

PUBLICATION

OIG Approves Free Vaccine Refrigeration Systems in Physician Offices in Advisory Opinion 16-09 [Ober|Kaler]

2016

On September 16, 2016, the Department of Health and Human Services, Office of Inspector General (OIG) released [Advisory Opinion 16-09 \[PDF\]](#), approving a refrigerator manufacturer's proposal to install a vaccine storage and dispensing system in physicians' offices, free of charge to the physicians. Due to a combination of factors, and in particular the unique public health benefit of vaccines, the OIG concluded that it would not impose administrative sanctions under the anti-kickback statute against the refrigerator manufacturer.

Overview of the Arrangement

The requester of the opinion (Refrigerator Manufacturer) manufacturers computerized point-of-care vaccine storage and dispensing systems designed for physicians' offices. Such systems are intended to assist physicians with (1) selecting the correct storage environment for each vaccine; (2) electronically tracking vaccine expiration dates; and (3) automating the vaccine inventory processes.

As part of the Refrigerator Manufacturer's proposal, it sought to partner with "Sole-Source Vaccine Manufacturers," i.e., those pharmaceutical manufactures that are the sole manufacturer of certain adult vaccines. Specifically, the Refrigerator Manufacturer would enter into agreements (Manufacturer Agreements) with Sole-Source Vaccine Manufacturers, pursuant to which the Refrigerator Manufacturer would assume the installation costs of its vaccine and dispensing refrigerator system in participating physicians' offices and, in exchange, the Sole-Source Vaccine Manufacturer would pay the Refrigerator Manufacture a fee (Per-Dispense Fee) for each unit of their vaccine that a participating physician administered from the refrigerator system.

Accordingly, and in light of the Manufacturer Agreement, participating physicians would not be charged for the initial purchase of the refrigerator system or for any installation costs. The Refrigerator Manufacturer certified that no portion of the Per-Dispense Fee would be shared with any participating physician.

Of note, the Refrigerator Manufacturer would make the refrigerator system available free of charge only to those physicians who had not previously stocked adult vaccines or had only done so sporadically. Upon installing the refrigerator system in a participating physician's office, the participating physician's continued use of the system would be subject to the following terms:

- The Refrigerator Manufacturer would retain title to the system, including all data stored in it;
- Once installed, participating physicians could continue to use the refrigerator system free of charge, although they would bear responsibility for operating costs, e.g., electricity and internet connectivity;
- The refrigerator system could be used by participating physicians to store and dispense any vaccine produced by any manufacturer, with the following two caveats: participating physicians (i) could not store in the refrigerator system any sole-source adult vaccine not covered by a Manufacturer Agreement; and (ii) must store at least one vaccine covered by a Manufacturer Agreement; and
- Participating physicians must enter into agreements documenting the aforementioned terms with the Refrigerator Manufacturer.

Participating physicians would remain free to exercise their independent medical judgment as to whether and to whom to administer a vaccine.

All vaccines subject to the Manufacturer Agreements, and in turn the Refrigerator Manufacturer's agreement with participating physicians, would be recommended by the Centers for Disease Control and Prevention (CDC) for routine use in adults. In addition, all such vaccines would be covered by Medicare.

Legal Analysis

The OIG began its analysis by highlighting its longstanding concerns about the provision of free goods. The OIG notes that while the Refrigerator Manufacturer is not directly involved in business related to federal health care programs, the refrigerator systems would be paid indirectly by the participating Sole-Source Vaccine Manufacturers through their Per-Dispense Fees. The OIG warned that the arrangement would allow the Sole-Source Vaccine Manufacturers to provide a valuable item that may encourage participating physicians to order products which are reimbursed by federal health care program.

