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Structuring Specialty Pharmacy Distribution Arrangements in a Turbulent Regulatory Environment

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Defining Specialty Pharmacy Arrangements

- Products: high-touch specialty medications
- Services: patient monitoring, prior authorization, data reporting
- Payment Features: discounts, tiered rebates, limited distribution networks, service fees, co-pay discount coupons

Fraud and Abuse Issues

- Anti-Kickback Statute (AKS)
  - Crime to knowingly offer, pay, or receive remuneration to induce or reward referrals or purchases of items or services reimbursable by federal health care programs
  - AKS violation = "false or fraudulent claim" under False Claims Act (FCA)
    - Under "taint" theory, government identifies related claims as "damages"
- Civil Monetary Penalties (CMPs)
  - Prohibition on inducement of federal beneficiaries to select pharmacies, PBMs, or other entities that file Medicare claims

Distribution Arrangements between Drug Manufacturers and Specialty Pharmacies

- Fundamental Question: does the arrangement involve provision of remuneration intended to induce referrals of FHCP benes, items and services?
- Two potential referral streams: (1) pharmacy may promote manufacturer's products to physicians and/or benes; and (2) manufacturer may channel or direct patients to one or more selected pharmacies by using limited distribution networks, or through use of reimbursement hubs, websites, or call centers.
- Key Components: in assessing legality of distribution arrangement:
  1. Compensation arrangement
  2. Types of pharmacy services employed

Compensation Arrangements

- Drug manufacturers typically compensate SPs by providing drugs at discounted prices and paying pharmacy service fees.
  - Must comply with AKS and CMP and must account for any discounts, rebates, and chargebacks when reporting drug prices to Medicare and Medicaid programs.

Discounts

- AKS's Discount Exception
  - Manufactures must ensure that discounts/rebates on drugs to SPs must be appropriately disclosed and passed along to FHCPs.
- "Bundled Arrangements": good or service provided at reduced price to induce purchase of different good; not permitted unless reimbursed under same fed program and charge is disclosed.
- OIG Advisory Opinion 13-07: favorable review of drug manufacturer's tiered rebate program: satisfied discount safe harbor because terms were fixed and disclosed in writing. Although rebates would be applied to all products sold, including goods reimbursed under different methodologies, not unlawful bundling because: (1) discount on one product not contingent on purchase of another (all purchases aggregated to determine rebate percentage); (2) discount attributable to each item purchased (percentage rebate to apply equally to each item purchased).

Discounts

- Compliance concerns: even where safe harbor compliance achieved, discounts can incite fraud and abuse risks where accompanied by other elements designed to induce referrals or interfere with physician prescribing habits.
  - Johnson & Johnson (2010): FCA suit alleging that J&J paid kickbacks, including "market share" rebates to Omnicare to promote J&J's drugs over similar medications. Even with discount safe harbor compliance, rebates were tied to Omnicare's efforts to induce prescribing of J&J's drugs.
  - Organon (2012): FCA suit alleged that Organon paid LTCPs "conversion rebates" and "therapeutic interchange bonuses" for switching patients to Remeron and/or giving preferred status
  - Amgen (2013): FCA suit alleged that Amgen used kickbacks of performance-based rebates to induce long-term care pharmacies to implement "therapeutic interchange" programs designed to switch Medicaid benes from competitor drug to Amgen's product, Aranesp.

Pharmacy Service Fees

- Bona fide service fees: manufacturers pay SPs for "hub" services, which are often handled by a manufacturer, to help patients/providers obtain permission to use, acquire reimbursement for, specialty drugs. Hubs staffed by patient care coordinators (nurses, pharmacists) to handle prior authorizations, refill reminders, adverse event investigations, REMS requirements, data reporting, etc.
- AKS's personal services and management contracts safe harbor: services are legitimate; agreement with one-year term; compensation fixed in advance; and FMV.
  - Flat rate service fees: may satisfy safe harbor
  - Per-product or per-transaction fees: cannot satisfy safe harbor and may incentivize pharmacies to generate referrals.
    - AO 14-06: negative opinion re: SP paying "per-fill" support services fee to local retail pharmacies each time they referred patients to SP
    - AO 14-05: positive opinion re: manufacturer paid per-transaction fees to pharmacy that was dispensing agent in direct-to-patient drugs sales arrangement
  - Per-product/service fees suspect when associated with pharmacy services designed to market manufacturer's products or are contingent on referrals; but permissible when solely based on services related to specialty drug dispensing

