HUNTON ANDREWS KURTH

Lawyer Insights

Health Providers Still Need Help Fighting Virus Kickback Risk

By Mark Hedberg, Matthew Jenkins and James Pinna
Published in Law360 | April 22, 2020

Both the Centers for Medicare & Medicaid Services and the U.S. Department of Health and Human Services Office of Inspector General have taken important actions to help reduce regulatory obstacles and attendant risks under the federal Stark Law and Anti-Kickback Statute with respect to certain financial relationships between physicians and health care providers to which they refer patients during the COVID-19 crisis.

While these actions are much welcomed by the provider community, there are still some gaps that need to be addressed to allow providers to effectively deal with the COVID-19 crisis without the risk of exposure to potential qui tam lawsuits under the federal False Claims Act.

On March 30, CMS Administrator Seema Verma issued the blanket waivers of Section 1877(g) of the Social Security Act due to the declaration of the COVID-19 outbreak in the U.S. as a national emergency.[1] These waivers had the effect of shielding physicians and entities from the referral and payment prohibitions of the Stark Law with respect to eleven specific types of financial relationships enumerated under the Stark Law waivers.

Claims submitted for services provided in circumstances covered by the waivers also should be protected from FCA liability because submission of the underlying claims would not be prohibited under the Stark Law. Although we pointed out in a prior article[2] several corrections that should be made to the Stark Law waivers, all in all they are a strong step in the right direction.

On April 3, the OIG issued a policy statement regarding application of certain administrative enforcement authorities due to the declaration of the COVID-19 outbreak in the U.S. as a national emergency.[3] In a nutshell, the OIG has said that it "will not impose administrative sanctions under sections 1128(b)(7)[4] or 1128A(a)(7)[5] of the [Social Security] Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute, with respect to remuneration that is covered by section II.B.(1)-(11) of the [Stark Law] Waivers."[4 - 5]

Although a welcome exercise of the OIG's discretion, the protections afforded by the AKS enforcement statement are technically limited and still leave the health care community exposed to potential risks of AKS-related criminal prosecution and FCA liability.

Specifically, the AKS enforcement statement suffers two principal shortcomings. First, the conduct protected by the AKS enforcement statement is tied to a subset of the conduct protected by the Stark Law waivers. Mechanically, paragraphs 1-11 under Section II.B. of the Stark Law waivers identify the types of

This article presents the views of the authors, which do not necessarily reflect those of Hunton Andrews Kurth LLP or its clients. The information presented is for general information and education purposes. No legal advice is intended to be conveyed; readers should consult with legal counsel with respect to any legal advice they require related to the subject matter of the article. Receipt of this article does not constitute an attorney-client relationship. Prior results do not guarantee a similar outcome. Attorney advertising.

financial relationships shielded from sanctions otherwise applicable under the Stark Law, and paragraphs 12-18 identify specific types of referrals, as opposed to types of remuneration, for which the Stark Law Waivers offer protection.

CMS' purpose in drawing this distinction appears to be based on the fact that the referral descriptions speak to financial relationships that arise out of ownership or investment interests rather than compensation arrangements. Whatever CMS' drafting intent, the OIG in its AKS enforcement statement saw fit to cover only the remuneration specified in paragraphs 1-11 of the Stark Law waivers. No protection is provided under the AKS enforcement statement for the types of financial arrangements identified in paragraphs 12-18 of the Stark Law waivers.

Second, the protections of the AKS enforcement statement only address the risk associated with administrative enforcement actions.[6] In the event conduct violates the AKS, the only protection offered is from sanctions under Sections 1128(b)(7) (the secretary's permissive exclusion authority for AKS) and 1128A(a)(7) (authorizing imposition of civil monetary penalties for AKS violations) of the Social Security Act.

To be sure, the OIG went as far as it could go using a policy statement as the protection mechanism. But under this approach the health care community remains exposed to the two most serious types of potential liability under AKS: criminal liability under Section 1128B(b) and FCA liability.[7]

And that risk is not inconsequential given the one-purpose test embraced by the U.S. Court of Appeals for the Third Circuit's holding in U.S. v. Greber[8] and a robust qui tam plaintiffs bar that may look to take advantage of a rich whistleblower environment as workers are furloughed or laid off as a result of the COVID-19 crisis.

What is needed is a protective mechanism addressing AKS liability risks that is as comprehensive as the protections offered by the Stark Law waivers. Unfortunately, the OIG's options are limited and not well suited to the task. An advisory opinion under Section 1128D of the Social Security Act[9] is not a practical alternative because advisory opinions are issued only in response to individual requests and bind only the HHS secretary and the party(ies) requesting the advisory opinion.

