



LHA IMPACT LAW BRIEF

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Headlines:

- ***OIG Finalizes New Anti-Kickback Status Safe Harbors and CMP Authorities***

Articles:

OIG Finalizes New Anti-Kickback Statute Safe Harbors and CMP Authorities

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On Dec. 7, 2016, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) issued two new final rules containing significant changes to the safe harbors to the Anti-Kickback Statute and the OIG's Civil Monetary Penalty (CMP) authorities, and a policy statement adjusting the monetary value of nominal gifts not subject to the CMP prohibition against beneficiary inducements. These new rules became effective Jan. 6, 2017. This summary addresses both OIG final rules issued on Dec. 7, 2016 (collectively the "Final Rules"), which included modifications to the Anti-Kickback Statute safe harbors and changes to the beneficiary inducement CMP statute and other CMP authorities.

The Final Rules revised existing safe harbors and added new safe harbors to the Anti-Kickback Statute to provide new "safe harbor" protection or to codify existing protections in an effort, generally, to facilitate certain arrangements that both *increase access to care* and *present low risk of abuse*. The modifications and changes to the Anti-Kickback safe harbors include:

- Protections for free and discounted local transportation for established patients;
- Protections for pharmacy cost-sharing waivers for financially-needy beneficiaries;
- Protections for manufacturer drug discounts on drugs furnished to beneficiaries under the Medicare Coverage Gap Program;
- Protections for certain payments between Medicare Advantage plans and federally-qualified health centers;
- Protections for cost-sharing waivers for emergency ambulance services furnished by state-or municipally-owned ambulance companies; and
- A technical correction to the existing safe harbor for referral services.

The OIG also revised the definition of "remuneration" in the CMP regulations at 42 C.F.R. part 1003 to implement CMP statutory provisions that except from the definition of "remuneration" certain patient



payment discounts and waivers. Under the Final Rules, the following arrangements are not considered “remuneration” subject to the CMP law:

- Copayment reductions for certain hospital outpatient services;
- Arrangements that pose a low risk of harm and promote access to care;
- Coupons, rebates and other reward programs that meet specified requirements;
- Certain payments to financially-needy individuals; and
- Copayment waivers for the first fill of generic drugs.

I. Anti-Kickback Statute Safe Harbors

Free and Discounted Local Transportation

The Final Rules added a new safe harbor that permits eligible entities to provide free or discounted local transportation services or “shuttle services” to “established patients” in order to access medically-necessary services. While the safe harbor is written in terms that are somewhat restrictive, it provides that free or discounted local transportation made available by an “eligible entity” to “established patients,” to obtain “medically necessary items or services” will be protected as long as all of the conditions are met.

The OIG defined an “eligible entity” as any individual or entity, other than those that primarily supply and sell healthcare items. For example, home health agencies, MA organizations, MCOs and accountable care organizations (ACOs) are considered to be “eligible entities,” and are not among the type of entities excluded from the definition of “eligible entities.” For purposes of the safe harbor, an “established patient” is any individual that selects and initiates contact with a provider or supplier to schedule an appointment.

The OIG stressed in the Final Rules that transportation cannot be used as a recruiting tool or for marketing purposes. The OIG also clarified that signage on vehicles is an important safety feature and would not be considered “marketing” for purposes of the safe harbor. Eligible entities (i.e., providers) are not permitted to market or advertise the free or discounted transportation services, or post signs or give patients pamphlets or other marketing materials.

The Final Rules included the following examples that fall within the new local transportation safe harbor:

- A transportation program that uses vouchers rather than having transportation provided directly by the eligible entity. However, the transportation cannot take the form of air, luxury, or ambulance-level services.
- Transportation back to the patient’s home.
- Transporting patients from one eligible entity to another. For example, a hospital that has discharged a patient may provide transportation for the patient to an appointment with a physician for follow up care as long as the patient is an established patient of both providers.
- Transporting patients to another provider or supplier that is a referral source as long as the transportation offer is not contingent upon the patient choosing a referral source. For example, a hospital could offer transportation services to its established patient diagnosed with cancer who needs to see an oncologist. The hospital would need to provide transportation to any oncologist that the patient chooses, not only to the oncologists who are referral sources for the hospital.
- Transporting patients through a shuttle service. Shuttle services are separately protected under this safe harbor and the Final Rules do not require shuttle services to be limited to established patients.

