Published on *The National Law Review* https://natlawreview.com

Office of Inspector General Rings in the New Year With New Anti-Kickback Statute Safe Harbors

Article By:

Jana L. Kolarik

Adam J. Hepworth

Just in time for the New Year, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services issued final regulations (Final Regulations) that revised two existing Anti-Kickback Statute safe harbors, added two regulatory safe harbors to complement existing statutory safe harbors, and created an entirely new safe harbor regarding local transportation services. These regulations, which became effective on January 6, 2017, finalized the proposed regulations that OIG released on October 3, 2014. OIG received comments from 88 distinct commenters in response to the proposed regulations and made several changes to the proposed regulations in response to the comments received.

In addition to addressing the Anti-Kickback Statute safe harbors, the Final Regulations also amended several aspects of civil monetary penalty regulations (42 C.F.R. part 1003).

The Final Regulations addressed the following Anti-Kickback Statute safe harbors:

Referral Services Safe Harbor (42 C.F.R. § 1001.952(f)(2))

The Final Regulations clarified that the referral services 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." According to OIG, this language was intended to be in the safe harbor but was inadvertently changed to "or business otherwise generated by either party for the referral service" during prior regulatory changes. 81 Fed. Reg. 88368, 88371 (Dec. 7, 2016). Also of interest, OIG noted in the regulatory preamble that this safe harbor does not exclude the use of online tools, which is an increasingly common method for health care referrals.

Cost-Sharing Waiver Safe Harbor (42 C.F.R. § 1001.952(k))

OIG made several changes to the Anti-Kickback Statute cost-sharing waiver under Section 1001.952(k). First, OIG expanded the reach of the cost-sharing waiver safe harbor to cover all federal health care programs, not just Medicare and state health programs.

Second, OIG added cost-sharing waiver protection for amounts owed to a pharmacy. Under this new cost-sharing waiver, cost-sharing amounts may be reduced or waived if (1) the waiver or reduction is not offered as part of an advertisement or solicitation, and (2) except for waivers or reductions offered to subsidy-eligible individuals, the pharmacy does not "routinely" waive or reduce cost-sharing amounts, and 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.

In response to comments, OIG confirmed that federally qualified health centers (FQHCs) may advertise sliding scale discount programs without such communications constituting an "advertisement" under the safe harbor. OIG also declined to define what constitutes a "routine" waiver or endorse a particular method for determining what constitutes "financial need," noting that both determinations are fact-specific. With respect to determinations of financial need, OIG noted that the adoption of a written policy describing the standards and procedures used for determining financial need, along with evidence that the policy was followed, would help document that the pharmacy had met the safe harbor requirement.

Third, OIG added safe harbor protection for waivers or reductions of cost-sharing amounts that are owed to an ambulance provider or supplier for emergency ambulance services for which a federal health care program pays under a fee-for-service payment system. To meet this safe harbor, the ambulance provider or supplier must (1) be owned and operated by a state, political subdivision of the state, or tribal health care program; (2) be engaged in "emergency response"; (3) offer the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and (4) not later claim the amount reduced or waived as bad debt for payment purposes under a federal health care program or otherwise shift the burden of the reduction onto a federal health care program, other payers, or individuals.

FQHCs and Medicare Advantage Organizations Safe Harbor (42 C.F.R. § 1001.952(z))

The Final Regulations added a regulatory safe harbor to complement the existing statutory exception for remuneration between an FQHC and a Medicare Advantage organization. The safe harbor, which tracks the statutory exception located at 42 U.S.C. § 1320a-7b(b)(3)(h), states that "'remuneration' does not include any remuneration between a federally qualified health center (or an entity controlled by such a health center) and a Medicare Advantage organization pursuant to a written agreement described in Section 1853(a)(4) of the Social Security Act [which addresses agreements between Medicare Advantage organizations and FQHCs]."

Medicare Coverage Gap Discount Program Safe Harbor (42 C.F.R. § 1001.952(aa))

This new safe harbor for the Medicare Coverage Gap Discount Program complements the existing statutory exception located at 42 U.S.C. § 1320a-7b(b)(3)(j), which was added by the Affordable Care Act. It provides that remuneration does not include a discount in the price of a drug when the discount is furnished to a beneficiary under the Medicare Coverage Gap Discount Program, as long as (1) the discounted drug meets the definition of "applicable drug" under the Medicare Coverage Gap Discount Program; (2) the beneficiary receiving the discount meets the definition of "applicable beneficiary" under the Medicare Coverage Gap Discount Program; and (3) the manufacturer of the drug participates in, and is in compliance with, the requirements of the Medicare Coverage Gap

Discount Program.

Several commenters indicated that the safe harbor was unnecessary because the existing statutory exception was sufficient. OIG responded that "for the sake of completeness, we generally incorporate and interpret statutory exceptions in our safe harbor regulations." 81 Fed. Reg. at 88378.

Local Transportation Safe Harbor (42 C.F.R. § 1001.952(bb))

One of the most noteworthy aspects of the Final Regulations is the addition of a safe harbor for local transportation and shuttle services. OIG had addressed issues of free transportation in OIG Advisory Opinions 00-7 and 16-10, and in a published letter from 2002 from the Chief of the Industry Guidance Branch.

The safe harbor for local transportation provides that an "eligible entity" may provide free or discounted local transportation to federal health care program beneficiaries if several conditions are met. OIG defines "eligible entity" as any individual or entity, except for individuals or entities that primarily supply health care items (e.g., medical supplies).

To qualify for this safe harbor, the following requirements must be met: (1) the availability of the free or discounted local transportation services must be set forth in a policy, which is applied uniformly and consistently, and is not determined in a manner related to the past or anticipated volume of federal health care program business; (2) the transportation services are not air, luxury, or ambulance level transportation; (3) the transportation services are not advertised or publicly marketed, 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, and drivers cannot be paid on a per-beneficiary-transported basis.

In addition, the free or discounted transportation services can only be provided to an "established patient," which is defined as a person who has selected and initiated contact to schedule an appointment with a provider or supplier, or who has previously attended an appointment with the provider or supplier. This is a broader definition than what was proposed, which was limited to patients who had selected a provider or supplier and initiated contact to schedule an appointment. The transportation services must be provided within 25 miles of the provider or supplier or within 50 miles if in a "rural area" (as defined in the regulations). This distance limitation is also more permissive than the 25 mile limitation in the proposed regulations. The transportation services must be provided for purposes of obtaining medically necessary items and services.

As with certain other safe harbors, the eligible entity must bear the costs of the transportation and may not shift the costs to federal health care programs, other payers, or individuals.

The safe harbor also protects free "shuttle services," which are defined as vehicles that run on a set route and schedule. The requirements applicable to shuttle services are generally similar to those outlined above for free or discounted transportation, except that, among other things, the shuttle services need not be provided to an "established patient," a policy is not required, and the shuttle service route and schedule details may be posted. Thus, the shuttle services can be provided to anyone, but the shuttles must run on a set route and cannot tailor their routes to accommodate individual patients.

Conclusion

The Final Regulations address a wide variety of financial arrangements in the health care industry. Providers and suppliers should consider whether any existing arrangements require modification (or new policies) given these safe harbors, and also whether potential new business opportunities and patient services may exist in light of these safe harbors.

National Law Review, Volume VII, Number 12