

Legal and Regulatory Issues Impacting Pharmacy, Supply Chain and GPO Commercial Arrangements

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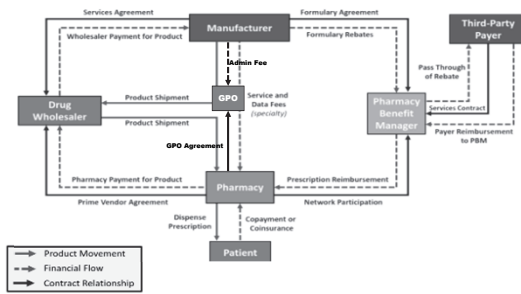
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Learning Objectives

1. Describe the pharmacy and supply chain legal and regulatory landscape, areas of risk and enforcement against pharmacies.
2. List the types of conduct of pharmacies, supply chain and GPOs (and their arrangements) that have invited government scrutiny, including activities that trigger audits and investigations and their legal obligations.
3. Identify enforcement trends in the supply chain, pharmacy and GPO industries, as well as contractual and regulatory risks presented by their commercial arrangements.
4. Describe best practices, legal requirements and risk management strategies.

Supply Chain: Overview

The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Prescription Drugs



Source: Fein, Adam J., The 2016 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2016. (Available at <http://drugchannelsinstitute.com/products/industry-report/pharmacies/>)

Supply Chain: Manufacturers, Wholesale Distributors and PBMs

- ▶ **Manufacturers:** The first step in the pharmaceutical supply chain
- ▶ Manufacturers manage the distribution of drugs from their facilities to drug wholesalers
 - May also distribute directly to pharmacies, hospital chains, and government purchasers
- ▶ **Wholesale Distributors:** Purchase pharmaceuticals from manufacturers for distribution to end users
- ▶ **PBMs:** Work with third party payors to manage consumer drug purchases
- ▶ PBMs may control:
 - Coverage / formulary
 - Reimbursement
 - Patient out-of-pocket cost

Supply Chain: Pharmacies and GPOs

- ▶ **Pharmacies:** Purchase product from wholesaler
 - Dispense to patient
 - Reimbursed by PBM / Payor
 - Various Types of Pharmacies
- ▶ **GPOs:** Purchasing agents authorized to act for their members
 - Members may include any type of provider
 - Hospitals
 - Pharmacies
 - GPOs negotiate agreements with suppliers
 - Economies of scale for better terms than members could obtain individually
- ▶ Funded by administrative fees paid by manufacturers

The Regulatory Landscape and Enforcement


- ▶ Health care industry regulated differently than other industries
- ▶ Legislators/regulators put quality of care and patient outcomes before company profits
- ▶ Practices that are common in other industries may violate the law in health care
- ▶ Supply Chain - Governing Laws
 - Anti-Kickback Statute
 - False Claims Act
 - HIPAA – Criminal Laws
 - Patient Protection and Affordable Care Act
 - Controlled Substances Act
 - State Laws

The Regulatory Landscape and Enforcement

- ▶ Increased Health Care Fraud Enforcement Initiatives
 - Federal
 - State
 - Local
- ▶ Highly Fragmented and Widely Dispersed
- ▶ Examples of Agencies with Investigative Enforcement Authority
 - OIG - Enforcement arm for fraud and abuse
 - DOJ, FDA, SAGs, MFCUs
 - State Inspector Generals
 - Counties (NY) Data Mining/Civil Damage Recoveries

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The Regulatory Landscape and Enforcement

 **Office of Inspector General**

MISSION:

Under the authority of the IG Act, we improve HHS programs and operations and protect them against fraud, waste, and abuse. By conducting independent and objective audits, evaluations, and investigations, we provide timely, useful, and reliable information and advice to Department officials, the Administration, the Congress, and the public.

