CMS Says Stark Law Final Rules Are Effective Despite Technical Deficiencies in Issuance and Biden Regulatory Freeze

By **Lori Beam**

CMS Statement
In an article last week, Business Valuation Resources' publication BVWire quotes a statement from the Centers for Medicare and Medicaid Services (CMS) – "The regulations finalized in [the final rule] are effective."

Concerns about the rules' effectiveness arose after the General Accountability Office concluded that both (1) the Stark Law final rules easing compliance with the Stark Law's physician self-referral prohibition and (2) the final rules issued by the Department of Health and Human Services Office of Inspector General (OIG) revising safe harbors to the Anti-Kickback Statute enhancing compliance flexibility had technical deficiencies. Specifically –

• Because the Stark Law final rules were published in the Federal Register on Dec. 2, 2020, with a stated effective date of Jan. 19, 2021, they did not comply with a statute applicable to all major rules that requires they not become effective earlier than 60 days after their publication in the Federal Register.
• Those technical deficiencies put the rules in limbo and made them potentially subject to the Biden Administration's inauguration day memo requesting agencies to consider postponing rules published in the Federal Register that had not yet taken effect.
• CMS's recent statement appears to indicate that CMS has determined it is not necessary to delay the effectiveness of the Stark Law final rules.

• Accordingly, per CMS, the Stark Law final rules are effective as of Jan. 19, 2021 – except for the rules' revisions to the group practice definition that CMS made effective Jan. 1, 2022, to give group practices time to comply with any changes affecting their physician compensation models.

This CMS statement gives hospitals, physicians and other health care providers greater comfort in relying on the various changes made in the Stark Law final rules that offer flexibility in establishing compliant ownership and compensation arrangements between referring physicians and providers of designated health services. As discussed in our Health Law Group's prior alerts, these changes include:
• New value-based arrangement protections
• Amended electronic health record donation exception
• New cybersecurity donation exception
• New exception for compensation at or below $5,000, and
• Several helpful clarifications relating to compensation.

No Similar Statement by the OIG
As of Feb. 23, the OIG has not made a statement regarding the effectiveness of the final rules to the Anti-Kickback Statute. But we do not expect the OIG to take a position different from CMS. CMS and the OIG coordinated closely on their final rules, and the rules have broad industry support. So, it's unlikely the Biden Administration will act to delay effectiveness.

Watch for More Alerts
So far, we have issued three alerts on the final rules to the Stark Law and Anti-Kickback Statute. These include one alert on compensation arrangements, one on EHR and cybersecurity donations and one overview. We will continue to break down the more than 1,600 pages of regulatory changes through future alerts. Be on the lookout for additional articles.

This article is general in nature and does not constitute legal advice.

Readers with legal questions should consult the author, Lori Beam (lbeam@sb-kc.com) or any other shareholders in Seigfreid Bingham's Health Law Group, including Mark Thompson, Joseph Hiersteiner, Mark Gilgus, John Neyens, Heath Hoobing and John Fuchs, or your regular contact at Seigfreid Bingham, at 816-421-4460.