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PCF 2017, Mini Summit 25: The Winding Path to the Patient: Balancing Risks in Patient and Product Support

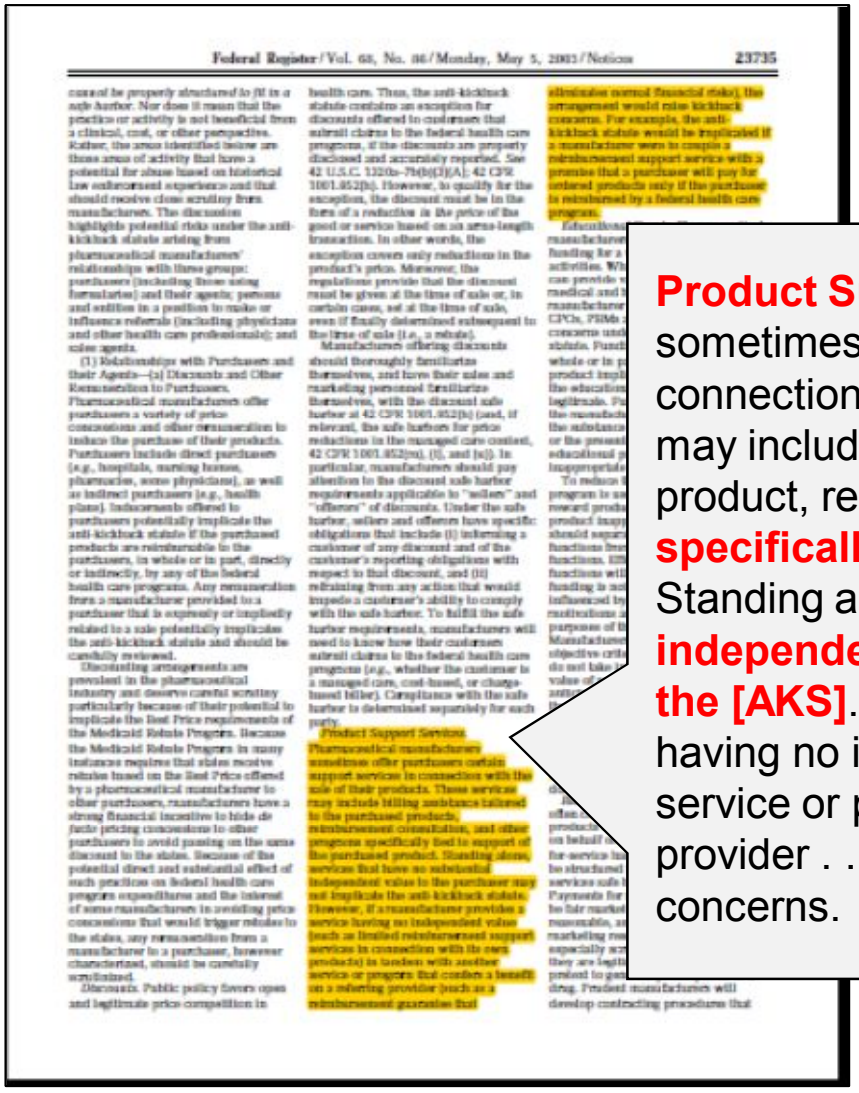
SIDLEY

- The viewpoints expressed by the speakers are entirely their own and do not represent the official position of their companies or firms.
- This is not intended as legal advice.

Overview

- The federal Anti-Kickback Statute ("AKS") is a criminal statute that prohibits offering, paying, soliciting, or receiving remuneration (i.e., something of value) to induce or reward the referral or generation of business reimbursable by a federal health care program ("FHCP"), including Medicare and Medicaid.
- The Office of Inspector General for the U.S. Department of Health and Human Services ("HHS-OIG") has provided express guidance on various
  - Product support
  - Free drug programs
  - Donations to independent charities
  - Co-pay and coupon cards
  - Vouchers
  - Bridge

OIG Guidance – Product Support



Federal Register / Vol. 68, No. 86 / Monday, May 5, 2003 / Notices 23735

Product Support Services. Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased product, reimbursement consultation, and other programs **specifically tied to support of the purchased product**. Standing alone, **services that have no substantial independent value to the purchaser may not implicate the [AKS]**. However, if a manufacturer provides a services having no independent value . . . in tandem with another service or program that **confers a benefit** on a referring provider . . . the arrangement would raise kickback concerns.