<p>VISION</p> <p>WE ARE GUARDIANS OF THE PUBLIC TRUST</p> <ul style="list-style-type: none"> ◉ Working with management, we will ensure effective and efficient HHS programs and operations. ◉ Working with decision makers, we will minimize fraud, waste and abuse in HHS programs. ◉ Working with our talented and motivated staff, we will maintain the highest standards as a Federal OIG. 	<p>VALUES</p> <p>WE VALUE:</p> <ul style="list-style-type: none"> ◉ Quality products and services that are timely and relevant. ◉ A service attitude that is responsive to the needs of decision-makers. ◉ Fairness, integrity, independence, objectivity, proficiency, and due care in performing our work. ◉ Teamwork and open communication among OIG components, and ◉ A positive environment that supports our personal and professional growth and encourages us to be innovative and reach our full potential.
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The Regulatory Landscape and Enforcement

- ▶ Enforcement Activity
- ▶ OIG Semiannual Report to Congress 2017

	2017
Investigative Recoveries	4.13 B
Exclusions	3,244
Criminal Actions	881
Civil Actions	826

- ▶ Enforcement against Executives on Rise

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The Regulatory Landscape and Enforcement

- ▶ HHS Office of Inspector General – AKS Enforcement
- ▶ Training of special agents and investigations-Investigate Pharmacy Practices
 - Enrollment
 - Marketing Schemes
 - Prescription Shorting
 - Manufacturer Copy Coupons
 - Double Billing (auto-refills, return to stock)
 - Kickbacks from Pharma
 - Sale of Samples/Expired Rx's
 - Usual and Customary Pricing
 - Charge brand/deliver generic
 - Selling same drug twice (returns)
 - Controlled Substances
 - Improper Patient Referrals
 - Prior Authorizations

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The Regulatory Landscape and Enforcement

Enforcement Activity – Recent Settlements

- ▶ Company #1 \$23.85 million (Used foundation as a conduit to pay the copays of Medicare patients taking three Company #1 drugs)
- ▶ Company #2 \$465 million (Improperly classified EpiPen as generic drug. Medicaid Drug Rebate Program)
- ▶ Company #3 \$280 million (Off-label marketing)
- ▶ Company #4 \$53.6 million (Unnecessary rehab and hospice services)
- ▶ Company #5 \$8 million (Dispensing practices put patient safety at risk)

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The Regulatory Landscape and Enforcement

- ▶ Federal Anti-Kickback Statute / FCA
- ▶ Why do we care?
- ▶ Costs of Non-Compliance – On the Rise
 - Fines and penalties
 - Suspension/exclusion programs
 - Disgorgement
 - Imprisonment
- ▶ Supply Chain
 - Historically a target
- ▶ OIG Work Plan
 - Continue to be targets

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Criminal and Civil Health Care Laws

- ▶ Federal Anti-Kickback Statute and False Claims Act
- ▶ The Federal Anti-kickback Statute is broad with potentially draconian consequences for violation including imprisonment
- ▶ Federal Anti-Kickback Statute
 - Criminal Statute
 - Intent-Based
 - Purposes:
 - Prevent over-utilization and increase in costs to government programs
 - Prevent interference with patient freedom of choice
 - Prevent anti-competitive practices

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Criminal and Civil Health Care Laws

- ▶ Federal Anti-Kickback Statute
- ▶ Prohibition – transfer of remuneration to induce referrals or “arranging” for referral of business
- ▶ Elements:
 - “Knowing and Willful” – offer or payment or solicitation or receipt
 - Remuneration – anything more than de minimis value
 - Referrals – return for referring or arranging for referrals
 - Government Programs – Medicare and Medicaid
- ▶ Greber – “One Purpose” Test

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Criminal and Civil Health Care Laws

- ▶ Safe Harbors
- ▶ Failure to Satisfy Safe Harbor
 - Does not equate to a violation of AKS
 - Totality of circumstances/aggravating factors
- ▶ Commonly Used Safe Harbors in Supply Chain
 - GPOs
 - Discounts
 - Personal Services and Management Contracts
 - Employment
 - Equipment/Space Rental

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Criminal and Civil Health Care Laws

- ▶ False Claims Act – Weapon of Choice
 - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment
 - Civil Fines
 - Treble damages
 - Claims submitted and resulting in violation of AKS constitutes a false claim (f/k/a False Certification Theory)
 - Result: Increase in FCA violations primarily on entities that participate in provision of products and services reimbursable under government programs but which do not submit claims (HIT Company)
 - Increase in *qui tam* actions

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Criminal and Civil Health Care Laws

- ▶ Enforcement – HIPAA (Civil & Criminal; Not PHI)
 - What is the Risk?
 - Introduced new categories of CMP violations:
 - Upcoding
 - Billing medically unnecessary services
 - Patient inducements
 - Criminal laws applicable to any health care benefit program, not just FHCPs:
 - Health care fraud
 - Theft or embezzlement
 - False statements
 - Conspiracy and Obstruction

