Health Care Alert

HEALTH CARE RELATED DEVELOPMENTS TO WATCH IN 2009 PART 2

MVA Healthcare Team

I, II, III, IV, V

In February, we provided you with a brief overview of five healthcare related developments to watch in 2009. This Alert summarizes five additional developments that may affect your business or practice this year.

I. RED FLAG RULES

On November 27, 2007, the FTC issued regulations directing "creditors" to implement programs designed to deter, detect and mitigate identify theft. The rules are commonly known as the "Red Flag Rules" because creditors must look for suspicious "red flags" that could signal the presence of identity theft. Although a healthcare provider is not a creditor in the traditional sense, it does qualify as a "creditor" under the Red Flag Rules. The implementation deadline for the Red Flag Rules was extended by the FTC to May 1, 2009.

The Red Flag Rules do not dictate specific requirements for identity theft programs, but only direct that a creditor establish reasonable policies and procedures in its program. To create these policies, a provider must determine what information is collected that is susceptible to identity theft and what patterns, practices or activities related to this information could be signs of identity theft. The Red Flag Rules also impose administrative requirements, including obtaining board approval of the program, assigning responsibility for its operation, making annual reports regarding compliance, periodically updating the program and training staff about its application.

The Red Flag Rules also impose certain requirements on creditors who use consumer reports. Healthcare providers may request consumer credit reports with respect to patients or applicants for employment or medical staff appointment as part of their screening processes. Any parties which use consumer credit reports were required to have procedures in place by November 1, 2008 to permit them to assess situations in which the address on a report does not match the address given by the patient or applicant.

II. REIMBURSEMENT AUDITING ACTIVITIES

Healthcare providers should be prepared for increased reimbursement auditing activities in 2009. The CMS Recovery Audit Contractor ("RAC") program has been made permanent and is expected to be implemented nationwide by August. The RAC program began as a three-year demonstration project to determine whether the use of RACs would be a cost-effective way to identify and correct improper Medicare payments. According to CMS, between 2005 and 2008, the RAC demonstration project identified and collected more than $1.03 billion in improper payments and returned more than $693 million to the Medicare Trust Fund. RACs use data analysis techniques to determine claims likely to contain overpayments, a process known as

"targeted review", and are prohibited from selecting claims at random to review. Providers should take steps throughout the year to identify and evaluate the components of their claims and billing processes that are likely to trigger review.

III. STRICTER RESTRICTIONS FOR DEVICE MARKETING ACTIVITIES

Both the Federal and state governments are becoming more aggressive when it comes to regulating the sales and marketing activities of pharmaceutical and medical device manufacturers and sanctioning those individuals and entities engaged in abusive practices, such as the provision and receipt of kickbacks. The OIG is increasingly using its administrative authority to sanction individuals and entities providing and receiving financial incentives which do not have any significant clinical value, such as consulting agreements, trips, sports tickets, dinners and other gifts. In addition, states continue to adopt standards restricting sales and marketing activities beyond what is required in other jurisdictions. Most recently, Massachusetts proposed regulations restricting drug and device manufacturing activities which are believed to be more aggressive than regulations in other states. Among other things, these regulations would require companies to file annual disclosures of all fees payments and economic benefits paid to healthcare professionals that total $50 or more.

In addition, both the Advanced Medical Technology Association ("AdvaMed") and the Pharmaceutical Research and Manufacturers of America ("PhRMA") recently released new stricter ethical standards limiting direct promotional activities by their members to physicians. AdvaMed's Revised and Restated Code of Ethics on Interactions with Healthcare Professionals, effective July 1, 2009, and PhRMA's revised Code on Interactions with Healthcare Professionals, effective January 1, 2009, prohibit members from giving non-educational gifts to healthcare providers and their staff. The codes also impose restrictions on the use of entertainment and recreational activities to promote products and the payment for meals, education and travel expenses for healthcare providers.

IV. DOCUMENTATION REQUIREMENTS FOR DME

The recent resolution of a decade-long Medicare payment dispute highlights to durable medical equipment ("DME") suppliers the importance of obtaining documentation of medical necessity, in addition to a certificate of medical necessity ("CMN"), in order to substantiate a claim for Medicare coverage of DME. In the case of Maximum Comfort, Inc. v. Leavitt, 512 F.3d 1081(9th Cir., 2007), a supplier of power wheelchairs who relied on CMNs signed by the physicians ordering the wheelchairs disputed a Medicare carrier's post-payment determination that the supplier failed to furnish documentation demonstrating that the wheelchairs were medically reasonable and necessary. The Court reaffirmed the position expressed by the Medicare Appeals Council that power wheelchairs and other DME furnished to beneficiaries by a supplier in reliance on a CMN may, nonetheless, be determined to be not medically reasonable and necessary absent supporting medical documentation. The Court ultimately held that Maximum Comfort was responsible for the overpayment. The Maximum Comfort case highlights the DME supplier's responsibility for obtaining from the prescribing physician sufficient information to establish medical necessity for the DME, including a prescription or order and medical documentation.

In 2009 and beyond, DME suppliers should closely monitor the Obama Administration's healthcare reform efforts. Proposed legislation could impact DME coverage and payment policies. In addition, we expect the new Administration to support heightened scrutiny of claims for Medicare payment. A CMS representative reportedly advised a group of healthcare attorneys recently that CMS intends to focus attention on the highest paid DME suppliers and the highest billed equipment and supplies.

V. Drug and Device Safety

With the increasing number of reports of counterfeit pharmaceuticals, prescription drug-related deaths and medical device malfunctions, the ability of the FDA to ensure the safety of drugs and devices has been called into question. Over the past decade, numerous OIG evaluations and audits have documented weaknesses in the FDA's oversight systems. Furthermore, a report issued on January 15, 2009 by the Government Accountability Office ("GAO"), the investigative arm of Congress responsible for enhancing the performance of all federal government agencies, concluded that the FDA has approved many medical devices that have never been shown to be safe or effective. Any healthcare reform effort by President Obama's Administration is likely to include changes to the FDA's operations. Drug and device manufacturers and distributors can expect new rules and regulations in the near future which could affect their business operations.