



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(s).]

Issued: March 4, 2026

Posted: March 9, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-03 (Favorable)

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 Requestor’s proposal to offer to certain ambulatory surgery centers (“ASCs”) a discount on intraocular lenses (“IOLs”) and other surgical supplies used to perform cataract surgery, contingent on affiliated physician practices purchasing Requestor’s software product (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, 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 Arrangement, 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 Arrangement. If material facts have not been disclosed, have been misrepresented, or change, 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 the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement 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.

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

A. Background

Requestor is a medical technology manufacturer and distributor for products in numerous fields, including ophthalmology and microsurgery. Requestor offers various ophthalmic products, such as diagnostic tools used by ophthalmologists and ophthalmic surgeons in their clinics to assess patients' eye health, including diagnostic tools necessary to evaluate whether a patient requires cataract surgery, as well as medical equipment, IOLs, and other surgical supplies used to perform cataract surgery.

Medicare reimburses for medically necessary cataract surgery through two set payments: (i) a global payment made to the ophthalmic surgeon for the surgeon's professional services associated with the pre-operative evaluation of a potential cataract patient, intraoperative surgical work, and post-operative follow-up for 90 days (the "Professional Services Fee"); and (ii) a payment made to the facility where the procedure is performed (often an ASC), which includes reimbursement for ASC staff, surgical dressings, supplies, implants (e.g., IOLs), most drugs and biologics, and equipment used in a covered procedure (the "Facility Fee").

During cataract surgery, the patient's natural lens of the eye is removed. Requestor certified that most modern cataract surgeries utilize the phacoemulsification technique to remove the patient's cloudy lens. Supplies for phacoemulsification generally are sold to ASCs in single per-case packs ("Phaco Packs"). Included in Requestor's Phaco Pack are the following items: a phaco cassette, a phaco tip, an irrigation-aspiration handpiece, and surgical drapes. All items in the Phaco Pack are disposable and not specific to any particular IOL (i.e., the choice of IOL and the choice of a Phaco Pack—or any particular phaco device or associated consumables—are independent of one another). One Phaco Pack typically is utilized per cataract surgery. These supplies are not separately reimbursed and are included in the Facility Fee.

IOLs replace the natural lens of the eye removed during cataract surgery. Requestor certified that there are many types of IOLs available to surgeons and patients. Prior to cataract surgery, patients and ophthalmic surgeons discuss and select the IOL that will best suit the patient's visual goals and eye health. Patients may choose between a conventional IOL or a premium IOL. Standard monofocal intraocular lenses ("Conventional IOLs") offer patients a sharp single point of focus, meaning that a person's vision can only be optimized for either near or distance

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.

vision but not both. Premium intraocular lenses (“Premium IOLs”) provide a broader range of vision or correct refractive errors, such as astigmatism.²

In addition to IOLs and other surgical supplies, Requestor offers a web-based software platform (the “Software”) that is a configurable digital planning tool specific to cataract surgery, which is not separately billable to Federal health care programs. The Software is designed to help ophthalmic surgeons organize—in one location—patient information from electronic health records, diagnostic test results, clinical observations, patient-reported visual complaints and surgical formulas utilized in planning a particular patient’s cataract surgery and the equipment, IOL, and surgical technique to be used. Requestor certified that the Software is used primarily in the ophthalmic surgeon’s clinic, but it also has the capability to transmit a patient’s data and surgical plan to the surgical facility (typically an ASC) where the ophthalmic surgeon will perform the surgery if the ASC operating rooms are equipped with the digital interfacing needed to pull through the Software information and the ASC staff is knowledgeable in its use.³ Requestor certified that the Software also allows the ophthalmic surgeon to track clinical outcomes, which (i) potentially facilitates timely identification of trends that may need to be addressed, and (ii) can contribute to educational materials presented to patients (e.g., data specific to the patient’s condition or outcomes data specific to the surgeon). Requestor certified that the Software is agnostic to the brand of electronic health record utilized by the physician or ASC as well as the diagnostic equipment utilized by the ophthalmic surgeon (i.e., the Software will work with diagnostic equipment sold by Requestor’s competitors).⁴ The Software’s output is a manufacturer-agnostic report of patient measurements used for the insertion of IOLs during a cataract surgery and that output can, therefore, be used for the selection of any manufacturer’s IOL. Requestor certified that the Software does not include any marketing or any clinical decision support that would direct a provider to particular products. The Software fees Requestor charges its customers include a monthly licensing fee and a one-time set-up fee. Month-to-month contracts with customers also include a per-gigabyte charge for use of data storage space on Requestor’s platform. Data storage fees are waived for customers with multi-year Software subscriptions.