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Controlled Substances Act

- ▶ Regulation of the Manufacture, Importation, Possession, Use and Distribution (and Dispensing) of Controlled Substances
- ▶ Purpose – Maintain closed system of distribution
- ▶ Enforcement Agency – U.S. Drug Enforcement Agency (Delegated by U.S. Attorney General)
- ▶ Office of Diversion Control
 - Prevent, detect and investigate the diversion of controlled substances from legitimate sources while ensuring an adequate uninterrupted supply for legitimate medical and scientific purposes
- ▶ Violation – Results in fines and suspension or revocation of registration

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Controlled Substances Act

- ▶ Pharmacy Obligations – Loss and Diversion of Controlled Substances
 - Prescription for legitimate medical purpose
 - Detailed records of controlled substance inventories – complete and accurate
 - Establish adequate security controls to minimize theft and diversion
 - Periodic filings with DEA
 - Controls to guard against theft and diversion
 - Duty to inquire if uncertain if person registered
 - Design and operate a system for recognizing “suspicious” orders of controlled substances and notify DEA Diversion Field Office

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Controlled Substances Act

- ▶ Pharmacy Obligations - Loss and Diversion of Controlled Substances
 - Theft or “significant loss” of controlled substance – notify in writing within one day of discovery / Diversion Field Office and local police
 - If questionable – err on side of caution – burden on pharmacy to determine “significant” loss
 - Determining “significant loss” – depends in large part on business of pharmacy and likelihood for rational explanation for particular occurrence
 - Consider quality, the controlled substance, pattern of losses or random and local trends

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Institutional Pharmacy: Best Practices

- ▶ Policies and procedures
 - Pharmacy controls
 - Storage and access
 - Processing claims
 - Prescription verification
 - Original orders; billing under different MD (than who signed Rx)
 - Initial fill — follow-up for physician signature; dates
 - Dispensing of medication
 - Refill orders (fax)
 - Delivery logs/receipts
 - Proper coding
 - Computer system
 - Pharmacy claims; Pharmacy screen prints; Patient, facility, and prescribing physician profiles; and System edits
 - Returns and reuse
 - Record retention - Back-up of claims
 - Purged claims — consistent with legal requirements

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Supply Chain: Commercial Arrangements

GPO Arrangements

- ▶ Manufacturers/Supplies
 - Administrative Fees
 - Growth Incentive Fees
 - “Other” Fees (“Marketing”)
 - Rebates
 - Services
 - Marketing/Sales vs. Education
 - Conferences/Summits
- ▶ Members
 - Consultants
 - Marketing
 - Offeror Rebates
 - Services Agreements

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Supply Chain: Commercial Arrangements

GPO Arrangements Implicating AKS

- ▶ Manufacturers and Suppliers
- ▶ Marketing Supplier’s Products and Services
- ▶ GPO’s enter into marketing arrangements with Suppliers or required to market Suppliers products
 - Implicate federal Anti-Kickback Statute
- ▶ Payment covered by GPO safe harbor
 - Administrative fee payments in excess of 3% -for marketing
- ▶ Consider applicability of personal services safe harbor

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Supply Chain: Commercial Arrangements

GPO Safe Harbor

- ▶ Used by GPOs and PBMs
- ▶ Elements of Safe Harbor
- ▶ What is a GPO for purposes of the safe harbor?
 - Purchasing Agent
 - GPO must have purchasing authority for Members
 - Authorization is part of agreement with Members
 - GPO Members may not be
 - Wholly owned by GPO
 - Subsidiaries of a parent company that wholly owns GPO

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Supply Chain: Commercial Arrangements

GPO Safe Harbor (cont.)

