CMS Coronavirus Stark Law Waivers Need Corrections

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In a Law360 guest article last month, we urged the Centers for Medicare & Medicaid Services to exercise the authority delegated to it under the Section 1135 waiver issued by U.S. Health and Human Services Secretary Alex Azar and issue a blanket waiver of sanctions under Section 1877(g) of the Social Security Act, also known as the Stark Law, to eliminate regulatory obstacles to various financial relationships between physicians and entities to which they refer patients.

Our premise was simple: In the current COVID-19 crisis, providers need to be able to act in good faith to shore up or expand their physician workforce without exposure to Stark Law sanctions or whistleblower suits under the federal False Claims Act.

On March 30, CMS Administrator Seema Verma issued blanket waivers for Section 1877(g) of the Social Security Act as a response to the COVID-19 pandemic in the U.S.[1] While a welcome exercise of regulatory authority, the blanket waivers must be revised in several key respects if they are to function as CMS no doubt desires them to work.

Mechanically, the blanket waivers describe types of financial relationships and types of referrals excepted from sanctions otherwise applicable under the Stark Law and regulations promulgated thereunder. Eleven specific types of financial relationships are described in text that identifies the source of a financial benefit, the nature of the benefit and the recipient (e.g., entity paying above fair market value remuneration to physician for personally performed services).

The chief problem with the blanket waivers is several of the circumstances describe remuneration that is protected only if it is below fair market value — but in the contexts given, a payment below fair market value seems highly unlikely. The blanket waivers are really needed to protect payments above fair market value when the physician is the recipient and payments below fair market value when the physician is the source.

But because many of the existing exceptions under the Stark Law require remuneration that is consistent with fair market value, the better approach is for CMS to follow the drafting convention it adopted for the first type of financial relationship protected under Section 2B of the blanket waivers (e.g., remuneration that is above or below fair market value) for the financial relationships described under paragraphs two through seven of Section 2B as well.[2]

Paragraphs 12 through 18 of Section 2B of the blanket waivers address specific types of referrals rather than types of remuneration for which the blanket waivers offer protection. CMS' purpose in drawing this distinction appears to be based on the fact that the descriptions speak to financial relationships that arise out of ownership or investment interests rather than compensation arrangements. In any case, the

descriptions in paragraphs 12 through 18 do not turn upon any fair market value considerations and, therefore, do not trip the above or below fair market value concern.

Another problem presented by the blanket waivers is that they apply only to direct financial relationships with physicians (or physician organizations in whose shoes the physician stands under Title 42 of Code of Federal Regulations 411.354(c)). This approach fails to recognize that the financial relationships necessary in this strange, new paradigm often will be between hospitals and physician groups, and many physicians do not stand in the shoes of their physician organizations. The blanket waivers need to be expanded to cover both direct and indirect financial relationships.

Providers also need to recognize that the blanket waivers fail to address potential collateral liability arising under the federal Anti-Kickback Statute.[3] While the AKS is a separate law, conduct that violates the billing and referral prohibitions under the Stark Law may be found to violate the AKS in instances where there is evidence of an intent to induce the referral of federal health care program patients with remuneration.

The blanket waivers do nothing to protect the remuneration or referrals described in paragraphs 1-18 of Section 2B from the risk of challenge under the AKS or as per se violations of the federal False Claims Act. CMS lacks authority to waive enforcement of the AKS, but such authority may be exercised by the HHS Office of Inspector General.

So, to accompany the blanket waivers and render them fully effective, the OIG needs to invoke its legal authority to promulgate a new regulation to safe harbor any remuneration or referral that qualifies for the CMS 1135 waiver of the Stark Law.

Finally, the blanket waivers suffer a timing issue. The waivers will terminate after 60 days (unless extended for additional periods of not more than 60 days each, or upon the termination of the applicable declaration of emergency or disaster or public health emergency. In some instances, the financial relationships contemplated, be they compensation arrangements or ownership or investment interests, are likely to continue beyond either such endpoint.

Providers relying on a blanket waiver need to be attentive to this issue and endeavor to structure any arrangements for which blanket waiver protection is required to expire contemporaneously with the expiration or termination of the applicable waiver.

The fixes that are needed here are not complex and will do nothing to undermine the enforcement goals and objectives of CMS as reflected in the blanket waivers. But the provider community can ill afford to rely upon incomplete waivers, or waivers that protect their Stark Law flank and leave them potentially exposed on the AKS flank.

Notes

1. https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.

2. Note that the CMS factsheet on Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19 (https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf) seems to indicate that CMS may have intended such broader protection when it states "[h]ospitals and other health care providers can pay above or below fair market value to rent equipment or receive services from physicians

(or vice versa)."

3. 42 U.S.C. §1320a-7b(b).

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