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: December 15, 2025

Posted: December 18, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-11 (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 certain discount structures that Requestor offers on particular vaccines (the "Arrangement").[1] Specifically, you have inquired whether the Arrangement 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 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 Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then 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 Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not

[1] We note that the Arrangement, as we describe it in Section I below, is a distilled summary of the types of discounts offered by Requestor in its request (originally received in 2023 and as modified by Requestor between then and the date of this opinion).

impose administrative sanctions on Requestor in connection with the 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 person[2] 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 is a biopharmaceutical manufacturer that manufactures, among other things: (i) [redacted] (the "Virus") messenger RNA vaccines in two different formats, one of which must be stored frozen (the "Frozen Vaccine") and a never-frozen pre-filled syringe ("PFS Vaccine"), (collectively, "Vaccine A"); (ii) [redacted] ("Vaccine B"), a vaccine for the prevention of [redacted]; and (iii) two vaccines, [redacted] and [redacted] (collectively, "Vaccine C"), for the prevention of [redacted]. Collectively, Vaccine A, Vaccine B, and Vaccine C are "the Vaccines." Vaccine A and Vaccine C are reimbursed under Medicare Part B, and Vaccine B is reimbursed under Medicare Part D; the Vaccines also are reimbursable by other Federal health care programs. Each of the Vaccines has at least one competing vaccine with a list price that is similar to Requestor's Vaccines.[3]

Under the Arrangement, Requestor offers various upfront discounts ("Upfront Discounts") and rebates ("Rebates") on the Vaccines (collectively, "Discounts") to its customers, some of which are retail customers (e.g., retail pharmacies) and others of which Requestor characterizes as non-retail customers[4] (e.g., group purchasing organizations ("GPOs"); integrated delivery networks ("IDNs"); long-term care facilities; physician buying groups ("PBGs"); mass immunizers; and additional customers in various areas of the health care industry, including health care providers and physician practices). The Discounts offered under the Arrangement fall into four broad categories: (i) Upfront Discounts; (ii) Upfront Discounts with a purchase requirement; (iii)

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[2] 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.

[3] See "CDC Vaccine Price List" ("CDC List"), https://www.cdc.gov/vaccines-for-children/php/awardees/current-cdc-vaccine-price-list.html (last updated Oct. 6, 2025; last accessed Oct. 17, 2025).

[4] Requestor certified that, for purposes of the Arrangement, the term "non-retail customers" does not include pharmacy benefit managers ("PBMs"). While the Arrangement includes discounts offered to entities that are affiliates of PBMs (e.g., retail pharmacies that may be vertically integrated with PBMs), Requestor's policy and practice is to manage contract negotiations and relationships with each of these affiliates separately and independently. The account managers responsible for arrangements with PBM affiliates receive training that contracts with each affiliate must be negotiated independently and that there may be no comingling or swapping of terms or finances, in the written agreements or otherwise, between Requestor's arrangements with different affiliates.

bundled Upfront Discounts with a purchase requirement; and (iv) bundled Rebates, each of which is detailed below.

A. Upfront Vaccine Discounts

Under the Arrangement, Requestor offers Upfront Discounts that are based solely on a certain percentage off the Vaccine A list price or a contract price[5] that is known and applied at the time of purchase. Examples of these Upfront Discounts are:

- Flat Upfront Discounts, which are price reductions that are expressed as a certain percentage off the list price for Vaccine A;
- Prompt-payment discounts, which are expressed as a percentage off the contract price for non-retail customers that order Vaccine A directly from Requestor and remit payment to Requestor within a designated period following delivery of Vaccine A, and are reflected on the sales invoice; and
- Supply reservation discounts, which are incremental Upfront Discounts for non-retail customers that reserve units of Vaccine A for the upcoming vaccination season prior to July 31 of the current season and are reflected on the sales invoice.

B. Upfront Discounts with a Purchase Requirement

Under the Arrangement, Requestor offers a second category of Upfront Discounts that involves offering a certain percentage off Vaccine A's list price, known and applied at the time of purchase, that also is contingent on having satisfied certain purchase requirements (i.e., market share or volume purchase requirements for a Vaccine) during a prior measurement period (e.g., prior quarter or 6-month period). Some Upfront Discounts have purchase requirements that are based on the purchaser achieving a specified percentage of market share, while other Upfront Discounts involve achieving a certain "tier" of market share (by way of example only, tiers could be structured such that Tier 1 requires only less than 60 percent market share, Tier 2 is between 60 and 80 percent of market share, and Tier 3 requires over 80 percent of market share). Examples of these types of Upfront Discounts include:

- Upfront market share discounts on purchases in a given quarter for customers whose purchases in the quarter that is two quarters prior met specified percentages of market share, structured into market share percentage tiers, with an increasing discount available as the market share tier increases; and

[5] Some Upfront Discounts are expressed as a percentage off Requestor's list price while others are expressed as a specific contract price (i.e., where a Discount is already incorporated into the price memorialized in the contract between the parties).

