

Regulatory and Compliance Issues for Employer-Based Sites

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Three Alternative Operating Models

- Service Contract - Employer holds any necessary facility licenses and contracts with third party vendors of medical, pharmacy and clinical lab services
- Fully Outsourced - Employer leases facility space to third party vendors of medical, pharmacy, and clinical lab services
- Clinic - Medical group (or clinic operator) holds any necessary facility licenses and subcontracts with third party vendors of pharmacy and clinical lab services

Key Players in the Models

- Employer
 - Employee Welfare Plan
 - PBM

- Medical service provider

- Pharmacy service provider

- Clinical lab service provider

Legal Basics – In General

- Health care services may be delivered only by licensed providers
- Physicians may practice in an office or a clinic facility (may require licensure)
- Pharmacy must be licensed as a community pharmacy or as part of a clinic
- Clinical lab must be licensed as a separate lab or part of a clinic depending on services to be provided

Legal Basics - Medical Services

- Can be delivered only by licensed practitioner acting within scope of license
- In some states, doctrine of corporate practice of medicine prohibits corporations from furnishing medical care through employees even when they are licensed professionals (sometimes differences in practice of medicine, nursing, therapy . . .)
- State laws frequently except professional corporations, hospitals, licensed clinics, and employer-sponsored health clinics
- Fee-splitting prohibitions prevent unlicensed persons from having a beneficial interest in revenue or profits from furnishing medical services

Legal Basics – Pharmacy Services

- Facility must be licensed
- Must comply with requirements for space configuration, staffing, stocking, compounding, recordkeeping, restricted physical access
- Operations must be supervised by licensed pharmacist designated as pharmacist in charge
- Must comply with state and federal controlled substances laws
- Subject to inspection by state Board of Pharmacy and federal DEA

Legal Basics – Clinical Lab Services

- Facilities performing clinical laboratory tests must be licensed and maintain records, equipment, facilities, hazardous waste disposal that are adequate and appropriate for services rendered
- Operations subject to control by laboratory director
 - Usually must be a physician
- May be subject to regulation under Clinical Laboratory Improvement Amendments of 1988 (“CLIA”)
- Must pass periodic proficiency testing
- Subject to inspection by state Department of Health and federal CMS

Legal Basics – Benefits Plan Issues

- If services paid at cost, clinic will be an Employee Benefit Plan subject to ERISA (benefits not taxable to U.S. citizens or residents)
- Using an intermediate entity may result in compliance requirements for funded plan
- Paying for services delivered to US citizens and residents at cost can be a deductible business expense
- Providing a wide variety of services beyond first aid to employees may make clinic a benefit subject to COBRA
- Alternative to making clinic covered under ERISA would be to run charges and reimbursements through regular health plan process using normal TPA for claims processing

Legal Basics – High Risk Areas

- Structural Considerations
 - Corporate practice of medicine/Fee splitting prohibition
 - Vicarious liability for medical negligence
 - Intermediate entity/Alter ego liability
 - Facility licensure and recordkeeping (medical practice, pharmacy, laboratory)

Legal Basics – High Risk Areas

- Additional Considerations
 - Credentialing/Scope of practice
 - ERISA/Prohibited transactions rules
 - Health information privacy, security, medical records compliance
 - FDA regulation (medical device)
 - Federal and state anti-kickback and fraud and abuse compliance

Intermediate Entity Considerations

- Can provide buffer to Employer's assets in event that
 - Malpractice liability reaches beyond contracted provider
 - Claims result from licenses held by other entities
- Isolates activities and responsible parties within clinic and enhances protections for Employer's Board
- Provides shield for organizational managers
- Can be reinforced with additional insurance

Intermediate Entity Considerations

- Holds some risk factors for piercing corporate veil
 - Identity of interest and ownership
 - Shared use of campus and employees

