

Regulatory and Compliance Issues for Hospital-Sponsored Sites

Ruth E. Granfors, K&L Gates
Jonathan K. Henderson, K&L Gates

www.klgates.com

Hospital Clinics – Different Models

- Hospital Owned and Operated
 - full control and full risk
- Hospital - Physician Joint Venture
 - shared control and risk negotiated between parties
- Hospital - Retail Clinic Operator Joint Venture
 - shared control and risk negotiated between parties
- Hospital Contractual Relationship with third parties
 - May lease space in a “big box” store
 - May contract with retail operator to supply medical expertise and professionals only

Overview – Legal Considerations Affecting Development

Critical development questions include:

- Where will the clinic fit in the current organizational structure?
- Will it operate as a separate legal entity, and if so, what type of entity?
- Who will own the clinic?
- Who will manage/operate the clinic?
- What services will be provided?

Overview – Legal Considerations Affecting Operations

Critical operational issues include:

- Who will staff the clinic
 - Employees?
 - Independent contractors?
 - What level of skill and experience?
- Will the clinic handle all walk-ins?
 - Emergencies?
 - Urgent care?
 - Preventive services, e.g., immunizations?

Overview – Legal Considerations Affecting Operations (cont.)

Critical operational issues include:

- How will the clinic interact with the patient's PCP?
- Will the clinic accept insurance – commercial or government – or only private pay?
- Will the clinic develop a separate electronic health record system or integrate with the hospital's or another organization's EHR system?

Overview – Legal Considerations Affecting Development and Operations

- Answers to the foregoing questions affect whether and how federal and state laws apply to the project
- In turn, the application of those laws may change the course of development plans or decisions pertaining to hospital operations
- Planning stage is key to understanding and limiting legal and business risk

Legal Issues in Development – Choosing the Legal Entity

- If formed within hospital system, may have an existing entity where operations for clinic fit, but may want to separate for liability reasons
- If hospital joint venture arrangement, must create a separate entity
- Corporation (profit or non-profit) or LLC are most likely vehicles
- Consider tax exempt status in JVs along with other typical choice of entity factors

Legal Issues in Development – Corporate Practice of Medicine

- Choice of legal entity may be limited by state laws or case precedent prohibiting the “corporate practice of medicine”
- Rule: Corporations, other than professional corporations and certain other types of entities varying by state, may not employ physicians
- States may also have related “fee-splitting” laws, which prevent licensed medical professionals from splitting fees with non-licensed individuals or entities

Corporate Practice of Medicine – State Approaches

Many states have abolished corporate practice of medicine doctrine, but it continues to exist in various forms:

- Illinois – provides a narrow exception for hospitals and hospital affiliates that meet certain requirements
- Pennsylvania – provides a broad exception for any health care facility or affiliate of a health care facility
- California’s Supreme Court upheld the doctrine in 2006
- Texas – has strong prohibition against corporate practice of medicine developed through statute and case law (but commonly used exception of 5.01(a) approved non-profit health corporation)

Legal Issues in Development – Regulatory Approvals

- Will the clinic require a certificate of need?
- Will the clinic need a license?
- Are there special facility construction standards?
- Will the clinic provide other services that are separately licensed, e.g., a clinical laboratory?

State laws vary from tight control through need review and licensure to no bar on development and licensing of practitioners only. In some states with these regulations, application to a particular project may depend on ownership, management, structure and proposed services.

Regulatory Approvals – Different State Approaches

Contrast the approaches in the following states:

- Pennsylvania – no CON, no separate facility license, could be covered by hospital license
- New Jersey – no CON, facility license depending on owner/operator
- New York – CON, facility license
- Massachusetts – no CON, special license for “limited service clinics”
- Texas – no CON, no separate facility license for retail clinic

If the clinic operates a laboratory or pharmacy, that requires a separate license. Other services may also be separately licensed.

Legal Issues in Development – Referral Restrictions

If the clinic will submit claims to government payors:

- Need to consider federal Stark law applicability when structuring physician relationships
- Rule: Physicians may not refer a patient for DHS to an entity with which the physician (or a family member) has a direct or indirect financial relationship
 - Physician involvement through ownership or employment (W-2 or contract)?
 - Referrals from these physicians to clinic for DHS?
 - Referrals from the clinic to the physicians' private practice?
 - Referrals to hospital or other hospital affiliates

Legal Issues in Development – Referral Restrictions (cont.)

If the clinic will submit claims to government payors:

- Need to consider analysis under federal and state anti-kickback law when drafting contracts.
- Rule: No person may offer or pay remuneration to another person in return for inducing referrals or business. No person may solicit or accept remuneration in return for purchasing, leasing, ordering, or arranging for any good, facility, service.
 - Relationships between clinic and physicians, pharmacy, hospital, or clinical lab involving payment?
 - Potential safe harbors?

Legal Issues in Development – Referral Restrictions (cont.)

If the clinic will submit claims to commercial insurers or workers compensation programs:

- Similar state law referral restrictions could cover commercial insurance (e.g., Ohio has laws similar to Stark and federal anti-kickback that would cover all insurers; Texas has similar laws to federal anti-kickback that cover all payor types, including private pay)
- State workers compensation laws may have prohibitions similar to the anti-kickback law (e.g., Pennsylvania has referral prohibitions and incorporates the federal anti-kickback safe harbors and Stark law exceptions in state regulation)

Legal Issues in Operations – Facility Staffing

Will the facility be able to operate efficiently, cost-effectively and ensure quality of services while meeting state law requirements? Need to consider:

- Level of physician involvement
- Use of nurse practitioners and other non-physician personnel
- Services to be provided
- Use of standing orders and treatment protocols
- Level and type of supervision for each type of practitioner
- Risk of legal entity under theories of negligence and “respondeat superior”

Legal Issues in Operations – Admissions Criteria

In order to manage risk, policies and procedures need to address criteria for admissions and scope of clinic practice.

- Establish relationships with referral facilities – hospitals, mental health clinics, specialty practices
- Determine if patient has a PCP
- Establish relationship with emergency transfer service
- Develop strict protocols on conditions that are treated and are not treated at the clinic; describe process for referral for conditions outside clinic scope of practice.

Legal Issues in Operations – EHR

- The use of electronic health records in hospital-based convenient care clinics may raise unique issues.
 - Will the records be integrated with the hospital's EHR systems?
 - Is the patient's PCP within the hospital system and will the clinic have access to PCP records?
- Convenient care ventures with big box stores or pharmacies may present issues regarding use of patient information for marketing

The background features several abstract, white dotted lines that curve and intersect across the dark blue field, creating a sense of movement and depth.

Questions?

Contacts:

jon.henderson@klgates.com

ruth.granfors@klgates.com