It is also important to note that the eligible entity can only make the transportation available within 25 miles of the provider. If the eligible entity (i.e., provider) is in a rural, area, the Final Rules provides that the distance may be up to 50 miles between that stop and all providers on the route.

Referral Services

The OIG proposed to make a technical correction to the safe harbor for referral services, located at 42 C.F.R. 1001.952(f). This safe harbor was amended in 1999 to clarify that the safe harbor did not offer protection for payment from participants to referral services that are based on the volume or value of the referrals to, or business otherwise generated by, either party for the other party. 64 F.R. 63518, 63526 (Nov. 19, 1999). This resulted in the safe harbor reading as follows:

(f) *Referral services.* As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value between an individual or entity (“participant”) and another entity serving as a referral service (“referral service”), as long as all of the following four standards are met— . . . (2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated **by either party for the other party** for which payment may be made in whole or in part under Medicare or a State health care program.

However, this clarification was altered in later revisions to the safe harbor. See 67 FR 11928, 11929, 11934 (Mar. 18, 2002). In 2002, the phrase “by either party for the other party” was revised to “by either party for the referral service.” *Id.* Thus, the OIG proposed a technical correction to this safe harbor to revert to the 1991 language (“by either party for the other party”). This change did not draw any comments, and was finalized in the Final Rules.

Cost Sharing Waivers by Pharmacies

The Final Rules created a new safe harbor for waivers or reductions by pharmacies of a Medicare beneficiary’s Part-D cost-sharing obligations. This safe harbor is available to all federal healthcare program beneficiaries, and not just those enrolled in Medicare Part D. To meet this new safe harbor, pharmacies are required to satisfy the following criteria: (1) the waiver or reduction is not advertised or part of a solicitation; (2) the pharmacy does not routinely waive or reduce cost-sharing; and (3) before waiving or reducing cost-sharing obligations, the pharmacy either determines in good faith that the beneficiary has a financial need or the pharmacy fails to collect the cost-sharing amount after making a reasonable effort to do so. The second and third elements would not be required for waivers or reductions on behalf of a subsidy-eligible individual as defined in 1860D-14(a)(3) of the Social Security Act.

However, the OIG emphasized that the waiver is only applicable to pharmacies and does not protect waivers by physicians for copayments of Part B drugs. The OIG also commented that the covered waivers should be unadvertised, non-routine waivers given at the pharmacy level based on individualized determinations of financial need. The safe harbor is not designed to protect a “program,” which offers structured savings.

In the Final Rules, the OIG referred to the OIG’s prior guidance where reasonable collection efforts were defined as “those efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to the parties.” 65 FR 24404 (Apr. 26, 2000). The OIG also commented that the “amount of the copayment or historical inability to collect cost-sharing amounts for a particular beneficiary might be factors that are considered in determining what reasonable collection efforts are . . .”

Cost Sharing Waivers for Emergency Ambulance Services

The OIG also created a new safe harbor for reductions or waivers of cost-sharing owned for ambulance services for which a federal healthcare program pays under a fee-for-service payment system. The OIG had recently issued favorable Advisory Opinions that have allowed public emergency transportation entities to waive certain cost-sharing obligation for Medicare beneficiaries. The following conditions must be met for this new safe harbor:

- (1) The ambulance provider is owned and operated by the state, political subdivision of the state, or a tribal healthcare program;
- (2) The ambulance provider is engaged in an emergency response;
- (3) The ambulance provider offers the reduction or waiver on a uniform basis to all of its residents or all individuals transported; and
- (4) The ambulance provider must not later claim the amount reduced as a bad debt for purposes under a federal healthcare program, or otherwise shift the burden of the reduction onto a federal healthcare program.