² While the Facility Fee includes payment for a Conventional IOL, the cost of Premium IOLs is partially covered by the Facility Fee and partially paid by the patient (i.e., the patient is responsible for any cost associated with the Premium IOL that exceeds the cost of insertion of a Conventional IOL).

³ While the Software can be accessed from any computer, smartphone, or tablet with access to the Internet, additional digital interfacing is required to allow the Software to offer meaningful utility at the ASC. Specifically, the ASC must install and use a gateway computer and networking equipment digitally linked to relevant surgical equipment to facilitate delivery of data produced by the operating room equipment to Requestor’s cloud servers. Requestor certified that it offers customers the option to purchase the necessary networking equipment and hardware at fair market value.

⁴ Requestor certified that, on rare occasions in the past, it has found the need to update Software interfaces to ensure full functionality with certain competitors’ diagnostic equipment. Such updates are provided free of charge for Software licensees.

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestor would offer discounts to ASCs on Requestor’s Conventional IOLs and surgical supplies contingent on a physician group practice with ophthalmic surgeons who perform cataract surgery at the ASC (each, a “Practice”) purchasing and entering into a subscription agreement for the Software.⁵ Specifically, Requestor would offer the ASC either an upfront, volume-based discount or a post-sale, volume-based rebate off the ASC’s standard purchase price for its Phaco Packs and Conventional IOLs. Neither the Practice nor the ASC would receive any discount on its Software subscription price regardless of the volume or value of items purchased by the ASC. A Practice and an ASC would be considered eligible to participate in the Proposed Arrangement if there is any overlapping ownership between the two entities. The Practice and the ASC would be required to complete an Ownership Certification Form, certifying to Requestor that there is at least one common direct owner of both entities.

Requestor would enter into separate agreements with the Practice and the ASC. Requestor would enter into a written purchase agreement with a Practice (the “Practice Agreement”) that covers the terms and conditions for the Practice’s Software subscription. Requestor also would enter into a written purchase agreement with an ASC (the “ASC Agreement”), coterminous with the Practice Agreement, that covers the terms and conditions of: (i) a consignment arrangement for the provision of IOLs, including any discounts offered to the ASC on the price of the lenses; (ii) purchase of the Phaco Packs, including any discounts offered to the ASC on the price of the Phaco Packs; and (iii) the ASC’s Software subscription, if any. Requestor certified that most Practice Agreements and ASC Agreements would have a term of one year and would be renewable if the parties agree. Requestor certified that it would provide ASCs with an invoice that reflects the discount received on purchases of the IOLs and Phaco Packs and include in the ASC Agreement that the entity must properly disclose and appropriately reflect the discount in Federal health care program claims for the items where applicable.

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

⁵ Requestor certified that the ASC is not required to purchase the Software to participate in the Proposed Arrangement. However, to allow full functionality of the Software, including the transfer of data between the ASC and the Practice, both the ASC and the Practice would have to purchase a Software subscription. Requestor certified that the fee structure would be the same for the ASC as it is for the Practice.

⁶ Section 1128B(b) of the Act.

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, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.⁹ In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.¹⁰ However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis.

The safe harbor for discounts¹¹ potentially applies to the price reductions under the Proposed Arrangement. This safe harbor interprets and expands upon a statutory exception that protects “a discount or other reduction in price obtained by a provider of services or other entity under [Medicare or a State health care program] if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under [Medicare or a State health care program].”¹² The discounts safe harbor specifies different requirements for sellers, buyers, and offerors of discounted items and services.¹³ As explained in more detail below, for the discounts offered under the Proposed Arrangement to be protected

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).

⁹ Section 1128B(b)(3) of the Act.

¹⁰ 42 C.F.R. § 1001.952.

¹¹ Id. § 1001.952(h).

¹² Section 1128B(b)(3)(A) of the Act.

¹³ See 42 C.F.R. § 1001.952(h)(1)–(3).

under the discounts safe harbor, they would have to meet the definition of a “discount” under the safe harbor, and Requestor would have to comply with the requirements for sellers.

