



Contracting with Specialty Pharmacies and Hubs

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Introduction – Specialty Pharmacies and Hubs

- **Defining Specialty Pharmacy**
 - Dispense high-touch specialty medications
 - Services may include: patient monitoring, prior authorization, data reporting
 - Payments may include: discounts, tiered rebates, service fees, co-pay discount coupons
- **Defining Hubs**
 - Connecting patients, providers, manufacturers and insurers
 - Services may include: Triage to a specialty pharmacy, quick start services, benefits verification, prior authorization, analytics, monitoring, care coordination, patient communication
 - Evolving mix of entities that may be affiliated with wholesalers, PBMs, insurers, retail or specialty pharmacies

Specialty Pharmacy Business

- Grew to \$78 billion in sales last year (2015) from \$20 billion in 2005
- SP offering to health plans: they can help save money by –
 - Helping patients deal with side effects or complex dosing/administration
 - Ensuring expensive drugs are not wasted
- “Hands-on” approach also makes SP offerings attractive to manufacturers

The Challenges for Manufacturers

- Questions to ask:
 - What kinds of services can you pay for?
 - What kinds of incentive payments or discounts can you offer?
 - How can you allocate referrals among the SPs in the network?
 - What other relationships do you have with the provider and its affiliates?
 - What are the services, roles and responsibilities?
 - Can we demonstrate business need, FMV and proof of performance?
 - How can we monitor performance?

Legal Background

Fraud and Abuse Enforcement

- **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 healthcare programs
- AKS violation:
 - Criminal & civil enforcement and administrative exclusion
 - “False or fraudulent claim” under the 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

AKS Safe Harbors

- Safe harbors exist for –
 - Service agreements that are:
 - In writing,
 - With a term of at least 1 year, and
 - Compensation that is fair market value and **fully set in advance** (i.e., no incentive fees)
 - Discounts (including rebates) that are fully and accurately disclosed to federal programs
 - DOJ has taken the position that the discount safe harbor protects only “**mere reductions in price**”

Non-Safe Harbored Arrangements

- Compliance with a safe harbor is not technically required in order for an arrangement to be legal
- When not within a safe harbor, enforcement authorities make a **case-by-case determination** of whether conduct presents a risk of fraud and abuse
- Based on the specific facts and totality of the circumstances, is it likely to:
 - Increase federal health care program costs?
 - Encourage overutilization?
 - Corrupt professional judgments or medical decision-making?
 - Impact patient safety or quality of care?

Specialty Drug Distribution Arrangements: AKS Analysis

- Fundamental Question under AKS: does the arrangement involve provision of remuneration intended to induce referrals of FHCP beneficiaries, items, or services?
- Two potential referral streams: (1) pharmacy may promote manufacturer's products to prescribers and/or benes; and (2) manufacturer may channel or direct patients to one or more selected pharmacies
- Key Components: in assessing legality of distribution arrangement:
 - Compensation arrangement
 - Types of pharmacy services employed

Remuneration

Specialty Pharmacy Remuneration

- Drug manufacturers may offer discounts to SPs and/or pay service fees
 - Must comply with the AKS and CMP and account for any discounts, rebates, and chargebacks appropriately when reporting drug prices to Medicare and Medicaid programs
 - Payments that satisfy AKS safe harbors generally addresses price reporting issues
 - Properly disclosed and reported discounts/rebates
 - Fair market value (FMV) contracts for legitimate (bona fide) services

Discounts

- Even where safe harbor compliance achieved, discounts may be scrutinized for fraud and abuse risks
 - Johnson & Johnson (2010): FCA suit alleging kickbacks, including “market share” rebates, to Omnicare to promote J&J’s drugs over similar medications
 - Organon (2012): FCA suit alleged that Organon paid LTCs “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 beneficiaries from competitor drug to Amgen’s product
 - CCS Medical Inc. (2016): Allegations of violating the AKS and FCA by accepting price reductions conditioned on converting patients to Coloplast products

Pharmacy Service Fees

- Consider AKS personal services and management contracts safe harbor
- Services that:
 - Are not directly related to prescription processing or being reimbursed under third party dispensing fee, or exceed what is typical in connection with dispensing
- Fair Market Value
 - Fees must be for bona fide commercially reasonable services
 - FMV supported by sound methodology and documented

Recent Enforcement Focus

- Patient referrals, rebates, or fees offered as remuneration in exchange for increased refills
- Providing services in a manner that would undermine or otherwise interfere with the clinical judgment of prescribers
- Market share rebates in exchange for switching
- Hiding financial interest when making recommendations to patients

What does this mean for Manufacturers?

- Incentive-based payments or rebates to SPs need to be carefully reviewed
 - Nature of performance metrics
 - How targets are established
 - Product characteristics
 - Are generic or other less costly alternatives available?
 - Does product have serious side effects?
 - Is it a longer term treatment?
 - Are there barriers to switching?
 - Used by a vulnerable patient population?

What kind of services?

Core Services vs. Custom May Vary

Core Services

- Process and dispense prescriptions
- Handling and storing product
- Standard shipping
- Insurance eligibility and benefits verification
- Obtain prior authorization
- Standard patient education and consultation
- Patient assistance referrals

Custom/Bona Fide Services

- Refill reminders
- Adherence and persistency calls
- Dedicated customer service line
- Specialized patient counseling
- Provide patients with product/program materials (e.g., welcome kits)
- Account set-up and management
- Special shipping requirements (e.g., oversized product)
- Inventory and sales reports
- Other data reporting

Specialty Pharmacy Services

- Attention to nature and purpose of pharmacy services
 - Services may not undermine or otherwise interfere with clinical judgment of HCPs
 - Services cannot have effect of encouraging HCPs to prescribe any specific product over another
- Compare:
 - Administrative services: e.g., drug storage, handling, dispensing
 - Drug-switching activities; recommendations to prescribers or patients regarding manufacturer's products
- Services must be carefully defined
 - OIG Advisory Opinion 08-12: (approving prior authorization services that are purely administrative in nature)
 - OIG Advisory Opinion 11-07: (manufacturer-sponsored patient reminder program for vaccine; reminders only for patients already prescribed medications; manufacturer's role disclosed)

Potential SP Performance Metrics

- **Fill rate: % prescriptions shipped vs. prescriptions received, not including cancelled prescriptions**
- **Time to first fill**
- **Patient wait time: e.g., before speaking to pharmacist or nurse educator**
- **Data reporting accuracy**
- **Inventory management**
- **Call center hours**
- **Market share rebates**
- **Refill rates, medication possession ratio**

How can you allocate referrals among SPs
in a network?

Referrals of “Discretionary” Patients

- Referrals of patients whose payors or physicians have not obligated the use of a particular SP may implicate the AKS
- Referral services safe harbor, 42 C.F.R. § 1001.952(f)
 - Requires disclosure of the method by which SPs are selected for particular prescriptions
 - But also prohibits requirements on the manner in which services are provided
 - May not be possible if performance conditions or criteria are used

Allocating Referrals

- “Round robin”
 - May exclude certain assignments, like referring discretionary patients to SP affiliated with PBM for patient’s payor
- Performance requirements that relate to customer service
 - Fill rate
 - Time to first fill
 - Patient wait times
 - Data reporting accuracy
 - Inventory management
 - Call center hours