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: December 4, 2017

Posted: December 11, 2017

[Name and address redacted]

Re: OIG Advisory Opinion No. 17-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical manufacturer's proposal to collaborate with a trade association, a Medicare Advantage plan, and a hospital system to implement, fund, and evaluate a pilot program to provide the Medicare Advantage plan pharmacists who conduct medication therapy management services with new technology that would permit real-time electronic access to patient discharge information (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

Under the Proposed Arrangement, [name redacted] ("Requestor"), the [name redacted] (the "Association"), and [name redacted] (the "Vendor"), would collaborate with a Medicare Advantage plan (the "MA Plan") and a hospital system (collectively, the "Collaborators") to implement, fund, and evaluate a pilot program (the "Pilot Program"). The Pilot Program would provide the MA Plan pharmacists who conduct medication therapy management ("MTM") services with real-time electronic access to certain discharge information for qualifying MA Plan beneficiaries.[1] According to Requestor, one goal of the Pilot Program is to gain insight into the degree to which technology that provides MTM pharmacists with real-time access to discharge information can help improve transitions of care and decrease re-hospitalizations.

Requestor certified that the Pilot Program would focus on MA Plan beneficiaries who were admitted to the hospital with one of the five diagnoses that are eligible conditions under the Hospital Readmission Reduction Program[2] ("HRRP"): pneumonia, congestive heart failure, acute myocardial infarction, chronic obstructive pulmonary disease, and elective total hip or knee arthroplasty.[3] The Vendor would develop and make available an interface (the "Interface") from which the participating MA Plan's MTM pharmacists could view relevant clinical data elements, taken directly from the hospital system's electronic medical record, in real time, for eligible patients discharged from the participating hospital system.

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[1] Requestor certified that the Proposed Arrangement would be compliant with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and implementing regulations. We express no opinion regarding the Proposed Arrangement's compliance with HIPAA.

[2] See Section 1886(q) of the Act.

[3] Requestor certified that it manufactures only two products that treat or prevent any of the eligible conditions, and that one of those products is a vaccine.

Patients' eligibility would be determined based on objective measures: discharge condition, MA Plan enrollment, and eligibility for MTM services. The MTM services provided under the Pilot Program would apply to any drug therapy taken by eligible patients, including both brand and generic alternatives. Requestor certified that MTM pharmacists would review patient information and, if the patient meets existing MTM eligibility standards or the pharmacist otherwise determines that MTM services would be appropriate for the patient, then the patient would receive MTM services under the Pilot Program.[4] As part of these services, the MTM pharmacist would review all of the patient's medications, contact the patient's retail pharmacy, interact with the patient's providers, recommend adjustments to the patient's medications as needed, and interact directly with the patient to assist with the MTM enrollment process and ensure that the patient understands which medications he or she is taking and appropriate usage (collectively, "MTM Interventions").

Roles of Collaborators

Each of the Collaborators would have a role in implementing the Pilot Program. The Vendor, an entity that currently works with hospitals to provide electronic medication and discharge reports and fill/refill information and helps identify patients at high risk for medication non-adherence, would develop the Interface. The Interface would be used solely for the Pilot Program until its conclusion, at which time the intellectual property in the Interface would belong to the Vendor exclusively.

The Association would serve as the Pilot Project's project manager. Requestor certified that, due to its membership composition, the Association is uniquely positioned to understand the benefits of managed care pharmacy services.[5] In its role as project manager, the Association would engage, align, and manage the various contracts between the Collaborators. At the Pilot Project's conclusion, the Association would analyze the data and author a project summary. If the Pilot Program is successful, the Association also would develop a training and implementation toolkit that could be provided to managed care professionals regarding the benefits of the type of technology used in the Pilot Program and how to implement and effectively use such technologies.

Requestor would provide funding for the Pilot Program. Requestor certified that it seeks to support the Pilot Program because, like the other Collaborators, Requestor has an interest in promoting patient health and well-being by providing high-quality care, encouraging medication adherence, and reducing hospital readmissions. Requestor's funding would be

[4] Requestor certified that patients would be enrolled in the Pilot Program only if they otherwise would be appropriate for MTM services in the absence of the Pilot Program.

