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Report on Medicare Compliance Volume 30, Number 5. February 08, 2021
Some Compliance Program Elements Require Rethinking in Wake of Stark Law Changes

By Nina Youngstrom

Hospitals will be revisiting some of their policies and procedures, auditing and monitoring, and other elements of their compliance programs in the wake of changes to the Stark Law regulation[1] that took effect Jan. 19. New and revised exceptions and definitions in the regulation pave the way for hospitals and other entities that provide designated health services (DHS) to prevent or repair noncompliant physician arrangements before racking up fat overpayments or false claims liability.

How the revised Stark regulation affects compliance programs depends on the nature of the change and the DHS entity's response to it, said attorney Ritu Kaur Cooper, with Hall, Render, Killian, Heath & Lyman PC in Washington, D.C. "There's a lot to wrap your mind around in these new rules."[2]

For example, CMS gave hospitals more flexibility with signature and writing requirements. They now have 90 days to get physician signatures on agreements, regardless of why they're missing (inadvertent or otherwise). Signatures may be electronic if that's allowed under state law, she said.

Hospitals also now have the option of using a collection of documents (e.g., emails, board minutes) instead of a formal contract for physician arrangements. The Stark regulation said that "a single formal written contract is not necessary to satisfy the writing requirement in the exceptions to the physician self-referral law.... Depending on the facts and circumstances, the writing requirement may be satisfied by a collection of documents." And CMS removed the frequency caps on the flexibility with signature and writing requirements, which had been limited to once every three years per physician, Cooper said at a Jan. 29 webinar sponsored by the Health Care Compliance Association.

In the wake of these changes, DHS entities may be tempted to relax their policies and procedures because many of them "still have problems ensuring agreements are signed on time, let alone within 90 days of the start date," Cooper said. But suppose a hospital decides not to change its policies on signatures and writing requirements, which are stricter than the revised rule. What should it do about educating employees who touch the area of physician contracts? "The question is, do you train them on the flexibility but inform them you decided to opt out of allowing the flexibility, and give a policy reason" for hewing to a stricter version than the regulation? "But then the cat is out of the bag," Cooper said. If employees know the regulation allows a 90-day grace period, will they be lax about the policy, or perhaps just confused about the disconnect between the policy and the regulation? Hospitals could opt not to inform employees about the regulatory change, but if they discover it on their own, perhaps their trust in the organization could be affected. "Deciding whether to educate is an important question for all of you as you go forward," she noted (see box, p. ?).[3]

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