Bloomberg Law

Health Law & Business News

Photographer: Andrew Harrer/Bloomberg via Getty Images

INSIGHT: OIG Proposed AKS Safe Harbors for Patient Incentives—Getting Patients Involved

Written by Kathleen McDermott, Matt Hogan, and Jacob Harper

Oct. 29, 2019, 3:01 AM

In Part 2 of a series on proposed Stark and anti-kickback rules, Morgan Lewis attorneys examine patient engagement provisions and note their essential role. But, they say, the OIG and CMS could go farther, for example, and relax their long-standing bias against cash, coupons, or cash equivalents to patients as part of support management activities.

The Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS) proposed safe harbors and exceptions to advance innovation in health care hold promise and present a good start in envisioning new paradigms for value-based care. An important objective is incorporating patients into their care coordination.

This promising objective is an essential ingredient to the success of value-based care. OIG commentary explains that empowering patients in care activities is critical to achieving the objectives of value-based care. Its commentary on the importance of addressing the social determinants of health to achieve good

clinical outcomes from value-based arrangements reflects a keen public health understanding of the challenges in making these arrangements actually work for patients.

The proposed patient engagement tools and other incentives are important efforts that complement other value-based participant efforts to coordinate care. While most of the regulatory effort is understandably structured on incentives for physicians and other stakeholders to do more and coordinate better, these incentives may not meet the promise of value-based care if the patient stays on the sidelines.

Giving patients incentives to participate in care coordination activities is critical to true health care innovation. After all, the patient is really doing the hard work to achieve better health outcomes that may yield extra compensation to their physician. In this regard, the proposed safe harbors go further than before with a few important innovations.

Are the Proposals Bold Enough?

Are the proposed rules bold enough, however, to change the patient's traditionally passive role in care management? In this area, there may be more the OIG and CMS could do to promote engaged patient participation in the care process, including relaxation of its long-standing bias against cash, coupons, or cash equivalents to patients as part of support management activities.

Both agencies expressly asked for feedback on its proposals related to patient incentives. While the OIG proposes standardization for CMS sponsored model patient incentives and a telehealth provision for dialysis treatment, two proposals and their related commentary warrant special attention for their emphasis on how the social determinants of health impact value-based care and the role of incentives to meet those challenges.

New Safe Harbor for Patient Incentives in VBE Arrangements

The OIG proposes a new safe harbor that allows for patient engagement tools and support in qualified value-based arrangements to promote outcomes and efficiencies. The incentive may only be offered by a value-based enterprise (VBE) participant to a VBE targeted patient population. The incentive must be recommended by the patient's physician to advance specific goals and is limited generally to an annual aggregate cap of $500. The OIG is considering certification obligation on the physician related to whether the patient needs or will use the engagement tool solely for a chronic condition.

Incentives would be limited to patient engagement tools or support that are in-kind preventative or monitoring items, goods or services with a direct connection to coordination and management of care such as health care technology or patient monitoring services. Pharmaceutical manufacturers, DMEPOS, distributors and laboratories are expressly excluded from providing such incentives.

Excluded from the definition of patient engagement tools and support are gift cards, cash or any cash equivalent (debit card or checks). The waiver of cost-sharing obligations also do not qualify as a patient engagement tools and support. However, the OIG is considering the allowance of gift cards in limited circumstances related to discrete circumstances (substance abuse treatment) and solicits feedback.

The OIG also is considering whether incentives may be allowed to address the social determinants of health (e.g., nutrition, housing, transportation) in recognition that these factors may dramatically impact

outcomes in coordinated care management and may save government health care programs over a trillion dollars if effectively addressed.

Revised Safe Harbor for Local Transportation

The OIG proposes to revise the safe harbor for local transportation to expand mileage limits in rural health areas to 75 miles and to permit without restriction transport for patients discharged from in-patient facilities to their residences.

Notably, the OIG is considering whether to expand the safe harbor to non-medical purposes in recognition of social determinant factors related to transportation access that may impact health outcomes. This is an extraordinary departure from enforcement policy and an important area for commentary given the role transportation plays in assuring access to health-care services.

Conclusion

Of course, there is much to debate in any new regulatory endeavor. The OIG and CMS have presented a credible framework to reduce barriers for health care innovation in patient care. The recognition that social determinants of health play a large role in the effectiveness of value-based and other arrangements is a solid foundation on which to explore further expansion or changes to the safe harbors.

There are indications that OIG will strongly consider changes to the proposed requirements based on feedback to the proposed rule. Health industry stakeholders should take advantage of the comment period and offer concrete feedback to the proposed changes by Dec. 31, 2019.

Author Information
Kathleen McDermott, a former assistant U.S. attorney and Department of Justice healthcare fraud coordinator, is a partner in Morgan Lewis's Washington, D.C., office. She represents healthcare and life sciences clients throughout the United States in government investigations and litigation matters relating to criminal, civil, and administrative allegations, including violations of the False Claims Act and its whistleblower provisions.

Matt Hogan, a former federal prosecutor, represents clients in a wide array of white collar matters, internal investigations, False Claims Act litigation, and other complex matters involving federal and state investigations and litigation. He is a partner in Morgan Lewis's Philadelphia office.

Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. He is an associate in Morgan Lewis's Washington, D.C., office.