2005 Special Advisory Bulletin: Key Safeguards for Free Goods

- HHS-OIG has advised that manufacturer PAPs pose a reduced risk under the AKS if the program includes the following safeguards:

  i. "The PAP includes safeguards that ensure that Part D plans are notified that the drug is being provided outside the Part D benefit so that no payment is made for the subsidized drug by the Part D plan and no part of the costs of the subsidized drug is counted toward any beneficiary's [true out-of-pocket costs ("TrOOP")];

  ii. The PAP provides assistance for the whole Part D coverage year (or the portion of the coverage year remaining after the beneficiary first begins reciting the PAP assistance);

  iii. The PAP assistance remains available even if the beneficiary's use of the subsidized drug is periodic during the coverage year;

  iv. The PAP maintains accurate and contemporaneous records of the subsidized drugs to permit the Government to verify the provision of drugs outside the Part D benefit;

  v. Assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the providers, practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled; and

  vi. The arrangement complies with any then-existing guidance from CMS"

2005 Special Advisory Bulletin: Key Safeguards for Donations

- OIG has long held that pharmaceutical manufacturers can donate to independent, *bona fide* charitable assistance programs
- According to a 2005 Special Advisory Bulletin published by OIG, under a properly-structured program, donations from a manufacturer to an independent, bona fide charity that provides cost-sharing subsidies for Medicare Part D drugs should raise few, if any, Anti-Kickback Statute ("AKS") risks, so long as:
  - No direct or indirect influence or control over the charity or the subsidy program;
  - The charity awards assistance in an independent manner (*i.e.*, the assistance provided cannot be attributed to the donating pharmaceutical manufacturer);
  - No regard to pharmaceutical manufacturer's interest or beneficiary's choice of product, provider, practitioner, supplier or Part D drug plan;
  - Reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and
  - The pharmaceutical manufacturer "does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions from its products"

2014 Supplemental Special Advisory Bulletin: Key Safeguards for Donations

- In May 2014, OIG issued a Supplemental Special Advisory Bulletin ("2014 Supplemental Bulletin"), based on experience the agency gained with independent charity PAPs since issuing the 2005 Special Advisory Bulleting and to address specific risks that had come to OIG's attention
- The 2014 Supplemental Bulletin "reiterates and amplifies" guidance from the 2005 Special Advisory Bulletin:
  - Disease funds should be consistent with widely recognized clinical standards and cover an array of products (not just subsets and not just expensive or specialty drugs).
  - Particular scrutiny on specific symptoms, symptom severity, method of drug administration, stages of a particular disease, or type of drug treatment
  - All funds should be treated equally (*e.g.*, limiting to on-label coverage for all funds, or allowing off-label coverage for all funds).
  - Medicare-only funds are permissible and subject to the same safeguards

2014 OIG Special Advisory Bulletin: Pharmaceutical Manufacturer Copay Coupons

- Issued concurrently with Office of Evaluation and Inspections (OEI) report analyzing manufacturer measures to prevent coupon programs from inducing Part D drug purchases.
- Findings of OEI report:
  - Not all coupon formats bear notice that excludes FHCP beneficiaries
  - Not all claims edits reliably identify all claims submitted in connection with Part D drugs.
  - Coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers.
  - CMS should cooperate with stakeholders to improve reliability of mechanisms to determine when coupons are used in connection with Part D drugs, including making coupons universally identifiable.
- Additional OIG conclusions:
  - "[M]anufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including [Part D drugs]."
  - "Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the [AKS]."

Voucher Programs: Advisory Opinion 08-04 (Feb. 5, 2008)

- OIG issued a favorable advisory opinion for a free-trial hemophilia product program, in which the manufacturer provided up to ten free doses of product directly to qualifying patients.
- The requesting manufacturer offered a limited number of patient enrollment forms to physician offices and hemophilia treatment centers (i.e., no more than 20 forms annually per provider), and a non-commercial pharmacy would dispense product directly to patients.
- OIG identified two potential AKS concerns: (1) improper remuneration from the manufacturer to participating physicians; and (2) relief of patient cost-sharing amounts for the trial supply that could induce patients to self-refer the medication in the future.

