PUBLICATION

HHS OIG Expands Safe Harbors, but Doubles Down with Enhanced Civil Monetary Penalties

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The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) published two rules on December 7, 2016, updating certain existing safe harbor regulations, adding new safe harbor rules under the anti-kickback laws and amending the civil monetary penalty (CMP) rules. These rules are effective 30 days after the rules are published in the Federal Register, on January 6, 2017.

Safe Harbor Rules

The safe harbor rules make a technical correction to the referral services of safe harbor; provide further protections for certain cost sharing waivers or reductions of copayments, coinsurance or deductible amounts applicable to all federal programs including pharmacy waivers of cost sharing for financially needy beneficiaries, cost sharing reductions or waivers for emergency ambulance services furnished by State or municipality owned ambulance services; provide protection for certain remuneration between Medicare Advantage (MA) organizations and federally-qualified health centers (FQHCs); provide protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and provides protection for free or discounted local transportation services that meet specified criteria.

The rule also amends the definition of "remuneration" and interprets and incorporates certain statutory exceptions. One such new exception is the safe harbor entitled "Local Transportation." The rule also adds five new exceptions to the beneficiary inducements CMP under the "remuneration" definition.

In general, the safe harbor for "Local Transportation" allows for the provision of free or discounted local transportation to federal health care program beneficiaries if:

- the facility has a policy which is routinely applied;
- the provision of transportation is not determined taking into account the past volume/value of business;
- the transportation is not air, luxury or similar to an ambulance;
- the offer of transportation is not marketed;
- the drivers are not paid per beneficiary; and
- transportation is only offered to established patients located within 25 miles of the provider or 50 miles if the patient resides in a rural area and the patient needs medically necessary services.

Also, the facility can provide a shuttle service which is bound by similar provisions as described above.

The five new exceptions to the beneficiary inducements CMP under the "remuneration" definition cover:

- copayment reductions for certain hospital outpatient department services;
- certain remuneration that poses a low risk of harm and promotes access to care;
- offering coupons/discounts/rebates on equal terms to the general public;
- free or discounted services not offered as part of an advertisement and the person is in financial need; and

- as of January 1, 2018, waiving the copayment for the first fill of a covered Part D generic drug.

Each of the above carve-outs have specific requirements which need to be reviewed to determine compliance.

The cost sharing waiver for pharmacy applies to all federal programs including Part D and Medicaid, but does not protect waivers by physician for copayments for Part B drugs. Pharmacies seeking to rely on the safe harbor do not have to conduct a financial need assessment for subsidy eligible individuals. The safe harbor permits pharmacies to waive cost sharing on an unadvertised, non-routine basis conducting a needs assessment (or failure to collect after reasonable collection efforts).

The cost sharing waiver for ambulance services must be offered on a uniform basis and cannot be based on patient-specific factors except the municipality can treat residents and nonresidents differently. The cost sharing waiver cannot be claimed as bad debt.

To conclude, this final rule gives providers and suppliers conclusive answers to long-awaited issues they have struggled with, including offering free transportation, waiving co-pays and providing medically necessary care to those financially in need.

Civil Monetary Penalties

In a separate but closely related final rule issued the same day, the HHS OIG revised its civil monetary penalty (CMP) rules to accommodate recent enhanced authorities, clarify existing authorities and to make the regulation on CMPs, assessments and exclusions more user-friendly. In particular, the expanded OIG authority in the Affordable Care Act (ACA), as well as the 2003 Medicare Prescription Drug Improvement and Modernization Act (MMA), among others, called for changes in 42 CFR Part 1003.

The ACA, and thus the regulations, expand CMPs to cover:

- failing to grant timely access to OIG for records, upon OIG's reasonable request;
- ordering or presenting services or items for payment by an excluded person who knows or should know that the service or item may be paid for under a federal health care program;
- making false statements, omissions or misrepresentations when enrolling or filing a bid or application to participate in a federal health care program;
- failing to report and repay an overpayment; and
- making or using a false record or statement material to a false or fraudulent claim (as is also covered under the False Claims Act).

The rule also clarifies that penalties and any applicable assessments can be imposed against a Medicare Advantage or Part D contracting organization whose employees, agents, providers or suppliers engage in CMP covered conduct. Thus, general liability of principals is expanded even if they are not agents. Such penalties extend to:

- enrolling a person without prior consent;
- transferring an enrollee from one plan to another without prior consent;
- transferring an enrollee just to earn a commission;
- failing to comply with designated marketing restrictions; and
- employing or contracting with anyone engaging in prescribed conduct.

While the authorities are now codified at 42 CFR § 1003.400(c) and the penalties and assessments at 42 CFR § 1003.410, CMS also retains sanctioning authority for Medicare Advantage and Part D organizations under 42 CFR Parts 422 and 423.

The rule also finalizes five primary factors for determining the degree of CMP sanctions:

- the nature and circumstances of the violation;
- the degree of culpability of the person;
- the history of prior offenses;
- other wrongful conduct; and
- other matters as justice requires.

The OIG notes that as the fifth factor demonstrates, these factors are illustrative and not comprehensive.

In addition to other technical changes, the new rule confirms substantively that the liability of a principal still means agents may be simultaneously liable for the same conduct. "Claim" is clarified to apply to applications for payment to contractors even if not directly made to a federal health care program. "Knowingly" is clarified to cover acts as opposed to information. "Material" matches the FCA definition.

Finally, under the Federal Civil Penalties Regulation Adjustment and Improvements Act of 2015, OIG will annually adjust its CMPs and publish them at 45 CFR Part 102. As effective on August 1, 2016, the correction for inflation incorporated in the Act has essentially doubled the dollar range of CMPs, making sanctions more painful for providers.

To discuss the content of this alert or any other issues related to health law, please contact any member of our Health Care Practice or Health Care Government Investigations Group.