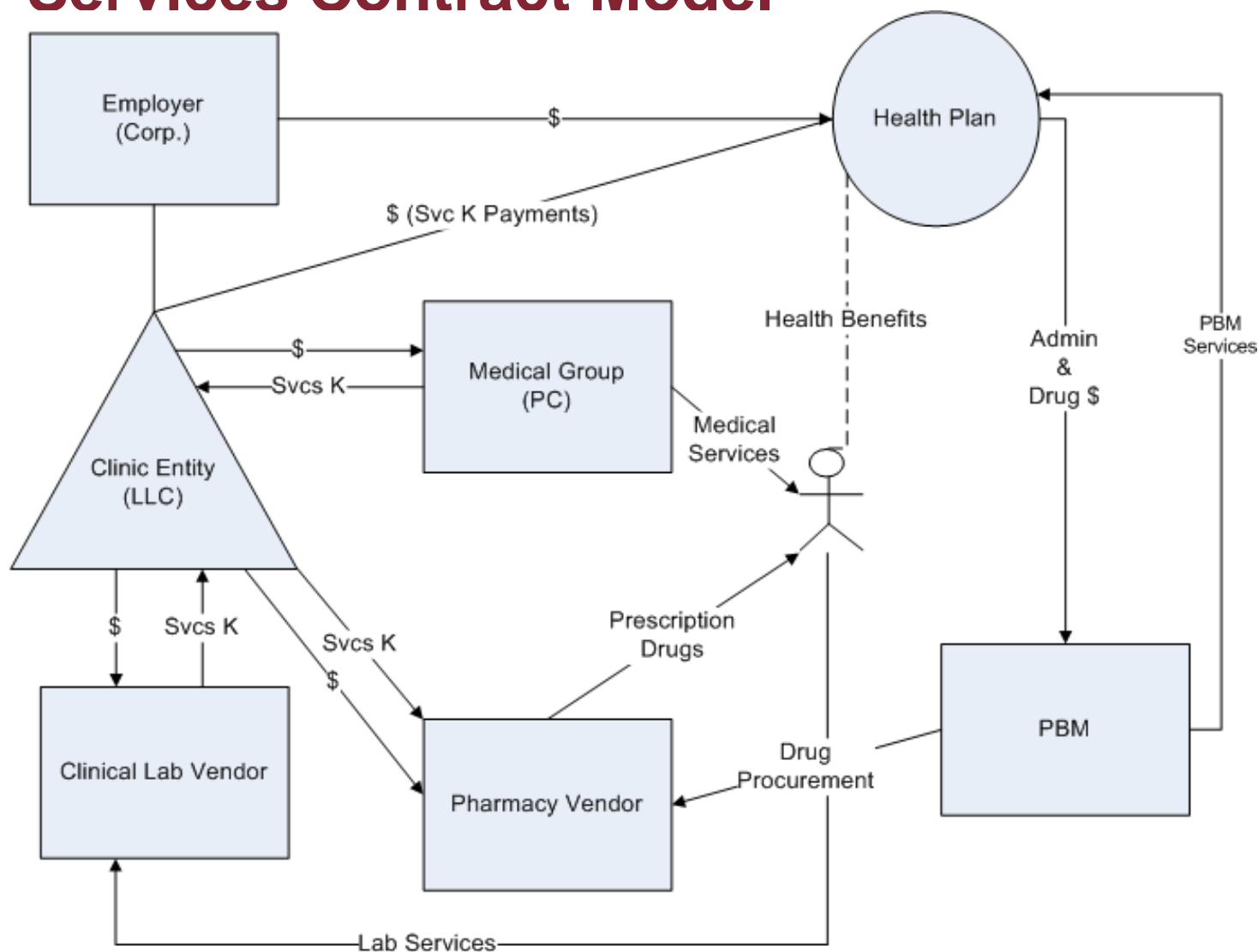
- Adds administrative complexity
 - Must follow corporate formalities to preserve independent status
 - Requires separate assets, accounting and insurance

