AIS's
HEALTH REFORM WEEK
Volume 2, Number 3 • January 31, 2011
Business News and Strategies for Health Plans, Pharma, Hospitals and Providers

New HHS Fraud-Prevention Rules Could Cause New Barriers to Entry for Providers

The final rules that HHS issued on Jan. 24 to implement fraud-prevention provisions in the health reform law include some "very scary tools" the department will have that could wind up hurting honest providers, according to a leading health care fraud attorney. She doesn't question the intent of the rules, but says they may have unintended effects in creating new and not challengeable barriers to entry at a time when the reform law is encouraging providers to engage in new kinds of transactions and forms of care.

In particular, says Carrie Valiant, a partner in law firm Epstein Becker & Green, P.C., the rules make no distinction between those providers starting out and those already existing, "and I think there should be" a distinction. They also leave big questions, according to Valiant, such as how a "credible allegation" of fraud that triggers actions under the rules will be defined.

In unveiling the rules at a news conference in Washington, D.C., HHS Sec. Kathleen Sebelius said they will enable the previous "pay and chase" enforcement approach to be replaced with a "more proactive" one. The new rules, she added, will make it possible to cut off the flow of funds to "suspected criminals" before the frauds they perpetrate get off the ground.

A key part of the regulation authorizes the suspension of payments to providers and suppliers while an enforcement action or investigation is underway if there is a "credible allegation" of fraud, as referred to in the reform law (*HRW* 7/12/10, p. 1).

In response to a question at the news conference about how a "credible allegation" will be defined, Peter Budetti, CMS deputy administrator for program integrity, said it will be done "in concert" with the HHS Office of Inspector General. Credible allegations under the rules, he said, can come through "tips," law-enforcement investigations or screening of claims, among other means. "The key is defining what is sufficiently credible and warrants suspension of payments," he added.

Among other provisions of the new rules are ones to:

◆ ***Create a rigorous screening process for providers and suppliers*** enrolling in Medicare, Medicaid and the Children's Health Insurance Program (CHIP) to keep fraudulent providers out. Such screenings, Budetti explained, will be based partly on the category of providers, as categories are assigned risk levels for fraud based on "experience" and "analysis of our own information." Subsequently, he added, individual providers can be "moved between categories."

◆ ***Require a new enrollment process for Medicaid and CHIP providers,*** with states having to screen providers who order and refer to Medicaid beneficiaries to determine if they have a history of defrauding government. Providers that have been kicked out of Medicare or another state's Medicaid or CHIP program will be barred from all Medicaid and CHIP programs.

◆ ***Temporarily stop enrollment of new providers and suppliers*** if Medicare and/or a state agency identifies a trend in a category of providers or geographic area that may indicate fraud — as long as the halt won't impact patient access to care. The government agencies may use advanced predictive modeling software for the identification purposes.

"I think these are some very scary tools that the OIG has at its disposal," Valiant tells *HRW*. "Suspension is the scariest aspect," she says, arguing that this puts much more power in the hands of "whistleblowers" making allegations and very little power in the hands of providers hoping for "due process" to challenge contentions.

She maintains that the rules are "extremely broad" in defining credible allegations and could enable occurrences such as complaints filed with "hotlines" to be the basis for suspensions. Many False Claims Act cases, according to Valiant, are filed by "disgruntled former employees," and providers already are expending large amounts of resources to deal with them, even though many ultimately "go away" or are settled in a "much more minor way" than originally sought. Now, she says, not only will the expense increase even if the allegations are unjustified, "but the government also can cut off your Medicare payments."

Adds Valiant: "'Credible' really is in the eye of the beholder." Furthermore, providers often don't have full

information early in a case with which to defend themselves against allegations, especially since complaints may be kept under court seal for years, she says.

The screening for new entrants that the new rules provides is "understandable" for keeping out fraudulent providers, she acknowledges. The impact, though, could be troublesome depending on how the powers are used, particularly since the reform law is encouraging formation of new entities, such as Medicare accountable care organizations, and "transactions." Many of the new features also will require new provider identifier numbers or expansion of existing entities into new locations, and all of those developments "implicate" the new screening aspects of the rules, Valiant asserts.

She says that it already can take providers many months to "jump through hoops" when they have ownership changes or even a new location, and "the screening will only increase this time frame." The result of the rules' "overreaching" screening provision, in Valiant's view, will be "creating further barriers to entry" at a time when the reform law hopes to achieve broader participation.

Valiant also takes issue with the permanent-exclusion provisions regarding Medicaid and CHIP. A provider should be allowed to "do your time" and become "reformed," especially since exclusions can result from such "relatively innocuous things" as failing to file an address change, she says, citing a case she was involved in.

Since the rules are final, what can providers do about them? Valiant recommends that providers look for some kind of "accreditation" or "*Good Housekeeping* seal of approval" that OIG will accept in lieu of more extensive screening procedures. Other steps she suggests are standard compliance program components such as to make sure Medicare forms are up to date, do thorough investigations of allegations by potential whistleblowers, and "dig deep" to be able to respond quickly in the event of a possible suspension.

Still, she says. "it's difficult to build a business plan" when "there are folks that could cut off your enrollment based on things unknown" to the providers involved.

Contact Valiant at (202) 861-1857. View the rules at http://www.ofr.gov/OFRUpload/OFRData/2011-01686_PI.pdf. ✧