



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor.]

Issued: June 23, 2022

Posted: June 29, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-14

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [redacted] (“Requestor”) regarding its proposed continuing education (“CE”) programs for local optometrists and four potential options to fund the programs. Under the first option, Requestor would cover all CE program costs and charge attendees a fair market value registration fee (“Proposed Arrangement A”). Under the second option, Requestor would cover all CE program costs with no registration fee or outside funding (“Proposed Arrangement B”). The third and fourth options (“Proposed Arrangement C” and “Proposed Arrangement D,” respectively) would include funding for the CE programs from industry sponsors (e.g., medical device and pharmaceutical companies). Under Proposed Arrangement C, Requestor would not charge any registration fee to CE program attendees. Under Proposed Arrangement D, Requestor would charge a registration fee to CE program attendees that would be subsidized by the funding received from industry sponsorships for the programs. We refer to Proposed Arrangement A, Proposed Arrangement B, Proposed Arrangement C, and Proposed Arrangement D collectively as the “Proposed Arrangements.”

Requestor has inquired whether the Proposed Arrangements, if undertaken, would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the “Act”) or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”).

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangements, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in

connection with the Proposed Arrangements. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although Proposed Arrangement A, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestor in connection with Proposed Arrangement A under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute. In contrast, we conclude that Proposed Arrangement B, Proposed Arrangement C, and Proposed Arrangement D, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

This opinion may not be relied on by any person¹ other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor, [redacted], is an ophthalmology practice with offices in [redacted] (the “State”). Requestor specializes in cataract and refractive surgery, with one ophthalmologist performing surgical procedures and three optometrists providing primary eye care in support of these surgeries. Requestor estimates that local optometrists outside of the practice refer half of the surgical procedures Requestor performs, and 30 percent of those patients return to the referring optometrist for post-operative care that is co-managed with Requestor’s ophthalmologist. Accordingly, Requestor performs all post-operative care within the practice for approximately 85 percent of its surgical cases and co-manages approximately 15 percent with local optometrists.²

Under the Proposed Arrangements, Requestor would offer, on an annual basis, two CE programs that would address new technology and pharmacological practice treatment protocols relevant to treating patients who require ophthalmic surgeries, including Requestor’s patients. The course options would consist of a full-day CE program providing 6 hours of CE credit and an evening CE program providing 2 hours of CE credit. Requestor would design the programs to meet requirements for CE certification for optometrists in the State. Requestor would seek approval for its CE programs from the Council on Optometric Practitioner Education or the State board of optometry. Upon approval by either certifying board, the CE program credit earned by attendees

¹ We use “person” herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

² Such co-management arrangements involve sharing the patient’s care and splitting the global fee for cataract surgeries under Medicare. Requestor did not seek, and we do not express, an opinion about its co-management arrangements. This opinion is limited to the Proposed Arrangements and focuses on the potential exchange of remuneration and referrals in connection with the CE programs.

would count towards the required 30 hours of CE that optometrists must complete every 2 years to maintain a license in the State.

The CE programs offered under the Proposed Arrangements would be open to all local optometrists in Requestor's service area, which comprises an approximately 20-mile radial area around [redacted]. Attendance would not be limited to optometrists who refer to Requestor, and there would be no requirement that attendees refer patients to Requestor as a condition of attendance. The selection of attendees also would not be based on past or expected prescribing or ordering of any industry sponsor's items or services payable by Federal health care programs. Requestor estimates that 100 optometrists would attend the full-day program and 30 to 50 optometrists would attend the evening program. Expenses for the full-day program would include a local venue rental with audio-visual support, faculty honoraria and expenses, and modest food items for attendees and faculty.³ Expenses for the evening program would include a local venue rental with audio-visual support and would include light food and non-alcoholic refreshments.⁴ For the CE programs' site, Requestor would select an appropriately sized conference space conducive to educational presentations in a geographic location convenient to Requestor's service area; the CE programs would not be held in conjunction with sporting or other recreational events.