- May result in compliance obligations for funded plan under ERISA

General Risk Management Strategies

- Avoid licensure or other direct involvement in delivery of patient care
- Provide appropriate signage clearly distinguishing providers of care from Employer/clinic entity
- Clearly disclose and obtain acknowledgement in consent form that care is provided through a third party
- Clearly describe the benefit as provided by third parties in Summary Plan Description and other beneficiary communications
- Require providers to wear name badges that identify their affiliation with the contracted third party provider

Services Contract Model



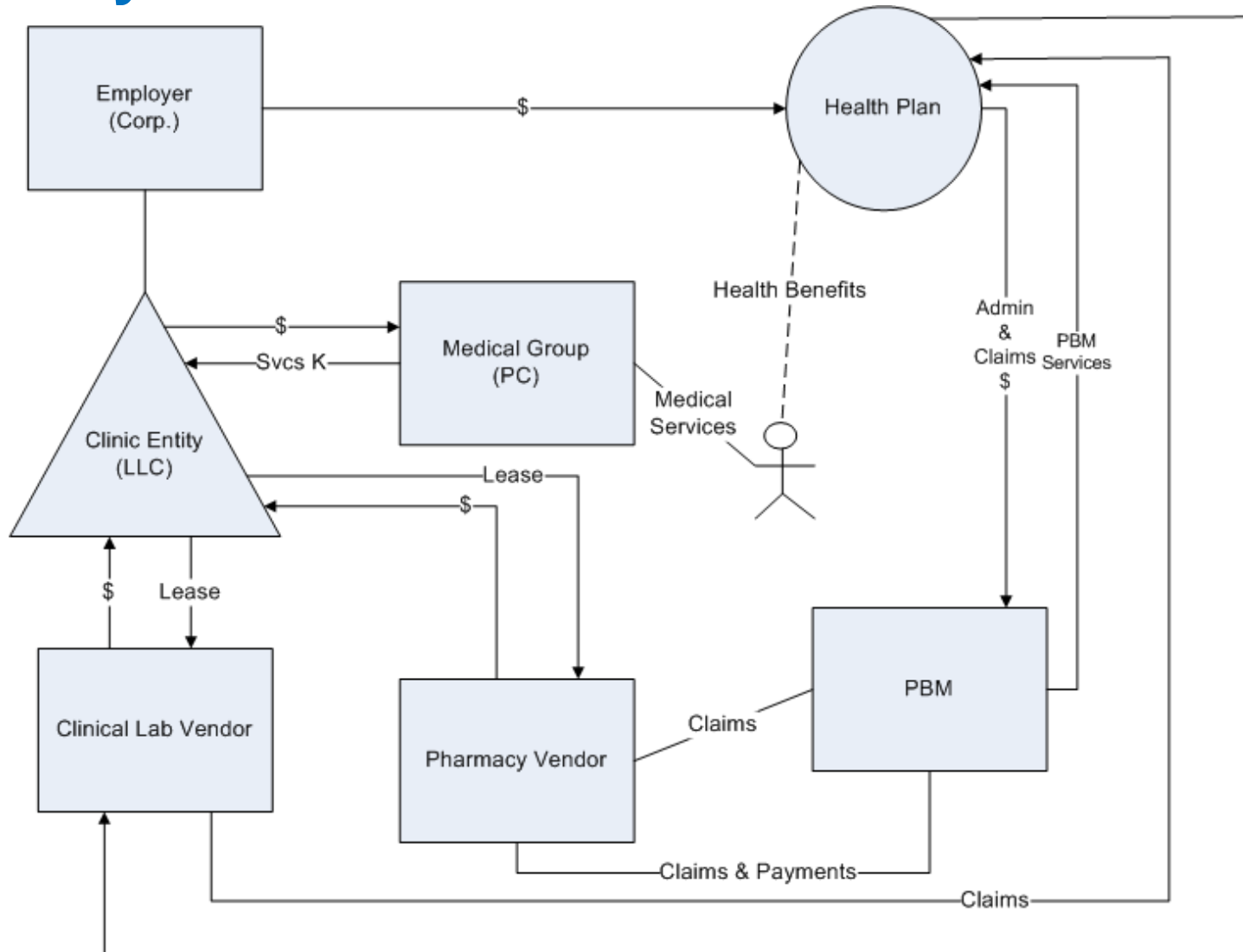
Service Contract Model – Compliance Risk Factors

