CMS issues guidance on fraud and abuse prevention measures

BY MYLA REIZEN AND KATHLEEN HARRISON

THE CENTERS FOR Medicare and Medicaid Services (CMS) recently took some key actions to implement provisions of the health care reform law passed in March 2010, the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), collectively known as the Affordable Care Act or ACA. These provisions are designed to provide governmental health care programs increased protection from fraud and abuse. This article is meant to highlight some of these measures.

A proposed rule published in the Federal Register on Sept. 23, 2010, sets forth a number of provisions in response to the ACA, one of which addresses ethics and compliance programs. Under Section 6102 of the ACA, a skilled nursing facility or nursing facility (with respect to the entity that operates the facility, referred to as the "operating organization") on or after 36 months after the date of enactment (March 23, 2010) must have in operation a compliance and ethics program that is effective in preventing and detecting certain criminal, civil and administrative violations under the ACA and in promoting quality of care consistent with certain regulations. The Secretary and Inspector General of the U.S. Department of Health and Human Services (HHS) must promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program, within two years of the ACA's enactment. This provision sets forth the required components of compliance and ethics programs.

Additionally, under Section 6401 of the ACA, on or after the date of implementation as determined by the Secretary of HHS, a provider of medical or other items or services or supplier within a particular industry sector or category, must, as a condition of enrollment under Medicare and Medicaid, establish a compliance program that contains certain core elements with respect to the provider or supplier and industry or category. This provision provides that the Secretary and Inspector General of HHS must establish these core elements, with the Secretary determining the timeline for the core elements and date of implementation for providers or suppliers within a particular industry or category.

In the recent proposed rule, CMS is soliciting comments on the compliance program requirements of the ACA. The deadline for submission is Nov. 16, 2010. CMS does not intend to finalize the compliance plan requirements when the other provisions of the proposed rule are finalized. Instead, CMS intends to do "further rulemaking on the compliance plan requirements and will advance specific proposals at some point in the future." They are interested in receiving comments about the use of the seven elements of an effective compliance and ethics program as described in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual as the "basis for the core elements of the required compliance programs for Medicare, Medicaid and CHIP enrollment."

Under the proposed rule, these elements include the following:

- the development and distribution of written policies, procedures and standards of conduct to prevent and detect inappropriate behavior;
- the designation of a chief compliance officer and other appropriate bodies (for example a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program and who report directly to high-level personnel and the governing body;
- the use of reasonable efforts not to include any individual in the substantial authority personnel whom the organization knew, or should have known, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program;
- the development and implementation of regular, effective education and training programs for the governing body, all employees, including high-level personnel, and, as appropriate, the organization's agents;
- the maintenance of a process, such as a hotline, to receive complaints and the adoption of procedures to protect the anonymity of complaints and to protect whistleblowers from retaliation;
- the development of a system to respond to allegations of improper conduct and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;
- the use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
- the investigation and remediation of identified systemic problems including making any necessary modifications to the organization's compliance and ethics program.

In addition to these elements, CMS is particularly interested in 11 other main areas, including the following:

- how and to what degree each element has been incorporated effectively into the compliance programs of different types of providers and suppliers considering their risk areas, business model and industry sector or particular provider or supplier category;
- the costs and benefits of compliance programs or operations, including aggregate or component costs and benefits of implementing particular elements and how these costs and benefits were measured;
- the types of systems necessary for effective compliance, the costs associated with these systems and the degree to which providers and suppliers already have these systems, including, but not limited to, tracking systems, data capturing systems and electronic claims submission systems; and
- a reasonable timeline for the establishment of a required compliance program for various types and sizes of providers and suppliers, assuming the compliance program core elements were based on the aforementioned U.S. Federal Sentencing Guidelines' seven elements of an effective compliance and ethics program, considering business model and industry sector or particular provider or supplier category.

The proposed rule also sets forth screening procedures for providers of medical or other services and suppliers who participate in Medicare, Medicaid, or the Children's Health Care Insurance Program (CHIP). CMS envisions that these screening measures will help it move away from the "pay and chase" approach to health care fraud. The new screening procedures would become applicable on March 23, 2011, to newly enrolling providers and suppliers, as well as to currently enrolled providers and suppliers revalidating their enrollment information. Applicability to other providers and suppliers currently enrolled in Medicare, Medicaid, or CHIP would be delayed until March 23, 2012.

Additionally, the proposed rule addresses parameters for the imposition of an enrollment application fee (mandated by the ACA) on institutional providers of medical or other items or services or suppliers. The fee, intended to cover the cost of screening and other program integrity efforts, would become effective on March 23, 2011. The rule also proposes circumstances under which CMS and the states would impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers in order to protect against fraud. Finally, the proposed rule would modify current regulations on the suspension of payments to a provider or supplier pending the investigation of a credible allegation of fraud.

CMS has requested comments on the proposed rule, which are due Nov. 16, 2010.

On Sept. 23, 2010, CMS also issued a self-disclosure protocol for actual or potential violations of the physician self-referral ("Stark Law") prohibitions. This protocol is available to all health care providers of services and suppliers and is not limited to any particular industry, medical specialty or type of service. It can be viewed on the CMS website.

For specific questions on these items or other provisions of the health care legislation, please contact Myla Reizen at (305) 679-5716 or Kathleen Harrison at (504) 582-8138 at Jones, Walker, Waechter, Poitevent, Carrère & Denègre LLP.

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