HAWAII HEALTH SYSTEMS
C O R P O R A T I O N

"Touching Lives Every Day"

COMPLIANCE ALERT 10-46

CMS Solicits Comments on Compliance Programs as Required by Affordable Care Act (ACA)

SUMMARY: CMS is soliciting comments on compliance program requirements included in the Patient Protection and Affordable Care Act (PPACA), now commonly called the Affordable Care Act (ACA). The ACA requires a compliance and ethics program for nursing or skilled nursing facilities by 2013. Furthermore, the ACA requires an established compliance program for hospitals and providers of medical services. To date, compliance programs were not mandatory. CMS is asking for input on the core elements for their requirements for a compliance program

The Affordable Care Act (Section 6401(a)) provides that "a provider of medical or other items or services or a supplier shall, as a condition of enrollment in Medicare, Medicaid or CHIP, establish a compliance program that contains certain "core elements." The statute requires the Secretary, in consultation with the HHS OIG, to establish the core elements for providers or suppliers within a particular industry or category. The statute allows the Secretary to determine the date that providers and suppliers need to establish the required core elements as a condition of enrollment in Medicare, Medicaid, and CHIP. The statute requires the Secretary to consider the extent to which the adoption of compliance programs by providers or suppliers is widespread in a particular industry sector or particular provider or supplier category."

Nursing homes must have a compliance program in place by 2013. No firm date has been set yet for hospitals. CMS will develop rules on compliance plan requirements and will advance specific proposals at some point in the future.

COMMENTS WANTED: CMS is soliciting comments on this program. "CMS is most interested in receiving comments on the following (CMS-6028-P; pages 100-103):

- 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 complainants 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."

These above elements are the long-established seven elements in the OIG's Guidance for effective compliance programs.

"In addition, CMS is particularly interested in comments about the following:

- The extent to which, and the manner in which, providers and suppliers already incorporate each of the seven U.S. Federal Sentencing Guidelines elements into their compliance programs or business operations. (CMS is) interested in 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.
- Any other suggestions for compliance program elements beyond, or related to, the seven elements referenced above considering provider or supplier risk areas, business model and industry sector or particular provider or supplier category including whether external and/or internal quality monitoring should be a required for hospitals and long-term care facilities.
- 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. (CMS) anticipates having providers and suppliers evaluate the effectiveness of their compliance plans using electronic data.

- The existence of and experience with state or other compliance requirements for various providers and suppliers and foreseeable conflicts or duplication from multiple requirements.
- The criteria (CMS) should consider when determining whether, and if so, how to divide providers and suppliers into groupings that would be subject to similar compliance requirements including whether individuals should have different compliance obligations from corporations.
- Available research or individual experience regarding the current rate of adoption and level of sophistication of compliance programs for providers or suppliers based on their business model and industry sector or particular provider or supplier category.
- How effective compliance programs have been for varied providers and suppliers and how the level of effectiveness was measured
- The extent to which providers and suppliers currently use third party resources, such as consultants, review organizations, and auditors, in their compliance efforts.
- The extent to which providers and suppliers have already identified staff responsible for compliance and, for those who already have staff responsible for compliance, the positions of these staff.
- A reasonable timeline for 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.

Next Steps: Please send any comments to your Regional Compliance Officer and/or the Chief Compliance and Privacy Officer by November 9. These comments will then be compiled into one response from HHSC that will be reviewed by the PCEO and General Counsel.

CMS must receive comments at one of the addresses provided below, **no later than 5 p.m. on November 16, 2010**. In commenting, please refer to file code CMS-6028-P. CMS does not accept comments by fax.

You may submit comments in one of four ways:

1. ***Electronically****:* You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the "Submit a comment" instructions.

2. ***By regular mail:***

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-6028-P,
P.O. Box 8020,
Baltimore, MD 21244-8020.

3. ***By express or overnight mail:***

Centers for Medicare & Medicaid Services,
CMS-6028-P 3
Department of Health and Human Services,
Attention: CMS-6028-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

4. ***By hand or courier***

Source: **CMS-6028-P**