- Contract prices where a discount is presented as a contract price rather than a percentage off the list price for Vaccine A based on a customer's actual market share during a prior 6-month period and pursuant to the set market share tiers.

C. Upfront Bundled Discounts With a Purchase Requirement

The third category of Upfront Discounts under the Arrangement includes offers of a specified percentage off the Vaccine A list price and the Vaccine B and/or Vaccine C list prices that are known and applied at the time of purchase and contingent on satisfying certain purchase requirements (i.e., market share or volume purchase requirements for two or more of the Vaccines) during a prior measurement period (e.g., prior quarter or 6-month period). This category of Upfront Discounts includes: (i) bundles of products reimbursed by the same Federal health care program using the same methodology (i.e., bundles with Vaccine A and Vaccine C, both of which are reimbursed under Medicare Part B); and (ii) bundles of products reimbursed by the same Federal health care program using a different methodology (i.e., a combination of Medicare Parts B and D). Examples of these Upfront Discounts are:

- Upfront Discounts expressed as price protection where, if a customer maintains specified minimum market share tiers for all three Vaccines in each 6-month period, the customer retains access to its reduced contract price rather than being subject to increases in contract prices that typically increase when a product's list price increases;

- An Upfront Discount comprised of two components: (i) a market share discount off the list price for customers that achieved specified market shares for purchases of Vaccine A relative to other Virus vaccines during the quarter that is two quarters prior to the quarter in which the market share discount is applied; and (ii) an incremental discount off the list price for customers that achieved specified market shares for purchases of Vaccine A and Vaccine C during the quarter that is two quarters prior to the quarter in which the incremental discount is applied;

- "2 for 2" and "3 for 3" offers: under the 2 for 2 offer, customers may receive a 2 percent incremental bundled Upfront Discount on purchases of Vaccine A and either Vaccine B or C if they achieve a specified market share for both Vaccine A and Vaccine B or C during a certain prior measurement period. Under the 3 for 3 offer, a non-retail customer can receive a 3 percent incremental bundled Upfront Discount on purchases of Vaccines A, B, and C for any quarter where they achieve a specified market share for all three Vaccines during a certain prior measurement period. In any particular quarter, customers are eligible for either the 2 for 2 Upfront Discount or the 3 for 3 Upfront Discount but not both; and

- IDN customers who signed a 2-year contract receive an incremental 2 percent Upfront Discount on purchases of all three Vaccines during a quarter if they achieve a specified market share for Vaccine C in the two quarters prior.

D. Bundled Rebates

Requestor offers bundled Rebates that involve offering a certain percentage off the Vaccine A list (or contract) price and the Vaccine B and/or C list (or contract) prices where: (i) the percent and terms are fixed and disclosed in writing in advance of any purchase; (ii) the Rebates are contingent on satisfying certain purchase requirements (i.e., market share or volume purchase requirements for two or more of the Vaccines) during a measurement period (e.g., prior quarter or four-quarter period); and (iii) the Rebate is provided for units purchased during the measurement period. This category of Rebates includes: (i) bundles of products reimbursed by the same Federal health care program using the same methodology (i.e., bundles with Vaccine A and Vaccine C, both of which are reimbursed under Medicare Part B); and (ii) bundles of products reimbursed by the same Federal health care program using a different methodology (i.e., a combination of Medicare Parts B and D). Examples of this type of Rebate are:

- Bundled incremental rebates on Vaccine A, Vaccine B, and Vaccine C if certain volume requirements are met on sales of all three Vaccines; and

- Retail customers may earn a 3 percent incremental rebate on purchases made on Vaccine A, Vaccine B, and Vaccine C if they meet the market share requirements during a specified time period. For example, for 2025, retail customers would obtain the 3 for 3 rebate on purchases of the Vaccines made from April 1, 2025, through March 31, 2026, if they achieve the applicable market share criteria for all Vaccines measured from April 1, 2025, through March 31, 2026.

