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Practice Update

# New Year, New Resolutions, New Safe Harbors

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As we welcome the new year and its endless possibilities, we also welcome some new Anti-Kickback Statute safe harbors and concomitant business possibilities. In December, the U.S. Department of Health and Human Services Office of Inspector General issued a final rule (the New Rule) supplementing and revising the safe harbors under the Anti-Kickback Statute. The rule, which codifies changes made by the Affordable Care Act (ACA), is effective January 6, 2017. Will these safe harbors make it through the new year or, as with most well-intentioned new year's resolutions, will the New Rule be "broken" early? President-Elect Donald Trump vowed that "70% of [federal] regulations can go. It's just stopping businesses from growing."[1] Is that sentiment a harbinger of things to come for the New Rule? We think not.

The AKS provides for criminal penalties to anyone who intends to receive or pay remuneration for the referral of business reimbursable by a Federal healthcare program. Since the AKS could jeopardize appropriate commercial arrangements, Congress carved out safe harbors that would provide protections from these AKS penalties. Accordingly, safe harbors offer more opportunities for providers to implement efficient, beneficial programs that eliminate barriers to care. It is that impact of these regulations that makes the New Rule less susceptible

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to reversal by a Trump Administration.

1. *Expansion of Cost-Sharing Waivers*. A previously existing safe harbor excluded from the term "remuneration" the waiver or reduction of certain patient cost-sharing obligations, such as amounts owed to a hospital for inpatient hospital services. The New Rule expands the existing safe harbor to cover cost-sharing waivers issues to all Federal health care program beneficiaries, which includes Medicare, Medicaid, the State Children's Health Insurance Program, TRICARE, the Veterans' Health Administration, and the Indian Health Service program.
2. *Pharmacy Waivers or Reductions of Cost-Sharing*. Consistent with the AKS exception for pharmacy cost-sharing waivers under the Medicare Prescription Drug Improvement and Modernization Act of 2003, the New Rule has added a safe harbor permitting pharmacies to reduce or waive cost-sharing amounts if: (a) the waiver or reduction is not offered as part of an advertisement or solicitation; (b) the pharmacy does not routinely waive or reduce cost-sharing amounts; and (c) the pharmacy first determines in good faith that the individual is in financial need, or after reasonable collections efforts have failed. It is important to note that this safe harbor is limited to pharmacies and, therefore, other types of providers would not be protected by this safe harbor from waiving or reducing any cost-sharing for Part B drugs. However, it does expand protection of cost-sharing waivers under all federal healthcare programs. The no advertising/no solicitation requirement is intended to deny safe harbor protection for potentially abusive steering arrangements, and individuals eligible for Medicare Part D subsidies need only meet that requirement to fall within the safe harbor. Waivers extended to all other individuals not receiving Medicare Part D subsidies must comply with all three requirements set forth above. Accordingly,

pharmacies should follow a written policy that accords with those requirements and provide training to personnel involved.

3. *Emergency Ambulance Service Waivers or Reductions of Cost-Sharing*. The New Rule creates a safe harbor for emergency ambulance services furnished by a state, municipality, or federally recognized Indian tribe to offer reduced cost-sharing or waivers of cost-sharing amounts owed under any Federal healthcare program. Unlike the pharmacy cost-sharing safe harbor, waivers for emergency ambulance services must not take into account insurance or financial status of the beneficiary, and the provider may not shift costs to any payor. Furthermore, the waivers must be offered uniformly and cannot exclude waiver recipients based on any "patient-specific factors" such as age or financial status.
4. *Free or Discounted Local Transportation*. The New Rule creates a safe harbor that allows eligible entities to provide Federal healthcare program beneficiaries with free or discounted local transportation or shuttle services to or from their home to obtain medically necessary items or services. Eligible entities cannot be, among other disqualified individuals and entities, providers of healthcare items, such as DME suppliers and pharmaceutical companies. The New Rule divides transportation into two categories – general shuttle service and other transportation offered to Federal healthcare program beneficiaries.

    a. With regard to shuttle service, which runs on a set route or schedule, certain additional limitations apply: (i) the shuttle may not involve "air, luxury, or ambulance level transportation"[2]; (ii) the service may not be marketed or advertised (other than to post route and schedule details) and no marketing of healthcare items and services can occur during the ride or at any time by the drivers and others arranging for the transportation may not be paid on a per-beneficiary

transported basis; (iii) the distance between the farthest stops must not be more than 25 miles or 50 miles in a rural entity; and (iv) the eligible entity may not engage in cost-shifting to any payor.

b. With regard to all other transportation offered to Federal healthcare program beneficiaries, in addition to the above-referenced requirements, eligible entities must also abide by the following: (i) the service must be set forth in a policy that is applied uniformly and consistently and not in a manner related to the volume or value of Federal healthcare business; and (ii) the transportation is only made available to established patients of the provider of the transportation and the patient is an established patient of the provider or supplier to or from which the individual is being transported.

5. *Protected Remuneration between FQHCs and Medicare Advantage Organizations*. The New Rule creates a new safe harbor that protects remuneration between a federally qualified health center (FQHC) and a Medicare Advantage organization (MAO) pursuant to a written agreement. Although the safe harbor does not involve a fair market value requirement, the payment to the FQHC must not be less than the level and amount of payment that the MAO would make to a non-FQHC entity.

6. *Medicare Coverage Gap Discount Program*. The ACA created the Medicare Coverage Discount Program (MCDP) under which prescription drug manufacturers may enter into agreements with the Department of Health and Human Services to provide beneficiaries access to discounts on Part D drugs when they fall into the "donut hole." The ACA also included protections from liability under the AKS. Consistent with that provision, the New Rule creates a safe harbor that protects a discount in a price of an "applicable drug" of a manufacturer furnished to an "applicable beneficiary" under the MCDP, provided, however,

that the manufacturer complies with all MCDP requirements. Notwithstanding the foregoing, it is important to note that the OIG specifically acknowledged that "minor, technical instances of non-compliance should not preclude safe harbor protection."[3]

The OIG has introduced these new safe harbors because it has determined that they further the goals of improved access to care and quality, promoting patient choice and enhancing appropriate utilization and competition while protecting against increased costs, inappropriate steering of patients, and inappropriate incentives tied to referrals. By providing greater opportunity for healthcare providers and payors to develop business arrangements that enhance patient access and care, the New Rule is likely to survive the Trump Administration's plan to reverse prior regulations.

[1] Reuters. "Donald Trump Says 70% of Federal Regulations 'Can Go'." *Fortune.com*. Fortune, 07 Oct. 2016. Web. 02 Jan. 2017

[2] 81 Fed Reg. 88,408 (2016).(to be codified at 42 C.F.R. §1001.952(bb)(2)(i))

[3] 81 Fed Reg.  88,378 (2016).

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