October 26, 2018

VIA ELECTRONIC SUBMISSION

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
Room 5513, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: [OIG–0803-N] Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Edwards:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the Office of the Inspector General's (OIG's) **Medicare Anti-Kickback Statute and Beneficiary Inducements CMP Request for Information**. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to three million people with Medicare, family caregivers, and professionals each year.

Changes in the way Medicare providers deliver care are an important aspect of the switch to value-based care. Providers point to certain statutes like the Anti-Kickback Statute and supporting regulations as limiting their ability to innovate effectively by generally forbidding waivers of co-payments or deductibles, strictly policing "fair market value" in terms that may not be fully congruent with health services, and banning remuneration that may influence the beneficiary's choice of provider or practitioner. The penalties for violation can be severe, from criminal and civil monetary penalties (CMPs) to denial of participation in Medicare, and fear of these repercussions could potentially hamstring providers who seek innovative partnerships, incentives, or strategies to reduce costs and increase beneficiary engagement or adherence to treatment.

However, it is vital to acknowledge how important robust consumer protections are to ensure that beneficiaries are not penalized through higher costs, poor or unnecessary care, or other occurrences that reduce the quality, accessibility, convenience, transparency, or affordability of their care. There must be robust oversight and enforcement of beneficiary protections to ensure both the program and the people who need it are safe.

We encourage OIG and CMS to explore the ways bad actors may use current or new structures to take advantage of programmatic rules or beneficiaries. We urge CMS to consult with policy and legal experts and, especially, with consumers to better understand how systems may be gamed and what impact that may have on beneficiaries.[1] Ultimately, people with Medicare suffer when loopholes and poor incentives are permitted.

1. Promoting Care Coordination and Value-Based Care

OIG asks what potential arrangements the industry is interested in pursuing that may implicate the anti-kickback statute or beneficiary inducements CMP. Prime examples of this would be the option to waive co-payments or deductibles, pay incentives for behaviors or compliance, or special discounts between providers that may not meet the "fair market value" definition.

While we do not categorically oppose these types of arrangements as they touch beneficiaries, any relaxation in the rules or creation of new safe-harbors must be thoughtfully considered and never agreed to out of a sense of expediency to promote the appearance of value. While creating a value-based system within Medicare is a worthy goal, it must not come at the expense of the very beneficiaries the program is meant to serve. Monetary benefits for beneficiaries are especially fraught with risk that the industry could use them to commodify health services in an inappropriate way. Many Medicare beneficiaries are low income and may not perceive monetary-type incentives as optional. For people with chronic conditions, incentives or discounts that accrue for provider visits, for example, could add up quickly into sums that patients might not feel they can afford to miss.

ACOs are newly able to create and offer beneficiary incentive programs. Any additional expansion of this option should wait until details and data are available from the ACO experience to ensure such incentive programs can be safe and free from discrimination or undue influence and that beneficiaries do not feel that it removes any real choice. They also may attract primarily beneficiaries who are in better health who feel they are more likely to meet whatever thresholds or goals the incentive arrangement may set.

Beneficiaries should be made aware of financial arrangements and potential conflicts of interest between providers, practitioners, and suppliers. An open, transparent environment can increase oversight as well as promoting confidence in the system.

2. Beneficiary Engagement

[1] Julie Carter, "Consumer Protections in New Medicare Payment and Delivery Models: A Checklist," AARP Public Policy Institute & Medicare Rights Center (November 20, 2017), https://www.aarp.org/ppi/info-2017/consumer-protections-in-new-medicare-payment-and-delivery-models.html.

A. Beneficiary Incentives

OIG asks what restrictions should be placed on the sources, types, or frequency of beneficiary incentives. It is vital that OIG consult with independent industry and legal experts to understand how differing providers may be able to use, or misuse, beneficiary incentive programs. Any use of such programs must be open and transparent, with information provided to consumers that is easily understood and actionable. We urge that CMS provide templates for all beneficiary notifications and use comprehensive consumer testing to ensure the notices make sense to people with Medicare and cannot be used to inappropriately steer beneficiaries or otherwise induce them into actions or choices to their detriment.

OIG asks what disclosures should be required from the offeror to the beneficiaries. Again, we support a CMS-provided template that would use consumer-tested language to share information about beneficiary incentives. This would ensure that the language is clear and is not unduly persuasive. Such a template should include information about the source of the incentive as well as thoroughly explaining the incentive program's rules or limitations.

B. *Cost-Sharing Obligations*

OIG seeks information about how relieving or eliminating beneficiary cost-sharing obligations might improve care delivery, enhance value-based arrangements, and promote quality of care, plus care scenarios in which cost-sharing obligations are particularly problematic. Cost sharing decreases the use of both necessary and unnecessary care, so eliminating cost sharing could increase the use of necessary care. Cost-sharing obligations are particularly problematic when beneficiaries need repeated follow-up visits or see large numbers of providers. They are also extremely confusing for patients when they apply unexpectedly, such as with telehealth or other services where consumers may not understand they are incurring a charge.

OIG asks what concerns arise if cost-sharing obligations could be subsidized by providers, suppliers, or other entities in a care delivery arrangement. Just as even minor incentives could add up to significant bonuses for beneficiaries, even minor expenses could add up to significant liabilities for providers. Waiving cost sharing could create an environment where more profitable providers are able to out-compete smaller providers on price, potentially meaning less real choice for people with Medicare as their preferred providers may be driven out of the Medicare program.

3. Other Related Topics of Interest

D. *Telehealth (Section 50302(c) of the Bipartisan Budget Act of 2018)*

OIG seeks input into protections or safeguards for telehealth technologies to be excepted from remuneration. As mentioned above, telehealth services have the potential to confuse beneficiaries who may not be aware that they are incurring a cost through their access to a provider via technology. So it is important that any telehealth technologies, even if provided at no cost, are not coupled with hidden or confusing charges revolving around their actual use.

Conclusion

As with all Medicare statutes, regulations, and guidance, rule changes related to this RFI must keep beneficiary needs and safety—both physical and financial—at the forefront. The importance of protections against self-dealing and conflicts of interest cannot be overstated. Because of this, we urge OIG and all of HHS to investigate closely any proposed changes for their potential to burden or unduly influence people with Medicare. We look forward to working together to advance policies that consider and balance the needs of all stakeholders while promoting high-value and high-quality care. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Senior Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

Joe Baker
President
Medicare Rights Center