A time-limited safe harbor would do the trick; the AKS does not apply to any payment practice specified in a safe harbor.[10] But the statute conferring the power to issue safe harbors would have posed a timing issue: it contemplates a 60-day period soliciting proposals followed by publication of proposed safe harbors with another 60-day comment period preceding publication of a final safe harbor.[11]

That process would take too long, and truncating it would leave any person relying on the new safe harbor open to attack on the ground that it was improperly promulgated. Nor does the OIG's authority to issue special fraud alerts offer an option — such alerts are used to flag concerning conduct, not to provide protections for tolerated forms of remuneration.

The ultimate goal here is coextensive protection. The best solution would be congressional action to amend the AKS to provide that it does not apply to any payment practice that is the subject of a Section 1135 waiver as to the Stark Law.

If a sufficient emergency exists to trigger Section 1135 waiver authority,[12] and the secretary determines a waiver of the Stark Law is necessary to ensure "to the maximum extent feasible ... that sufficient health

care items and services are available to meet the needs of individuals in such area enrolled in [Medicare, Medicaid and the State Children's Health Insurance Program]" and that "health care providers ... that furnish such items and services in good faith, but that are unable to comply with one or more requirements [that may be waived under Section 1135], may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse," then the AKS also should be waived.

Otherwise, providers may be reluctant to take full advantage of the flexibility afforded by the Stark Law waivers fearing Monday morning quarterbacking by the qui tam plaintiffs bar.

Absent congressional action, the executive branch should take as many steps as possible to head off such challenges. Building on the AKS enforcement statement, we would propose (1) the U.S. Department of Justice issue a memorandum to all U.S. attorneys providing guidance as to AKS enforcement during the pandemic-related emergency, and (2) CMS issue a policy statement regarding the materiality of any AKS violation associated with a financial arrangement that satisfies the Stark Law waivers as to the payment of claims by CMS.

The DOJ memorandum could be modeled after the Aug. 29, 2013, memorandum addressing marijuana enforcement under the Controlled Substances Act and further contemplate proactive dismissals of relator filings related to provider activities during the COVID-19 crisis, consistent with the Granston memorandum.

The CMS statement should make clear that any potential violations of the AKS associated with financial arrangements satisfying the Stark Law waivers are not material to CMS' claims payment decisions.[13] These steps, while not providing absolute protection, would significantly reduce the potential risks that providers might face in dealing with potential qui tam actions under the FCA arising out of financial relationships with physicians during the COVID-19 crisis.

Notes

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

2. Jenkins, Hedberg & Pinna, CMS Coronavirus Stark Law Waivers Need Corrections, Law360, April 7, 2020.

3. https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf.

4. 42 U.S.C. § 1320a-7(b)(7).

5. 42 U.S.C. § 1320a-7a.

6. Another theoretical issue is that the AKS Enforcement Statement is an indication of what OIG will do in the future on the enforcement front when confronted by a particular set of facts. There would not seem to be any binding authority that prevents OIG from changing its mind.

7. 42 U.S.C. § 1320a-7b(b) & (g).

8. See United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

© 2020 Hunton Andrews Kurth LLP

9. 42 U.S.C. § 1320a-7d(b).

10. 42 U.S.C. § 1320a-7b(b)(3)(E).

11. 42 U.S.C. § 1320a-7d(a).

12. A sufficient emergency would be one resulting in an emergency or disaster declaration by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act and a public health emergency declaration by the Secretary pursuant to the Public Health Service Act. 42 U.S.C. § 1320b-5(g).

13. See Universal Health Services v. United States ex rel. Escobar, 579 U.S. ___, 136 S. Ct. 1989 (2016).

***Mark S. Hedberg** is a partner in the firm's Business Finance & Health Care group in the firm's Richmond office. With a deep knowledge of the business and regulatory matters facing the industry, Mark focuses on delivering creative, cost-effective solutions for his health care clients. He can be reached at +1 (804) 788-8314 or mhedberg@HuntonAK.com.*

***Matthew D. Jenkins** is a partner in the firm's Business Finance & Health Care group in the firm's Richmond office. As the head of Hunton Andrews Kurths' health care practice, Matt devotes his practice to the firm's leading health care clients and coordinates the delivery of comprehensive legal services to such clients across the firm's various practices. He can be reached at +1 (804) 788-8736 or mjenkins@HuntonAK.com.*

***James M. Pinna** is a partner in the firm's Business Finance & Health Care group in the firm's Richmond office. Jim advises health care clients on matters involving regulatory compliance (including fraud and abuse, licensure, health privacy and reimbursement issues), structuring of business transactions, corporate governance and tax-exempt status issues. He can be reached at +1 (804) 788-8566 or jpinna@HuntonAK.com.*

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.