



October 15, 2014

OIG PROPOSES REVISIONS TO ANTI-KICKBACK SAFE HARBORS AND CIVIL MONETARY PENALTY RULE

By: Daniel O. Carroll, Esq. and Meghan V. Hoppe, Esq.

On October 2, 2014, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) released a proposed rule containing revisions to both the Anti-Kickback Statute (AKS) safe harbors and the civil monetary penalty (CMP) rule. The proposed rule was published in the October 3, 2014, *Federal Register* ([79 Fed. Reg. 59717](#)) with a public comment period ending on December 2, 2014. The OIG's proposed revisions "seek to strike an appropriate balance between protections for beneficial arrangements and safeguards to prevent unscrupulous individuals and entities from taking advantage of the safe harbors to increase costs to programs and patients or compromise quality of care."

The proposed rule would add new safe harbors to the AKS that would implement provisions from the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Patient Protection and Affordable Care Act (PPACA). The OIG also proposed to amend the AKS safe harbor regulations by modifying certain existing safe harbors. The OIG's stated goal in proposing these changes "is to protect beneficial arrangements that enhance the efficient and effective delivery of health care and promote the best interests of patients, while also protecting the Federal health care programs and beneficiaries from undue risk of harm associated with referral payments." The proposed changes include:

- Protection for free or discounted local transportation services available only to established patients, determined in a manner unrelated to any past or anticipated volume or value of federal health care program business, and otherwise meet various safeguards, including prohibiting air, luxury or ambulance transportation, prohibitions on marketing the services and prohibiting transports in excess of 25 miles;
- A technical correction to the existing safe harbor for referral services, which clarifies that the safe harbor "precludes protection for payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, *either party for the other party*";

- Protection for certain cost-sharing waivers, including pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries and waivers of cost-sharing for emergency ambulance services furnished by state-owned or municipality-owned ambulance services;
- Protection for certain remuneration between Medicare Advantage (MA) organizations and federally qualified health centers (FQHC), which would require that the written agreement between the two entities specifically provide that the MA organization “will pay the contracting FQHC no less than the level and amount of payment that the plan would make for the same services if the services were furnished by another type of entity”; and
- Protection for discounts in the price of an “applicable drug” of a manufacturer that is furnished to an “applicable beneficiary” under the Medicare Coverage Gap Discount Program, as long as the manufacturer participates in, and is in full compliance with, all requirements of the program.

The OIG also proposed to codify certain revisions to the definition of “remuneration” added by the Balanced Budget Act (BBA) of 1997 and PPACA. According to the OIG, “these exceptions are intended to protect certain arrangements that offer beneficiaries incentives to engage in their wellness or treatment regimens or that improve or increase beneficiary access to care, including better care coordination.” The proposed modifications to the regulations would add certain statutory exceptions for:

- Copayment reductions for certain hospital outpatient department services;
- Certain remuneration that poses a low risk of harm and promotes access to care;
- Coupons, rebates, or other retailer reward programs that meet specified requirements;
- Certain remuneration to financially needy individuals; and
- Copayment waivers for the first fill of generic drugs.

Finally, the OIG proposed to adopt a regulation implementing the gainsharing CMP rule set forth in section 1128A(b) of the Social Security Act. The gainsharing CMP prohibits a hospital from knowingly paying a physician to induce the physician to reduce or limit the services provided to Medicare or Medicaid beneficiaries under the physician’s direct care. While the OIG has stated that this prohibition is not limited to reductions or limitations of medically necessary items or services, it has recognized the benefits of gainsharing and has approved 16 gainsharing arrangements through its advisory opinion process. The OIG explained that the gainsharing CMP has not been amended by Congress and “[w]ithout a change in the statute, we continue to believe that we cannot read a ‘medically necessary’ element into the prohibition.” However, the OIG stated that it is considering a narrower interpretation of the term “reduce or limit services.” While the OIG did not propose text for a definition of “reduce or limit services,” it did solicit comment on whether there should be a regulatory definition and if so what specific proposals and safeguards should be included “to ensure that the goal of the statute is met: To prevent hospitals from paying physicians to discharge patients too soon or take other action that inappropriately limits a beneficiary’s care.”

CLIENT ALERT

October 15, 2014
Page 3

Comments on the proposed regulations can be submitted up until December 2, 2014. Instructions for submitting comments can be viewed on the *Federal Register's* [website](#).

For more information on the proposed rule to amend the safe harbors to the AKS and the CMP rules or related issues, please feel free to contact any member of the firm's Health Care Law practice group for a further discussion.

DISCLAIMER: This Client Alert is designed to keep you aware of recent developments in the law. It is not intended to be legal advice, which can only be given after the attorney understands the facts of a particular matter and the goals of the client. If someone you know would like to receive this Client Alert, please send a message to Daniel O. Carroll, Esq., a partner in the Health Care Practice Group at doc@spsk.com or Meghan V. Hoppe, Esq. an associate in the Health Care Practice Group at mvh@spsk.com.

FLORHAM PARK 220 Park Avenue PO Box 991 Florham Park, NJ 07932 Tel: 973-539-1000 www.spsk.com	PARAMUS Country Club Plaza 115 West Century Road Suite 100 Paramus, NJ 07652 Tel: 201-262-1600	SPARTA 351 Sparta Avenue Sparta, NJ 07871 Tel: 973-295-3670	NEW YORK 116 West 23 rd Street Suite 500 New York, NY 10011 Tel: 212-386-7628
---	---	---	---