[5] According to Requestor, the Association provides general guidance on the formulary process, but does not have any ability to influence formulary decisions either as an entity or through its members.

in an amount not to exceed $257,000, which would be distributed in stages following completion of specific delivery milestones: contract signing, engagement of the hospital system and MA Plan, deployment of the Interface, completion of data analytics, completion of project summary, and completion of training and the implementation toolkit (if applicable). If the operations committee (described below) determines that the Pilot Program was successful, the Association would develop the training and implementation toolkit,[6] which would be branded with Requestor's name but would be product-neutral (e.g., it might report on the impact that the Pilot Program had on drug utilization at the drug class level, such as "anticoagulant" or "benzodiazepine," but not at the individual drug level). Similarly, Requestor certified that all of the materials used in the Pilot Program, as well as the Interface, would be unbranded with respect to Requestor and any products it manufactures. Other than providing funding, Requestor certified that it would have no role in developing the Interface, including the selection of data points,[7] nor would it have access to the Interface or the data transmitted through it. Requestor also would ensure that the Pilot Program complied with legal and regulatory guidelines.

The MA Plan would ensure that the hospital system's discharge notification system is integrated into the MA Plan's existing workflows for initiating MTM services, engage the MTM pharmacists for MTM Interventions, and report on various metrics[8] to the operations committee (described below). The Collaborators had not identified a specific MA Plan to participate in the Proposed Arrangement as of the date of this opinion. However, Requestor certified that the MA Plan selected would be an MA-PD plan, responsible for covering its members' Part D drugs, and that the MA Plan would not be selected to participate in the Pilot Program based on its use of, or prescribing patterns for, Requestor's pharmaceutical products. Requestor certified that the criterion for selecting an MA Plan would be whether the MA Plan had a sufficient number of beneficiaries with hospital discharges in the five

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[6] The toolkit, if developed, would include written materials that may be made available in hard copy or in digital format (i.e., PDF files, but not as software or an interface). The toolkit would include information contained in the project summary as well as key learnings from the Pilot Project.

[7] Requestor certified that the specific data points have not yet been selected, but would include, inter alia, basic demographic information, diagnoses at admission and discharge, laboratory values, setting to which the patient is discharged, and any known risk stratification metrics (e.g., lack of social support, low health literacy).

[8] Examples of metrics that the MA Plan would track are: the number of discharges in the reporting period, percentage of male vs. female patients discharged, percentage of patients engaged in MTM, average time to engagement, percentage of MTM Interventions delivered within 24, 48, and 72 hours, and various outcomes results (such as readmissions, percentage of medication dosing errors, or duplication identified).

eligible diagnoses described above such that the Pilot Program could evaluate at least 200 patients. Requestor certified that all services the patients would receive under the Pilot Program, including prescription medications, MTM Interventions, and post-hospital care, would be within the bounds of the MA Plan's services.

The hospital system would identify and engage administrators, quality officers, discharge planners, and other leadership needed to promote understanding that the Pilot Program would be a process improvement that would align the goals across members of the acute care team responsible for the discharge of patients. The hospital system also would ensure that sufficient resources are available to identify and recruit patients. The Collaborators had not identified a specific hospital to participate in the Proposed Arrangement as of the date of this opinion. The potential hospital system Collaborator would need to meet certain criteria including Medicare Advantage admissions representing a significant portion of total Medicare admissions and a sufficient number of admissions with the eligible diagnoses for meaningful evaluation under the Pilot Program. Moreover, the hospital system must already be using the Vendor's existing electronic tools as an electronic medical record ("EMR") and be in the selected MA Plan's network. Requestor certified that selection of a hospital system would be unrelated to the hospital's use of, or prescribing patterns for, any of Requestor's pharmaceutical products.

The Pilot Program would be available only to patients who qualify (i.e., patients who are enrolled in the MA Plan and were admitted to the hospital with a qualifying diagnosis).[9] The MA Plan and hospital system would enter into a contract with the Association to fulfill their obligations under the Pilot Program. Requestor certified that agreements and operative documents would make clear that collaboration under the Pilot Program would have no direct or indirect bearing on formulary recommendations or referrals of business, nor would it be intended to induce or reward a purchase, recommendation, or prescribing decision in favor of any of Requestor's products.

