

HHS-OIG issues final rules on anti-kickback and civil monetary penalty statutes

December 6, 2016

Earlier today, the US Department of Health & Human Services, Office of Inspector General (HHS-OIG) issued two final rules.

The first final rule addresses (i) the federal health care program anti-kickback statute (AKS) and (ii) the federal civil monetary penalty (CMP) law governing the offering of inducements to federal health care program beneficiaries (Beneficiary Inducement CMP).

With respect to the AKS, the changes include safe harbor protections for:

- Certain cost-sharing waivers, including (i) pharmacy waivers of cost-sharing for financially needy beneficiaries, and (ii) waivers of cost-sharing for emergency ambulance services furnished by government-owned ambulance services
- Certain remuneration between Medicare Advantage organizations and federally qualified health centers
- Discounts offered by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program
- Free or discounted local transportation services that meet certain criteria

With respect to the Beneficiary Inducement CMP, the changes address:

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

The second final rule amends a number of other CMP regulations in order to implement or codify provisions in the Affordable Care Act, including those addressing:

- Failure to grant HHS-OIG timely access to records
- Ordering or prescribing while excluded
- Making false statements, omissions or misrepresentations in an enrollment application
- Failure to report and return an overpayment
- Making or using a false record or statement that is material to a false or fraudulent claim

Dentons is closely reviewing both of these final rules and will issue a follow-up client alert highlighting the most significant provisions of each later this week.

Your Key Contacts



Christopher G. Janney
Partner, Washington, DC
D +1 202 408 9151
christopher.janney@dentons.com



Gadi Weinreich
Partner, Washington, DC
D +1 202 408 9166
M +1 301 325 5385
gadi.weinreich@dentons.com