

The Intersection of Specialty Pharmacy and the Law



Target Audience: Pharmacists

ACPE#: 0202-0000-18-018-L03-P

Activity Type: Knowledge-based



Disclosures

I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

• Target Audience

• ACPE#

• Activity Type

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.



Learning Objectives

1. Understand the unique aspects of the specialty pharmacy model that drives unique legal analysis.
2. Generally understand laws applicable to specialty pharmacy.
3. Apply the general legal concepts to the unique specialty pharmacy model.
4. Highlight “landmine” and tricks of the trade applicable to specialty pharmacy.

1. Assessment Question

1. Specialty Pharmacies often have contractual relationships
 - A. With wholesalers only
 - B. With multiple parties including drug manufacturers, hubs, and wholesalers
 - C. With patients
 - D. None of the above

Activity Type



2. Assessment Question

1. Specialty Pharmacies may not use PHI when performing services for drug manufacturers.
 - A. True under all circumstances
 - B. False under all circumstances
 - C. True, with the only exception being if the patient provides an authorization
 - D. Generally true, but the patient may authorize the use or the specialty pharmacy may meet the Refill Reminder Guidance

3. Assessment Question

1. It is a violation of the anti-kickback statute if
 - A. The sole purpose of the arrangement is to induce the use of goods or services
 - B. One purpose of the arrangement is legitimate, but another purpose is to induce the use of goods or services
 - C. Payments are made to a referral source
 - D. A and B only

Activity Type



4. Assessment Question

1. Employees with laptops containing PHI
 - A. Will not lead to HIPAA liability if the laptop is encrypted
 - B. Is not permitted under HIPAA
 - C. Can result in HIPAA liability if they are lost or stolen
 - D. Can result in HIPAA liability if they are lost or stolen, but only if the employee was negligent in some way

Activity Type



Specialty Pharmacy ~ More than just a Specialty Drug



Cost

- Over \$10k per year; or
- Over \$500 per month
- Sometimes very costly (upwards of \$100k per year)



Handling and Administration

- Special Handling Issues (temperature controlled, breakable)
- May be injectable or infusible
- Safety monitoring
- REMS issues
- Patient registries



Compliance and Persistence

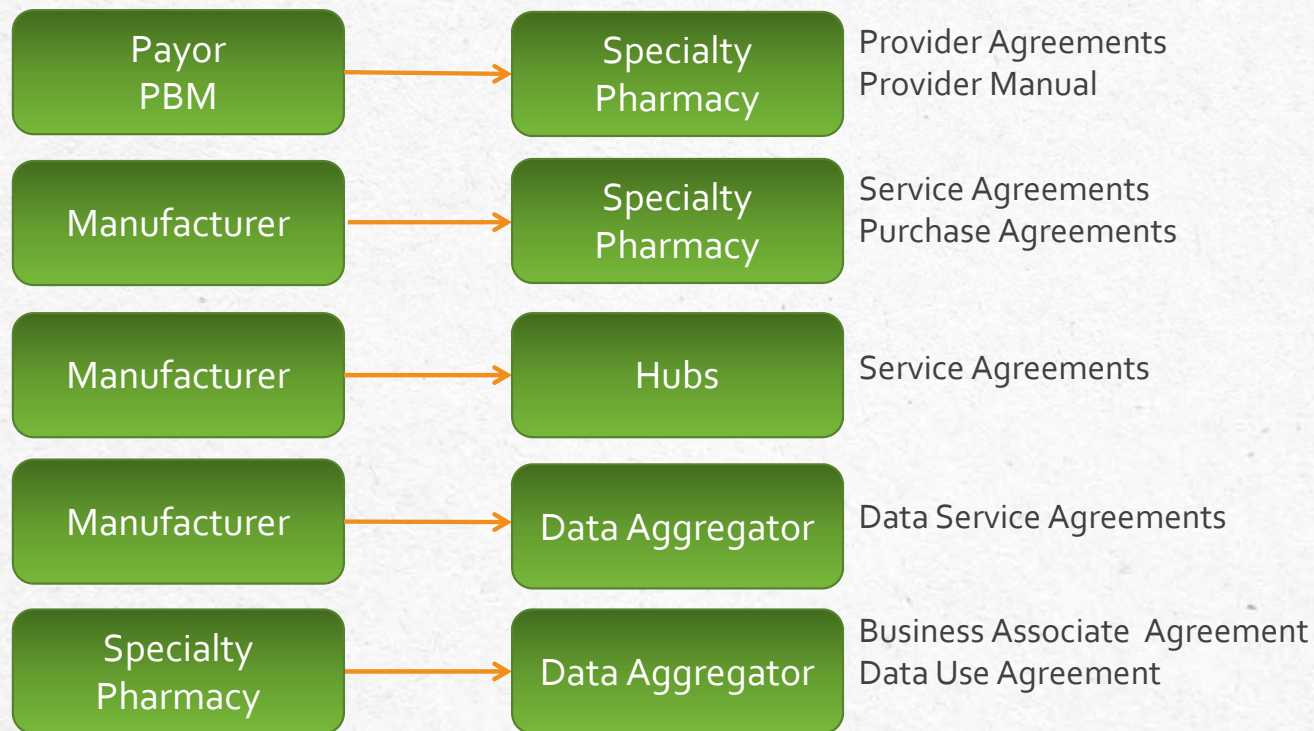
- Requires ongoing patient coaching and education
- May need sophisticated coordination of care
- Non-adherence can lead to significant adverse events