E. Requirements Applicable to all Discounts

Requestor certified that it complies with all price reporting requirements for pharmaceutical manufacturers under all Federal and State health care programs.[6] In addition, for all types of Discounts, Requestor provides customers the information necessary (i.e., all Discount terms) and notification of their reporting obligations in written agreements and invoices, as applicable, to ensure customers can properly disclose and appropriately reflect the Discounts on applicable cost reports or claims submitted to Federal health care programs.

Other than certain Upfront Vaccine Discounts (prompt payment and supply reservation discounts), which are reflected solely on invoices, Requestor certified that the applicable fixed percentage Upfront Discounts and Rebates and associated terms generally are set in advance pursuant to a written agreement[7] with the customer. Requestor certified that it: (i) fully and

[6] We have not been asked to opine on, and we express no opinion regarding, Requestor's price reporting obligations.

[7] The agreements with some customers state that Requestor may increase the Discount offered, lower the market share requirements for particular market share tiers during the contract term, or both after providing advance notice to the customer. To meet competition, Requestor has made (and may continue to make) adjustments during the contract term to reduce certain customers' purchase requirements or increase the Discount. With the exception of certain bundled Rebates

accurately reports the existence of the Upfront Discount or Rebate terms in the contract (except as specified in footnote 7) and Upfront Discount amounts on invoices for direct purchases made by the customer; (ii) informs the customer in its contracts and on its invoices for direct purchases made by the customer that the customer may have obligations to report the Discounts to appropriate payors; and (iii) refrains from doing anything that would impede the customer or the customer's members from meeting any obligation to report the Discounts. In its written contracts, Requestor certified that it obligates PBG and GPO customers to inform their members of their obligations to report any price concessions on purchases through the GPOs and PBGs to payors, as applicable.

For Upfront Discounts made on direct purchases, Requestor certified that it sends an invoice to customers identifying the amount due, net of any Discounts, and notifying customers of their reporting obligations. If a customer's Upfront Discounts are contingent on certain purchase requirements, then before the Discount period begins and at the end of each performance period, Requestor sends an explanation of the Discount program tier for which the customer has qualified and the total Upfront Discount to which the customer is entitled. For Rebates, at the end of each performance period, Requestor certified that it sends each participating customer a report that includes the customer's total qualifying purchases for a Rebate and a calculation of the total Rebate to which the customer is entitled.

Requestor further certified that it implemented a number of additional safeguards against fraud and abuse, including: (i) prohibiting personnel from discussing grants, service agreements, quality programs, or any other items of value in connection with the Discount structure; (ii) conducting internal training programs and enacting compliance policies that require personnel to memorialize all Discount terms in the written Discount agreement with the customer and on the customer invoices for direct purchases (i.e., Requestor prohibits its personnel from making any written or unwritten agreements with customers that are not reflected in the terms of the written Discount agreement); (iii) enacting prohibitions and safeguards to prevent personnel from "marketing the spread" and engaging in swapping arrangements; (iv) conducting ongoing compliance monitoring of field personnel; and (v) having contractual terms with customers clarifying that the Discounts are not contingent on any performance, switching, or conversion requirements. In particular, Requestor certified that none of the Discounts are contingent on the customer providing any additional services or promotional activities. For example, Requestor certified that any market share or incremental Discounts described above are offered solely pursuant to market share or volume purchasing requirements and do not require the customer or

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where the purchase requirements were (and may be in the future) lowered during the contract term to account for evolving market dynamics, the customer is aware of the adjustment before making the purchases to which the Discount applies. Requestor certified that Upfront Discounts are reflected on the invoices submitted to customers for direct purchases. For Rebates, customers receive reports at the end of the performance period with information regarding qualifying purchases and the rebate calculation that reflects the updated terms.

its agents to take any steps to promote any of the Vaccines (e.g., implementing utilization management techniques or other actions that would impede use of a competing product).[8]

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.[9] 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.[10] 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.[11] 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.

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[8] Requestor's Discount agreements specify that nothing in the agreements is intended to require the customer or its members or clinical staff, as applicable, to promote any of Requestor's products or otherwise to engage in switches or therapeutic conversions. While an agreement might require a product to be "preferred" to obtain a Discount, the agreements do not limit the sale of competing products. In addition, Requestor's GPO and PBG agreements require the customers to represent and warrant that neither the customer, nor any of its affiliates, shall implement any intervention technique or counsel or encourage any facility, physician, or any other health care professional to switch a patient who has been prescribed, or previously vaccinated with, a competitor product.

