

OIG: Continuing Education Programs Have Independent Value Under AKS

WRITTEN BY

Brianna M. Alunni | Allison DeLaurentis | Miranda Hooker

In the wake of the global pandemic, which forced manufacturers, trade organizations, and all other players in the health care industry to rethink how to provide medical education and communication on new product offerings to health care providers and consumers, the Department of Health and Human Services Office of Inspector General (OIG) recently weighed in on the potential inducement implications involved with manufacturer-sponsored continuing education. On June 29, OIG issued Advisory Opinion No. 22-14, addressing a proposed continuing education program, and not surprisingly concluded that *bona fide* continuing education programs that qualify for state-required continuing education credits, with no suspect characteristics, have independent value under the Anti-Kickback Statute (AKS). Consequently, OIG concluded that any requestors' proposals to provide such programs to potential referral sources at no cost created risk of fraud and abuse, but it issued a favorable opinion as to the requestor's proposal to charge attendees fair market value to attend.

The requestor, an ophthalmology practice, intended to provide optometrists, geographically local to its practice, with continuing education programs about new technologies and treatments for patients and designed to meet continuing education certification requirements in that state. The practice estimated that costs associated with the programs, including venue rental, faculty honoraria, audio-visual support, and food, would range from \$500-\$9,000, depending on the program's length (partial vs. full-day) and the venue.

The practice estimated that optometrists who attend these programs referred half of the surgical procedures the practice performed. The program would not require its attendees to refer any patients to the practice as a condition of attendance, attendee selection would not be based on past or expected prescribing, and the practice would advertise the program broadly, across open-sourced optometric association email lists and address lists for local optometry practices.

The practice proposed four different arrangements for financing these programs:

- Under Proposed Arrangement A, the practice would charge registration fees consistent with the fair market value for similar programs. The practice would fund any remaining expenses, with no other outside financing, and any excess registration fees exceeding the program's cost would be donated to charity.
- Proposed Arrangement B would *not* require a registration fee payment, and the practice would bear all costs of the program.

- Proposed Arrangement C would similarly not require any registration payment, but would include funding from industry sponsors, such as pharmaceutical manufacturers, with any leftover expenses funded purely by the practice and any excess revenue donated to a local charity.
- Finally, Proposed Arrangement D would require a registration fee and would solicit funding from industry sponsors.

As a threshold matter in evaluating the proposed arrangements, OIG first analyzed the suspect characteristics it described in its *November 2020 Special Fraud Alert on Speaker Programs*, and concluded that the proposed continuing education programs “do not exhibit the types of suspect characteristics highlighted” in the Special Fraud Alert because the proposed food and beverages (bagels, pizza, and nonalcoholic beverages) are modest, the venue is conducive to educational presentations, the attendee and faculty selections are not based on referrals, and the faculty honorarium is fair market value.

OIG then analyzed each proposed arrangement, finding only that Proposed Arrangement A presented a “sufficiently low risk under the Federal anti-kickback statute” upon which OIG would “not impose administrative sanctions.” This is because Proposed Arrangement A required payment of a registration fee, consistent with fair market value for similar programs, and would involve no industry sponsors or sources of funding outside these registration fees or the practice’s own contribution for any remaining expenses.

Conversely, the opinion found Proposed Arrangements B and C “would pose more than a minimal risk of fraud and abuse,” and the OIG “could potentially seek to impose administrative sanctions” on the practice if these proposals were pursued because these arrangements required no payment of fair market registration fees and would create a “heightened risk this remuneration could induce the optometrist attendees ... to refer surgical patients.” The opinion emphasized that industry sponsorships, such as those proposed under Arrangement C, would create an additional risk of inducing attendees to prescribe or order that sponsoring company’s products.

OIG reasoned that Proposed Arrangement D, despite charging a registration fee, still posed risk of fraud and abuse because the program would involve industry-sponsor payments where “the medical device manufacturers and drug companies would pay expenses that [the practice] otherwise would incur,” and to the extent that the sponsorship exceeded the expenses for the continuing education programs, the requestor’s ability to donate the excess funds to charity constitutes remuneration from the industry sponsors.

In light of OIG and industry’s recent focus on the suspect characteristics associated with marketing and education programs directed toward physicians, Advisory Opinion No. 22-14 serves as a reminder that absent any of these suspect characteristics, programs can implicate the AKS if they seek to confer independent value on a referral source. Optometrists must complete continuing education to maintain their licenses. OIG reasoned here that this continuing education programming typically requires a registration fee that optometrists pay themselves. An ophthalmologists’ direct or indirect (here through the facilitation of industry sponsorship) payment of those registration fees for potential referrer optometrists implicates the AKS. Providers and manufacturers alike should be vigilant in evaluating all programs, even those that are *bona fide*, educational, and lacking in suspect characteristics, by analyzing whether any independent value is conferred on a referral source.

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