For the full-day and evening programs, Requestor's ophthalmologist and optometrists would serve as faculty. Additional faculty for the full-day program would include one or two faculty members from professional schools. These external faculty would be paid an honorarium plus expenses at a fair market value rate that would not take into account the volume or value of past business generated or potential future business generated for Requestor or for an industry sponsor by the faculty.⁵ The selection of external faculty would not be based on referrals to Requestor or past or expected prescribing or ordering of any industry sponsor's items or services payable by Federal health care programs. All faculty would possess first-hand professional experience that enables them to provide particular expertise and input on new technology and pharmacological practice treatment protocols relevant to treating patients who require ophthalmic surgeries, including Requestor's patients.

Requestor would advertise the CE programs by sending emails to optometrists in the local area serviced by Requestor. The email addresses would be obtained through open-sourced emails

³ Requestor estimates that current total costs for the full-day program would be \$6,000–\$9,000. Food provided at the program would include items such as bagels and coffee in the morning and pizza at lunch (estimated to be about \$20 per attendee).

⁴ Requestor estimates that current total costs for the evening program would be \$500–\$1,500 (with food items estimated to be \$15–\$20 per attendee). Depending on the number of attendees, the evening program could be held at one of Requestor's offices, eliminating the need for an outside venue. Requestor estimates that the cost of an outside venue, if needed, would be \$500. The evening program may be held virtually, which would further reduce costs.

⁵ Requestor estimates that current faculty honoraria and expenses would be \$1,000 per external presenter.

from the State Optometric Association, as well as addresses contained in Requestor's contacts list. In addition, Requestor would send postcards to publicly available office addresses for optometrists in its service area. Requestor would broadly distribute such emails and postcards and would not target optometrists who refer to Requestor.

For the Proposed Arrangements, Requestor proposes the following four financing options:

- Under Proposed Arrangement A, Requestor would charge all attendees a registration fee consistent with fair market value for such CE programs. The registration amounts Requestor proposes to charge and the number of attendees anticipated to register comport with the estimated amount of expenses, such that any revenue shortfall or overage should not be substantial. Depending on the number of registrations, however, Requestor would pay for any expense shortfalls itself, with no outside funding. If revenue received from the registration fees exceeds Requestor's costs to run the CE programs, Requestor would donate the excess revenue to a local charity that is not an entity that bills Federal health care programs or provides health care items or services payable by Federal health care programs (a "Local Charity").
- Under Proposed Arrangement B, Requestor would not charge any registration fee to attendees and would cover all costs with no outside funding; in other words, the entire financial burden of the CE programs would be borne by Requestor.
- Under Proposed Arrangement C, Requestor would not charge any registration fee to attendees. Proposed Arrangement C would include funding from industry sponsors (e.g., medical device and pharmaceutical companies). Requestor would inform industry sponsors that all guidelines set forth in the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Integrity and Independence in Accredited Continuing Education would apply to their sponsorship of the CE programs. Requestor would pay for any expense shortfalls or alternatively donate any excess revenue received to a Local Charity.
- Under Proposed Arrangement D, Requestor would charge a registration fee to attendees, and Requestor would solicit and receive funding from industry sponsors (e.g., medical device companies and pharmaceutical companies). Requestor 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. Requestor would pay for any expense shortfalls or alternatively donate any excess revenue received to a Local Charity.

II. LEGAL ANALYSIS

A. Law

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service

reimbursable under a Federal health care program.⁶ The statute’s prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.⁷ For purposes of the Federal anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.⁸ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

The Proposed Arrangements implicate the Federal anti-kickback statute because, under each, Requestor would give something of value (the CE programs) to local optometrists who are positioned to refer patients, including Federal health care program beneficiaries, to Requestor for surgery. In addition, Proposed Arrangement C and Proposed Arrangement D would involve remuneration to Requestor, external faculty members, and attendees in the form of industry sponsorships from pharmaceutical and medical device companies—entities that may, in turn, receive orders for their products from Requestor, external faculty members, and attendees. It is in the context of these streams of remuneration, as applicable, that we analyze the facts and circumstances of each of the Proposed Arrangements below.

