

February 9, 2011

www.ober.com

IN THIS ISSUE

IN THIS ISSUE

Increased Scrutiny to Obtain and Maintain Medicare and Medicaid Enrollment - Final Regulations Published by Donna J. Senft

<u>Rewarding Quality?</u> <u>Not Exactly - CMS</u> <u>Proposes Value-Based</u> <u>Purchasing Rule</u> *by Kristin Cilento Carter*

<u>Can We Use 340B</u> <u>Drugs for...? New</u> <u>Answers on the</u> <u>Horizon</u> *by Christine M. Morse*

Editors: <u>Leslie Demaree</u> <u>Goldsmith</u> and <u>Carel T.</u> <u>Hedlund</u>

Increased Scrutiny to Obtain and Maintain Medicare and Medicaid Enrollment – Final Regulations Published

By: Donna J. Senft

Providers and suppliers face significant changes in Medicare and Medicaid enrollment with the implementation of regulations responding to aspects of the health care reform legislation designed to enhance enrollment procedures to protect against fraud. The intent of the legislation was to prohibit *unqualified* individuals and entities from obtaining or maintaining enrollment; however, legitimate providers and suppliers will need to understand the new requirements so that billing privileges are not affected by a failure to comply with the rules. The final regulations, which become effective March 25, 2011, <u>"Medicare, Medicaid, and Children's Health Insurance Programs: Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and <u>Compliance Plans for Providers and Suppliers</u> [PDF] were published on February 2, 2011. Many of the <u>proposed rules [PDF]</u> were adopted as final with little to no change; however, there were some notable changes.</u>

Provider and Supplier Screening

CMS has established three categories of providers and suppliers, i.e., "limited," "moderate," or "high" risk. The level of risk will dictate the Medicare enrollment screening activities, with more rigorous screening as the perceived risk increases. There were several changes in the list of providers and suppliers in each of the three categories:

- The final regulations contain no distinction between publically-traded and private companies.
- Portable x-ray suppliers, physical therapists and physical therapy groups, and all ambulance companies are now in the moderate risk category.



• Competitive acquisition programs and pharmacies enrolling using the CMS 855B form are now in the limited risk category.

Refer to the <u>Tables [PDF]</u> included in the final rule for the list of each provider or supplier typed in each category.

The screening for each category remains essentially unchanged, with the following screening procedures required for all initial enrollments, applications for a new practice location, and any required revalidation application. Screening for **Limited Risk** providers and suppliers:

- Federal and State Requirements Satisfied: Verification that the enrollee meets Federal 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 licenses.
- Database Checks: Database checks to include: taxpayer identification verification, SSA (so as to check for deceased individuals), NPPES (NPI data), OIG's List of Excluded Individuals/Entities, and GSA 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 onsite inspection or survey required for certified providers and suppliers.

Additional screening for High Risk providers and suppliers:

 Fingerprint-Based Criminal History Record Check: The proposed regulations would have required this level screening for persons with ownership and controlling interests, including authorized and delegated officials and managing employees. In the final regulations, only individuals



with an ownership interest (direct or indirect) of 5% or more will be subject to this screening.

For "high risk" screening, CMS acknowledges the privacy and operational concerns regarding conducting the fingerprinting, analyzing the results, and storing the background check results. In response to comments and concerns, CMS has delayed the implementation of the "high risk" fingerprint-based criminal history record check **until 60 days following the publication of additional guidance**. For that reason, CMS is soliciting **additional comments through April 4, 2011**, on this one aspect of the regulations. CMS has indicated that the delay will allow adequate time to coordinate with CMS' law enforcement partners, adequately address privacy concerns, and ensure that our contractors are adequately prepared to implement this new process.

Other Enrollment Provisions

- Medicaid Enrollment Revalidation: Similar to existing Medicare rules, Medicaid agencies will be required to conduct revalidations or reenrollments on an every 5-year cycle.
- Medicaid Enrollment Terminations: Similar to the existing Medicare enrollment regulations, the Medicaid rules will require billing privilege terminations with accompanying appeal rights under specified situations. For terminations required because the provider or supplier was terminated from Medicare or another state Medicaid program, the rules do not allow the termination to occur until all appeal rights have been exhausted for the Medicare or other state termination. The proposed rule would have required Medicaid agencies to deactivate an enrollment for lack of claims submission in a 12-month period, but this provision was not included in the final regulations.
- Application Fee: Each "Institutional Provider" will be required to pay an application fee at the time of the initial enrollment, when requesting to add a practice location, and when submitting a requested revalidation.
 "Institutional Provider" is defined to include all providers who enroll in Medicare using the CMS 855A, CMS 855B, or CMS 855S enrollment form, with the exception of physician and non-physician group practices.



The initial application fee for 2010 was set at \$500.00, with an annual update. The final regulations include the 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.

- 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." For Medicare enrollments, CMS will announce any planned moratoria in the Federal Register along with its rationale for why a particular moratorium is needed. An imposed moratorium would 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 ownership generally are not affected by a moratorium. There is, however, an exception for any HHA change of ownership that is affected by the 36-month rule (i.e., the new owner would not be able to accept assignment of the provider agreement); such a situation would equally be affected by a 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." In response to concerns expressed about the length that an investigation may continue, the final regulations set an 18-month limit to the payment suspension except in certain specific situations. The final regulations continued to include reasons justifying when a decision not to suspend payments is warranted, such as when there is a risk the payment suspension may jeopardize an ongoing undercover investigation.

Ober|Kaler's Comments

These final 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. Providers and suppliers may want to consider incorporating enrollment





activities into the overall compliance plan with responsibility for enrollment tasks assigned to the appropriate staff.