It is important to note that this safe harbor only protects emergency services that are owned and operated by the state, a political subdivision of the state or tribal health program. It does not protect an emergency service provider that contracts with the state to provide the services. When offering the waiver on a

“uniform basis,” the OIG interpreted this to mean that the provider cannot discriminate on the basis of any factor other than residency, or if applicable, tribal membership. For example, an ambulance provider can waive cost-sharing amounts for all residents, but charge cost-sharing amounts to nonresidents. However, the provider cannot waive cost-sharing amounts for patients transported for a condition that requires hospitalization (or vice versa).

Ambulance transport services that furnish only nonemergency transportation would not fall within this safe harbor. The OIG initially proposed that the ambulance provider must be a Medicare Part B provider of emergency ambulance services. However, the OIG removed this requirement, citing its decision to expand this safe harbor to include other federal healthcare programs.

Federally Qualified Health Centers and Medicare Advantage Organizations

The OIG also added a new safe harbor to protect “any remuneration between a federally qualified health center (FQHC) (or an entity controlled by such a health center) with a Medicare Advantage (MA) organization pursuant to a written agreement described in section 1853(a)(4)” of the Social Security Act. Section 1853(a)(4) generally describes the payment rule for FQHCs that provide services to patients enrolled in MA plans that have an agreement with the FQHC. The OIG commented that this new safe harbor does not protect “all remuneration” that the parties might exchange. For example, the provision of free office or conference room space by the FQHC to the MA organization would not be protected because the safe harbor “protects payments related to FQHCs treating MA plan enrollees, not arrangements unrelated to MA plan enrollees being treated at the FQHC.

Medicare Coverage Gap Discount Program

Section 3301(d) of the ACA amended the Anti-Kickback Statute to create a statutory exception for discounts under the Medicare Coverage Gap Discount Program, which provides beneficiaries with discounts on covered Part D drugs while they are in the coverage gap or “donut hole.” In the Final Rules, the OIG added a new safe harbors that protects discounts for “applicable drugs” furnished to an “applicable beneficiary” as these terms are defined in the Medicare Coverage Gap Discount Program statute.

II. Civil Monetary Penalties Law

Exceptions to the Definition of Remuneration in the CMP Law

The beneficiary inducement provision of the Civil Monetary Penalty Law (“CMP Law”) provides that a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to \$10,000 for each wrongful act. For purposes of the beneficiary inducement prohibition in the CMP Law, “remuneration” is defined to include waivers of copayments and deductible amounts and transfers of items or services for free or for other than fair market value, with a limited number of exceptions. The Final Rules amend the definition of “remuneration” in the CMP regulations at 42 C.F.R. part 1003 by codifying certain statutory exceptions added by the Balanced Budget Act of 1997 and the Patient Protection and Affordable Care Act of 2010, as amended (ACA).

1. Exception for Copayment Reductions for Certain Hospital Outpatient Department Services: The Final Rules codify a statutory exception that permits hospitals to reduce copayment amounts for certain covered hospital outpatient department services pursuant to sections 1833(t)(8)(B) and 1128A of the Social Security Act. Section 1128 permits hospitals to reduce copayment amounts for some or all covered hospital outpatient department (HOPD) services to 20 percent of the Medicare HOPD fee schedule amount.

2. Exception for Items or Services That Poses a Low Risk of Harm and Promotes Access to Care:

The OIG exempts items or services from the definition of “remuneration” that “improve a particular beneficiary’s ability to obtain items and services that are payable by Medicare or a State health care program” and pose a low risk of harm to patients and federal healthcare programs. Remuneration is considered to posed a “low risk of harm” if the remuneration (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to federal healthcare programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns.

