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L. EDWARD BRYANT, JR.
NATIONAL HEALTH LAW
TRANSACTIONAL COMPETITION

OFFICIAL PROBLEM

Introduction

Bryant Health System (“BHS”) has retained your law firm to provide legal and strategic counsel on a potential partnership, affiliation, or other arrangement with Oncology Alliance Group (“OAG”), a consortium of independent for-profit oncology practices operating throughout the state of Loyola. The Strategic Planning Committee of BHS, comprised of the CEO, CFO, and select Board Members, has initiated discussions regarding this opportunity as part of BHS’s long-term goal to enhance its oncology services and expand its regional footprint.

BHS is a leading Catholic, not-for-profit, integrated healthcare system operating in multiple states, including Loyola, and delivering a range of services across urban, suburban, and rural settings. Known for its comprehensive offerings, BHS seeks to deepen its oncology services by forming a strategic affiliation with OAG to coordinate oncology care across a wider geographic area, integrating clinical services, and improving access to innovative treatments. A key priority for BHS is to reinvigorate its rural markets, including its critical access hospital, Pearson Medical Center, ensuring that underserved populations have improved access to comprehensive cancer treatment.

Background

Bryant Health System

Founded in 1965, BHS has grown into a regional healthcare powerhouse, dedicated to patient-centered care, innovation, and accessibility. BHS operates:

- Ten acute care hospitals, three of which are designated as Level II trauma centers.
- Fifteen outpatient clinics, located in both urban and rural areas and offering primary care, urgent care, and specialty services, including oncology.
- Five specialty care facilities, including a dedicated cardiac center, a behavioral health unit, and an advanced imaging center.

BHS employs over 12,000 healthcare professionals, with a yearly operating budget of \$1.5 billion, but has faced recent challenges such as:

- A recent 10% decline in revenue due to increased competition, particularly from for-profit health systems entering the market.
- Elevated operational costs stemming from staffing shortages, particularly in nursing and specialized fields. BHS has recently initiated an aggressive recruitment campaign to attract healthcare professionals to address staffing shortages. While this campaign has received media coverage and positive responses from the community, it has further strained the budget.
- Ongoing investments in technology, including a new electronic health record (“EHR”) system, which has temporarily strained resources.

BHS recently launched a new telehealth platform aimed at providing virtual care to patients in its rural markets. While this initiative has garnered positive attention and patient engagement, it has led to increased operational costs due to the need for additional IT support and cybersecurity measures. BHS is also involved in a high-profile community health initiative that focuses on improving maternal health outcomes in Loyola. While this initiative has received state funding

and community support, it has also diverted resources and attention from BHS's oncology expansion plans, creating tension among leadership regarding prioritization of projects.

BHS has made oncology a priority due to increasing cancer incidence and gaps in coordinated cancer care across its service area. The organization has invested heavily in clinical trials, advanced treatment modalities, and multidisciplinary cancer care teams. Despite solid financial footing, BHS faces pressure to maintain operational efficiency in a changing healthcare reimbursement landscape, particularly due to recent state-level policy changes in Loyola that affect Medicaid and Medicare reimbursement.

Oncology Alliance Group

OAG consists of five independent oncology practices offering medical oncology, radiation therapy, and palliative care services, and operates two proton beam therapy centers. Although these practices are loosely connected through a management board that provides limited coordination on business, management, and strategic decisions, such as compensation, business development, staffing, and strategic planning, OAG's member practices refer a significant portion of their patients to OAG-owned ancillary services, including radiation therapy and imaging. Each practice retains its own autonomy. Each practice retains its own autonomy.

OAG serves around 8,000 patients annually, with a large Medicare and Medicaid population. OAG has seen revenue drop from \$20 million to \$15 million over three years, primarily due to increased competition. The organization also faces regulatory challenges, including compliance with updated patient safety protocols. OAG remains known for clinical excellence, despite financial struggles. It is a trusted provider in its community, having participated in clinical trials and developed robust palliative care programs. Notwithstanding, OAG has faced difficulty recruiting and retaining oncologists due to competitive pressures and a shrinking talent pool in Loyola. Recently, OAG has also been in discussions with a private equity firm interested in investing in its practices to stabilize operations and enhance profitability.

