



Summary of Department of Health and Human Services

Office of Inspector General Advisory Opinion 22-14

Summary and Takeaway:

Doctors of Optometry should be cautious about receiving free continuing education from a ophthalmology surgical practice to which they may refer patients. In June 2022, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published an advisory opinion that characterizes such arrangements as a potential violation of federal anti-kickback legislation, designed to induce referrals to the surgical practice which will be paid for by a federal healthcare program (i.e. Medicare or Medicaid).

Background:

An ophthalmology practice specializing in cataract and refractive surgery petitioned the HHS OIG for an opinion on the practice's recent proposal to establish two annual continuing education programs for doctors of optometry in its area that would cover new technology and pharmacological practice treatment protocols relevant to treating patients who require ophthalmic surgeries, including the practice's patients. The courses would be open to all optometrists in the local area, and participation in the practice's referral network would not be a requirement. Attendees would also not be required to be customers of the industry sponsors of the CE programs. CE would be approved by relevant educational accrediting agencies. Course offerings would include the following:

- full-day CE program providing 6 hours of CE credit (practice physicians would serve as faculty in conjunction with some paid external faculty);
- an evening CE program providing 2 hours of CE credit (practice physicians would serve as faculty in conjunction with some paid external faculty).

The opinion notes that the ophthalmology practice has extensive relationships with its referral network of optometrists in their area. The practice is seeking the OIG's opinion as to whether the proposal runs afoul of federal anti-kickback statutes (Sec. 1128 of the Social Security Act). The practice's proposal included four alternative means for funding the program, and asked OIG to provide guidance on each:

Option A: Practice would charge attendees a registration fee consistent with Fair Market Value (FMV);

Option B: Practice would cover program costs without a registration fee;

Option C: An industry sponsor would cover program costs and the practice would not charge a registration fee;

Option D: An industry sponsor would cover program costs and the practice would charge a below FMV registration fee. Practice would inform industry sponsors that all guidelines set forth in the ACCME Standards for Integrity and Independence in Accredited Continuing Education would apply to their sponsorship of the CE programs.

In all cases, the practice would cover any revenue shortfalls (for example, if attendance is less than estimated). Any excess revenue would be donated to a local, unrelated charity. For Options C and D (industry sponsored CE), the practice would inform industry sponsors that all guidelines set forth in the Accreditation Council for Continuing Medical Education Standards for Integrity and Independence in Accredited Continuing Education would apply to their sponsorship of the CE programs.

OIG Opinion of Each Proposal

Option A: OIG believes there is sufficiently low risk for fraud and abuse under the Federal anti-kickback statute that it would not impose administrative sanctions.

Options B & C: Due to the fact that the programs would be funded entirely by the practice in both proposals, the OIG believes there is a risk for fraud and abuse (i.e. patient steering) under each. The doctors of optometry attending the program would be receiving free CE credits, presumably with the expectation that it would generate referrals. HHS OIG states that it may seek sanctions on such programs.

Option D: In this scenario, in which some of the costs of the CE are underwritten by an industry sponsor, HHS OIG states that it would potentially impose sanctions. In this instance, the main focus is on the relationship between the industry sponsor and the practice, and less on the possibility of referrals between doctors of optometry and the ophthalmology practice. However, since the sponsorship will presumably allow the practice to charge less than FMV for the CE courses, there is still a risk of an anti-kickback issue involving the optometrist.

Conclusion

Although the focus of any enforcement action would likely fall upon the surgical practice that sponsors the program, there are technically two parties to a kickback scheme. An optometrist who receives free CE and then makes a referral to the practice that provided the CE is – likely without their knowledge – participating in the scheme, and is thereby theoretically subject to possible sanction. Doctors of optometry are advised to avoid such situations. If an optometrist is himself or herself an owner of a surgical practice, then the prospect of sanctions for violating the anti-kickback statute in connection with the provision of free CE is more serious, and competent legal counsel should be obtained before deploying any such program. A poorly designed program could cause the practice to violate anti-kickback laws either in its relationship with the recipients of the CE, or in its relationship with industry sponsors of CE.