OIG Advisory Opinion Says Hospital Can Provide Free In-Home Services

Jennifer D. Burgar and Barbara J. Rogers

On March 6, 2019, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) posted Advisory Opinion No. 19-03, which permits a non-profit medical center (Requestor), and its affiliated clinic, both under the sole control of a Health System which operates in three states, to provide free, in-home follow-up care to discharged patients. Requestor developed, and wishes to expand upon, a program in which it provides free in-home follow-up care to patients with congestive heart failure (CHF) and, if allowed, chronic obstructive pulmonary disease (COPD) – chronically ill patients who are at a higher risk for admission or readmission to a hospital. The OIG determined it would not impose sanctions under either the Civil Monetary Penalty provision (CMP) or the federal health care program Anti-Kickback Statute (AKS), despite its conclusion that the free services offered under the arrangement could potentially violate the AKS and CMP if the requisite intent were present, and there is no applicable exception or safe harbor to shelter the arrangement.

Program Overview

The goals of both of the in-home arrangements are to increase patient compliance with discharge plans, improve patient health, and reduce hospital inpatient admissions and readmissions. To be eligible for the programs, patients must meet the following requirements:

- A patient must be currently admitted as an inpatient, or receiving outpatient care with a previous inpatient admission within the previous 30 days;
- A clinical nurse leader must identify the patient as high risk for hospital inpatient readmission using a risk assessment tool recognized throughout the industry;
- A patient must have already arranged follow-up care at the Requestor's outpatient center;[1]
- The patient must be willing to enroll in the in-home service arrangement after consultation with the clinical nurse leader; and
- The patient must be discharged to, or reside at, a personal residence or an assisted living facility in the Health System's service area.

Patients enrolled in the in-home program receive two visits each week for approximately thirty (30) days following enrollment from a community paramedic, who is employed by the Requestor. Each visit lasts approximately sixty (60) minutes and includes the following services:

- Review of patient's medication;
- Assess the patient's need for follow-up appointments;
- Monitor the patient's compliance with the discharge plan of care or the patient's disease management;
- Perform a home safety inspection; and
- Perform a physical assessment, which may include checking the patient's pulse, blood pressure, listening to the patient's heart and lungs, checking wounds, running an electrocardiogram, drawing blood and running blood tests, or administering medication.

1 The Requestor confirmed that if the outpatient care had not been arranged, the patient would not, and will not, receive information about the in-home services.

OIG Analysis

Under the in-home services arrangements, the services would be limited to patients who had already selected the Requestor for follow-up care for their CHF or COPD. The Advisory Opinion (AO) acknowledges that the program would provide a "significant benefit to patients in the form of free health care services and care management furnished in their home." Moreover, this significant benefit could influence a patient to select the Requestor or its affiliated clinic for federally reimbursable items and services, which implicates CMP as well as AKS. OIG determined that there was not an applicable safe harbor or exception.[2]

Despite the OIG's analysis and conclusion, it exercised its discretion to not impose sanctions under CMP or AKS for the following reasons:

- The in-home services arrangements' benefits outweigh any risk of inappropriate patient steering that the law was designed to prevent (i.e., the risk that the remuneration will induce patients to choose Requestor or the clinic for CHF or COPD related services is negligible because patients have already made this selection). The OIG stated that the numerous safeguards in the arrangements that protect patients combined with the goal to improve patient health by offering this free care to chronic patients, allows the OIG to conclude that the remuneration poses a low risk of harm to patients or the Federal health care programs.
- If the arrangements work as intended, they are unlikely to lead to increased costs to Federal health care programs or patients through overutilization or inappropriate utilization.
- The risk that the arrangements will interfere with or skew clinical decision making is low.
- Requestor certified that it does not, and would not, advertise or market the arrangements to the public, and Requestor does not, and would not, publicize them on its website.
- The scope and duration of the in-home services provided by the community paramedics appear reasonably tailored to accomplish Requestor's goals of increasing patient compliance with discharge plans, improving patient health, and reducing hospital inpatient admissions and readmissions.

Lending further support for its position, the OIG cited to its August 27, 2018 request for information, which stated in part, "OIG has identified the broad reach of the anti-kickback statute and [CMP] as a potential impediment to beneficial arrangements that would advance coordinated care."[3]

Takeaways

- While the AO may not be relied upon by anyone other than the entity requesting it, the AO offers important guidance and reassurance to others who may be considering implementing similar patient outcome improvement programs.
- The services offered by the Requestor are tied to conditions (CHF and COPD) that come with readmission penalties under the Hospital Readmissions Reduction Program. The OIG has previously stated that hospitals may need to become more engaged in a patients' care during the post-discharge period. OIG Advisory Opinion No. 13-10 (Aug. 16, 2013); see also OIG Advisory Opinion No. 17-07 (Dec. 11, 2017). Whether the OIG would have concluded the same to a wider range of diagnoses is unclear.
- The AO ignores licensure requirements for the Requestor's employed paramedics and raises important questions related to the provision of home health services as it relates to state licensure and scope of practice. Notably, these issues may be negated if a hospital contracts with a home health agency for these services. Thus, while this may not offer a clearer business model path for home health agencies, it does not preclude agreements between hospitals and home health agencies.

2 With regard to CMP, the OIG analyzed the "promotes access to care exception" but determined that it did not apply.
3 Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43, 607, 43,608 (Aug. 27, 2018).

Authors and Contributors

Jennifer D. Burgar
Partner, Atlanta Office
404.873.8194
Jennifer.burgar@agg.com

Barbara J. Rogers
Associate, Atlanta Office
404.873.8522
barbara.rogers@agg.com

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