



December 2, 2014

Office of Inspector General
Department of Health and Human Services
Attention: OIG-403-P3
330 Independence Avenue SW
Washington, DC 20201

Re: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing ("Proposed Rule")

The National Association of ACOs ("NAACOS") is an organization of approximately 120 accountable care organizations ("ACOs") participating in the Medicare Shared Savings Program ("Shared Savings Program"). We believe that the fundamental goal of the ACO program is to improve care quality and patient outcomes while, at the same time, lowering Medicare cost growth. Our members' experience to date has demonstrated that achieving financial savings through clinical practice redesign is a difficult, time-intensive, and costly process. Over the past several years, we have developed an even greater appreciation for how difficult it is to successfully (1) redesign clinical care delivery to improve care quality and (2) collect and accurately report clinical data to satisfy the ACO program's quality performance benchmarks. Although there is no precise relationship between quality and price, or quality and outcomes, we remain committed to improving patient and population outcomes and clinical cost efficiency.

NAACOS is pleased to submit the following comments on the Proposed Rule issued by the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"). Our comments focus on (1) the federal health care program anti-kickback statute ("AKS") safe harbor concerning the provision of free or discounted local transportation services ("Free Transportation Safe Harbor"); and (2) the beneficiary inducement civil monetary penalty law ("BIL") exception concerning remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs ("Access to Care Exception").

NAACOS strongly supports the goal of preventing health care fraud and abuse. Providing excessive or medically unnecessary services harms patients and financially strains the Medicare and Medicaid programs. ACOs, of course, do not fall into the typical fee-for-service model. That is, ACOs are not financially rewarded by ordering additional tests or providing referrals in exchange for remuneration. To the contrary, ACOs are rewarded only to the extent they are able to reduce program costs while, at the same time, maintaining care quality. Overutilization provides no benefit for ACOs and may lead to financial penalties. NAACOS encourages the OIG to take into consideration the unique nature of ACOs as it finalizes fraud and abuse exceptions and safe harbors.

Local Transportation Safe Harbor

The OIG proposes to establish a new Local Transportation Safe Harbor, 42 C.F.R. §1001.952(bb), which would protect free or discounted local transportation services provided to federal health care program beneficiaries. In the preamble to the Proposed Rule, the OIG notes that "Congress intended that the



statute not preclude the provision of complimentary local transportation of nominal value." The proposed Safe Harbor would protect free or discounted local transportation made available to a patient (and a person to assist the patient, if needed) to obtain medically necessary items and services. The OIG would impose five conditions on free or discounted local transportation as follows:

1. The free or discounted local transportation must be available only to established patients and be determined in a manner unrelated to the past or anticipated volume or value or federal health care program business. OIG solicits comments on six elements of this condition.
 - a. Only "Eligible Entities" could offer or provide free or discounted local transportation under the Proposed Rule. As it currently stands, the Proposed Rule would permit ACOs to be an Eligible Entity. We encourage the OIG to ensure that ACOs be permitted to provide free or discounted local transportation in the final rule.
 - b. The proposed Safe Harbor would limit the provision of free or discounted local transportation to established patients. We encourage the OIG to permit the offer of free or discounted local transportation to new ACO patients as well. Medicare beneficiaries who are assigned to an ACO under the Shared Savings Program may not have an established relationship with an ACO provider. By permitting free or discounted local transportation to new ACO-assigned beneficiaries, these beneficiaries will be encouraged to seek proper care, including preventive and primary care.
 - c. The OIG proposes that the Safe Harbor would not protect free or discounted local transportation if an Eligible Entity makes the transportation available only to patients who were referred to it by particular providers or if the transportation is contingent on a patient seeking a particular provider. In the Proposed Rule, the OIG recognizes that ACOs present a unique situation and the OIG seeks comments on the impact of this condition on ACOs. NAACOS believes that this particular condition should not apply to ACOs or should be modified to permit ACO-referred care. The OIG's condition is premised on the idea of reducing the risk of using the free or discounted local transportation services to increase referrals -- a health care fraud and abuse concern shared by NAACOS. However, increased referrals run contrary to the goals and financial incentives for ACOs. Increasing referrals, and thus, Medicare spending, does not provide a financial benefit to an ACO, which is designed to reduce health care spending while increasing quality. Referrals to ACO network providers are inherently designed to prevent future health care spending and improve the care provided to Medicare beneficiaries, rather than increase the provision of Medicare services.
 - d. Granting free or discounted local transportation services may not be based on the type of treatment a patient might receive under the Proposed Rule. NAACOS supports this condition as proposed.
 - e. The OIG is considering, and seeks comments on, whether to require Eligible Entities to maintain documented beneficiary eligibility to demonstrate the need for transportation. NAACOS believes that preventing misuse of this proposed Safe Harbor is vital and