- ▶ Elements (cont.)
- ▶ Written agreement with members for which items or services are furnished
- ▶ Administrative Fee
 - Agreement provides that vendors will pay fee to GPO of 3% or less of purchase price
 - If fees not fixed at 3% or less – agreement must specify amount (or maximum amount) the GPO will be paid
 - Disclosure of fees from each vendor for each member
 - Annually to members
 - To Secretary of HHS upon request

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Supply Chain: Commercial Arrangements

Institutional Pharmacy Arrangements Implicating AKS

- Free Goods and services or at less than FMV
- Pharmacy paying for hardware/software technology in exchange for entering into long-term contracts
- Pharmacy paying for services or providing services at no charge
- Pharmacy offering extended payment terms or non-payment terms to obtain access to third-party reimbursement
- Facilities splitting profits with pharmacies in exchange for reduced supply costs
- Facility owners and relatives being offered equity positions in pharmacies at little or no cost in exchange for facility's business
- Reduced charge for services to a facility (Part A) in exchange for higher-priced services billed to Government (Part D) – known as "swapping"

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Supply Chain: Commercial Arrangements

Pharmacy Arrangements Implicating AKS

- ▶ Safe Harbors
- ▶ Management Contracts, Services Agreements and Distribution Agreements
- ▶ Personal Services and Management Contracts Safe Harbor
 - FMV
 - Aggregate compensation set in advance
 - Commercially reasonable
- ▶ Discounts
 - Requirements based on type of buyer or seller
 - Disclosure – suppliers to buyers
 - Reporting and transparency – buyers to government

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Supply Chain: Commercial Arrangements

Discounts

- ▶ **OIG Position:** Discounts and rebates constitute remuneration to GPO Members to induce Members to purchase Supplier's products and services
- ▶ **Discounts Safe Harbor**
 - **Discount:** A reduction in the amount a buyer (i.e., a GPO Member) is charged for an item or service based on an arms-length transaction
 - **OIG's Position:** Discount is the difference between price vendor normally sells a product and the price the vendor sells product to a particular buyer
 - **Rebates:** Any discount the terms of which are fixed and disclosed in writing at the time of sale, but which is not given at the time of sale
 - **OIG Fraud Alert:** Up-front rebates, prebates and signing bonus payments not protected by discounts safe harbor
 - Cash Payments and Bundled Sales – Not Discounts

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Supply Chain: Commercial Arrangements

GPO Discounts/Rebates to Members

- ▶ Discounts safe harbor – GPO considered offeror
 - **Offeror:** Entity that is not a seller, but promotes the purchase of an item or service at a reduced rate
- ▶ Offeror obligations
 - Similar to Vendor obligations
 - Advise Member of its disclosure/reporting obligations
 - Refrain from taking action that would impede Member's ability to meet obligations
 - **Recommended:** Fully and accurately report discount to Member
- ▶ Buyer/member must comply with reporting/disclosure obligations
- ▶ Offeror rebates – Consider Medicaid Best Price Rules
 - Covered Outpatient Drugs
 - Members getting better price than reported to Medicaid

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Supply Chain: Commercial Arrangements

GPO Distributions/Dividends to Member Shareholders/Owners

- ▶ **OIG's Position:** Federal Anti-Kickback Statute implicated since distributions/dividends could be viewed as remuneration to Member shareholders in return for purchasing products or services off of GPO-negotiated Vendor Agreements
- ▶ **Safe Harbors**
 - Cooperative Hospital Service Organization (CHSO)
 - Protects payments made between CHSO and member hospitals
 - Member hospital payments to CHSO must constitute payment for bona fide operating expenses of CHSO
 - CHSO payment to Member hospital must be for purpose of paying distribution of net earnings required to be made under 501(e)(2) of IRC
 - Limitation: Does not protect non-hospital owned GPOs

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Supply Chain: Commercial Arrangements

GPO Distributions/Dividends to Member Shareholders/Owners

- ▶ Small Investment Interest Safe Harbor
 - Key Elements
 - **Investment Test:** No more than 40% of the value of the investment interests may be held in previous fiscal year or 12-month period by investors in a position
 - to make or influence referrals to entity
 - furnish items or services to entity
 - or otherwise generate business for the entity
 - **Revenue Test:** No more than 40% of entity's gross revenue related to furnishing of health care items and services in previous fiscal year or 12-month period may come from referrals or business otherwise generated from investors
 - Limitation – Member-owned GPOs typically in position to refer

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Supply Chain: Commercial Arrangements

GPO Arrangements with another GPO

- ▶ GPO Shared Services Arrangements
- ▶ OIG – may take position Federal Anti-Kickback Statute implicated
 - GPO safe harbor
 - Personal services safe harbor
- ▶ Access Agreements (Adv. Opin. 1-6)

