BRYAN CAVE
A Broader Perspective

Alert

Life Sciences and Health Care Client Service Group

To: Our Clients and Friends March 21, 2011

Providers and Suppliers Burdened by New CMS Enrollment Requirements

On February 2, 2011, the Centers for Medicare and Medicaid Services ("CMS") issued final rules which dramatically change how providers and suppliers enroll with Medicare. The new regulations, intended to carry out various provisions of the Patient Protection and Affordable Care Act ("PPACA"), greatly expand the reach of the enrollment requirements which were first proposed by CMS on September 22, 2010, and signify CMS' focus on preventing fraud and abuse before it begins.

The final regulations divide providers into three categories of risk: limited, moderate, and high. Providers and suppliers are divided among the risk categories based upon historical patterns of fraud and abuse and the relative risk CMS perceives each provider type poses to the integrity of the Medicare program.

The effective date of the final regulations is March 25, 2011. However, CMS has indicated that it will consider public comments only on the fingerprinting requirements (discussed below) until April 4, 2011. The effective date of the fingerprinting requirements will be 60 days following the publication of subregulatory guidance.

We would be pleased to discuss the impact of these new regulations on your organization. Please feel free to contact any team member of the Bryan Cave **Life Sciences and Health Care Client Service Group.**

Limited Risk

Providers that Fall within "Limited Categorical Risk" include: Physicians or non-physician practitioners; medical groups or clinics; ambulatory surgical centers; competitive acquisition program/Part B vendors; end-stage renal disease facilities; FQHC's; histocompatibility laboratories; hospitals (including critical access hospitals); VA hospitals; mammography screening centers; mass immunization roster billers; pharmacies newly enrolling or revalidating with the CMS-855B application; religious non-medical health care facilities; rural health clinics; and skilled nursing clinics.

New Enrollment Screening Requirements for Limited Risk Providers:

- Verification that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination
- License verifications, including licensure verifications across State line lines for physicians or non-physician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling
- Database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet their respective enrollment criteria

Moderate Risk

Providers and Suppliers that Fall within "Moderate Categorical Risk" include: Ambulance service suppliers; community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent clinical laboratories; independent diagnostic testing facilities; physical therapists enrolling as individuals or group practices; portable x-ray suppliers; revalidating home health agencies and revalidating DMEPOS suppliers.

New Enrollment Screening Requirements for Moderate Risk Providers and Suppliers:

- Verification that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination
- License verifications, including licensure verifications across State line for physicians or non-physician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling
- Database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet their respective enrollment criteria
- On-site visits

High Risk

Providers and Suppliers that Fall within "High Categorical Risk" include: Prospective (newly enrolling) home health agencies and prospective (newly enrolling) DMEPOS suppliers.

New Enrollment Screening Requirements for High Risk Providers:

- Verification that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination

- License verifications, including licensure verifications across State line lines for physicians or non-physician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling

- Database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet their respective enrollment criteria

- On-site visits

- Submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier

- Fingerprint-based criminal history record check of the FBI's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier

Application Fees and Temporary Moratoria

In addition to the screening requirements discussed above, CMS has also promulgated regulations that impose a $500 application fee for initial applications, applications to establish a new practice location, and the submission of applications in response to a CMS revalidation request. Beginning in 2011 and continuing for each subsequent year, the application fee will be adjusted by the percentage change in the consumer price index for all urban consumers. Furthermore, the new regulations permit CMS to impose temporary moratoria on the enrollment of new Medicare providers and suppliers if a significant potential for fraud, waste, or abuse exists with respect to a provider or supplier type, a particular geographic area, or both.

How the New Rules Will Affect Our Clients

The new regulations impose further financial and administrative burdens on providers and suppliers wishing to expand their operations and will likely increase the time it takes to process applications. Unlike the proposed regulations, the final rules do not provide any distinction between publically traded and private companies. The absence of such a distinction greatly expands the reach of the proposed rules. For example, publically traded DMEPOS suppliers and home health providers would have fallen into the "limited" risk category under the proposed regulations. However, under the new rules, all newly enrolling DMEPOS suppliers and home health providers must adhere to the heightened screening processes of the "high" risk category.

Furthermore, some forms of a change in ownership transaction for home health agencies and DMEPOS suppliers trigger the need to enroll as a new supplier. Thus, the buyer will be subject to the "high" risk screening requirements, despite the likelihood of redundancies given that the business, much of which remains after the purchase, has already been verified and authenticated. In addition, we anticipate longer approval and verification periods which will impact billing cycles and cash flows. Health care providers, suppliers, and investors must carefully consider the impact the new screening requirements have on business operations and bottom lines.