# PUBLICATION

## OIG Issues Favorable Opinion for Pharmaceutical Manufacturer's Free Drug Program

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**The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services has issued Advisory Opinion 2022-22, stating that it would not impose sanctions related to a proposed arrangement where a pharmaceutical manufacturer provides a limited number of free trial units of its drug to hospitals for inpatient use. While only the Requestor is afforded protection from prosecution related to the favorable opinion, it is instructive to other pharmaceutical manufacturers and suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) because the OIG's analysis appears to rely heavily on the potential enhanced patient outcomes that could be derived from the proposed arrangement. This conclusion is significant because the OIG has historically expressed concerns about the pharmaceutical industry and accordingly excluded drug manufacturers from participating in value-based enterprises (VBEs) under the related safe harbors implemented in 2020 to promote the delivery of care designed to promote efficiency and better patient outcomes.**

### Background

The Requestor is a pharmaceutical company that manufactures a long-acting injectable (LAI) atypical antipsychotic drug. According to peer-reviewed articles, non-adherence to the medication is common for patients with the related medical disorder and leads to increased costs to the health care system due to exacerbated clinical symptoms, increased rates of hospitalization, and increased lengths of hospital stays.

The Requestor's drug is given once a month through subcutaneous injection in an outpatient or inpatient setting. Studies have found that LAI antipsychotic drugs provide significant benefits, including that hospital inpatients treated with LAI antipsychotics have significantly lower readmission rates than those treated with daily oral doses of antipsychotics; are more likely to be compliant with their medications than patients taking daily oral doses; and are less likely to experience the loss in efficacy of the drugs that could occur from a missed daily dose.

Under the proposed arrangement, the Requestor manufacturer would permit hospitals that do not accept and dispense drug samples under the Prescription Drug Marketing Act (PDMA) (see 21 U.S.C. § 353) to request a maximum of 20 units of the drug per month, limited to two free units per eligible inpatient per year. Participating hospitals will be required to register and enroll in the program on an annual basis. Upon enrollment, a third-party administrator of the program would ship five initial free trial doses of the drug to the participating hospital's pharmacist. After these initial doses have been administered to eligible inpatients, the hospital's pharmacist may order five replacement doses so the hospital's inventory of the drug would never exceed five doses.

It is worth noting that providing free samples to licensed prescribers is a widespread industry practice under the PDMA; however, hospitals routinely prohibit participation in free drug sample programs due to concerns related to managing PDMA compliance and potential for these arrangements to violate hospital pharmacy protocols.

### OIG Analysis

While the proposed arrangement implicates the federal anti-kickback statute because the free drug units being provided constitute remuneration to the participating hospitals that may be referral sources for the drug through the development of formularies, the OIG used its historical review of relevant criteria to evaluate the arrangement and conclude that it presents sufficiently low risk of fraud and abuse. Those criteria include risks of overutilization, increased costs to the federal health care programs, corruption of medical decision-making, patient-steering, and unfair competition.

Specifically, in evaluating this proposed arrangement, the OIG found that the risk of patient-steering of inpatients was sufficiently low because clinicians at participating hospitals would in no way be required to use the Requestor's drug, and prescribers would be permitted to freely exercise clinical judgment for the treatment of each particular patient. It is notable that there are at least seven competing LAI atypical antipsychotic drugs, and the Requestor submitted data demonstrating that there is no known clinical barrier to switching patients to a different LAI or to oral antipsychotic drugs after initially receiving the Requestor's drug.

The OIG also determined that the proposed arrangement would not be likely to increase costs to the federal health care programs. Noting information that the Requestor provided from peer-reviewed studies showing that the LAI antipsychotics reduce negative patient outcomes, the OIG concluded that promoting the use of these drugs could reduce non-adherence and related risks of negative outcomes that could ultimately decrease aggregate costs to federal health care programs.

Finally, the proposed arrangement included several meaningful safeguards that the OIG found to sufficiently minimize risk of fraud and abuse. Those safeguards include:

- Participating hospitals are required to agree that the free trial units could not be sold, resold, traded, distributed for sale, or billed to any patient or payor.
- Participating hospitals could only receive a limited number of doses per year and per eligible patient.
- Clinicians at participating hospitals would retain the ability to exercise clinical judgment in the best interest of each patient.
- No participating hospital or clinician is required to continue using, prescribing, or recommending the drug, or any other product or service, as a condition of receiving the free doses.
- The free trial doses can only be administered to inpatients consistent with the drug's FDA label indication.
- Participating hospitals and their pharmacies must have the ability to track use of the free trial units by each patient and to establish adequate controls to ensure that these free units are appropriately segregated and tracked.

## Key Takeaways

This Advisory Opinion provides meaningful and useful insights into the factors the OIG considers in evaluating arrangements that implicate the anti-kickback statute that do not otherwise qualify for safe harbor protection. In this instance, the Requestor's ability to provide credible data to support a conclusion that providing remuneration to participating hospitals was likely to improve patient outcomes and therefore ultimately have the potential to lower costs to the federal health care programs seems to have been an important consideration.

This analysis and conclusion are clearly consistent with the continued focus on improving quality of care and enhanced patient outcomes from the 2020 regulatory safe harbor protection provided to VBEs and their participants. The pharmaceutical manufacturers, along with DMEPOS suppliers and laboratories, were expressly excluded from the safe harbor protection for value-based arrangements because of historical concerns about their improper relationships with health care providers. Specifically, the OIG broadly excluded these industry segments from VBE safe harbor protection, stating:

On the basis of our historical enforcement and oversight experience, we are concerned that some companies within these types of entities, which are heavily dependent upon practitioner prescriptions, might misuse the proposed safe harbor primarily as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors by improving the coordination and management of patient care, reducing inefficiencies, and lowering health care costs. 84 Fed. Reg. 55694 at 55703 (October 17, 2019).

Despite this historic concern, the recent Advisory Opinion acknowledges that it is possible and, under certain facts and circumstances, permissible for pharmaceutical manufacturers to provide remuneration to practitioners when the arrangement is designed to protect against potential fraud and abuse while achieving enhanced patient outcomes and lowering costs over time.

Although this Advisory Opinion is limited to the specific facts of the Requestor's proposed arrangement, it indicates some willingness to allow pharmaceutical manufacturers to enjoy some level of protection when engaging in free drug programs that are structured to be sufficiently low-risk. Regulatory agencies are undoubtedly likely to continue to be skeptical of the pharmaceutical, DMEPOS, and laboratory industry segments, but this Advisory Opinion is a promising step for these industries. While this Advisory Opinion does not comment on the proposed arrangement's potential for liability under the PDMA or the False Claims Act, it does provide insights into the types of programs that could be implemented without anti-kickback liability by focusing on arrangements designed to promote better patient outcomes and lower costs to patients and payors.

If you have questions about this opinion's implications or would like to submit a request for an advisory opinion, contact Robert Wells, Tenia Clayton, or any member of the Baker Donelson Health Law Team.