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Supply Chain: Commercial Arrangements

Lessons Learned

- ▶ Federal Anti-Kickback Statute
- ▶ U.S. v. J&J/Omnicare Settlement (D. Mass. 2011)
 - At Issue: Switching, Rebates, Data and Grants
 - Lessons Learned for Supply Chain Members:
 - Arrangement should not compromise independent, professional judgment of physician
 - Government will look to see if a party is acting as an "extension of sale force" to create "referral" nexus
 - "Active Intervention Programs"
 - Dear Doctor/Patient Authorization letters
 - Moving market share – a primary driver or consequence of arrangement
 - Government very interested in arrangements that could compromise patient care and increase government costs
 - Service arrangements should be for legitimate services, documented and actually be performed
 - Do what you say and document what you do (not just in agreement but in company files)

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Corporate Response to Compliance

- ▶ Enforcement – Risk Mitigation
 - How to Minimize Risk?
 - Develop and Implement Corporate Compliance Plan
 - Origin
 - 1991 Federal Sentencing Guidelines and CIAs
 - Mitigation of damages in enforcement action
 - Purpose
 - Foster overall ethical behavior of organization
 - Promote adherence to applicable federal and state laws
 - Ensure accurate, complete and correctly documented billing
 - Minimize organization's exposure to fines and penalties
 - Use OIG Model Compliance
 - Hospitals – 1998
 - Pharmaceutical manufacturers – 2003

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Corporate Response to Compliance

- ▶ Risk Mitigation
- ▶ Board of directors increasing oversight
- ▶ Fiduciary duties of directors
 - Duty of care
 - Duty of loyalty
 - Duty to undertake reasonable efforts to assure that compliance programs are in place
 - Actively monitor and restore compliance
 - Duty to inquire when made aware of system failures
 - Duty to undertake reasonable efforts to become aware of signals of system weaknesses
 - Duty to exercise general supervision of quality of care and patient safety
 - OIG/AHIA joint white paper – June 2007
 - Links obligation to oversee compliance with obligation to oversee quality

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Questions and Answers

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**Legal & Regulatory Issues Impacting the Supply Chain,
Pharmacy and GPO Commercial Arrangements**

Assessment Questions

1. Which of the following laws do not apply to pharmacies?
 - a) Federal Anti-Kickback Statute
 - b) False Claims Act
 - c) Controlled Substances Act
 - d) All of the above apply

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

2. Which law is the government's weapon of choice when enforcing fraud and abuse laws?
 - a) Federal Anti-Kickback Statute
 - b) False Claims Act
 - c) Controlled Substances Act
 - d) HIPAA

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

3. Which agency is the government's enforcement arm for fraud and abuse?
 - a) Food and Drug Administration
 - b) Office of Diversion Control
 - c) Board of Pharmacy
 - d) Office of Inspector General

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

4. What area of pharmacy is the government not focused on?
 - a) Marketing
 - b) Double billing
 - c) Controlled Substances
 - d) Kickbacks
 - e) Government is focused on all of the above

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

5. Government enforcement actions and criminal actions against executives are on the rise. (T/F)

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

6. Which of the following conduct of pharmacies has invited government scrutiny?
 - a) Dispensing drugs in emergency without a prescription
 - b) Diversion
 - c) Selling same drug twice
 - d) Shorting prescriptions
 - e) All of the above

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

7. Pharmacies have no obligation to obtain a written signed prescription from the prescribing doctor in a non-emergency situation. (T/F)

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

8. Which of the following is not a pharmacy obligation?
- a) Notify authorities of significant loss of drugs
 - b) Maintaining records of dispensing
 - c) Writing the prescription
 - d) Inquiring if person registered with DEA

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

9. What is not a key component to pharmacy risk management?
- a) Develop and implement compliance plan
 - b) Rely on facility for compliance
 - c) Adopt policies and procedures
 - d) Train employees

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Assessment Questions

10. Is it a good idea to not adopt policies and procedures for documentation of pharmacy operations where they are not required by law. (T/F)

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**Legal & Regulatory Issues Impacting the Supply Chain,
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Answer Key:

- 1. D
- 2. B
- 3. D
- 4. E
- 5. T
- 6. E
- 7. F
- 8. C
- 9. B
- 10. F

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