An operations committee consisting of representatives from the Vendor, the participating MA Plan, and the participating hospital system would be formed to guide the implementation and use of the Interface; neither Requestor nor the Association would participate in the operations committee. The operations committee would establish Pilot Project protocols and manage daily implementation activities (e.g., by addressing any interruptions or gaps in data transfer between the hospital system and the MA Plan). A separate steering committee would be formed that would include representatives from all of

[9] Requestor certified that the hospital system would not need an interface or any other technology to participate in the Pilot Program. The Vendor would need to modify the hospital system's existing technology to grant the MA Plan's Interface access to the key data points in real-time, but other than having the ability to identify appropriate patients, the hospital system would not experience changes to its current system as part of the Pilot Program.

the Collaborators. The steering committee would receive periodic updates that would include aggregate, summary level data (e.g., number of patients discharged, number of patients engaged in MTM, percentage of readmissions within 30, 60, or 90 days), and information on issues encountered, decisions made, and lessons learned as part of implementation. The steering committee would not receive any patient-level data or make any operational decisions. In particular, as noted above, Requestor would have no access to the Interface, nor would it have any other view into the information exchanged, including demographic information, diagnoses, discharge summaries, comorbid conditions, or any other patient-level data.

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 "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. 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), 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

An essential element to analyze under the Federal anti-kickback statute is whether a party would offer or give remuneration to a potential source of referrals. Thus, at the outset, we must examine whether the Proposed Arrangement involves remuneration and, if so, whether that remuneration would be given to a potential referral source.

The Proposed Arrangement includes various potential sources of remuneration. Requestor would contribute funds for the Pilot Program; the Association would contribute services; and the Vendor would contribute technology. The MA Plan and the hospital system would receive technology or related services. However, not all of these parties are referral sources for each other. The Vendor and the Association do not provide federally reimbursable health care services, and thus would not receive referrals of Federal health care program business under the Proposed Arrangement. However, the MA Plan and the hospital system, both of which potentially would receive remuneration, are potential referral sources for Requestor's products. Thus, we must analyze each relationship in turn.

Remuneration to the Hospital

Requestor certified that the hospital system would not receive any new technology; the hospital system's existing EMR simply would be modified to enable the MA Plan's Interface to access the relevant data in the EMR in real time. We recognize that, by participating in the Pilot Program, the Hospital might be able to avoid HRRP penalties. However, granting the MA Plan real-time access to data would be only one aspect of the hospital system's post-discharge plan, and any role it might play in a successful avoidance of penalties would be speculative. We do not consider that speculative benefit, or the modifications to the hospital system's existing EMR, to be remuneration to the hospital system.

Remuneration to the MA Plan

The MA Plan would receive the Interface, which would allow it to access discharge information in real time. We previously have stated that the donation of a limited-use interface alone is not remuneration.[10] When we have made this assertion in the past, however, we generally were examining the donation of an interface that was integrally related to the donor's services (such as a laboratory donating an interface to allow a physician practice to receive test results). Here, the Interface would not be "donated" by a health care provider or supplier in the manner that we have examined in the past. The Vendor does not provide health care services and, although Requestor manufacturers and markets pharmaceutical products, the information that the Interface would transmit would not necessarily relate to Requestor's products. Further, the Proposed Arrangement would involve more than the donation of a simple interface. The Interface would transmit more than raw data to the MA Plan; it would provide a collection of data from different aspects of the hospital system's EMR, and it would do it in real time. This immediate and robust data transmission could remove an administrative burden from the MA Plan and its MTM pharmacists. Thus, the Interface would have independent value, and the Proposed Arrangement could result in remuneration to the MA Plan. Further, MTM pharmacists are in a position to refer or recommend Requestor's products, because they have the ability to

[10] See, e.g., 78 Fed. Reg. 79202, 79210 (Dec. 27, 2013).

influence which medications a patient receives or is prescribed. Accordingly, we must consider whether such remuneration would be likely to interfere with the MTM pharmacists' clinical decision-making, result in increased costs through overutilization or inappropriate utilization, raise patient safety or quality of care concerns, or result in any of the other harms that the anti-kickback statute is designed to prevent. For the combination of the following reasons, we would not impose sanctions in connection with the Proposed Arrangement.

