

Morgan Lewis

8th National Rx
Drug Pricing Boot Camp

Avoiding Anti-Kickback Challenges Related to
Pricing and Contracting

Andrew Ruskin

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Types of PAPs

- Charitable foundation
- Free drug
- Coinsurance support
- Coupon
- Bulk replacement

PAP Features

- Drugs subject to policy
- Eligibility Criteria
- Description of Benefit
- Process and timeframes
- Protections against supporting off-label use

Legal Concerns

- Price Reporting
 - Question of implications both for AMP and BP.

Legal Concerns *(cont'd)*

- **Anti-Kickback Statute**
 - Knowingly and willfully offering anything of value in exchange for Federal healthcare business.
 - Criminal statute.
 - Also derivative False Claims Act issues.
- **No concern with Beneficiary Inducement Statute**
 - Inducing patients to purchase items or services from a particular provider or supplier.

Price Reporting

- PAP Exception
 - The drugs are given for free without any purchase requirement, or are based on the financial need of low income individuals and families.
 - The amount of the subsidy is determined by a manufacturer, without negotiation with any third party.
 - The entire amount of the free product or subsidy is made available to the individual patient, without any portion of the benefit being conferred on a third party, such as a retail pharmacy.
 - The pharmacy collects either no additional payment, or only a bona fide service fee.

Price Reporting *(cont'd)*

- **Coupon Exception**
 - The coupon is not contingent upon any purchases by individuals.
 - The amount of the subsidy is determined by a manufacturer, without negotiation with any third party.
 - The entire amount of the free product or subsidy is made available to the individual patient, without any portion of the benefit being conferred on a third party, such as a retail pharmacy.
 - The pharmacy collects either no additional payment, or only a bona fide service fee.

Price Reporting *(cont'd)*

- Free drug with no contingencies is also an exclusion.
- No separate exclusion for coinsurance support, which CMS places in the category of PAPs.
- Unclear what impact the repeal of AMP provisions has.

OIG PAP Guidance

- Independent Charity PAP (manufacturer donation of cash to foundation)
 - No manufacturer exerts any direct or indirect influence over the charity.
 - The assistance to beneficiaries is independent from any manufacturer's funding.
 - The assistance is not tied to use of a particular manufacturer's product, or the receipt of items or services from a particular provider

OIG PAP Guidance *(cont'd)*

- Independent Charity PAP (manufacturer donation of cash to foundation)
 - Assistance is rendered based on reasonable and uniform measures of financial need.
 - Limits on data to manufacturers.
 - BUT aggregate data about the number of applicants needing assistance with respect to a particular disease category is acceptable

OIG PAP Guidance *(cont'd)*

- Outside of Part D
 - PAP notifies Part D plans to ensure that no payment is made from the Part D plan.
 - CMS data sharing agreement facilitates exclusion of drug utilization from Part D coverage.
 - The assistance is provided during the entire coverage year (or the remainder of the year, if the beneficiary enrolls mid-year).
 - Assistance is available, even if the beneficiary's need is periodic.

OIG PAP Guidance *(cont'd)*

- Outside of Part D
 - PAP's assistance is accurately documented and capable of verification by the government.
 - Assistance is rendered based on reasonable and uniform measures of financial need.
 - The arrangement complies with any guidance from CMS.
 - Assistance is given without regard to providers or suppliers used by enrollee or Part D plan the beneficiary is enrolled in.

PAP Decision Points

- Create internally, or donate to a foundation?
 - Accept Federal healthcare program beneficiaries, or limit to self-pay and commercial?
 - Coinsurance support, free drug, or both?
 - Set dollar amount, or set out-of-pocket amount?
 - All patients, or just financially indigent?
 - Safeguards against off-label use?

Other Stakeholders

- MCOs/PBMs
- Employer self-funded plans
- Dept. of Insurance
- State AG's office