- LLC holds licenses for pharmacy and lab and is ultimately responsible for compliance and service rendered
- LLC employee may coordinate clinic services
- Service contractor relationships with providers create potential for ostensible agency or partnership argument
- Facility located on campus and payment for services by health plan enhances potential for finding special relationship between Employer and clinic patients
- Court may be inclined to consider Employer alter ego in light of management activities by LLC employee and benefits personnel and funding of services on cost basis

Service Contract Model – Compliance Mitigating Strategies

- Avoid any involvement (including LLC employee) in patient care
- Implement adequate signage and prominent disclosures in consent forms and summary plan description to clearly identify contractors as care providers
- Obtain and require service providers to obtain substantial insurance coverage for applicable risks
- Sufficiently capitalize LLC and restrict funds flow for payments under service agreements to LLC
- Obtain appropriate indemnities from service providers and select providers with adequate resource and experience to meet licensure compliance obligations
- Require service provider personnel to wear badges disclosing affiliation

Fully Outsourced Model



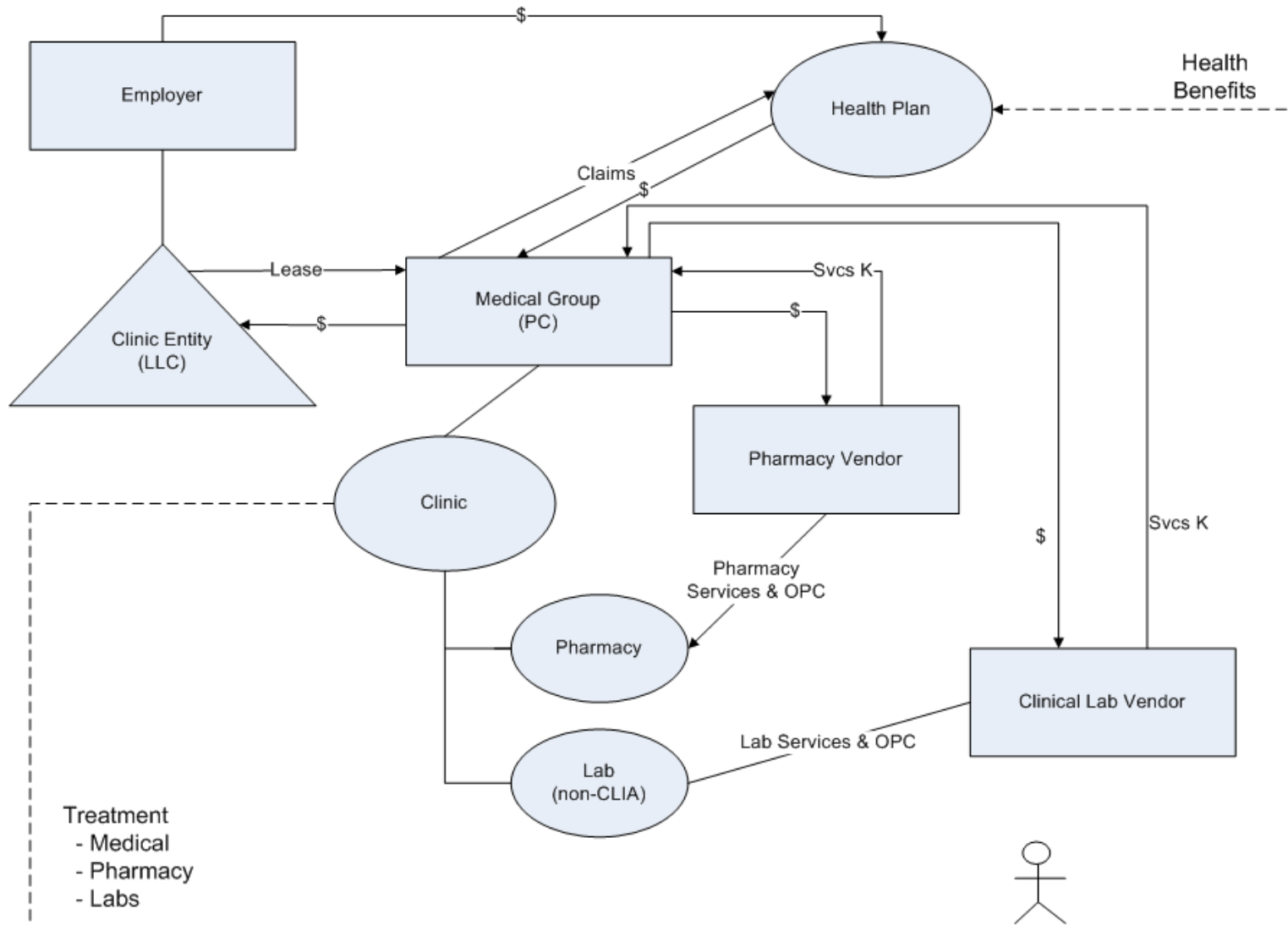
Fully Outsourced Model – Compliance Risk Factors

