ARNOLD & PORTER

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AKL Terms

- The AKL prohibits any person from:
  - Knowingly or willfully
  - Offering, paying, soliciting or receiving
  - Anything of value (“Remuneration”)
  - Directly or indirectly
  - With the intent to induce or reward business reimbursed under federal healthcare programs
- Applies broadly to customers, patients, and vendors
- Safe harbor may be available

Key Themes Arising

- Emerging cases reflect changing healthcare landscape, and evolving manufacturer activities and interactions
  - Focus on managed and specialty markets
  - Interactions with payors, formulary committees
  - Interactions involving health economic, quality and outcomes information
  - Coupon/patient support programs
- Perception that prescription drug prices are increasing. Critics argue that manufacturer programs and actions make some stakeholders insensitive to price
- Customer budgets are declining – focus on outcomes and value, rather than cost

AKL Decision Tree

1. Does the arrangement implicate the anti-kickback statute?
   - Is there any payment/transfer of value?
   - Is one intent to reward or induce purchasing, prescribing or recommending?
   - Is the product or service federally reimbursable?

2. Does the arrangement fall within a safe harbor (or exception)?
   - Discount – writing and transparency?
   - Service – FMV, bona fide service, not based on volume
   - Administrative fee?
   - Other?

AKL Decision Tree (Cont'd.)

3. The "Prudential Factors"
   - Is the product more expensive than alternatives?
     - Is there a less-expensive generic competitor?
   - Is the product less safe or less effective than alternatives?
     - Is there a patient safety risk (e.g., a boxed warning or known adverse events) different from alternative products?
   - Would the arrangement inappropriately skew clinical decisions?
   - Does the arrangement involve a "white coat" (e.g., a doctor or a pharmacist) engaged in promotion of the product?
   - Would the arrangement result in unfair competition?