Pink Sheet
Pharma intelligence

Pharma-Funded Pilot To Improve Adherence, Lower Readmissions Gets OIG Nod

- ***21 Dec 2017***
- ***Analysis***

Cathy Kelly Catherine.Kelly@informa.com

Executive Summary

Medicare Advantage plans might eventually use toolkit being developed by the Academy of Managed Care Pharmacy, which is a partner in the initiative.

CAN PHARMA FIGURE OUT A WAY TO MAKE MEDICATION USE STICKIER?

The HHS Office of Inspector General has okayed a pharmaceutical manufacturer-funded pilot program to improve medication adherence among enrollees in a Medicare Advantage plan and help reduce hospital readmissions.

The opinion, which was requested by the unnamed pharmaceutical manufacturer, concludes the program will not draw enforcement under federal anti-kickback laws, which makes it a criminal offense to knowingly and willingly offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by federal health care programs.

"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 … in connection with the proposed arrangement," the advisory opinion posted Dec. 11 states.

"The proposed arrangement as described herein presents minimal risk to patients or federal health care programs," the opinion adds. However, "we emphasize that a similar type of arrangement with different facts and circumstances might result in a different conclusion."

The arrangement involves collaboration between the manufacturer, the Academy of Managed Care Pharmacy, a Medicare Advantage plan and a hospital system. AMCP is not named in the opinion but a spokesperson for the group confirmed it is involved.

The partners would implement a pilot program to provide plan pharmacists who conduct medication therapy management (MTM) services with new technology that would permit real-time electronic access to patient discharge information.

MTM services are mean to optimize drug treatment by improving adherence and avoiding drug-drug interactions, among other things. Adherence programs have been the subject of a number of requests to OIG in recent months for anti-kickback safe harbors. (Also see "Value-Based Contracts Getting More Safe Harbor Attention From OIG" - Pink Sheet, 10 Dec, 2017.)

One goal of the pilot program is to evaluate whether improved access to discharge information can help MTM programs decrease hospital readmissions. It applies to patients with one of the five diagnoses included in the Medicare Hospital Readmission Reduction Program. They include pneumonia, congestive heart failure, acute myocardial infarction, chronic obstructive pulmonary disease and elective total hip or knee arthroplasty.

Manufacturer Makes Only Two Drugs For Conditions Covered

The manufacturer requesting the program certified it makes only two products that treat or prevent any of the eligible conditions and that one of the products is a vaccine. The MTM services provided would apply to any drug taken by eligible patients, including brand and generic alternatives.

The pharma company would provide funding for the program in an amount capped at $257,000. The funding would be distributed in stages following specific delivery milestones.

The manufacturer would not have access to the technology interface used in the pilot, "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," the opinion points out.

The MTM services would involve plan pharmacists reviewing a patient's medications, contacting the patient's retail pharmacy, interacting with providers, recommending adjustments to medications as needed and interacting directly with the patient to help them enroll in the MTM program and ensure the patient understands which medications he or she is taking and appropriate usage.

The participating MA plan had not been chosen as of the date of the opinion. However, the requestor certified the plan would not be chosen based on its use of, or prescribing patterns for, its drugs. The plan will be chosen based on whether it has a sufficient number of enrollees with hospital discharges in the five eligible diagnoses so that the program could evaluate at least 200 patients.

The participating hospital system had not yet been chosen either, but must be already using the participating technology vendor's electronic medical records tool and be in the selected MA plan's network.

The requestor certified that agreements between the plan and hospital "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," the opinion says.

AMCP Training, Implementation Toolkit Would be Produced

If the pilot is successful in improving care and reducing hospitalizations, AMCP will 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."

In a statement on the project, AMCP said it "supports MTM as a means to improve health outcomes and reduce costs of care. Appropriate medication management is crucial in transitions of care and managed care pharmacists' role has not been well studied. Therefore, this project could help to advance the body of evidence in this area and allow AMCP to begin to develop tools and resources for best practices in using MTM in transitions of care."

The toolkit would be branded with the manufacturer's name but would be product neutral, meaning "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," OIG explains.