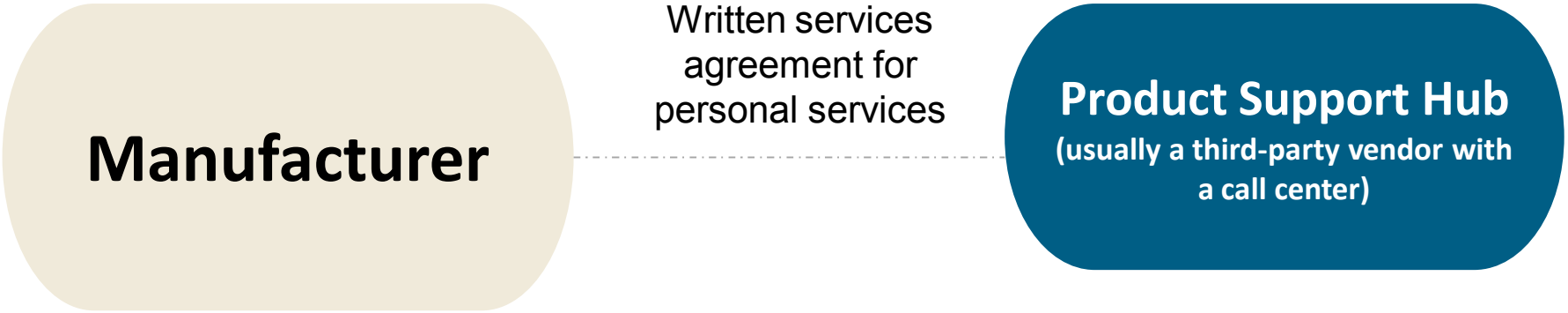
Voucher Programs: Advisory Opinion 08-04 (Feb. 5, 2008) (cont'd)

- OIG ultimately issued a favorable opinion to the requesting manufacturer, citing the following factors as relevant to the AKS analysis:
  - *No Cost to FHCPs*
  - *Low Risk of Patient Steering*
  - *Low Risk of Overutilization*
  - *Additional Safeguards.*
    1) physicians would not take possession of the medication;
    2) enrollment would be highly limited on a facility-by-facility basis;
    3) patients were informed there is no obligation to purchase the medication in the future in order to participate with the program; and
    4) the requestor certified that the program would comply with the PDMA.
  - "The Proposed Arrangement is distinct from problematic programs that offer free goods or other remuneration to prescribers as a means to "seed" or introduce new products into the marketplace . . . the specific facts and circumstances of the Proposed Arrangement readily distinguish it from riskier programs targeted at patients that are designed to create consumer demand on physicians to prescribe medications."

Bridge Programs: Advisory Opinion 15-11 (August 5, 2015)

- HHS-OIG issued a favorable advisory opinion approving a program in which a manufacturer provided up to two free, 30-day supplies of Breakthrough Designation Statute drug to patients, including FHCP beneficiaries, experiencing a delay in the insurance coverage determination process.
- In its analysis, HHS-OIG noted the following factors, among others:
  - Patient Eligibility Requirements: Patients were required to: (i) be new starters on the drug; (ii) have received a prescription for the covered drug; (iii) have an on-label diagnosis; (iv) be insured (by a commercial insurer or FHCP); and (v) have experienced a delay in receiving an insurance coverage determination of at least five (5) business days.
  - Low Medicare Utilization Rates: Only "0.0008 percent of all shipments of the Drug have been shipped under the Arrangement, approximately one-third of which went to Medicare or Medicaid beneficiaries."
  - Non-Commercial Specialty Pharmacy: Bridge product was dispensed through a non-commercial SP, which guarded against steering patients toward a particular provider to obtain federally payable prescriptions.
  - Diligent Pursuit of Appeals: Patients were eligible for a second 30-day refill of the drug, so long as the patient continued to pursue appeal rights diligently. No further free supplies of the drug were dispensed under the arrangement, regardless of the status of the appeal.
  - No Third Party Reimbursement: Participants were instructed that no patient, pharmacy, or payor would be billed for the free drug. Part D plans received notice if Part D beneficiaries receive free product through the program.
  - Limited Advertising/Not Actively Marketed to Patients: The program was not advertised in any direct-to-consumer advertisements, third-party websites, or media commonly used by potential enrollees.

Product Support Hub



The AKS Personal Services Safe Harbor

- Given the potential breadth of the AKS, both statutory and regulatory safe harbors protect various activities
- The personal services safe harbor may apply to arrangements with third party contractors
- As used in the AKS, remuneration excludes payments to agents as long as the following standards are met:
  - (1) The agency agreement is set out in writing and signed by the parties
  - (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent
  - (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic, or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals

The AKS Personal Services Safe Harbor (Cont'd)

- (4) The term of the agreement is for not less than one year
- (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other FHCPs
- (6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law
- (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services

42 C.F.R. § 1001.952(d)(1)-(7)

What Can You Do?