[9] Section 1128B(b) of the Act.

[10] Id.

[11] 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).

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[12] In addition, OIG 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.[13] 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 discounts[14] potentially applies to the Discounts under the 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]."[15] The discount safe harbor specifies different requirements for sellers, buyers, and offerors of discounted items and services.[16] As explained in more detail below, for the Upfront Discounts and Rebates offered under the Arrangement to be protected under the discount safe harbor, each price reduction would have to meet the definition of a "discount," and Requestor would have to comply with the requirements for sellers.

B. Analysis

The Discounts under the Arrangement implicate the Federal anti-kickback statute because, in exchange for customers' agreement to purchase the Vaccine(s) (which may be paid for by a Federal health care program), Requestor offers remuneration to customers in the form of an Upfront Discount or a Rebate on the price of the Vaccine(s). Next, we analyze whether the Discounts under the Arrangement meet the conditions of the discount safe harbor.

1. Sellers' Obligations Under the Discount Safe Harbor

To meet the requirements of the discount safe harbor, sellers have certain notification requirements, depending on the type of buyer.[17] In general, the seller must provide the buyer with sufficient information to meet the buyer's reporting requirements. With respect to cost-reporting buyers, when the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice and inform the buyer of its obligation to report such discount and to provide information in accordance with the

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[12] Section 1128B(b)(3) of the Act.

[13] 42 C.F.R. § 1001.952.

[14] Id. § 1001.952(h).

[15] Section 1128B(b)(3)(A) of the Act.

[16] See 42 C.F.R. § 1001.952(h)(1)–(3).

[17] See 42 C.F.R. § 1001.952(h)(2).

buyer's requirements set forth at 42 C.F.R. § 1001.952(h)(1). When the amount of the discount is known, the seller must provide the buyer with documentation of the calculation, identifying the specific goods and services to which the discount will be applied, and refrain from doing anything that would impede the buyer's obligations.[18] The requirements for sellers are similar under 42 C.F.R. § 1001.952(h)(2)(iii)(B) with respect to discounts offered to other types of buyers.

Requestor certified it would meet all obligations of a seller under the safe harbor for each of the categories of Discounts described in the Facts section. Specifically, Requestor provides customers the information necessary (i.e., all Discount terms) and notification of their reporting obligations in written agreements and invoices, as applicable to ensure customers can properly disclose, and appropriately reflect, the Discounts on applicable cost reports or claims submitted to Federal health care programs. In addition, when the Upfront Discounts are contingent on a purchase requirement, then before the Discount period begins and at the end of each performance period, Requestor sends an explanation of the Discount program tier for which the customer has qualified and the total Upfront Discount to which the customer is entitled. For Rebates, at the end of each performance period, Requestor certified that it sends each participating customer a report that includes the customer's total qualifying purchases for a Rebate and a calculation of the total Rebate to which the customer is entitled. Requestor also certified that it complies with all price reporting requirements for pharmaceutical manufacturers under all Federal and State health care programs. Finally, Requestor certified it would refrain from doing anything that would impede the buyer's reporting obligations.

We conclude that Requestor would meet the obligations of a seller under the safe harbor. However, we also must consider whether each of the categories of Discounts meets the definition of a "discount" or "rebate" under the safe harbor.

2. Definitions of "Discount" and "Rebate"

Under the discount safe harbor, the term "discount" is defined as "a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction."[19] A "rebate" is a type of "discount," "the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale."[20] The definition of "discount" includes certain caveats. For example, a "discount" does not include "services provided in accordance with a personal or management services contract."[21] Requestor certified that no services, including promotional activities or switching patients from one product to another, are required to obtain any of the price reductions described

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[18] See 42 C.F.R. § 1001.952(h)(2)(ii).

[19] 42 C.F.R. § 1001.952(h)(5).

[20] 42 C.F.R. § 1001.952(h)(4).

[21] 42 C.F.R. § 1001.952(h)(5)(vi).

above.[22] If any services were required to obtain the price reductions, then the remuneration would not meet the definition of a "discount," and we might opine differently on the Arrangement.