The OIG recognizes that CE programs are a mainstay for physicians and other licensed practitioners to update their technical knowledge and skills and to learn about new or modified diagnostic and treatment options. Most state licensing authorities (the State included) require optometrists to complete a certain number of accredited CE hours during a prescribed timeframe. CE programs that are educational in nature, however, also may constitute a vehicle to provide remuneration to referral sources in violation of the Federal anti-kickback statute in some circumstances.

The OIG and the Department of Justice have investigated and resolved numerous fraud cases involving allegations that remuneration offered and paid in connection with speaker programs

⁶ Section 1128B(b) of the Act.

⁷ Id.

⁸ E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

violated the Federal anti-kickback statute—prompting the recent issuance of OIG’s Special Fraud Alert: Speaker Programs (the “SFA”).⁹ The SFA highlights the risks associated with speaker programs organized and paid for by pharmaceutical and medical device companies for health care professionals (“HCPs”). While we recognize the overarching difference in scope of the Proposed Arrangements and the speaker programs described in the SFA (namely, Requestor rather than a pharmaceutical or medical device company would organize the programs), we find the following suspect characteristics identified in the SFA to be instructive here: (1) a company sponsors a speaker program where little or no substantive information is actually presented; (2) alcohol is available or a meal exceeding modest value is provided to attendees; (3) the program is held at a location not conducive to the exchange of educational information; (4) selection of HCP speakers or attendees is based on past or expected revenue that these individuals have or will generate by prescribing or ordering the company’s products; and (5) a company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the HCPs.

While each of the Proposed Arrangements warrants its own assessment, the CE programs as a general matter do not exhibit the types of suspect characteristics highlighted in the SFA. The content for Requestor’s CE programs would address new technology and pharmacological practice treatment protocols relevant to treating patients who require ophthalmic surgeries, including Requestor’s patients. Faculty, which would include Requestor’s physicians, would possess first-hand professional experience that enables them to provide particular expertise and input on these topics. In addition, Requestor would ensure each of the CE programs it offers is approved for CE credit by an appropriate professional CE certification board. Only modest food items, such as bagels, coffee, pizza, and non-alcoholic refreshments, would be provided. The venue would be one of Requestor’s offices or another appropriately sized conference space conducive to educational presentations in a geographic location convenient to Requestor’s service area; the CE programs would not be held in conjunction with sporting or other recreational events. The CE programs would be open to all local optometrists; attendance would not be limited to optometrists who refer to Requestor, and there would be no requirement that attendees refer patients to Requestor as a condition of attendance. Neither the selection of attendees nor the selection of external faculty would be based on referrals to Requestor or past or expected prescribing or ordering of any industry sponsor’s items or services payable by Federal health care programs. Requestor certified that external faculty would be paid an honorarium plus expenses at a fair market value rate that would not take into account the volume or value of past business generated or potential future business generated for Requestor or for an industry sponsor by the faculty presenter.

Notwithstanding that the foregoing factors would distinguish the Proposed Arrangements from some of the suspect characteristics identified in the SFA, we must analyze each funding option for the CE programs to determine if it presents more than a minimal risk of fraud and abuse under the Federal anti-kickback statute. We conclude that, while Proposed Arrangement A

⁹ OIG, Special Fraud Alert: Speaker Programs (Nov. 16, 2020), <https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf>.

would pose a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute, the other three Proposed Arrangements each would present more than a minimal risk.

1. Proposed Arrangement A

Under Proposed Arrangement A, Requestor would charge attendees a registration fee consistent with fair market value for such CE programs. To the extent revenue generated from the fair market value registration fees does not cover the CE programs' expenses, Requestor would cover those costs. Conversely, to the extent the revenue from the registration fees exceeds the CE programs' expenses, Requestor would donate the excess amount to a Local Charity. Requestor certified that the registration amounts Requestor proposes to charge and the anticipated number of attendees comport with the estimated amount of expenses, such that any revenue shortfall or overage should not be substantial. There would be no industry sponsors or sources of funding other than the registration fees and, in certain circumstances, Requestor's contribution to cover remaining expenses. In this scenario and in combination with the low-risk aspects of the CE programs highlighted in the preceding paragraphs, we conclude that Proposed Arrangement A would be sufficiently low risk under the Federal anti-kickback statute, and, in an exercise of our discretion, we would not impose administrative sanctions.