What Can You Do?

- Overview: Aegerion CIA requirements
  - The government's complaint alleged that Aegerion:
    - distributed Juxtapid for intended uses not approved by FDA
    - failed to comply with a Risk Evaluation and Mitigation Strategy required by the FDA for Juxtapid
    - employees made false and misleading statements about Juxtapid
    - violated certain patient privacy requirements
    - made payments to an independent charity (Patient Services, Inc.) for patient co-payment assistance that violated the Anti-kickback Statute, and that PSI promoted its ability to create a "reimbursement vehicle" for Aegerion
  - Outcomes:
    - $40m: $7m criminal fine; $29m reimbursement to fed/state healthcare programs; $4m SEC fine
    - DPA related to HIPAA violations (3 year)
    - FDA Consent Decree (related to REMS and inadequate labeling allegations)
    - CIA (5 year)

Aegerion CIA Requirements

- Policies and Procedures
  - Must address arrangements and interactions with (including donation funding of, sponsorship, or contributions to) independent third-party patient assistance programs (Independent Charity PAPs).
  - Must be designed to ensure that arrangements and donation funding comply with all applicable Federal health care program and FDA requirements.
  - Must be designed to ensure that arrangements, interactions, and funding comply with all guidance issued by the OIG relating to the support and funding of patient assistance programs

- IRO Reviews
  - Systems Review covers systems, processes, policies, and procedures relating to arrangements with (including donation funding of, sponsorship, or contributions to) independent third party patient assistance programs
  - Transactions Review… TBD (Additional Items)

Aegerion CIA Requirements

Further requirements:

- **Establishment of an Independent Charity Group**, in which the company must vest sole responsibility and authority for budgeting and other activities relating to Independent Charity PAPs (including interactions with such PAPs) in a department or group within the company (Independent Charity Group) that is **separate and independent from the commercial business units** of the company (including from the sales and marketing departments).
  - The Independent Charity Group must operate independently from the commercial organization.
  - The commercial organization must have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to arrangements with or funding of Independent Charity PAPs.
- **The Independent Charity Group must be the exclusive component of the company that is authorized to or responsible for communicating with, or receiving information from, Independent Charity PAPs.**
  - The commercial organization must not influence or be involved in any such communications.
  - The Independent Charity Group must not share information related to donations to Independent Charity PAPs or donations to any specific disease state funds with the commercial organization.
  - Members of the commercial organization (such as sales representatives) are not permitted to discuss specific Independent Charity PAPs or their disease state funds with HCPs or patients.

Aegerion CIA Requirements

- The Independent Charity Group must **establish a budget process to be followed for donations to Independent Charity PAPs**.
  - The Independent Charity Group must develop the annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the Legal Department (with input from the Compliance Department.)
  - The commercial organization must have no involvement in the budget process for donations to Independent Charity PAPs.
  - The company must approve the annual budget for donations to Independent Charity PAPs at a level above the commercial organization (e.g., at the executive level).
  - After the annual budget is approved, the Independent Charity Group must have sole responsibility (with no involvement from the commercial organization) for allocating the approved budget across donations to Independent Charity PAPs and to any disease state funds established by the Independent Charity PAPs.
- The Independent Charity Group must **have sole responsibility for assessing requests for funding from Independent Charity PAPs outside of the annual budget**.
  - Requests must be assessed against standardized, objective criteria established by the Independent Charity Group (with input from legal and compliance).
  - Legal and compliance personnel must be involved in the review and approval of requests for additional/supplemental funding, as requested by the Independent Charity Group

Aegerion CIA Requirements

- The Independent Charity Group (with input from the Legal Department and Compliance Departments) must **establish standardized, objective written criteria that govern donations** to Independent Charity PAPs and any specific disease state funds of such Independent Charity PAPs.
  - The criteria must be designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from the company to patients and does not impermissibly influence patients' drug choices.
- The Independent Charity Group must **gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control** over the entity operating the Independent Charity PAP or over its assistance program.
- The company **must not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease state fund** operated by the Independent Charity PAP.