OAG has several existing financial arrangements with some pharmaceutical companies and device manufacturers and leases several of its clinics from third-party owners, who are unaware of the proposed affiliation. These leases contain provisions requiring landlord consent before a change in management or control.

OAG has recently undergone a CMS survey, which uncovered deficiencies in its radiation therapy services related to equipment sterilization and record-keeping. OAG has submitted a corrective action plan to CMS, which is pending CMS review. CMS also raised concerns about inadequate cybersecurity protections in OAG's existing electronic health record system and about patient data security, particularly as the practices expand their use of telemedicine. OAG has faced allegations of non-compliance with state-level Medicaid reimbursement regulations, particularly involving documentation of services provided to low-income patients. Additionally, two of OAG's member practices are currently engaged in a dispute with a commercial payor regarding denied claims, leading to additional financial strain.

The independent physicians within OAG have expressed concerns about how an affiliation with BHS will impact their clinical autonomy and decision-making. Some members worry that BHS's corporate governance structure may impose restrictions on how they run their practices, such as

standardizing treatment protocols or limiting their ability to participate in clinical research independent of BHS.

Loyola Law

The state of Loyola currently has the following laws:

- **Loyola Charity Care Act (LCCA):** Requires nonprofit healthcare providers to provide a minimum of 5% of their annual operating budget in charity care to low-income patients. The law mandates that all charity care must be documented and reported annually to the state's Department of Health.
- **Proton Beam Therapy Regulation (PBTR):** Establishes stringent operational and clinical protocols for the use of proton beam therapy, including patient eligibility criteria and quality assurance measures. Facilities operating such services must submit biannual reports detailing treatment outcomes and compliance with safety standards.
- **Independent Practice Integration Act (IPIA):** Prohibits the acquisition or merger of for-profit practices by nonprofit health systems unless the transaction results in demonstrable improvements in access to care and is approved by the state's Attorney General. The law also mandates a public comment period prior to approval.
- **Patient Referral Transparency Law (PRTL):** Requires all healthcare providers to disclose referral relationships and financial incentives associated with ancillary services, including imaging and therapy. Providers must obtain informed consent from patients before referring them to affiliated services.
- **Rural Healthcare Access Improvement Act (RHAIA):** Mandates that healthcare systems developing partnerships in rural areas demonstrate how they will enhance healthcare delivery and accessibility. The law provides incentives for projects that include telehealth services and mobile clinics.
- **Confidentiality of Health Records Act (CHRA):** Enhances protections for patient health information, requiring all healthcare entities to implement robust cybersecurity measures and conduct annual audits to ensure compliance with data protection standards.
- **Anti-Kickback Compliance Framework (AKCF):** Establishes a state-level framework that mirrors federal anti-kickback laws, with additional provisions for the healthcare industry to avoid any financial incentives that could compromise patient care. Violations could result in hefty fines and loss of licensure.
- **Corporate Practice of Medicine:** Prohibits the corporate practice of medicine by restricting business corporations from engaging in the practice of medicine or employing physicians to render medical services.

Assistance Required

BHS is seeking your counsel to develop and guide them through the various options available for a potential strategic affiliation, partnership, or other arrangement with OAG. BHS has asked you to, at minimum, provide feedback and guidance on the following factors in the course of providing your proposed options:

1. Assess the strategic, cultural, and operational factors that BHS should consider before proceeding with each proposed arrangement.

2. Analyze the regulatory risks posed by each option presented, including the risk exposure and solutions on how to address or mitigate risks at both the federal and state levels. Include risks that may arise both pre- and post-transaction.
3. Identify potential liabilities that BHS could inherit through each option. Propose strategies for addressing these risks during the process of effectuating each option.
4. Outline areas for supplemental due diligence and identify whether they are high or low priority, as well as your objectives with your diligence requests.
5. In addition to providing the pros and cons of each proposed option, provide an ultimate recommendation on how BHS should proceed out of the options presented and your rationale.
6. Identify any key missing facts that could impact your ultimate recommendation and how your analysis would change.