Despite this “problematic aspect” of the proposed arrangement, the OIG ultimately concluded that it would not impose administrative sanctions under the anti-kickback statute against the Refrigerator Manufacturer. The OIG relied on the following unique aspects of the proposed arrangement in reaching its conclusion:

- *Reduced risk of unfair competition:* Subject to narrow exception, participating physicians could store in the refrigerator system vaccines from *any* pharmaceutical manufacturer, not just vaccines from Sole-Source Vaccine Manufacturers. Consequently, the OIG concluded the arrangement posed a reduced risk of unfair competition, and furthermore, that it did not view the arrangement as merely a means to funnel business back to the Sole-Source Vaccine Manufacturers. That being said, the OIG acknowledged that the proposed arrangement barred participating physicians from storing in the refrigerator system sole-source vaccines *not* covered by a Manufacturer Agreement. However, the OIG accepted the Refrigerator Manufacturer's certification that, without this exception, Sole-Source Vaccine Manufacturers would have no incentive to enter into Manufacturer Agreements in the first instance.
- *Unique nature of “sole-source” vaccines:* The OIG further highlighted the unique nature of the vaccines subject to the Manufacturer Agreements – specifically, the fact that if a participating physician determines a patient needs a sole-source vaccine, then the physician has, in essence, already chosen the manufacturer at the same time (i.e., the Sole-Source Vaccine Manufacturer). The OIG concluded that this also protects against unfair competition. With respect to the exclusion of sole-source vaccines not subject to a Manufacturer Agreement, the OIG noted that participating physicians would not be barred from stocking such vaccines in a storage unit other than the Refrigerator Manufacturer's refrigerator system.
- *Per-dispense fee safeguards limit potential influence on federal health care program business:* Despite acknowledging that the per-dispense fee structure inherently reflects the volume or value of vaccines ordered and administered, the OIG cited several safeguards around the per-dispense fee that, according to the OIG, limit the potential risks:
 - The fee would be paid to the Refrigerator Manufacturer, who is not in a position to generate federal health care program business;
 - No part of the fee is shared with participating physicians;
 - The Refrigerator Manufacturer would not advertise, market, or otherwise promote any vaccine manufacturers or products;

- Beyond free use of the refrigerator system, participating physicians would receive no other remuneration under the proposed arrangement;
- Participating physicians would, according to the OIG, “receive no more financial gain for administrations of adult vaccines under the Proposed Arrangement than they would” without the proposed arrangement; and
- There is no minimum number of administrations of Sole-Source Vaccines to obtain or keep possession of the refrigerator system.
- *Limited scope*: The OIG noted that adult vaccines are administered in a limited manner. The OIG also contrasted vaccines with drugs used to treat illness and ongoing chronic conditions, stating that vaccines seek to prevent diseases that could lead to additional and more costly services.
- *Public health focus*: Lastly, the OIG emphasized the public health focus of the proposed arrangement, and specifically the fact that it may ultimately facilitate the CDC's goal of increasing adult vaccination rates.

Ober|Kaler's Comments

OIG Advisory Opinion 16-09 presents an extremely unique set of facts and is unlikely to have much, if any, applicability outside of the context of vaccines. The OIG seems to have been willing to overlook potential risks associated with the proposed arrangement in light of the fact that the arrangement is designed to address a critical public health mission – increasing adult vaccination rates and, thereby, preventing incidences of diseases that could lead to additional and more costly services.

For example, the OIG states that participating physicians “would receive no more financial gain for administrations of adult vaccines under the Proposed Arrangement than they would” without the proposed arrangement. This statement appears to be true with respect to direct payments – no part of the per-dispense fee (or any other amount) is shared with participating physicians and there is no change in the reimbursement paid by federal health care programs for the vaccines. The statement, however, seems to ignore (or significantly downplay) the indirect financial benefit to participating physicians – physicians receive the free use of the refrigerator system, which means the physicians do not otherwise have to purchase a refrigerator system. Thus, the practical effect is that physicians are able to profit more from each vaccine administered because the physicians do not have to incur the expense of obtaining a refrigerator system.