McDermott Will & Emery

CMS Publishes Proposal to Implement Affordable Care Act Provider and Supplier Fraud and Abuse Screening Requirements

November 4, 2010

Authorized by the Affordable Care Act of 2010, CMS issued proposed regulations that will implement provisions to screen providers based on the level of risk for fraud, require payment of fees for enrollment and revalidation of institutional providers, and allow for temporary moratoria on new provider enrollment and suspension of payments to providers.

The Centers for Medicare and Medicaid Services (CMS) published in the September 23, 2010, *Federal Register* proposed regulations (Proposal) that will implement provisions of the Affordable Care Act of 2010 requiring that CMS establish categories of risk for fraud and waste to the Medicare and Medicaid programs, and levels of screening of providers (mainly health care entities that furnish services primarily payable under Medicare Part A) and suppliers (mainly health care entities that furnish services primarily payable under Part B) corresponding to the level of risk associated with that category of provider. (While there are legal distinctions between "providers" and "suppliers," to avoid duplication of terms, the single term "provider" is used to refer to both.) Institutional providers, with the exception of Part B medical groups or clinics and physician and non-physician practitioners, will be subject to an application fee beginning on March 23, 2011. Eligible professionals, such as physicians and nurse practitioners, are excluded from paying this fee. Revalidating institutional providers will be subject to the fee starting after March 23, 2011. The Proposal contains provisions for temporary moratoria on enrollment of Medicare, Medicaid and CHIP providers in six-month increments in situations where CMS identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, including where a state has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type. As authorized by the Affordable Care Act, the Proposal will implement provisions for suspension of payment to a provider pending an investigation of a credible allegation of fraud unless CMS determines that there is good cause not to suspend payments. The Proposal also solicits comments on requirements for compliance programs by Medicare and Medicaid certified nursing facilities, and for providers. CMS is accepting comments on the proposed screening and enrollment regulations until November 16, 2010.

Levels of Screening Proposed for Providers Posing "Limited," "Moderate" and "High" Risk of Fraud

The Affordable Care Act requires CMS to determine the level of screening applicable to providers according to the risk of fraud, waste and abuse posed by each category of providers, as determined by CMS. CMS proposes three categories of risk: "limited," "moderate" and "high." Included in the limited risk category are physicians, non-physician practitioners, and medical clinics and group practices, which are considered to pose limited risk because these professionals are state licensed. Similarly, CMS believes that a provider or supplier that is publicly traded on the NYSE or NASDAQ poses a limited risk because of the oversight provided by investors, boards and the U.S. Securities and Exchange Commission. A non-exhaustive list of providers in the limited risk category includes hospitals, including critical access hospitals; ambulatory surgery centers (ASCs); skilled nursing facilities; end-state renal disease (ESRD) facilities; federally qualified health centers; mammography screening centers; rural health clinics; and radiation therapy centers. Screening of limited risk providers will entail verification that a provider or supplier meets applicable federal and state requirements for its provider type, verification that licensure requirements are met, and a database check on a pre- and post-enrollment basis to ensure that enrollment criteria continue to be met.

With the exception of providers that are publicly traded and therefore considered limited risk, CMS proposes that the following provider and supplier types be considered a moderate risk for the purpose of determining the appropriate level of screening: non-government-owned or -affiliated ambulance service suppliers, community mental health centers (CMHCs), comprehensive outpatient rehabilitation facilities (CORFs), hospice organizations, independent diagnostic testing facilities (IDTFs) and independent clinical laboratories. Since these provider and supplier types are generally highly dependent on Medicare, Medicaid or CHIP to pay salaries and operating expenses, and are subject to less government or professional oversight than the providers in the limited risk category, CMS would mandate that Medicare contractors conduct unscheduled and unannounced pre-enrollment site visits to ensure that the prospective providers meet CMS's enrollment requirements prior to enrolling in the Medicare program. Such visits would be in addition to the categorical screening tools used with limited risk providers. CMS proposes that currently enrolled (revalidating) home health agencies (HHAs) or suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), except for any such provider that is publicly traded and considered limited risk, should be characterized as moderate risk and subject to this additional screening. The Medicare government contractor will conduct an unannounced and unscheduled pre-enrollment and/or post-enrollment onsite visit during the revalidation process to certain providers that are not publicly traded: non-government-owned or -affiliated ambulance service suppliers, CMHCs, CORFs, DMEPOS suppliers, HHAs, hospice organizations, IDTFs and independent clinical laboratories.

