

PUBLICATION

Real-Time EMR Interface Program to Reduce Readmissions Finds Favor in OIG Advisory Opinion 17-07

December 2017

A pilot program that could improve the efficacy of medication therapy management (MTM) services among Medicare Advantage (MA) beneficiaries would present minimal risk to federal health care programs and patients, according to the OIG in Advisory Opinion 17-07. Under the arrangement, the requestor – the pharmaceutical manufacturer sponsoring the program – would collaborate with several key parties seeking to test the following theory: whether real-time access to certain discharge information by MTM pharmacists can help decrease re-hospitalizations for certain conditions identified under the Hospital Readmission Reduction Program (HRRP).

MA pharmacists provide MTM services to patients when they determine it is appropriate according to the patient's discharge condition. Such services can include an evaluation of the patient's current medications, interaction with the patient's providers and local pharmacy, recommendation to adjust medications as needed, and direct contact with the patient to ensure proper understanding and usage. One of the goals of these MTM services is to decrease hospital readmissions, which are responsible for increased costs to Medicare plans and can decrease hospital reimbursement by CMS under the HRRP if they are determined to be excessive.

The sponsoring pharmaceutical manufacturer would collaborate with an MA Plan, a hospital system, an IT vendor, and a trade association to design and implement a data transmission program that provides electronic discharge and medication information from the hospital system to the MA Plan (the Interface). The IT vendor would modify the hospital system's existing electronic medical record (EMR), then design and implement the Interface, allowing "immediate and robust" data transmission for use by the MA Plan pharmacists. The MA Plan would then track and report on metrics such as discharge volume, timing of MTM service delivery, and outcomes. If the program is successful, the trade association would then promote written training materials and a program summary, which would be branded with the pharmaceutical manufacturer's name and include impact findings on the drug class level, but not on the individual drug level.

In its analysis, the OIG addressed the remuneration to the hospital system, stating the IT vendor's modification to existing EMR was not a receipt of new technology, and if the hospital system were to avoid HRRP penalties through the success of this program, the role of the program in this avoidance would be speculative. Therefore, the OIG did not consider the modifications or the speculative avoidance of HRRP penalties to be remuneration.

The OIG did find the potential for remuneration to the MA Plan because of the Interface's value in delivering real-time, organized data and relieving significant administrative costs to the MA Plan and its MTM pharmacists. However, while in other circumstances such remuneration could create a high risk for influence and favorable treatment of the pharmaceutical manufacturer, the OIG highlighted a variety of significant safeguards and other reasons why the proposed arrangement presented a minimal risk. First, only two products made or marketed by the pharmaceutical manufacturer (one of which is a vaccine) could potentially be used to treat or prevent the eligible conditions being monitored in the program. Second, any agreements between the collaborators will expressly state that participation in the program will have no relation to product recommendations or business referrals. Third, the pharmaceutical manufacturer's role would be limited to funding the program and engaging in certain legal and compliance functions. In addition to these safeguards, the OIG relied on the pharmaceutical manufacturer's certifications that it would have no involvement in

selecting Interface data points and no access to the Interface or individual patient data, and that the materials and Interface used during the program would not be branded with the pharmaceutical manufacturer's name.

Furthermore, the OIG pointed out that the arrangement would be unlikely to produce increased costs or overutilization because, as the entity responsible for medical and drug expenses, the MA Plan is incentivized to take cost-effective measures and not to participate in activities that would be contrary to its interests. The clinical decisions of the MTM pharmacists would also unlikely encounter interference due to the fact that there would be no recommendation or guidance prompts for products in the Interface. (Interestingly, [CMS approved web-based portal alerts](#) for diagnostic tests earlier this year.) Finally, the OIG noted that the small scope and cost of the program, as well as the fact that the success of the program would increase the quality of patient care rather than negatively impact it, also reduced the risk of improper influence within the arrangement.

Baker Donelson's Comments

Notably, on more than one occasion the OIG referred to the pharmaceutical manufacturer's certifications as "crucial" in importance and to the OIG's conclusion in this opinion. It also offered alternative facts, such as an increase in the number of products made by the pharmaceutical manufacturer that treated eligible conditions monitored in the program, which would change the OIG's conclusion. The recent [rescission of OIG Advisory Opinion 06-04](#), which was announced on November 28, 2017, illustrates just how important it is to abide by the representations made to the OIG and captured in the advisory opinion.