B. Analysis

Under the Proposed Arrangement, Requestor would offer discounts to ASCs on Phaco Packs and Conventional IOLs contingent on a Practice purchasing the Software. These discounts would not be protected by the discounts safe harbor. While the discounts safe harbor can protect discounts that are bundled with other full-price purchases under certain circumstances, the safe harbor does not protect arrangements like the Proposed Arrangement that putatively “bundle” discounts by requiring one party (here, a Practice) to make a full price purchase in order for a different party (here, the ASC) to qualify for a discount on other products. In addition to the Proposed Arrangement’s purchase requirement not qualifying as a protected bundled discount, it also requires performing a service to obtain the discount—a practice that is expressly outside the safe harbor.¹⁴ Specifically, to be eligible for the discounts, an ASC must (directly or indirectly) secure participation of a Practice with at least one common owner to purchase the Software. Because the reduction in price is conditioned not just on the purchase of the product at issue but rather requires additional action, it does not meet the definition of a “discount” under the safe harbor. However, failure to fit into a safe harbor does not end the analysis, and we therefore assess the facts and circumstances of the Proposed Arrangement.

In general, we do not find price reductions conditioned on performing a service to be low risk under the Federal anti-kickback statute. However, the Proposed Arrangement has some unique features that mitigate these risks. For the combination of the following reasons, we believe the risk of fraud and abuse presented by the Proposed Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Proposed Arrangement should not increase costs to Federal health care programs or result in overutilization. The cataract surgeries at issue in the Proposed Arrangement involve set Facility Fees and set Professional Services Fees. Neither the Software nor the discounted items are separately billable items. Requestor would discount items necessary to the surgery (i.e., the Phaco Packs and IOLs) that are included in the Facility Fee paid by Federal health care programs, while the Software, which is not an item specifically contemplated by either the Facility Fee or the Professional Services Fee, would be full price. In sum, Federal health care programs pay the same amount regardless of which products and services are used for the surgery and the Proposed Arrangement would not change that.

Second, the Proposed Arrangement presents a low risk of interference with clinical decision-making. Requestor certified that the discounted Phaco Packs are not specific to any particular IOL and the discounted IOLs do not require use of any particular Phaco Pack, and the Software will be functional regardless of: (i) the brand of electronic health record utilized by the surgeon, the ASC, or both; (ii) the diagnostic equipment utilized by the ophthalmic surgeon (i.e., the

¹⁴ The definition of “discount” at 42 C.F.R. § 1001.952(h)(5) excludes certain practices. For example, a “discount” does not include “services provided in accordance with a personal or management services contract.”

Software will function with diagnostic equipment sold by Requestor’s competitors); and (iii) the brand of Phaco Pack and Conventional IOL. While we realize that the surgeon with common ownership with the ASC could get an indirect benefit from a discount on a particular IOL or Phaco Pack (if the discounted items cost less than competitors’ products), the cost of these items is only one factor a surgeon might consider when choosing a product. Moreover, in order to participate in the Proposed Arrangement, the Practice must invest in the Software (as might the ASC to get the full benefit from the Software), and the Software is a tool, the cost of which is not specifically considered when setting reimbursement rates for the ASCs or the surgeons involved in the cataract surgery. As such, the Software presents an additional expense to the Practice and, thus, would not act as a financial incentive that would distort clinical decision-making.

Finally, the Proposed Arrangement does not present an inappropriately high risk of steering or unfair competition. Many factors can impact competition, such as price, quality, and convenience. We assume that, as rational economic actors, the ASCs and Practices both will consider a variety of factors in their selection of Phaco Packs, Conventional IOLs, and practice-related software platforms, and consequently, the Proposed Arrangement would not present an inappropriately high risk of steering to Requestor’s Products or unfair competition. In addition, given that one party makes a full price purchase to facilitate a different party receiving a discount, we must assess the risk of steering from the Practice to the ASC. Here, the referral source (the Practice) must purchase the Software at full price for the ASC (the referral recipient) to get discounts on items included in its Facility Fee for the surgery. If the opposite were true (i.e., if an ASC were paying full price for an item or service that resulted in a Practice—a referral source to the ASC—receiving discounts or other remuneration), then the risk of inappropriate steering would be much higher, and we may have come to a different conclusion.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement 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.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement 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.
- 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 Arrangement, 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.

OIG will not proceed against Requestor with respect to any action that is part of the Proposed Arrangement 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 the Proposed Arrangement in practice comports with the information provided. 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, OIG will not proceed against Requestor with respect to any action that is part of the Proposed Arrangement 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 OIG.

Sincerely,

/Spencer K. Turnbull/

Spencer K. Turnbull
Acting Assistant Inspector General for Legal Affairs