In addition, a discount does not include:

> [s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.[23]

We must assess each category of Discounts to determine whether it meets the definition of a "discount" under the safe harbor.

a) Upfront Vaccine Discounts

Requestor provided several examples of Upfront Discounts that are calculated solely as a certain percentage off Vaccine A's list price or reflect a reduced price on the invoice with the customer. These reductions in price are known to the customer and applied at the time of sale. Each of the Upfront Discounts in this category meets the definition of "discount" and is protected by the discount safe harbor.

b) Upfront Discounts with a Purchase Requirement

Within this category of Upfront Discounts, Requestor offers a certain percentage off the Vaccine A list price, known and applied at the time of purchase, that also is contingent on having satisfied certain purchase requirements (i.e., market share or volume purchase requirements for Vaccine A) during a particular measurement period. Requestor offers a variety of discount structures within this category.

Requestor certified that all Upfront Discounts in this category are either volume-based or involve calculating the market share tier percentage or amount based on a previous, set time period of purchases, such that the customer knows at the time of purchase the total price of Vaccine A it is purchasing. We are aware that many entities offering discounts based on volume or market share often require, explicitly or implicitly, some level of services from the purchaser (e.g., marketing

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[22] We recognize that the practical effect of price reductions based on market share or having a "preferred" status may be that customers choose to stock and provide Requestor's Vaccines over a competitor's vaccines. Importantly, however, Requestor does not require that customers switch from competitor vaccines to its Vaccines or take other actions to impede the sale of competing vaccines. In addition, none of the Discounts with purchase requirements require exclusivity, which may reduce the risk that customers would make stocking decisions based on factors that are not in the best interest of patients.

[23] 42 C.F.R. § 1001.952(h)(5)(ii).

the products or switching patients from one product to another). Requestor certified that it prohibits such services in connection with the Arrangement. Based on these certifications, we conclude that each of these Upfront Discounts meets the definition of "discount" and is protected by the discount safe harbor. If any services were required to qualify for these Discounts, then we would come to a different conclusion: specifically, that the price reductions would not be protected by the discount safe harbor and likely would not be sufficiently low risk for OIG to issue a favorable advisory opinion.

c) Upfront Bundled Discounts with a Purchase Requirement

This third category of Discounts under the Arrangement also involves Upfront Discounts, but these Upfront Discounts apply to bundles of multiple Vaccines and are contingent on satisfying purchase requirements in prior measurement periods. Like the previous category of Discounts, these market share and incremental discounts are reductions in price, known to the customer and applied at the time of sale.

However, the purchasing requirements tie together two or three of the Vaccines, which means that the bundle could include Vaccines reimbursed under two different methodologies, and therefore this category of discounts does not meet the definition of "discount" in the safe harbor. As noted above, the definition of "discount" under the safe harbor excludes "[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology . . . ." We have expressed concerns about discounts on bundled items when the bundled items are reimbursed under two different reimbursement systems, such that a reduced price on one item is used to induce purchases of other products for which the Federal health care programs pay the full price. These bundled discounts shift costs among reimbursement systems or distort the true costs of all items.[24] For example, a company might offer a discount to a hospital on items reimbursable under Medicare Part A (not separately billable) to induce the purchase of items reimbursable under Medicare Part B (separately billable). Not only would the product cost be shifted among reimbursement systems, but it would be difficult to determine the net price of any item for reporting purposes. We noted in the preamble to the 1999 Final Rule, however, that "discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale."[25] That particular statement was made to support the concept of allowing bundled discounts when the goods and services are reimbursed by the same payment methodology, but it also applies to the bundles in this category of Upfront Discounts under the Arrangement.

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[24] OIG, Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti- Kickback Statute, 64 Fed. Reg. 63,518, 63,530 (Nov. 19, 1999) ("1999 Final Rule").

[25] Id.

Under the Arrangement, the Discounts in the examples for this category constitute a "bundle" in that purchases of more than one type of the Vaccines must reach certain market share or volume requirements to obtain the Upfront Discount on any of the Vaccines. However, the market share or volume requirements are clear for each of the Vaccines in the bundle, and the resultant upfront percentage price reduction also is clear. For example, in the 2 for 2 Discount offer, a customer receives a 2 percent incremental bundled Upfront Discount on purchases of Vaccine A (reimbursable under Medicare Part B) and Vaccine B (reimbursable under Medicare Part D) if the customer achieved a specified market share for both Vaccine A and Vaccine B during the measurement period. Therefore, if the customer achieved the specified market share on both Vaccines during the measurement period, then the customer would get a 2 percent discount on both Vaccines after that time, which would be known at the time of sale and reported on the invoice. If, however, the customer achieved less than the specified market share on either Vaccine A or Vaccine B during the measurement period, then the customer would not earn the 2 percent discount on either of the Vaccines. In other words, unlike the example of discounting items reimbursable under Medicare Part A to induce purchases reimbursable under Medicare Part B, the Discounts here are readily attributable to each separately billable item, and each Medicare reimbursement system (e.g., Medicare Parts B and D) benefits equally from the Discount if the preconditions are met. Moreover, Requestor discounts each Vaccine in the bundle, further distinguishing the Arrangement from one in which an entity offers a deep discount on one product to induce the full price purchase of a different product, potentially distorting prices on both products.

