specific situations.

These new enrollment regulations provide significant changes and will increase the time and expense associated with obtaining and maintaining both Medicare and Medicaid enrollment, not to mention the risk of losing billing privileges for failing to comply. The Medicare requirements were rather explicit; however, state Medicaid agencies will need to modify state rules to implement the required procedures. Therefore, it will be necessary to monitor Medicaid-enrollment procedures as changes will be occurring to comply with the law. Providers and suppliers may want to consider incorporating enrollment activities into the company's overall compliance plan with responsibility for enrollment tasks assigned to appropriate staff members. Additional information about these new rules and CMS' guidance for implementing the regulations is available at www.medicareforgeeks.com.

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