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HEALTH LAW
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Proposed Revisions to Anti-Kickback Safe Harbors and Civil Monetary Penalty Provisions

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On October 3, 2014, the Office of Inspector General ("OIG") released proposed revisions and requested comments to the Anti-Kickback ("AKS") safe harbors and the Civil Monetary Penalty rule ("CMP").[1] These proposed revisions add new safe harbors, including safe harbors that codify statutory changes from the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") and the Patient Protection and Affordable Care Act, as amended "(ACA"). The proposed revisions also codify the definition of remuneration added by the Balanced Budget Act of 1997 ("BBA") and ACA, as well as adding a gainsharing civil monetary penalty provision.

ANTI-KICKBACK

Referral Services Safe Harbor

The OIG proposes to make a technical correction to the safe harbor for referral services, 42 CFR 1001.952(f) (2), to avoid unintended ambiguity from a revision in 2002. The correction would change text of the referral safe harbor back to the 1999 version to prohibit referrals based on the value or volume of referrals to or business generated by "either party for the other party…" instead of just "by either party."

Cost Sharing Waivers

The OIG wishes to modify the safe harbor for waiver of beneficiary coinsurance and deductible amounts by adding two cost-sharing waivers: by pharmacies and for emergency ambulance services. In addition, OIG seeks comment as to whether to protect the waivers under all Federal healthcare programs.

Pharmacies

The OIG wishes to reflect the exception from the MMA for cost sharing waivers by pharmacies. Pharmacies waiving Part D cost sharing qualify for the proposed safe harbor protection if:

a) the waiver is not advertised or part of solicitation,
b) the pharmacy does not routinely waive cost sharing, and
c) before waiving the cost sharing, the pharmacy determines in good faith that the beneficiary is in financial need or the pharmacy fails to collect after reasonable effort.

1 https://www.federalregister.gov/articles/2014/10/03/2014-23182/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

Emergency Ambulance Service

In response to continuing requests for advisory opinions despite existing advisory opinions on emergency ambulance service, OIG proposes a new safe harbor on emergency ambulance service. As proposed, a reduction or waiver of coinsurance and deductibles for emergency ambulance services does not violate the anti-kickback statute if:

a) the provider or supplier is owned and operated by a state or local government or a federally recognized Indian tribe,
b) the service is Medicare Part B,
c) the reduction is offered uniformly,
d) the waiver or reduction in coinsurance cannot be claimed as bad debt, and
e) services are on an emergency rather than nonemergency basis.

This safe harbor would not apply to contractors supplying the service for the state or local government.

Federally Qualified Health Centers and Medicare Advantage Organizations

The OIG seeks to incorporate an amendment to the MMA to include any remuneration between a federally qualified health center and a Medicare Advantage Organization pursuant to a written agreement.

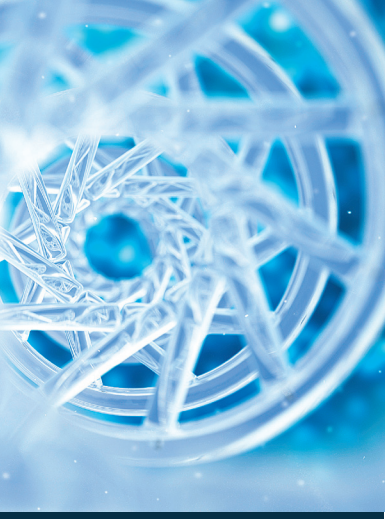
Medicare Coverage Gap Discount Program

OIG would like to codify the self-implementing Section 3301 of ACA to protect discounts provided under the Medicare Coverage Gap Discount whereby an applicable beneficiary receives a discounted price for an applicable drug as long as the manufacturer in is full compliance with all requirements of the Medicare Coverage Gap Discount Program.

Local Transportation

The OIG proposes a new safe harbor for local transportation up to 25 miles (potentially more expansive for rural areas), including through family or a friend, that is free or discounted for established patients obtaining medically necessary items and services. The OIG suggests several protections such as a) not having the service contingent on the patient seeing a particular provider or supplier; b) not basing the service on a type of treatment; c) not publicly advertised and marketed transportation and d) not paying for the service per beneficiary but rather on an hourly or mileage basis.

The OIG seeks comments on a number of aspects of the proposed safe harbor such as: exclusion of certain types of providers from the safe harbor, a requirement that the patient show financial need or risk associated with failure to comply with treatment and whether the services should be restricted to medical purposes.



CIVIL MONETARY PENALTY

The OIG proposes revisions to the CMP laws in two main contexts.

Remuneration

First, the OIG has proposed to amend the definition of what constitutes "remuneration" by stating that the following scenarios will not be deemed to be remuneration for CMP violation and/or enforcement purposes:

a) Copayment reductions for particular hospital outpatient department services;
b) Remuneration that poses a low risk of harm to patients and improves a patient's ability to obtain medically necessary health care items and services.
c) Coupons, rebates, or other retailer reward programs that meet specific requirements;
d) Assistance for financially needy individuals that meets specific requirements; and
e) Copayment waivers generic drugs (first fill only).

Gainsharing

The OIG seeks to develop specific regulations and standards for gainsharing arrangements. The main compliance concern and prohibition with respect to gainsharing arrangements is ensuring that the parties do not directly or indirectly reduce of limit the services provided or available to patients as a result of the gainsharing arrangement. The OIG is now open to and seeking comments on how to develop a more narrow interpretation of what terms, actions, circumstances and/or arrangements would constitute or result in the reduction or limitation of services. In this regard, the OIG has asked for comments on specific areas of concern such as "Should a hospital's decision to standardize certain items (e.g., surgical instruments, medical devices, or drugs) be deemed to constitute reducing or limiting care?" The development of new gainsharing arrangement laws will hopefully enable hospitals to implement protocols that increase quality and/or decrease cost, while allowing physicians at the hospital to share in the resulting savings.

Comments to the proposed rule are due to the OIG by December 2, 2014. If you have questions or comments regarding the proposed revisions, please contact one of the members of our Health Law Practice Group in Washington, DC or Hartford, CT.

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