Finally, we note that each of the Vaccines has at least one competing vaccine with a list price that is similar to Requestor's Vaccines, which lowers the risk that these non-safe harbored bundled discounts serve to obfuscate the pricing of any Vaccine in the bundle to raise prices or maintain a higher list price, and thus distinguishes them from higher-risk bundling arrangements involving combinations of drugs, for example.

Therefore, while the bundled Discounts in this category do not meet the definition of "discount" in the safe harbor, we believe the risk of fraud and abuse presented by this aspect of the Arrangement is sufficiently low under the Federal anti-kickback statute (subject to the caveats discussed in the previous section regarding volume and market share discounts).

d) Bundled Rebates

This final broad category of Discounts involves bundled Rebates, whereby Requestor offers a certain percentage off the Vaccine A list (or contract) price and the Vaccine B or C list (or contract) prices and: (i) the percent and terms are fixed and disclosed in writing in advance of any purchase; (ii) the Rebates are contingent on satisfying certain purchase requirements (i.e., market share or volume purchase requirements for two or more of the products) during a measurement period (e.g., prior quarter or four-quarter period); and (iii) the Rebate is provided for units purchased during the measurement period. This category includes two different types of bundles: one group where the bundle includes only Vaccines A and C, which are reimbursed by the same methodology, and another group where the bundle includes all three Vaccines (e.g., the 3 for 3 rebates) and are not reimbursed by the same methodology. In certain cases (i.e., when Requestor adjusts either the purchase requirements or the amount of the Rebate percentage) during the term of the contract, the precise terms of the Rebate may not be known at the time of sale.

The definition of a "rebate" [26] requires that the price reduction be a discount (i.e., a reduction in the amount a buyer is charged for an item or service based on an arms-length transaction[27]) and that its "terms . . . [be] fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale."[28] This requirement is met for some bundled Rebates in the Arrangement, but not for the Rebates where the terms change after the initial purchase is made. However, where the terms are not fixed at the time of the initial purchase in this Arrangement (i.e., the agreement specifies that there may be changes, and the changes are made to meet competition), we conclude that the risk of fraud and abuse is sufficiently low for OIG to issue a favorable opinion. We reach this conclusion because the customer is aware before the time of initial purchase that adjustments may be made to the terms of the discount. In addition, allowing the terms to be adjusted to meet competition might increase patient choice. For example, if Requestor lowers the number of units a customer must purchase to qualify for a Rebate, then the customer may be more likely to keep both Requestor's and its competitors' vaccines in stock rather than being incentivized to stock and sell more of Requestor's Vaccines (instead of a competitor's vaccines) to meet the pre-set volume or market share requirements to obtain the Rebate.

When there is no adjustment to the Rebate terms during the contract year, and when the bundle includes only Vaccines A and C, both of which are reimbursed by Medicare Part B, the Rebates meet the definition of a "discount" under the safe harbor. In addition, Requestor certified that it sends each participating customer a report that includes the customer's total qualifying purchases for a Rebate and a calculation of the total Rebate to which the customer is entitled. Therefore, these Rebates qualify as "discounts" under the safe harbor and are protected.

Our analysis of the Rebates that are bundled where the Vaccines are not reimbursed by the same methodology is the same as for the bundled Upfront Discounts: while these Rebates do not meet the definition of a "discount" under the safe harbor, we believe the risk of fraud and abuse presented by this aspect of the Arrangement is sufficiently low for OIG to issue a favorable opinion for the same reasons specified in section II.B.2.c above.

We note that if any services were required to qualify for any of the Discounts under the Arrangement, then we would come to a different conclusion: specifically, that the price reductions would not be protected by the discount safe harbor and likely would not be sufficiently low risk for OIG to issue a favorable advisory opinion.

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[26] 42 C.F.R. § 1001.952(h)(4).

[27] 42 C.F.R. § 1001.952(h)(5).

[28] 42 C.F.R. § 1001.952(h)(4).

III. CONCLUSION

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

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs