Health Care Law Information Memo

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SIGNIFICANT FRAUD AND ABUSE MEASURES IN FEDERAL HEALTH CARE REFORM

Although enforcement initiatives were not in the spotlight during the long debate on health care reform, the Patient Protection and Affordable Care Act (PPACA) makes significant changes in Medicare and Medicaid program integrity processes. Many of these changes expose health care providers to intensified scrutiny, greater potential liability for unintentional errors, and higher risk of exclusion.

While some provisions will not be fully implemented for up to two years, others take effect immediately. This Information Memo summarizes selected highlights.

Increased Penalties and More Exposures

The PPACA removes the element of actual knowledge or specific intent from violations of the federal health care fraud statute. This shift is consistent with recent amendments to the federal False Claims Act. In both statutes, Congress has made it clear that proof of intent – traditionally the central element of a fraud case – is no longer essential when government money is involved. To drive the point home, the PPACA amends the federal sentencing guidelines to impose harsher sentences for health care fraud violations.

Knowingly making a false record or statement material to a false or fraudulent claim will carry a penalty of $50,000 for each false statement or record. False statements, or omissions or misrepresentations on an application for enrollment will also carry a penalty of $50,000 – and may trigger a permissive exclusion. Failure to grant timely access for purposes of audit, investigation or evaluation will carry a penalty of $15,000 per day. Treble damages are still available to the Office of Inspector General (OIG) as well.

Underscoring the federal government's authority to prosecute anti-kickback violations under the False Claims Act, the PPACA makes it clear that claims made for items or services resulting from a violation of the anti-kickback statute constitute false claims.

Suspension of Payment Pending Investigation

The Department of Health and Human Services (HHS) will be able to suspend payments to a Medicare provider or supplier pending an investigation of "a credible allegation of fraud" against that entity, unless HHS determines that there is good cause not to issue the suspension. HHS is required to issue regulations to implement this provision.

There is no time limitation on HHS's authority to suspend Medicare payments, and the statute does not specify any parameters for the triggering allegation or investigation, except that HHS is required to consult with the OIG in making the determination of whether there is a credible allegation of fraud. When HHS has made such a determination, the state may also suspend Medicaid payments to that provider or supplier, in accordance with regulations to be issued by HHS. By application of these provisions, a provider under investigation for alleged fraud could suffer catastrophic cash flow interruptions.

Repayments and Exclusions

Providers will be required to report *and repay* overpayments <u>within 60 days</u> after the overpayment is identified, or by the date on which the corresponding cost report is due (if applicable), whichever is later. Any overpayment not reported and returned within the time limit will become an "obligation" that may subject the provider to civil monetary penalties as well as potential liability under the False Claims Act.

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Moreover, as of January 1, 2011, states may exclude from Medicaid any individual or entity that owns, controls or manages (or is owned, controlled or managed by) an entity that has unpaid overpayments, is suspended or excluded from participation, or is affiliated with an individual or entity that is suspended, excluded or terminated from participation.

In New York, where the Office of Medicaid Inspector General (OMIG) has been vigorously pursuing recoupment of overpayments, providers are often permitted to repay overpayments over time. It is unclear whether such a repayment plan, approved by OMIG, would constitute an "unpaid overpayment" that could subject the provider's affiliates to exclusion during the repayment period. OMIG, already in a mode of aggressive enforcement, may have a new tool in its arsenal.

Compliance Plans

HHS will issue regulations to establish minimum standards for compliance plans. Implementation dates may differ for various provider types. State Medicaid Plans must also require providers to have compliance plans meeting the federal standards.

New York State already requires entities licensed under Articles 28 or 36 of the Public Health Law and Articles 16 or 31 of the Mental Hygiene Law to have compliance plans, regardless of the amount they bill. In addition, all other entities billing or expecting to bill Medicaid $500,000 or more in any consecutive 12-month period are required to have compliance plans.

Federal regulations, once adopted, may require more entities to have compliance plans. The PPACA would allow HHS to impose the compliance plan requirement on all providers enrolled in the Medicare and Medicaid programs, regardless of the amount that they bill. It is also foreseeable that the federal regulations may impose requirements beyond the requirements of current New York law. In any event, New York providers will need to revisit their compliance plans to ensure that they comply with the federal minimum standards.

Provider Screening, Oversight, and Enrollment

New and current Medicare providers will be subject to screening based on HHS's assessment of the risk of fraud, waste and abuse. Provider screening requirements will take effect in six months for re-enrollments and in one year for new enrollees. Screening will include licensure verification, and may, when deemed appropriate by HHS, include a criminal background check, fingerprinting, unscheduled site visits, and database checks.

New providers will be subject to increased oversight, such as prepayment review and payment caps, for up to a year. Also, beginning in 2011, if HHS determines that there is a significant risk of fraudulent activity specifically among durable medical equipment suppliers, it may withhold Medicare payments for 90 days.

HHS may impose temporary moratoria on enrollment of new providers if HHS deems it necessary to prevent or combat fraud, waste or abuse. Temporary moratoria cannot be challenged by judicial review.

Disclosure Requirements

Providers seeking to enroll or re-enroll in Medicare or Medicaid will be subject to new and potentially burdensome disclosure requirements, beginning one year after PPACA enactment. Among the new requirements are the disclosure of any current or previous "affiliation" with a provider that has uncollected debt; has been excluded; has been subject to payment suspension; or has had billing privileges denied or revoked.

HHS will be able to use certain information from the IRS when determining the provider's enrollment status, in any proceeding relating to a denial of enrollment, and in determining the provider's level of "enhanced oversight." The information that the IRS is required to disclose to HHS is limited to identifying information and the amount and tax year of any "seriously delinquent" tax debts.

Data Mining

Data sharing by and among certain federal agencies will be stepped up. The United States Attorney General, as well as the OIG, will have access to Medicare claims and payment data for purposes of conducting law enforcement and oversight activities.

States will be required to report information on formal proceedings concluded against health care practitioners by a State licensing or certification agency, as well as any final adverse action in which a finding of liability has been made against a provider by a State law enforcement or fraud enforcement agency. At a minimum, this increased communication between state and federal agencies may cause the OIG to look more closely at its permissive exclusion authorities for even minor actions taken against providers at the state level.

Manufacturers of drugs, devices, biologicals and medical supplies will be required to report payments and transfers of value to physicians. Those manufacturers, as well as group purchasing organizations, will be required to report ownership or investment interests held by physicians. In the context of increasing scrutiny of physician financial relationships with the pharmaceutical and medical device industries, these requirements portend data mining.

Future Developments

The federal government will apportion significant additional funds to combat fraud, waste and abuse for fiscal years 2011-2016. By some estimates, health care fraud and abuse costs federal, state and local governments upwards of $100 billion annually, and an expectation of reducing fraud and abuse was a factor in assessing the cost of the PPACA. The financial stakes are high, and all providers – even providers that commit unintentional errors – can expect increasingly aggressive enforcement in the years to come.

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