### Beyond the Affordable Care Act: Preparing for Increased Compliance Enforcement

Now that it has been held constitutional by the United States Supreme Court, federal efforts to implement the Patient Protection and Affordable Care Act (PPACA), including the provisions related to the prevention and prosecution of fraud and abuse, will continue and likely increase. As a result, it is more important than ever for health care providers to ensure they have an effective compliance program.

In particular, health care providers should ensure their compliance program addresses the following: (1) PPACA's requirement to report and refund overpayments within 60 days, the so-called "60-Day Rule"; (2) exclusion screening of employees and contractors; and (3) compliance program effectiveness, including annual risk assessments and evaluation of internal compliance performance measurement standards.

The 60-Day Rule, one of the most aggressive PPACA provisions put in place to combat fraud, requires providers to report and refund identified overpayments within 60 days of discovery. Although the proposed regulations implementing the 60-Day Rule have not yet been finalized, health care providers need to evaluate their current compliance reporting mechanisms, policies, and procedures to ensure they identified potential overpayment issues to be brought to the attention of management as early as possible. Under the proposed regulations, health care providers who identify a potential overpayment have a duty to undergo a "reasonable inquiry" and proceed with "all deliberate speed" to refund the overpayment. Examples included in the preamble to the proposed regulations of "identified" overpayments include: (1) reviews of billing or payment records which clearly indicate a code was incorrectly applied resulting in increased reimbursement; (2) a patient's death occurred prior to a date of service on a claim submitted; (3) services provided by an unlicensed or excluded provider or entity; and (4) services performed were not medically necessary.

When implementing any changes to the compliance reporting processes, health care providers also must ensure they have a robust education and training program that will inform employees and agents of their reporting obligations and internal reporting procedures. In addition to ensuring effective reporting mechanisms, health care providers should work with their legal counsel to

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develop investigation policies and procedures that will protect the ability of the provider to fully evaluate potential noncompliance while still ensuring compliance with the 60-Day Rule.

Another compliance enforcement priority of the federal Department of Health and Human Services, Office of Inspector General (OIG) is health care providers who employ or contract with excluded individuals or entities. Health care providers who participate in federal health care programs are required to screen all parties with whom they have a business relationship (e.g., employees, medical staff and independent contractors) against OIG Lists of Excluded Individuals and Entities, as well as the General Service Administration. Notably, the prohibition is not limited to persons involved in the provision of health care items and services. The ban also applies to administrative and management services not directly related to patient care, but which are a necessary component of providing items and services to Medicaid recipients, when those payments are reported on a cost report or are otherwise payable by a federal health care program. In addition, a health care provider may not submit a claim for payment for any items or services ordered or prescribed by an excluded physician or other authorized person when the individual or entity furnishing the services either knew or should have known of the exclusion. This prohibition applies even when the payment itself is made to another provider, practitioner or supplier that is not excluded.

Examples of items or services that may not be reimbursable when provided by excluded individuals or parties are as follows:

- Services performed by excluded nurses, technicians or other excluded individuals who work for a hospital, nursing home, home health agency, hospice or physician practice;
- Services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in the filling of prescriptions for drugs reimbursed, directly or indirectly, by a federal health care program;
- Services performed by excluded ambulance drivers, dispatchers and other employees involved in the transport of the patient to a hospital or nursing facility;
- Services performed by excluded individuals who sell, deliver or refill orders for medical devices or equipment reimbursed by a federal health care program;

- Services performed by social workers who are employed by health care entities to provide services to federal health care program recipients;
- Services performed by an excluded administrator, billing agent, accountant, claims processor or utilization reviewer that are related to and reimbursed, directly or indirectly, by a federal health care program;
- Items provided or services performed by an excluded individual who works for an entity that has a contractual agreement with, and is paid by, a federal health care program; and
- Items or equipment sold by an excluded manufacturer or supplier, used in the care or treatment of recipients and reimbursed, directly or indirectly, by a federal health care program.

In response to the increased need to conduct thorough exclusion screening, health care providers should be reviewing their screening practices with respect to volunteers, employees, agents and vendors, as well as ordering or prescribing health care providers. Screening of all such individuals should be performed on a monthly basis. In addition, policies and procedures should be adopted to ensure such individuals are aware that they must affirmatively report any pending or threatened exclusion. Health care providers should work with legal counsel to ensure that vendor service agreements contain appropriate provisions to address screening and reporting obligations. Hospitals also should ensure they implement procedures to conduct monthly screenings of all medical staff members, instead of limiting screening to the bi-annual reappointment process.

Finally, the OIG has made it clear that having a compliance program on paper alone is not sufficient. Health care providers need to have a process for annually conducting and documenting a risk assessment and applying the findings to the design and implementation of the organization's compliance program. New areas of risk identified need to be addressed through implementation of policies and procedures and training, as well as auditing and monitoring activities. In addition, health care providers should be establishing internal compliance performance measures that provide feedback regarding the effectiveness of the organization's compliance efforts. For example, the number of proactive audits, the number of compliance hotline calls or compliance reports should be reviewed. In addition, the status of ongoing investigations and completion of corrective action plans should be reported. Health care provider boards and board committees overseeing the compliance program also should be receiving reports, at least

annually, on the outcome of these efforts.

In conclusion, as the federal enforcement efforts grow increasingly aggressive, health care providers must take proactive steps to detect and prevent noncompliance by having an effective compliance program that includes robust reporting mechanisms; exclusion screening programs; an annual risk assessment process that includes a requirement to develop responsive compliance program revisions and education and training; and the development and monitoring of internal compliance performance measures. If you have questions about the Affordable Care Act, the key regulatory changes and their implications for providers, please contact your Reinhart attorney or any Reinhart Health Care attorney.

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