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## Program Integrity: Disenrollment Threat Looms Large Under New PI Rule

**Are you performing your required due diligence on those you work with?**

Get ready to enter a potential enrollment minefield when it comes to affiliated providers.

So indicates a final rule recently issued by the **Centers for Medicare & Medicaid Services**, "Program Integrity Enhancements to the Provider Enrollment Process." The rule, which took effect Nov. 4, implements Affordable Care Act provisions that require Medicare, Medicaid, and CHIP providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers and gives CMS additional authority to deny or revoke a provider or supplier's Medicare enrollment in certain circumstances.

Medicare touts its new fraud-fighting authority in a particularly strongly worded release about the rule. The regulation "strengthens the agency's ability to stop fraud before it happens by keeping unscrupulous providers out of our federal health insurance programs," CMS says in the release. "This first-of-its-kind action - stopping fraudsters before they get paid - marks a critical step forward in CMS' longstanding fight to end 'pay and chase' in federal healthcare fraud efforts and replace it with smart, effective and proactive measures."

CMS Administrator **Seema Verma** adds, "For too many years, we have played an expensive and inefficient game of 'whack-a-mole' with criminals - going after them one at a time - as they steal from our programs. These fraudsters temporarily disappear into complex, hard-to-track webs of criminal entities, and then re-emerge under different corporate names. These criminals engage in the same behaviors again and again. Now, for the first time, we have tools to stop criminals before they can steal from taxpayers. This is CMS hardening the target for criminals and locking the door to the vault. If you're a bad actor you can never get into the program, and you can't steal from it."

The rule adds an affiliations authority, which defines who or what is "affiliated" (see details in story, p. 93) and requires providers, including hospices, to report affiliated providers who have a "disclosable event" (see details in story, p. 93). And it expands the reasons for denying or revoking a provider's enrollment and increases penalties (see story, p. 94).

The affiliates provision presents numerous hardships for providers, experts warn.

Under the rule, "providers will significantly increase information required to be secured from owners and managing employees," says consulting firm **The Health Group** in Morgantown, West Virginia, in its electronic newsletter.

"This rule may create more problems than it solves, particularly given an overly broad definition of what constitutes an 'affiliation," says the **American Physical Therapy Association** in online analysis of the rule. "The likely result: undue administrative burden for providers and suppliers who have been compliant from the start."

**For example:** The 5 percent ownership threshold that determines affiliation is "extremely low," judges the trade group. APTA asked CMS during the rulemaking cycle to increase the threshold to 25 percent, but Medicare officials didn't take the group's advice on that point.

**Watch out:** "The rule's inclusion of indirect ownership interests in the definition of affiliation includes parties with ownership interests through a publicly traded company, mutual fund or other large investment vehicle," advise **Foley** attorneys **Jill Wright** and **Judith Waltz** in online analysis.

The new requirements will make providers guilty by association, protest **Sheppard Mullin** attorneys **Michael Paddock**, **Erica Kraus**, and **Theresa Thompson** in online analysis. CMS will be able to base denials and revocations on an

associate's conduct.

Medicare can deny or revoke enrollment "based on any disclosable event that CMS determines poses 'an undue risk of fraud, waste, or abuse,' or based on a failure to disclose a disclosable event," the Sheppard Mullin attorneys point out.

The timeline for affiliations and disclosable events is also problematic, Wright and Waltz indicate. The final rule determines that "it does not matter whether the affiliation has ended or whether the providers or suppliers were enrolled in a federal health care program at the time of the affiliation," they note.

Being required to "disclose relationships with affiliates who weren't enrolled in Medicare at the time" is "burdensome to say the least," APTA criticizes.

And "except for a current uncollected debt, the timing of the disclosable event is irrelevant," Wright and Waltz emphasize. "Thus, if the enrolled or enrolling provider or supplier had an affiliation with a provider/supplier in the past five years, and that provider/supplier at any point - prior to or after the termination of the affiliation - had a payment suspension, exclusion or a denial, revocation or termination of billing privileges, the affiliation must be disclosed."

The rule's "poorly defined 'lookback' requirement ... puts a five-year limit on how far back a provider must scour its records for bad-actor affiliates but no similar timeframe on how long ago that affiliate's violations may have occurred," APTA protests. "Providers and suppliers will be forced to become private investigators to determine whether an affiliate ever had its enrollment denied, revoked, or terminated," the group continues. "This is simply not feasible" and will take away from patient care time.

**Result:** "The disclosure requirements have the potential to snare honest providers," Wright and Waltz warn.

In addition to the new affiliation provisions and expanded denial/revocation authority, CMS is increasing the time that offenders are not allowed to reenroll from three to 10 years, with certain exceptions, Wright and Waltz note. And the rule prohibits enrollment in the Medicare program for up to three years if a provider or supplier's enrollment application is denied because of false or misleading information submitted.

Keep in mind that Medicare intends these new rules to serve as a deterrent as well as an enrollment enforcement tool, notes law firm **Alston & Bird** in online analysis.

**Bottom line:** The final rule's new requirements are overly burdensome and "will not make the Medicare program appreciably safer," APTA laments. "This rule threatens to sacrifice patient access to care for the sake of a shotgun approach to the problem, adding further unnecessary burden to providers who already follow the rules."

Nearly in conjunction with the PI final rule, CMS released a new transmittal outlining other changes to the enrollment application process. Those changes include a list of new reasons for application rejection (such as not responding to the Medicare contractor's request for information within 30 days of the request) and for application return (such as submitting the application more than seven months before the due date).

"Don't think for a second that the timing of the final rule and these revisions are unrelated," the Health Group says in its electronic newsletter.

Note: The 64-page PI final rule on enrollment is at www.govinfo.gov/content/pkg/FR-2019-09-10/pdf/2019-19208.pdf. The transmittal on enrollment changes is online at www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R896PI.pdf.