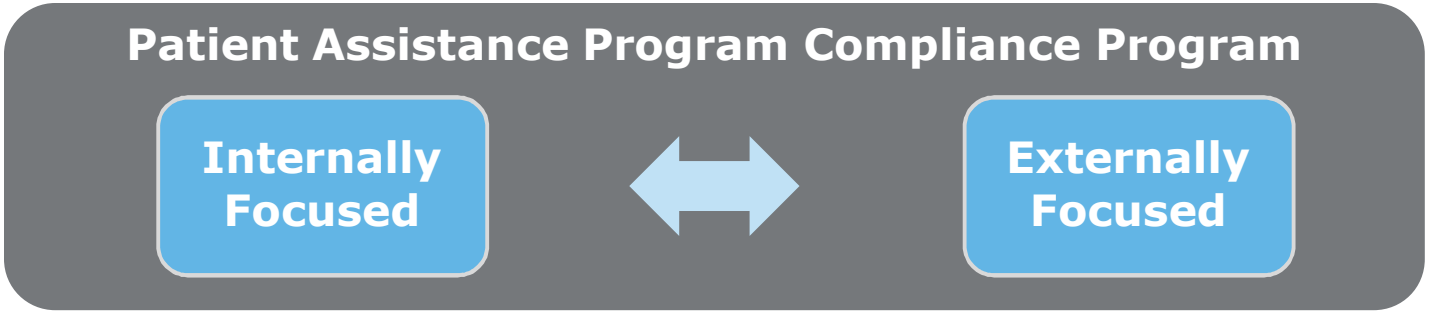
Aegerion CIA Requirements

- No donations can be made until a **written agreement is executed between the company and the Charity Entity** relating to the donation.
  - Must be reviewed and approved by Legal and Compliance prior to execution.
  - Donations must be provided only pursuant to, and in a manner consistent with, the written agreement.
- The written **agreement must preclude the company from exerting (directly or through any affiliate) any influence or control** over the Charity Entity or its assistance program.
- The CIA also specifies exact language that must be included in the written agreement with the Charity Entity

Aegerion CIA Requirements

- Monitoring Requirements
  - The company must **establish an Independent Charity PAP Review Program (PAP Review Program) through which it must conduct annual audits of donations to Independent Charity PAPs**.
    - The number of programs is TBD by OIG, which will take into account the number of donations to Charity Entities and to the disease state funds of those entities.
    - The PAP Review Program must judgmentally select donations for review
  - Monitoring Personnel must review:
    1. Budget documents;
    2. Documents relating to any decision to provide donations to a particular Independent Charity PAP;
    3. Written agreements in place between the company and the Charity Entities;
    4. Correspondence and other documents reflecting communications and interactions between the company and the Independent Charity PAPs; and
    5. Any other available information relating to the arrangements and interactions between the company and the Independent Charity PAPs.
  - Results from the PAP Review Program, including the identification of potential violations of policies, must be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate

Compliance Considerations: Independent Charity PAPs



	Internally Focused	Externally Focused
Compliance Assessment Steps	• Initial risk assessment • Policy & procedure review • E-mail & transactions review • Training of relevant staff on PAP & ICPAP compliance obligations • Monitoring program design • Ongoing risk assessment • Risk-based monitoring	• Foundation qualification and ongoing certification • Foundation compliance program reviews: foundation processes & controls; compliance with OIG guidelines and donation agreement • Review foundation's independent compliance/financial audit reports
Benefits	• Understand risk exposure • Risk-driven compliance resource allocation • Demonstrable commitment to compliance	• Understand ongoing compliance of foundation with relevant law and OIG guidance • Demonstrate commitment to compliance

Risk Assessment Considerations

- Determine whether controls are in place to ensure assistance is not provided to patients that do not meet the appropriate criteria
- Include in your annual risk assessment a review of your PAP processes and charitable relationships
- Determine whether eligibility criteria are consistently applied
- Catalog the different types of PAP arrangements your company has in place and develop a risk profile for each arrangement
- Identify the different third parties, including charitable organizations that offer PAPs, with which your company does business
- Confirm that all PAPs meet the CMS definition for government pricing exclusions

Monitoring Considerations

- Include PAP activities (full range of products, customers, vendors, foundations) in your company's auditing and monitoring program
- Require applicable PAP vendors and foundations to provide periodic performance reports, including certifications that they are applying the applicable eligibility criteria and/or complying with OIG requirements
- Develop and implement a process for the internal review and verification of services performed by PAP vendors and foundations
- Periodically review monitoring trends, outliers, and certain program metrics (e.g., the number of applications approved/denied)

Questions?