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OIG Advisory: Yet Another Favorable Decision for Medical Device Manufacturers

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Partners Scott Liebman and Dominick DiSabatino cover the Office of the Inspector General for the Department of Health and Human Services (OIG)'s latest OIG Advisory Opinion (AO) No. 22-05, relating to subsidization of certain Medicare cost-sharing obligations in the context of a clinical trial involving medical devices (the Proposed Arrangement). This is the third AO in a recent series of AOs (see AO 21-17 on Nov. 19, 2021 and AO 21-13 on Oct. 4, 2021) focused on Medicare cost subsidies in a clinical trial setting for serious conditions that affect large portions of the population in the United States. Like these other AOs, OIG found that while the Proposed Arrangement could generate fraud and abuse risks under both the federal anti-kickback statute (i.e., § §1128A(a)(7) and 1128B(b) of the Social Security Act (Act)) and the Beneficiary Inducements CMP (i.e., §1128A (a)(5) of the Act), the Proposed Arrangement nevertheless presented a minimal risk of fraud and abuse under the law on the facts presented.

Medical device manufacturers should pay close attention to this trend when considering trial designs and patient populations. Sponsor-provided Medicare cost subsidies for trials requiring multiple follow-up visits should help with both patient enrollment and retention. More efficient enrollment and strong patient retention can drive down research spend and help companies hit development program milestones.

Attorneys

Dominick P. DiSabatino

Scott S. Liebman

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