This exception may reach a broader scope of arrangements than most exceptions as the Final Rules do not specify which particular arrangements would fall under this exception. The OIG commented that the form of remuneration does not matter (as long as it is an item or service, and not cash or a cash equivalent), and could include participation in smoking cessation, nutritional counseling, or disease specific support groups. The OIG also makes clear that promoting access to care does not incorporate the concept of rewarding patients for accessing care. The Final Rules do not specify particular arrangements that would fall under this exception, and thus leave evaluation of arrangements subject to a facts-and-circumstances analysis.

3. Exception for Retailer Reward Programs: The Final Rule codifies a statutory exception to the beneficiary inducement CMP that protects coupons, rebates, and other rewards from a retailer that (i) are made available to the general public regardless of health insurance status and (ii) are not tied to the provision of other items or services reimbursable by a state or federal healthcare program. The OIG clarified that retailers include entities that sell items directly to consumers, such as online retailers and independent or small pharmacies. Retailers do not include individuals or entities that primarily provide services; therefore, service providers such as hospitals or physicians would not qualify for this exception. However, an entity that provides both goods and services, such as a hospital system with a separate retail component, could have its own rewards program if it meets the exception's remaining criteria.

The OIG recognized that "the retailer rewards exception creates a pathway for retailers to include Medicare and Medicaid beneficiaries in their rewards programs" without violating the beneficiary inducement prohibition in the CMP regulations. However, the retailer rewards exception is only applicable to the beneficiary inducement CMP regulations. Complying with an exception to the beneficiary inducement CMP regulations does not guarantee that the arrangement will be shielded from the Anti-Kickback statute.

4. Financial Need-Based Exception: The Final Rules codified a statutory exception that protects the offer or transfer of items (other than cash or cash equivalents) or services for free or less than fair market value after a good faith determination that the recipient is in financial need, and provided that the items or services (i) are not offered as part of any advertisement or solicitation; (ii) are not tied to the provision of other reimbursable items or services; and (iii) are reasonably connected to the medical care of the individual.

The OIG explains that this exception is not intended to induce patients to seek additional care, "but rather to help financially needy individuals access items or services connected to their medical care." Medical care refers to the treatment and management of illness or injury and the preservation of health through certain services. Whether the item or service is reasonably connected to a patient's medical care must be determined from a medical and financial perspective on a "patient-specific" basis.

5. Exception for Waivers of Cost Sharing for the First Fill of a Generic Drug: Beginning Jan. 1, 2018, a Medicare Part D plan sponsor may waive the copayment that would otherwise be owed by its enrollees for the first fill of a generic drug covered by Medicare Part D. The Medicare Part D plan sponsor must disclose the waiver in the plan's benefit package submitted to the Centers for Medicare & Medicaid Services (CMS).

Gifts of Nominal Value

Concurrently with the publication of the Final Rules, the OIG also announced a statement increasing the monetary value of gifts considered "inexpensive" or of "nominal value" under the statutory exception for nominal gifts exception to the beneficiary inducement CMP. The OIG now interprets "nominal value" as having a retail value of no more than \$15.00 per item and \$75.00 annually per patient. These values increased from the standards of \$10.00 per item and \$50.00 annually that were previously issued in 2002. If the gift has a retail value at or below these thresholds, then the gift does not require an exception to the remuneration prohibition.

Alternative Methodology for Employer Excluded Persons

The OIG codified the OIG's Self-Disclosure Protocol (SDP) alternate damages methodology for calculating the assessment for employing or contracting with excluded persons to provide items or services that are billed to federal healthcare programs as part of a bundled payment. Recognizing the numerous types of providers, individuals and entities that may provide these items or services and the variety of ways in which items and services are billed and reimbursed by the federal healthcare programs, the Final Rules codify two alternate methods for calculating penalties and assessments, including separately billable items or services and non-separately billable items or services.