Reimbursement Challenges

- Complex coordination of benefits
- High cost co-pay or co-insurance
- Use of “hubs”
- Complex prior authorization or step-edit processes

Key Contractual Relationships



Laws and Regulations: FCA

False Claims Act- 31 U.S.C. §3729

Civil Statute

Cannot knowingly submit false/ fraudulent claims or cause someone else to submit false or fraudulent claims for government reimbursement

A penalty mechanism for AKS and Stark

Whistleblowers rely on False Claims



Laws and Regulations: AKS and CMP

Anti-kickback Statute 42 U.S.C. §1320a-7b(b)	Beneficiary Inducements CMP 42 U.S.C § 1320a-7a(a)(5)
Criminal Statute - Liability to both sides of an arrangement	Civil Statute- Applies only to providers, practitioners, or suppliers
Cannot offer, pay, solicit or receiving remuneration if any one purpose is to induce referral or federal program business	Cannot offer remuneration to federal program beneficiaries in order to induce them to use products or services reimbursed by the federal program
Interpretative and Vague	Medically necessary is not a defense
Safe Harbors are available; cannot rely on CMP exceptions	Exceptions available; AKS safe harbors apply



Laws and Regulations: Stark and HIPAA

Stark Law 42 USC § 1395nn	Health Insurance Portability and Accountability Act of 1996 (HIPAA) <i>HITECH Act of 2009 revised certain parts of HIPAA</i>
Strict Liability	Privacy Rules and Security Rules
Prohibits referring a patient to an entity in which the physician (or an immediate family member) has a financial relationship (ownership or compensation)	Governs use and disclosure of PHI
For the furnishing of designated health services (including outpatient prescription drugs)	Breach reporting requirements
Otherwise payable by Medicare/Medicaid	Remote use issues
Unless a specific exception is met	Increased enforcement



HIPAA: Refill Reminder Exception

Marketing	Examples	Exceptions
A communication by a covered entity	Communications about a recently lapsed prescription	Financial remuneration received by the covered entity for making the communication is reasonably related to the covered entity's cost of making the communication
For which it receives remuneration		
About a product or service that encourages recipients to purchase or use the product or service	Adherence communications encouraging individuals to take prescribed medicines as directed are marketing	Direct and Indirect Costs
Unless an exception applies		If not, need authorization

Novartis, BioScrip, Accredo, Amerisource - Settlement \$390,000,000 (Novartis)

Allegations:

- Novartis provided discounts and rebates to specialty pharmacies in connection with Myfortic, Exjade, and 3 other drugs.
- Corrupted pharmacist judgment by tying financial incentives to dispensing costlier and less effective Novartis drugs instead of rival products.
- Alleged that the Novartis hub awarded referrals based on scorecards - increased refills were rewarded. Included a limited distribution network in which Novartis assigned prescriptions based on pharmacy hitting "adherence targets".

Lessons:

- Pharmacists are not agents of pharmaceutical companies or their sales teams and should always use their unbiased best judgment in recommending drugs
- Manufacturer should not dictate talking points
- Risk associated with assigning undesignated prescriptions based on volume of refills (i.e. patient adherence success)
- Ensure patient adherence protocols include accurate and appropriate monitoring of side effects
- Clinicians making patient contact should be educated on the side effects of the drug

[Manhattan U.S. Attorney Announces \\$370 Million Civil Fraud Settlement Quoted Over Its Side Effects From Direct Purchase Involving High-Priced Prescription Drugs, Along With \\$20 Million Forfeiture Of Proceeds From The Scheme | USAO-SDNY | Department of Just](#)



Warner Chilcott - Settlement \$125MM

Allegations:

- From 2011 to 2013, Warner Chilcott employees knowingly and willfully submitted false, inaccurate, or misleading prior authorization requests and other coverage requests to federal health care programs for the osteoporosis medications Atelvia® and Actonel®.
- Employees used PHI from physician's offices to complete prior authorizations.

