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 associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: September 16, 2016

Posted: September 23, 2016

[Name and address redacted]

Re: OIG Advisory Opinion No. 16-09

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to install a computerized point-of-care vaccine storage and dispensing system in physicians' offices for the physicians' use (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed 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.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the

Office of Inspector General ("OIG") would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] ("Requestor") is a company that manufactures a computerized point-of-care vaccine storage and dispensing system (the "Refrigerator System") for use in physicians' offices. The Refrigerator System, which is the size of a small refrigerator, is designed specifically for vaccine storage; it is not intended to store any items other than vaccines. The Refrigerator System provides three principal vaccine management benefits to physicians:

(1) selection of the correct storage environment for each vaccine based on the National Drug Code embedded in the vaccine's package barcode, which is scanned when the vaccine is loaded into the Refrigerator System;

(2) electronic tracking and notification of expiration dates; and

(3) automated inventory counts, unit dose control, stock rotation, and temperature monitoring.

The U.S. Centers for Disease Control and Prevention ("CDC"), as well as numerous medical associations, encourage adult immunizations and approve immunization schedules for adults living in the United States each year.[1] Despite longstanding

[1] The CDC's Advisory Committee on Immunization Practices ("ACIP") approves immunization schedules recommended for persons living in the United States. The adult immunization schedule provides a summary of ACIP recommendations on the use of licensed vaccines routinely recommended for adults aged 19 years or older (limited in some cases to smaller age groups, such as persons aged 60 or older). The adult immunization schedule also is approved by the American College of Physicians, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Nurse-Midwives. See http://www.cdc.gov/vaccines/schedules/hcp/adult.html.

recommendations for use of many vaccines, the CDC reports that vaccination coverage among U.S. adults is low and has called for improvement in adult vaccination to reduce the health consequences of vaccine-preventable diseases among adults.[2]

There are vaccines recommended by the CDC for routine use in adults that are manufactured by only a single manufacturer ("Sole-Source Vaccines"); others are manufactured by multiple manufacturers. All adult vaccines recommended by the CDC are covered by Medicare.[3]

Under the Proposed Arrangement, Requestor would enter into two separate types of agreements: (1) agreements with physicians who have not previously stocked adult vaccines (or have done so only sporadically or in low volumes) in their offices ("Physician Agreements") and (2) agreements with any manufacturer of Sole-Source Vaccines ("Manufacturer Agreements") (collectively, "Agreements"). These Agreements would not require exclusivity with Requestor regarding the use or purchase of vaccine storage equipment; participating physicians and participating Sole-Source Vaccine manufacturers would be free to enter into similar arrangements with other vaccine storage equipment makers.

Under the Physician Agreements, Requestor would install the Refrigerator System in the participating physicians' offices at no cost, and would allow the participating physicians to use the Refrigerator System free of charge, so long as they agree to stock at least one Sole-Source Vaccine made by a manufacturer participating in a Manufacturer Agreement with Requestor.[4] The participating physicians would agree to pay all costs associated with operating the Refrigerator System, including internet connectivity and utilities costs. Requestor would retain title to the Refrigerator System and the data stored within it.[5] Once installed, participating physicians also could use the Refrigerator System free of

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[2] See *Vaccination Coverage Among Adult Populations — United States, 2014*, February 5, 2016; available at http://www.cdc.gov/mmwr/volumes/65/ss/ss6501a1.htm.

[3] Medicaid coverage varies by state.

[4] Participating physicians are not required to administer any quantity of any Sole-Source Vaccine covered by a Manufacturer Agreement. If a participating physician stocks at least one Sole-Source Vaccine covered by a Manufacturer Agreement, then the Refrigerator System would not be removed from the physician's office, regardless of whether he or she actually administers any units of a Sole-Source Vaccine.

[5] Requestor certified that it would use the data to invoice participating manufacturers for amounts owed under Manufacturer Agreements. To the extent any protected health information is stored in the Refrigerator System, Requestor certified it would comply with applicable privacy laws.

charge to store and dispense any vaccine produced by any manufacturer,[6] except that a participating physician would not be permitted to store in the Refrigerator System any Sole-Source Vaccines that are not covered by a Manufacturer Agreement.[7]

Pursuant to the terms of the Manufacturer Agreements, the Sole-Source Vaccine manufacturers would pay Requestor a fee for each unit of their Sole-Source Vaccines that the participating physicians administer from inventory stored within the Refrigerator System (the "Per-Dispense Fee"). The Refrigerator System automatically records each time a vaccine is removed from the storage unit; participating manufacturers are not charged the Per-Dispense Fee when an expired vaccine is removed. Requestor certified that no portion of the Per-Dispense Fee would be shared with any participating physician.

Aside from the requirement in the Physician Agreement that the participating physician must stock at least one Sole-Source Vaccine covered by a Manufacturer Agreement, the Agreements would not address the terms and conditions related to vaccine purchases; Requestor would not be a party to any vaccine supply arrangement negotiated by the participating physician or any vaccine manufacturer. Further, the Agreements would not otherwise obligate participating physicians to purchase, or any participating manufacturer to sell, any particular volume of any particular vaccine from or to each other. Each participating physician would be free to exercise his or her independent medical judgment as to whether and to whom to administer a vaccine.