If the item or service provided by the excluded person is separately billable (such as physicians billing for office visits and pharmacist filling prescriptions), the employing or contracting party will continue to be subject to assessments and penalties based on the number and value of those separately billable items and services. If the item or service provided by the excluded person is non-separately billable, assessments are based on the total costs to the employer or contractor of the excluded person (including salary, benefits, etc...). Non-separately billable item or service means an item or service that is a component of, or otherwise contributes to the provision of, an item or service, but is not itself a separately billable item or service. Examples of non-separately billable item or service include, for instance, nursing or clerical services associated with a physician office visit, care provided by the skilled nursing facility per diem payment, nursing care covered by a hospital DRG payment or radiology technician services associated with a specific procedure.

For separately billable items or services, the penalty and assessments are based on the number and value of the separately billable items or services. For non-separately billable items or services, the penalty may be up to \$10,000 for each item or service provided by the excluded person.

New ACA Authorities Subjecting a Person to Penalties, Assessments and/or Exclusion

The ACA expands the OIG's ability to protect federal healthcare programs from fraud and abuse. This most recent broadening of the CMPs adds five new basis for subjecting a person to penalties, assessments and/or exclusion from participation in federal healthcare programs. A summary of the each new covered basis codified in the Final Rules, and the relevant citation, follows:

1. Failure to grant OIG timely access to records upon reasonable request (42 CFR 1003.200(b)(10));
2. Ordering or prescribing while excluded when the excluded person knows or should know that the item or service may be paid for by a federal healthcare program (42 CFR 1003.200(b)(6));
3. Making false statements, omissions, or misrepresentations in an enrollment or similar bid or application to participate in a federal healthcare program (42 CFR 1003.200(b)(7));
4. Failure to report and return an overpayment (42 CFR 1003.200(b)(8)); and
5. Making or using a false record or statement that is material to a false or fraudulent claim (42 CFR 1003.200(b)(9)).

New EMTALA Penalties

The Final Rules makes clarifications and minor tweaks to existing regulations on CMPs and Exclusions for violations of the Emergency Medical and Labor Act (EMTALA). Hospitals and physicians who violate EMTALA may be liable for up to \$50,000 in CMPs (\$25,000 for hospitals with less than 100 beds). While physicians have always been potentially liable for EMTALA violation, there has historically been less enforcement against physicians than hospitals. In the rule, the OIG mentions this type of enforcement and clarifies that the physicians who may be subject to penalties include on call physicians at hospitals with specialized capabilities who refuse to accept a transfer.

The final rule also updates the factors that the OIG will consider mitigating or aggravating in all EMTALA violations. The rule adds as a mitigating factor whether a hospital took appropriate and timely corrective action in response to the violation. The corrective action must be completed prior to a CMS investigation and must include a disclosure of the violation before CMS receives a complaint or learns about the violation from another source. The Final Rules also removes as a mitigating factor circumstances where a patient demonstrates a clear intent to leave the hospital voluntarily, noting that such an intent may arise from the hospital's failure to screen the patient within a reasonable amount of time.

The Final Rules also clarify that aggravating circumstances in a violation will include (1) a request for insurance, prior authorization or payment prior to screening or initiating stabilizing treatment or requesting payment prior to stabilizing an emergency medical condition, (2) where patient harm or risk of patient harm resulted from the incident, and (3) where the individual presented and requested examination or treatment for an actual emergency medical condition.

CMP for Drug Price Reporting

The ACA, as codified in the Final Rules, establishes a drug-pricing program for covered outpatient drugs that manufacturers sell to covered entities. Under the program, manufacturers must agree to charge a price that does not exceed the statutorily formulated price and must also provide certain drug pricing and product information to the Secretary, such as best price, wholesale acquisition cost, average sale price (ASP) and average manufacturer price (AMP). The program also provides for verification surveys of AMP information.

The Final Rules impose penalties for a wholesaler, manufacturer or direct seller of a covered outpatient drug either refusing a request for information by or knowingly providing false information to the Secretary about charges or prices in connection with a verification survey. The penalty for such a violation is not more than \$100,000 for each such violation.

Additionally, the Final Rules also impose a penalty for failing to provide the requisite drug pricing and product information. The penalty for failing to provide the information is not more than \$10,000 for each day that such information has not been provided.

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