supports reasonable documentation of a patient's need for free or discounted local transportation services.

- f. The OIG solicits comments on whether free or discounted local transportation should be limited to providing transportation for medical purposes or whether Eligible Entities should receive safe harbor protection if transportation is provided for other purposes that relate to the patient's health care (e.g., obtaining counseling or social services). NAACOS supports providing free or discounted local transportation for medical purposes. We also support providing free or discounted local transportation for other services related to a patient's health care, so long as the health care purposes related to care coordination and adherence to a patient's plan of care. As we have noted, ACOs are not incentivized to commit abuse this proposed safe harbor protection and the ability to encourage care coordination will reduce health care costs and improve patient outcomes.
2. The OIG proposes that the free or discounted local transportation at issue exclude from protection air, luxury, and ambulance-level transportation. NAACOS supports this condition as proposed.
3. The OIG proposes three limitations that would exclude from Safe Harbor protection transportation that, in reality, is designed to pay for patient recruitment: (i) transportation services publicly advertised or marketed to patients; (ii) payment by Eligible Entities to drivers or others involved in transportation on a per-beneficiary basis, rather than (for example) hourly or by mileage; and (iii) transportation that includes marketing of health care items or services during the course of the transportation. NAACOS supports these limitations as proposed.
4. OIG proposes to limit the Safe Harbor to local transportation. The OIG proposes a 25 mile distance to be considered local, while soliciting comments on other appropriate distances, including a more expansive service area for rural or underserved areas or a "facts and circumstances" safe harbor for transportation beyond 25 miles. NAACOS supports clear guidelines from OIG regarding what is considered "local" transportation. We support establishing a 25-mile distance that automatically will be deemed to be local under the safe harbor. We also support an expanded distance for rural and underserved areas and that the OIG permit free or discounted local transportation to be provided in excess of 25 miles under appropriate circumstances.
5. The OIG proposes requiring that Eligible Entities bear the cost of the free or discounted local transportation services. NAACOS supports this condition as proposed.

Access to Care Exception

The OIG proposes an Access to Care Exception under the BIL pursuant to Section 1128A(i)(6)(F) of the Social Security Act. The Exception would cover remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs.

The OIG proposes that "promotes access to care" would mean that the remuneration provided improves a particular beneficiary's ability to obtain medically necessary health care items and services. Promoting



access to care may include encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient for patients than it otherwise would be.

The OIG proposes to interpret the phrase "poses a low risk of harm to patients and federal health care programs" to mean that the remuneration: (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient-safety or quality-of-care concerns.

NAACOS supports the finalization of the Access to Care Exception. As noted above, ACOs are not driven or rewarded by the overutilization of health care services. Rather, an ACO (and by association, the Medicare program) is only successful by improving a beneficiary's ability to obtain medically necessary care. Supporting patient access to care is how an ACO improves Medicare beneficiary outcomes and reduces Medicare program spending. In fact, the OIG notes in the preamble to the Proposed Rule that "in some circumstances, patients might be offered incentives to encourage them to engage in arrangements that lower health care costs (without compromising quality) or that promote their own wellness and health care." NAACOS believes that incentives can be designed to truly encourage and foster greater patient outcomes and reduce spending, while at the same time, preventing fraud and abuse.

Conclusion

We appreciate the consideration of our comments to the Proposed Rule. NAACOS looks forward to working with the OIG and all other agencies within HHS to ensure the success of the ACO model of health care delivery.

Sincerely,

A handwritten signature in black ink, appearing to read "Clifton Gaus", written in a cursive style.

Clifton Gaus
CEO
National Association of ACOs