Under the Proposed Arrangement, Requestor would not advertise, market, or otherwise promote any vaccine manufacturer or product. Requestor does not have any other lines of business related to items or services payable by Federal health care programs.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible

[6] Requestor certified that pediatric vaccines could be stored in the Refrigerator System, but the Proposed Arrangement is focused on adult vaccines, for which rates of administration are significantly lower.

[7] Requestor certified that, without this exception, Sole-Source Vaccine manufacturers would have no incentive to enter into Manufacturer Agreements.

"kickback" transaction. For purposes of the 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 was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); 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), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

OIG has a longstanding concern about the provision of free goods or services to an existing or potential referral source. There is a substantial risk that free goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business. Under the Proposed Arrangement, participating physicians are the potential referral sources. Requestor, which is the party that would be giving possession and use of the Refrigerator System to the participating physicians for free, is not an entity otherwise engaged in business related to items or services payable by Federal health care programs; however, the Refrigerator System would be indirectly paid for (by way of the Per-Dispense Fee) by participating Sole-Source Vaccine manufacturers, which are entities engaging in business that is payable by Federal health care programs. In these circumstances, the Proposed Arrangement would enable manufacturers to provide use of a valuable item that will facilitate, and thus encourage, the use of its products by referral sources, the physicians.

Notwithstanding this problematic aspect of the Proposed Arrangement, the combination of the following additional unique factors allows us to conclude that we would not subject Requestor to administrative sanctions in connection with the Proposed Arrangement.

First, any Sole-Source Vaccine manufacturer could enter into a Manufacturer Agreement with Requestor. Accordingly, more than one Sole-Source Vaccine manufacturer might be paying Requestor the Per-Dispense Fee for Sole-Source Vaccines administered from storage in the same Refrigerator System. In addition, as long as a participating physician

stocks at least one Sole-Source Vaccine covered by a Manufacturer Agreement, the physician would be free to stock in the Refrigerator System any vaccine produced by any manufacturer (with the exception of any Sole-Source Vaccine that is not covered by a Manufacturer Agreement). Thus, the Proposed Arrangement would allow participating physicians to store in the Refrigerator System vaccines from manufacturers other than the participating manufacturers funding the Refrigerator System. This reduces the risk of unfair competition that we typically see in arrangements where an entity provides free equipment to a referral source in order to funnel most or all of the referral source's business back to the entity providing the free equipment.

Second, only manufacturers of Sole-Source Vaccines would participate in the Manufacturer Agreements. If a physician determines a patient needs the Sole-Source Vaccine, the physician effectively chooses the manufacturer at the same time. If a manufacturer chooses not to enter into a Manufacturer Agreement, the physician may still stock the manufacturer's Sole-Source Vaccine in a storage unit other than the Refrigerator System, and nothing in the Proposed Arrangement would discourage the physician from doing so. Because only Sole-Source Vaccines are potentially excluded, it would not be possible for a physician to choose an alternative vaccine that could be stored in the Refrigerator System.

Third, although the Proposed Arrangement would involve a Per-Dispense Fee structure (which would inherently reflect the volume or value of vaccines ordered and administered), the participating manufacturers would pay the fee to Requestor, which would not be the party in a position to generate Federal health care program business. Requestor certified that no portion of the Per-Dispense Fee would be shared with any participating physicians, and that it, Requestor, would not advertise, market, or otherwise promote any vaccine manufacturers or products. In addition, participating physicians who receive free use of the Refrigerator System would not receive any other remuneration under the Proposed Arrangement. They would receive no more financial gain for administrations of adult vaccines under the Proposed Arrangement than they would in the absence of the Proposed Arrangement. Furthermore, there is no minimum requirement for the number of administrations of any Sole-Source Vaccine (or any other vaccine) to obtain or keep possession of the Refrigerator System under the Proposed Arrangement.

Fourth, the Proposed Arrangement focuses on adult vaccines, which are administered in a limited manner. Unlike drugs that are necessary to treat illness and ongoing, chronic conditions, vaccines protect against preventable diseases that could lead to additional and more costly services.

Finally, the Proposed Arrangement may facilitate a stated goal of the CDC to improve adult vaccination rates.[8] One challenge for health care professionals to ensure their patients are fully vaccinated is proper vaccine storage and management. As we stated in an OIG report:

> Vaccines licensed by the Food and Drug Administration (FDA) are labeled with required storage temperature ranges and expiration dates. Vaccines must be stored within the required ranges to ensure that the vaccines maintain the highest possible level of strength and effectiveness. Additionally, vaccines must not be administered after their expiration dates because they may lose potency and efficacy, reducing their ability to provide maximum protection against preventable diseases.

Vaccines for Children Program: Vulnerabilities in Vaccine Management, (OEI-04-10-00430), June 2012. By electronically monitoring specific temperature levels and expiration dates and automating other administrative vaccine management tasks, the Refrigerator System addresses these types of vulnerabilities that can disrupt physicians' efforts to administer adult vaccines.

The unique combination of all of these factors leads us to conclude that we would not subject Requestor to administrative sanctions under the anti-kickback statute in connection with the Proposed Arrangement. We stress that no individual factor set forth above, nor any subset of them, would justify this conclusion.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

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[8] The CDC calls on all health care professionals to take steps to ensure that their adult patients are fully vaccinated. See "Standards for Adult Immunization Practice," available at http://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party 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 [name redacted] 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. 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 [name redacted] 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 the OIG.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General