Pharmacy Service Fees

- Fair Market Value
  - In many SP arrangements, service fee rates exceed ordinary dispensing fees
  - Fees must be for bona fide commercially reasonable services
  - Should ensure that service fees are tied to "hub" services that are not directly related to prescription processing or being reimbursed under third party dispensing fee. Fees warranted because they exceed the services typically undertaken by pharmacy in connection with prescription processing.
  - Independent valuation expert to determine FMV
  - Distribution agreements should require pharmacy to refund any overpayments to manufacturer within certain time frame

Specialty Pharmacy Services

- Attention to nature and purpose of pharmacy services: should not be designed to generate referrals
- Safe: administrative services: e.g., drug storage, handling, dispensing; other services which are considered closely tied to dispensing
- Suspect: marketing and drug-switching activities; recommendations to prescribers or patients regarding manufacturer's products
- Gray area: insurance pre-authorizations and refill reminder services must be carefully scripted and narrowly focused to ensuring reimbursement or promoting drug adherence, and not marketing.
  - AO 08-12 (approving prior authorization services that are purely administrative in nature)
  - AO 11-07 (manufacturer-sponsored patient reminder program for vaccine; reminders only for patients who already prescribed medications and manufacturer's role disclosed)

Specialty Pharmacy Services

- "Bridge" or "Quickstart" Programs
  - Manufacturers provide a short-term supply of free product to patients until insurance authorization is obtained
  - Must be clinically appropriate
    - Does the disease state benefit from immediate therapy?
    - Can the patient safely switch to something else if coverage is not obtained?
    - On-label uses only
  - Special consideration for government beneficiaries
    - Programs must not be intended to "hook" patients on expensive therapies that government must then pay for
  - AO 15-11: Bridge Program that included government program beneficiaries was permissible
    - Waiting period before dispensing (to give time to seek reimbursement)
    - Limited in scope and time (small percentage of prescriptions, short time period)

Specialty Pharmacy Services

- Novartis: FCA allegation that Novartis paid kickbacks in form of patient referrals and rebates to BioScrip in exchange for recommending refills for Exjade patients.
    - Government alleges that BioScrip recommended Exjade refills and patient "restarts" to enable Novartis to meet sales targets; BioScrip employees, who lacked clinical knowledge, emphasized refill benefits while downplaying side effects; Novartis tied volume of patient referrals and rebates to BioScrip's ability to increase refills.
    - Gov alleges that this refill reminder arrangement utilized kickbacks designed to turn BioScrip's employees "into salespeople for Exjade."

Specialty Pharmacy Services

- Novartis: FCA allegation that Novartis paid kickbacks in form of "market share rebates" in exchange for specialty pharmacies switching immunosuppressant patients to Myfortic or maintaining them on Myfortic.
    - Complaint alleges that SPs committed to conversion program in exchange for rebates.
    - Gov alleges that recommendations were presented as being based on clinical judgment and SPs failed to disclose financial interest.
    - Existence of generic competitor creates basis for government allegation that program cost issues are implicated.

Specialty Pharmacy Services

- Health Insurance Portability and Accountability Act (HIPAA):
  - Refill reminders must comply with HIPAA's marketing rules:
    - Absent patient's written authorization, prohibits use of PHI to make marketing communication to patient unless: (1) communication about currently prescribed drug; and (2) payments by manufacturer to pharmacy reasonably related to pharmacy's cost of making communication.
  - Refill reminder programs: targeted by civil lawsuits under Telephone Consumer Protection Act; however, FCC declaratory exception to TCPA for "important medication refills."
  - Manufacturers contract with SPs to report drug utilization and clinical outcomes data. Pharmacies must enter into BAAs and data must be de-identified before reaching manufacturer; seek to obtain patient HIPAA authorizations early

First Amendment Argument

- Manufacturers have a right to work with downstream customers (e.g., SPs) to provide truthful, non-misleading information about products
- Government has legitimate interest in preventing conversions driving by corrupt financial motives
  - AKS plus factors: 1) subvert clinical judgment; 2) overutilization; 3) increased cost; 4) unfair competition
- First Amendment creates limits on application of AKS to marketing programs
  - Commercial Speech Doctrine (*Central Hudson* test): 1) untruthful or misleading, or concerns unlawful activity; 2) substantial government interest; 3) restriction "directly advances" interest; 4) restriction "not more extensive than necessary to serve that interest"
- Trend: *Sorrell v. IMS* – Court expands view of commercial speech, not sympathetic to paternalistic justification