2. Proposed Arrangement B and Proposed Arrangement C

Under Proposed Arrangement B and Proposed Arrangement C, no registration fee would be charged to attendees. The CE programs would be free to all local optometrists—funded entirely by Requestor (Proposed Arrangement B) or funded entirely by industry sponsors or funded in part by industry sponsors and in part by Requestor (Proposed Arrangement C). The OIG has a longstanding concern about the provision of free goods or services to an existing or potential referral source. The provision of goods or services that have independent value to the recipient or for which the recipient would otherwise pay confers a benefit on the recipient. With respect to Requestor's funding under Proposed Arrangement B and Proposed Arrangement C, there is heightened risk this remuneration could induce the optometrist attendees and external faculty to refer surgical patients, including Federal health care program beneficiaries, to Requestor, which could result in inappropriate patient steering. With respect to industry sponsorships by medical device and pharmaceutical companies under Proposed Arrangement C, there is heightened risk this remuneration could induce Requestor, external faculty, and the optometrist attendees to prescribe or order a sponsoring company's products, including those payable by Federal health care programs, which could result in inappropriate patient steering or inappropriately increased costs to Federal health care programs. Accordingly, we conclude that Proposed Arrangement B and Proposed Arrangement C would pose more than a minimal risk of fraud and abuse under the Federal anti-kickback statute, and we could potentially seek to impose administrative sanctions.

3. Proposed Arrangement D

Under Proposed Arrangement D, Requestor would charge a registration fee to attendees, and Requestor would solicit and receive funding from industry sponsors for the CE programs. Across the health care industry, we recognize that CE programs often are fully or partially subsidized by commercial sponsors that provide educational grants or other funding to CE program organizers. Frequently, these sponsors are manufacturers of medical devices and drugs

related to the topic of the CE program. The CE program organizers in these scenarios, however, often are independent entities not directly involved in the provision of patient care (e.g., a professional organization). In contrast, Requestor is an ophthalmology practice and potentially a direct referral source for sponsoring medical device and pharmaceutical companies. By paying sponsorships to Requestor to fund its CE programs, the medical device manufacturers and drug companies would pay expenses that Requestor otherwise would incur. In addition, to the extent that sponsorships would exceed expenses for the CE programs, Requestor's ability to use the excess funds to make a charitable donation to a Local Charity of Requestor's choosing also would constitute remuneration to Requestor from the medical device or drug manufacturer sponsors. Accordingly, we cannot conclude here that the industry sponsorships in Proposed Arrangement D would pose a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute such that we would not potentially seek to impose administrative sanctions.¹⁰

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although Proposed Arrangement A, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestor in connection with Proposed Arrangement A under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute. In contrast, we conclude that Proposed Arrangement B, Proposed Arrangement C, and Proposed Arrangement D, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

IV. LIMITATIONS

- This advisory opinion is limited in scope to the Proposed Arrangements and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

¹⁰ We note Requestor would receive remuneration through the industry sponsorships and would pass it through to attendees (by subsidizing part of their registration fees) and to the external faculty (by partially or fully funding their honoraria and expenses). When a pharmaceutical or medical device manufacturer rewards high-prescribing or ordering physicians by directing a CE program organizer to select and pay those physicians to be CE faculty or to selectively choose those physicians as attendees for subsidized CE, that payment may be prohibited remuneration under the Federal anti-kickback statute. Based on Requestor's certifications regarding the selection of, and fair market value payment to, external speakers, as well as the availability of the CE programs to all local optometrists who pay a registration fee, Proposed Arrangement D is distinguishable from the types of problematic scenarios involving rewards for high-prescribing or ordering physicians, notwithstanding our conclusion that Proposed Arrangement D would, overall, present more than a minimal risk of fraud and abuse.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangements, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against Requestor with respect to any action that is part of Proposed Arrangement A taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and Proposed Arrangement A in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against Requestor with respect to any action that is part of the Proposed Arrangement A taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Acting Assistant Inspector General for Legal Affairs