

Regulatory Review: Proposed New Screening Requirements for Enrollees

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On September 23, 2010, the Centers for Medicare and Medicaid Services (CMS) released its proposed rule, pursuant to Section 6401(a) of the Affordable Care Act, to establish new screening requirements for enrollees in Medicare, Medicaid, and the Children's Health Insurance Programs (CHIP). If finalized, these new screening procedures will be effective March 23, 2011 for new enrollees and March 23, 2012 for current enrollees seeking to revalidate their enrollment.

The current screening measures applied by CMS are uniform for all enrollees: examining licensure requirements, performing site visits, checking databases, inspecting criminal backgrounds, and reviewing the Medicare Advantage Organization reports. In an effort to reduce fraud, waste, and abuse in the Medicare system, CMS proposes to establish a three-tiered system in which providers and suppliers are categorized into one of three risk levels: limited, moderate, or high. Each tier is associated with different enrollment screening procedures.

Based upon the proposed rule, the substantial majority of radiology providers and suppliers are expected to be categorized in the limited or moderate (rather than high risk) tiers (insofar as only home health agencies and DMEPOS suppliers are categorized as high risk on account of their specialty type). However, as explained below, a radiology provider or supplier is not immune from being categorized as high risk. The radiology providers and suppliers included in the limited-risk category are physician or non-physician practitioners, and medical groups or clinics, hospitals, critical access hospitals, mammography screening centers, portable x-ray suppliers, and radiation therapy centers. Moreover, any entity, regardless of the kind of supplier or provider, will be considered to pose only a limited risk if it is publicly traded on the New York Stock Exchange or the NASDAQ Stock Market, as there is financial oversight provided by investors, corporate boards of directors, and the Security Exchange Commission. CMS proposes that limited risk providers and suppliers be subject to the least stringent screening requirements, which include verification and pre-enrollment determination that a provider or supplier meets the applicable federal regulations, or State requirements for the provider or supplier type; verification of licenses; and verification and pre-and post-enrollment database checks.

The radiology providers and suppliers considered to be of

moderate risk are the independent diagnostic testing facilities (IDTFs). In addition, moderate risk providers and suppliers are those that enter a line of business without clinical or business experience. For instance, those providers and suppliers that lease minimal office space and equipment are presumptively deemed to pose a comparatively higher risk of fraud and abuse. CMS proposes the screening procedures for moderate risk providers and suppliers to include (in addition to all of the screening procedures required for the limited risk suppliers and providers) pre-and post-enrollment site visits. CMS takes the position that this will reduce the incidence of the "pay and chase" approach (which enables Medicare to conduct a heightened review of those providers and suppliers who, based on their profile, tend to more often engage in conduct that ultimately requires Medicare to take recoupment actions against such entities).

Radiology providers and suppliers should be aware that, once an entity has been classified in a particular risk category, that categorization is subject to modification. CMS proposes that it should have the authority alter a supplier or provider's risk category to address specific program vulnerabilities. CMS identifies five situations in which it would increase a provider or supplier's risk level to "high" for the six months, following the date upon which CMS lifts the temporary moratorium: (1) CMS obtains evidence from or concerning a physician or non-physician practitioner (NPP) that another individual is using his/her identity; (2) the provider or supplier has been placed on a previous payment suspension within the past 10 years; (3) the provider or supplier has been denied Medicare billing privileges within the past 10 years; (4) the provider or supplier has had its Medicare billing privileges revoked within the past 10 years; or (5) the provider has been terminated or precluded from Medicare billing.

If a provider or supplier is re-classified to the high risk category, it will be subject to all of the screening requirements imposed upon the moderate risk providers and suppliers, in addition to criminal background checks and fingerprint submission of the owners, authorized or delegated officials, or managing employees.

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In cases in which CMS requires additional information to ensure that providers and suppliers are complying with the program requirements, the agency proposes to be able to impose temporary moratoria of six months each, with the option of imposing consecutive moratoria when necessary. CMS would have the authority to impose a temporary moratorium in any of the following situations: (1) if CMS identifies a trend in a type of supplier or provider, a particular geographic area, or both; (2) if a state has imposed a moratorium on enrollment in a type of supplier or provider, in a particular geographic area, or both; or (3) if CMS, in concert with the Office of Inspector General, the Department of Justice, or both, identifies a particular provider or supplier type, a particular geographic area, or both. CMS also proposes to impose temporary moratoria on newly enrolling providers and suppliers and those providers and suppliers that are establishing new practice locations. The temporary moratoria would not apply to changes of practice location, changes in ownership (CHOW),

mergers, or consolidations.

Under the proposed rule, those providers or suppliers that are subject to temporary moratoria will not have an opportunity for a judicial appeal. However, CMS proposes that administrative appeals should be directed to the Department Appeal Board level of review. To lift a temporary moratorium, the president must declare a disaster, the circumstances warranting the moratorium no longer apply, or the secretary must determine the moratorium is no longer necessary.

While this is merely the proposed rule, the final rule is not expected to deviate significantly from CMS' proposed version. For those radiology suppliers or providers seeking to enroll or revalidate enrollment with CMS, they should be mindful of these new screening procedures and must ensure their practices comply with all state and federal fraud and abuse laws and regulations.