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New Safe Harbors for Transportation Programs, Certain Cost-Sharing Waivers, and Gap Discount Programs

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The OIG has issued new regulatory safe harbors that allow healthcare providers to offer government program beneficiaries certain valuable items without running afoul of the federal Anti-Kickback Statute ("AKS"). (81 F.R. 88368 (12/7/16), available here). The AKS generally prohibits offering or giving remuneration to induce or reward referrals for items or services covered by federal healthcare programs unless the transaction fits within a regulatory safe harbor. Violation of the AKS is a felony, and may result in criminal, civil and administrative penalties; accordingly, it is important to structure transactions with federal program beneficiaries and other referral sources to fit within a regulatory safe harbor if possible.

Local Transportation Programs. The new safe harbor allows healthcare providers to provide free or local transportation programs if: (1) the transportation program is set forth in a policy which the provider applies uniformly and consistently, and is not determined based on the volume or value of federal health care program business; (2) the transportation services are not air, luxury, or ambulance-level transportation; (3) the healthcare provider does not publicly market or advertise the transportation services, and no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation; (4) drivers or others arranging for the transportation are not paid on a per beneficiary-transported basis; (5) the healthcare provider makes the transportation available only to an individual who is an established patient (as defined in the regulations) within 25 miles of the healthcare provider, or within 50 miles if the patient resides in a rural area, for the purpose of obtaining medically necessary items and services; (6) the healthcare provider bears the costs of the free or discounted local transportation services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals. (42 CFR 1001.952(bb)(1)).

Shuttle Services. If the healthcare provider operates a "shuttle service" (*i.e.*, a vehicle that runs on a set route and set schedule), the following conditions must be met to satisfy the safe harbor: (1) the shuttle service is not air, luxury, or ambulance-level transportation; (2) the shuttle service is not marketed or advertised (other than posting necessary route and schedule details), no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation; (3) drivers or others arranging for the

transportation are not paid on a per-beneficiary-transported basis; (4) the healthcare provider makes the shuttle service available only within the provider's local area, *i.e.*, there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 50 miles between that stop and all providers or suppliers on the route; and (6) the eligible entity that makes the shuttle service available bears the costs of the free or discounted shuttle services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals. (42 CFR 1001.952(bb)(2)).

Hospital Waiver of Cost-Sharing Amounts. The AKS and CMPL generally prohibit a provider from waiving Federal program beneficiary copayments, coinsurance, deductibles and other cost-sharing amounts subject to certain exceptions. The OIG generally retains the existing safe harbor for hospitals by which hospitals may waive beneficiary cost-sharing amounts for inpatient services payable under the prospective payment system if: (1) the hospital does not claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals; (2) the hospital must offer to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group ("DRG") for which the claim for reimbursement is filed; and (3) the hospital's offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy. (42 CFR 1001.952(k)(1)).

Pharmacy Waiver of Cost-Sharing Amounts. The new regulation allows pharmacies to waive cost-sharing amounts if: (1) the waiver or reduction is not offered as part of an advertisement or solicitation; (2) the pharmacy does not routinely waive or reduce cost-sharing amounts; and (3) the pharmacy waives the cost-sharing amounts only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts. (42 CFR 1001.952(k)(3)).

State-Owned Ambulance Provider Waiver of Cost-Sharing Amounts. The regulation now allows ambulance providers to waive cost-sharing amounts for emergency ambulance services paid on a fee-for-service basis if: (1) the ambulance provider is owned and operated by a state, a political subdivision of a state, or a or a tribal health care program; (2) the ambulance provider engaged in an emergency response; (3) the ambulance provider offers the reduction or waiver on a uniform basis to all of its residents or tribal members, or to all individuals transported; and (4) the ambulance provider or supplier must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals. (42 CFR 1001.952(k)(4)).

Other Safe Harbors. The regulation contains additional safe harbors applicable to Medicare coverage gap discount programs and arrangements between federally qualified health centers ("FQHCs") and Medicare Advantage organizations. (*See* 42 CFR 1001.952(z) and (aa)).

The new safe harbors are available on January 6, 2017.

For questions regarding this update, please contact:
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