Lessons:

- Do not submit false or misleading claims
- Yates Memo – the government will identify and charge corporate officials responsible for fraud
- Risks are associated with inappropriate reimbursement support information or inappropriate support of prior authorizations
- There are risks associated with manufacturers inappropriately accessing and using PHI

[Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \\$125 Million to Resolve Criminal Liability and False Claims Act Allegations | OPA | Department of Justice](#)



DaVitaRx- Settlement \$63.7MM

Allegations:

- Used copay cards for federal program beneficiaries
- Billed drugs that were never shipped or returned
- Engaged in automatic shipment of refills
- Routine waiver of copayments
- Billed medications as if sent to pharmacy rather than dialysis center, for which costs should be subsumed by dialysis fee

Lessons:

- Operational process can lead to liability when checks are not in place

<https://www.justice.gov/usao-ndtx/pr/davita-rx-agrees-pay-637-million-resolve-false-claims-act-allegations>



Advance Care Scripts— Settlement \$9.3 MM

Allegations:

- Faxes from radiation treatment center to medical providers describing the its medications and services did not contain the opt-out language under the Telephone Consumer Protection Act.
- Used third party to send the faxes and claimed fault of the third party

Lessons:

- TCPA liability should be considered
- Provider is responsible for the acts of third parties- watch your indemnification rights

Hospice Plus, Curo Health Services – Settlement \$12.2 MM

Allegations:

- The hospice defendants allegedly provided referral sources including and nurses as well as hospitals and long-term care facilities inducements including cash, gift cards, lunches, dinners, happy hours, tickets to sporting events, holiday gifts, cars, manicures and pedicures, guns, and the services of skilled nursing staff free.
- Sales members were instructed to give more expensive items to administrators and directors of nursing and less expensive items to charge nurses and nursing staff.

Lessons:

- Train on sales force spending policies
- Require expense reporting
- Track spending by referral source

[Hospice Companies To Pay \\$12.2 Million To Settle Kickback Claims | USAO-NDTX | Department of Justice](#)



Nashville Pharmacy Services – Settlement \$7.8 Million

Allegations:

- Automatically refilled medications without a request from the beneficiary, their physician, or a person acting as the beneficiary's agent.
- Routinely and improperly waived TennCare and Medicare co-payments without individualized assessment of inability to pay.
- Improperly used manufacturers' co-pay cards to pay co-payments of Medicare recipients.
- Billed Medicare and TennCare for medications dispensed after death.
- Billed Medicare or TennCare for medications that lacked a valid

prescription from a licensed provider.

Lessons:

- Paperwork matters
- Pharmacies must pay attention to the details
- Small and large pharmacies alike can be placed under government scrutiny
- Even minor mistakes can have serious financial implications



Caremed - Settlement \$7.8 Million

Allegations:

- CareMed made false statements to Medicare Part D sponsors when seeking prior authorization for drug prescriptions.
- Staff posed as physician office employees when placing telephone calls to secure prior authorizations.
- Staff fabricated patient's medical information provided in response to clinical questions.
- Staff provided false medical information that they knew would meet the PA requirements – which they had learned through online resources, discussions with colleagues, and company training materials – instead of obtaining patient's actual clinical information.
- Caremed installed caller ID blocking that prevented its name and location from

appearing when outgoing calls were made to insurance companies.

Lessons:

- Must be honest and transparent in all communications with payors

Total “Stolen Laptop” Penalties for 2016&17 \$16.7 MM

HHS.gov

Office for Civil Rights

Company	Allegations	Lessons
\$2.5MM - CardioNet - April 24, 2017	Self-report of laptop stolen from employee's car	<ul style="list-style-type: none"> • Insufficient risk assessment • Only draft HIPAA policies and procedures
\$3.2 MM - Children's Medical Center of Dallas - February 1, 2017	Self-report of lost unencrypted Blackberries and later stolen laptop	<ul style="list-style-type: none"> • Failure to implement remediation measures from risk assessment, including implementing controls on remote technologies
\$5.55MM - Advocate Health Care Network - August 4, 2016	Self-report of lost unencrypted laptop	<ul style="list-style-type: none"> • Failure to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to all of its ePHI • Failure to implement policies and procedures and facility access controls to limit physical access to the ePHI • Failure to obtain satisfactory assurances in BAA
\$1.55MM - North Memorial Health Care - March 2016	Password protected laptop was stolen from a locked vehicle	<ul style="list-style-type: none"> • NMHC failed to enter into an agreement with a business associate who had access to the database and failed to institute a risk assessment
\$3.9MM - Feinstein Institute for Medical Research - March 2016	Laptop containing PHI of 13,000 patients and research participants was stolen from an employee's car	<ul style="list-style-type: none"> • Security management process was limited in scope, incomplete and insufficient to address risks and vulnerabilities to the ePHI • Lacked proper policies and procedures regarding security access by its workforce



Questions?



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