- LLC has lessor relationship with ultimate licensees for pharmacy and lab services, Employer health plan pays claims for lab and pharmacy services through normal channels
- Service contractor relationships with medical provider paid for at cost creates potential for ostensible agency or partnership argument
- Facility located on campus and payment for services by Employer's health plan enhances potential for finding special relationship between Employer and clinic patients
- Court may be inclined to consider Employer alter ego in light of any management activities performed by LLC employee and benefits personnel and funding of services on cost basis

Fully Outsourced Model – Compliance Mitigating Strategies

- Structure commercial lease terms at fair market value
- Require lessees to put up self-referential signage
- Distinguish LLC/Employer from service providers in signage, consent forms, Summary Plan Description and other beneficiary communications
- Permit pharmacy and lab vendor's to run business entirely independently using reimbursement under plan for control
- Obtain and require service providers to obtain substantial insurance coverage for applicable risks
- Sufficiently capitalize LLC and restrict funds flow for payments under service agreements to LLC
- Obtain appropriate indemnities from service providers and select providers with adequate resources and experience to meet licensure compliance obligations
- Require service provider personnel to wear badges disclosing affiliation

Clinic Model



Clinic Model – Compliance Risk Factors

- LLC has lessor relationship with medical group, which is licensee and contracts for pharmacy and lab services
- Medical group manages/coordinates services provided at clinic - no involvement of Employer or LLC personnel
- Facility located on campus and payment for services by health plan enhances potential for finding special relationship between Employer and clinic patients
- Payment for services is on claims basis preserving Employer's existing relationship to care as sponsor of health plan

Clinic Model – Compliance Mitigating Strategies

- Structure commercial lease terms at fair market value
- Require lessees to put up self-referential signage
- Describe Employer's role as payor Summary Plan Description and other beneficiary communications
- Permit medical group to run business entirely independently using reimbursement criteria and performance standards under plan for control
- Require Medical group to obtain and require of others substantial insurance coverage for applicable risks
- Select medical service provider with adequate resources and experience to meet licensure compliance obligations and select appropriate subcontractors
- Require service provider personnel to wear badges disclosing affiliation

Discussion and Questions???

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