First, we recognize that a pharmaceutical manufacturer's involvement in providing free technology to be used by MTM pharmacists could present a high level of risk under different circumstances. Such remuneration could directly influence an MTM pharmacist to recommend the manufacturer's products, and could influence the MA plan to give the manufacturer's products favorable formulary placement. However, we conclude that the Proposed Arrangement includes a number of safeguards that reduce these risks. Of crucial importance, Requestor manufactures only two products, one of which is a vaccine, that treat or prevent any of the eligible conditions under the Pilot Program. In addition, Requestor expressly certified that agreements and operative documents would make clear that collaboration under the Pilot Program would have no direct or indirect bearing on formulary recommendations or referrals of business. Requestor's involvement would be limited to providing a relatively modest amount of funding and performing certain legal and compliance services. Requestor's certifications that it would have no involvement in selecting data points to be used, that it would not have access to the Interface or underlying data, and that the Pilot Program materials and Interface would be unbranded with respect to Requestor are crucial to our conclusion that the Proposed Arrangement is low risk. The combination of these safeguards reduce the risk that Requestor's involvement in the Proposed Arrangement would influence prescribing or formulary decisions in favor of Requestor's products. If these certifications are inaccurate now, or become inaccurate over time, this opinion is without force and effect. We caution that we likely would reach a different conclusion with respect to the risk presented by this type of arrangement under different facts, such as if a manufacturer sponsor made or marketed more drugs to treat eligible conditions, the manufacturer branded any of the information being presented to MTM pharmacists during the Pilot Program, or if the interface was designed to recommend one drug over another.

Second, the Proposed Arrangement would be unlikely to lead to increased costs or overutilization of federally reimbursable services. The MA Plan, as the payor, has a strong incentive for its members to receive the most appropriate and cost-effective treatment to promote their recovery and good health. The Interface the MA Plan would receive would be designed to enable the MTM pharmacists to more quickly and efficiently enroll appropriate patients (already identified by the hospital system as meeting the requirements for participation) in MTM services, which should help patients comply with their discharge plan. Engaging in conduct that would increase patient care costs through overutilization or otherwise would be against the MA Plan's interest.

Third, the Proposed Arrangement would be unlikely to interfere with the MTM pharmacists' clinical decision-making. Although MTM pharmacists would review the discharge plan and recommend adjustments if necessary, nothing in the Interface would guide the MTM pharmacist to choose one product over another. As noted above, the MA Plan, which would be responsible for both medical and drug expenses, has an incentive to decrease costs, by ensuring that patients receive treatment that is both cost-effective and the most appropriate treatment to lead to a favorable outcome. Any remuneration resulting from the Proposed Arrangement would not change that incentive.

Fourth, the Proposed Arrangement would be unlikely to have a negative impact on patient quality of care. In fact, if the Pilot Program achieves its goal, it should improve quality of care. We recognize that the transition from a hospital into a different setting is a vulnerable time for a patient. If an MA Plan is able to access relevant information about the patient's inpatient stay immediately upon discharge, then the MTM pharmacists can work with patients right away to avoid any gaps in care and help prevent readmissions.

Finally, the Proposed Arrangement is limited in number of patients (approximately 200), scope (the five HRRP diagnoses), and monetary investment. To avoid incurring the HRRP penalties, hospitals must establish processes to reduce unnecessary hospital readmissions. Similarly, MA plans generally seek to contain costs, and hospital readmissions are expensive. The Pilot Program seeks to test whether certain minor improvements in technology involved in MTM services that the MA Plan already provides can help achieve the goal of decreasing readmissions. The small scale of the Pilot Program reduces the risk that remuneration involved would influence referrals to or recommendations for Requestor's products.

Overall, the Proposed Arrangement as described herein presents minimal risk to patients or Federal health care programs. We emphasize that a similar type of arrangement with different facts and circumstances might result in a different 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.

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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs