



## BNA's Health Care Daily Report<sup>TM</sup>

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### ***Provider Regulation***

#### **AHA Calls for Two-Track Review Process For Self-Referral Disclosure Protocol**

The Centers for Medicare & Medicaid Services should implement a two-track review process for provider disclosures of physician self-referral violations, creating an expedited review process for noncomplex issues and providing for detailed reviews in more complicated situations, according to a letter from the American Hospital Association to Department of Health and Human Services Secretary Kathleen Sebelius.

"Creating an expedited process recognizes that many actual or potential violations do not involve a complex set of facts, while detailed review would be used when the circumstances require a more involved description or analysis," the July 16 letter from Rick Pollack, executive vice president of AHA, said.

Section 6409 of the Patient Protection and Affordable Care Act (PPACA, Pub. L. No 111-148) requires the secretary of health and human services to create a self-referral disclosure protocol through which providers can disclose actual or potential violations of the physician self-referral act (Stark law).

A two-track review process would reduce administrative burdens on both CMS and providers by providing for the quick resolution of low-risk violations, the letter said, while still retaining the ability to engage in detailed reviews when appropriate.

"The AHA does not want the two-track process to be so defined as to limit its utility and the ability of CMS to address complex situations that must be evaluated on a case-by-case basis, so a desk review would be a key first step to the process," Jana Kolarik Anderson, an attorney with Nelson Mullins Riley & Scarborough, told BNA July 19.

The letter also said that CMS should take into account a number of mitigating factors not already specified under the PPACA, when assessing a self disclosure, including whether the violation was intentional or accidental, as well as whether any corrective steps have been taken by the provider.

PPACA specifically authorizes HHS to reduce penalties when a provider is self-disclosing a violation based on four mitigating factors, including:

- the nature of the violation;
- the timeliness of the self-disclosure;
- the level of cooperation from the provider; and
- any other factors that the HHS secretary deems appropriate.

"HHS has tried very hard to get providers to self-disclose potential fraud, but in all its efforts it hasn't done a good job of convincing the provider community that there are any significant benefits to using the protocol," Kirk Nahra, an attorney with Wiley Rein, told BNA July 19. "The AHA comments are designed to give some reasonable protections to this protocol. If HHS wants to make this protocol work, it needs to give providers a realistic reason to use it."

Anderson said the lack of a self-disclosure protocol has kept providers from self-disclosing any Stark violations, as penalties for even technical violations have been large, including the need to refund any reimbursement claimed, large civil monetary penalties, and the possibility of exclusion from federal health care programs.

The Stark law, which is contained in Section 1877 of the Social Security Act, prohibits physicians from referring Medicare and Medicaid patients to an entity in which they have a financial relationship, either through a direct investment or through family. The law includes certain exceptions, such as allowing a physician to refer a patient for certain designated health services within the physician's own practices, also known as the in-office ancillary services exception.

The letter also said that CMS should establish stipulated damages for Stark law violations that pose the least risk to the Medicare program, such as a situation where a signature is missing. In such cases, damages could range up to \$10,000, reflecting the relative risks of the violations.

*By James Swann*

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*The AHA letter is at <http://www.aha.org/aha/letter/2010/100716-cl-ppaca.pdf>.*

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