The high risk category includes newly enrolling home health agencies and suppliers of DMEPOS, unless they are publicly traded. CMS also proposes to adjust a provider or supplier from the limited or moderate level of risk to the high level of risk for reasons such as the following:

- The provider or supplier has been placed on a previous payment suspension.
- The provider or supplier has been excluded by the Office of Inspector General or had its Medicare billing privileges denied or revoked by a Medicare contractor within the previous 10 years, and is attempting to establish additional Medicare billing privileges for a new practice location or by enrolling as a new provider or supplier.

CMS believes that providers that have been terminated or otherwise precluded from billing Medicaid should be adjusted from the limited or moderate category to the high category. For providers within the high level of risk, CMS proposes that, in addition to the screening applicable to the limited and moderate levels of risk, Medicare contractors use the following screening tools in the enrollment process: criminal background check and submission of fingerprints using the FD-258 standard fingerprint card. CMS proposes that these tools be applied to owners, authorized or delegated officials, or managing employees of any provider or supplier within the high level of risk category.

Application Fee for Provider Enrollment and Revalidation

The Affordable Care Act requires that CMS impose a fee on each application of an institutional provider of medical or other items or services or supplies, and on required revalidation applications. The fee will be used to cover the cost of screening providers and to carry out the screening and program integrity efforts under the Affordable Care Act. While the Affordable Care Act excludes eligible professionals, such as physicians and nurse practitioners, from paying an enrollment application fee, CMS takes a comprehensive view of what is an "institutional provider of medical or other items or services or supplier," with the exception of Part B medical groups or clinics and physician and non-physician practitioners who submit the CMS 855I form to enroll in Medicare. CMS includes, for example, hospitals, ASCs, HHAs, hospices, DMEPOS suppliers and ESRD facilities as "institutional providers." CMS will begin collecting the enrollment application fee beginning on March 23, 2011, for new enrollments, and from revalidating entities for all revalidation activity beginning after March 23, 2011. The Affordable Care Act establishes a $500 application fee for providers in 2010 as a starting base, and for 2011 and each subsequent year, the amount for the preceding year will be adjusted by the percentage change in the Consumer Price Index. CMS can, on a case-by-case basis, exempt a provider from the application fee if its application would result in a hardship. CMS may waive the fee for Medicaid providers where a state demonstrates that the fee would impede Medicaid beneficiaries' access to care.

Temporary Moratoria on New Provider Enrollment

The Affordable Care Act authorizes CMS to impose a moratorium on the enrollment of new Medicare providers in six-month increments in situations where CMS identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, or where a state has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type. CMS proposes that enrollment moratoria be limited to newly enrolling providers and the establishment of new practice locations, not to a change of practice locations. The temporary moratoria would not apply to existing providers or suppliers unless they were attempting to expand operations to new practice locations where a temporary moratorium was imposed. The temporary moratoria would not apply to situations involving changes in ownership of existing providers or suppliers, mergers or consolidations. Under the Proposal, a state Medicaid agency must comply with a temporary moratorium imposed by CMS unless it determines that the imposition of a moratorium would adversely affect beneficiaries' access to medical assistance.

Suspension of Payments

The Affordable Care Act provides that CMS may suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud unless CMS determines that there is good cause not to suspend payments. The Act also provides that Federal Financial Participation in the Medicaid program shall not be made with respect to any amount expended for items or services furnished by an individual or entity to whom a state has failed to suspend payments during any period when there is a pending investigation of a credible allegation of fraud as determined by the state in accordance with the Proposal, unless the state determines that good cause exists not to suspend such payments. The Proposal invites comments on how CMS proposes to implement these new provisions of the Affordable Care Act under CMS regulations.