

Using Partnerships to Accelerate Mission Objectives

Opportunities and Regulatory Considerations

Webinar Goals

- Recognize the ongoing healthcare environment
- Explore three categories of activities in which a strategic partner might accelerate your organization's ability to thrive in uncertain times – opportunities to
 - Diversify care delivery locations
 - Increase efficiency, reduce cost and support patient safety
 - Drive increased reimbursement for services
- Review regulatory considerations common to many partnership arrangements

Why create Partnerships?

■ Recent National Market Intelligence

- Modern Healthcare 2020 CEO Power Panel survey - 69.2% of CEOs indicated joint partnerships were part of their strategic plans (up from 50% the prior year; M&A less a strategy for second year in a row)
- Guidehouse “COVID-19 Hospital & Health System Survey (May 2020) – 67% predict that will be using 5 times more telehealth than pre-COVID but only 1/3 of those believe their organization has the needed telehealth capability
- Others predict continued M&A post-Covid with emphasis on smaller and mid-size deals (Strategic Role of Systemic HealthCare M+A in Remaking the Future of Healthcare White Paper May 2020, Polsinelli)

Uncertain Times

- Snapshot:
 - Uncertain trajectory for return of patient volumes
 - Patient demand for new access points
 - Economic uncertainty for consumers' ability to afford care
 - Potential to respond to additional waves of Covid-19
 - Reimbursement challenges; payer mix shifts; declining margins
 - Need to invest in digital and other strategies
 - Disrupters outside of traditional healthcare

Emerging Consensus

- Healthcare will not return to its “pre-Covid” state
- Challenges well-defined including consumerism
- Ability to thrive dependent on ability to
 - Pivot
 - Innovate
 - Engage consumers
 - Respond to disruption

Wide Variety of Partnerships Structures

- Legal structures
 - Contractual: vendor contracts, management services agreements, joint operating agreements
 - Ownership: equity joint ventures, member substitution, wholly owned subsidiaries, acquisition
- Choice of legal structure typically balances:
 - Governance considerations, clinical integration opportunities, economics, speed to market, branding, tax-exempt status; legal authority; market dynamics

Partnerships: Digital Health

▪ Digital Health

- Acceleration of existing strategies:
 - National companies + clinicians with care provider branding
 - National companies + care provider delivery
- Innovation
- Disruptors

▪ Examples

- Telemedicine visits of all types
- Remote patient monitoring
- Patient triage and screening pre-procedure
- Repurposed online care management portals to maximize population management opportunities
- Increased usage of chat/text
- Portions of care moving to routinely virtual delivery
- New apps for delivery of mental health and behavioral health services

Partnerships: Ambulatory Strategies

■ Ambulatory

- Accelerated shift of care from in-patient to out-patient
- Consumer preference
- Patient safety concerns
- Cost of care differential

■ Examples

- JV ambulatory surgery centers
- Partners to create temporary expansions of traditional hospital through Public Health Emergency (PHE) Waivers
- Partnerships with disruptors to deliver more care outside traditional healthcare settings

Partnerships: Post-Acute Strategies

■ Post Acute

- Covid and restrictions on physical access to post-acute care settings driving new approaches and innovation

■ Examples

- Delivery of medical director services via telehealth to manage restrictions on accessing facility
- Better coordination and tools to avoid re-admissions
- Services moving to home settings; augmenting clinical staff; evidence-based pathways
- “Hospital at Home” services

Partnerships: Home Health Strategies

■ Home Health

- Innovation and disruptors actively looking to do more care in home settings

■ Examples

- Telemedicine for recertification visits
- Expansion of care team members
- “Office-administered” drugs
- Cancer infusion
- Acute care services
- Dialysis

Partnerships: Improve how you do provide your services

- Partnerships that

- Increase Efficiency
- Reduce cost
- Further Patient Safety & Satisfaction

- Examples

- Strategic sourcing
- Artificial intelligence to plan for surges and expand work force capacity
- Using value-based care platforms for broader population engagement and triaging
- Maximize opportunities to lower expenses

Partnerships: To Drive Reimbursement

- Payers

- Create Win-Wins

- Examples

- Bundles
 - Digital codes for reimbursement
 - Sites of Service
 - Negotiate for new forms of reimbursement
 - Access to data

Risk Considerations-Depends on Arrangement

- Consider what risk is present – could the arrangement:
 - Interfere with clinical decision-making?
 - Increase the cost to healthcare consumer?
 - Result in healthcare over-utilization?
 - Reduce patient choice?
 - Be anticompetitive?
 - Be viewed as not fair market value or commercially reasonable for the services?

Key Laws to Consider

- Anti-kickback statute
- Stark law
- False claims act
- Civil monetary penalties
- OIG Fraud Alert on Contractual Joint Ventures
- Tax-exempt issues
- Antitrust
- EMTALA
- Corporate practice of medicine
- Conditions of Participation
- Certificate of need
- State licensure
- Accreditations/certifications
- Reimbursement issues
- Standard of Practice
- HIPAA privacy and security

Federal Criminal Statutes

- Medicare-Medicaid Anti-Fraud and Abuse Statute
 - Prohibits a variety of conduct including but not limited to false statements, concealing or failing to disclose relevant information regarding benefits, submission of claims for physician services without a license, false representations and violations of the anti-kickback statute. 42 U.S.C. Section 1320a-7b(a)
 - Criminal penalties include fines up to \$100,000, 10 years in prison or both if a felony and if a misdemeanor, includes fines up to \$20,000 and up to one year in prison.
 - Note: There are also other non-healthcare specific criminal statutes.

Anti-kickback Statutes

- Federal Anti-Kickback Statute (AKS) for all types of providers and federal healthcare programs
 - Criminal offense to knowingly and willfully offer, pay, solicit or receive remuneration in connection with referring an individual for items or services reimbursed under any federal healthcare program as well as other types of fraudulent conduct. 42 U.S.C. Section 1320a-7b(b)
 - Criminal penalties include fines up to \$100,000, 10 years in prison or both depending on if a felony or misdemeanor;
 - Civil monetary penalties per violation and three times the overpayment amount, and/or federal program exclusion
 - Statutory and regulatory safe harbors create immunity but are not required.

Anti-kickback Statutes

- Federal Anti-Kickback Statute (AKS) for recovery homes, clinical treatment facilities and laboratories and all healthcare benefit programs
 - Eliminating Kickbacks in Recover Act of 2018 (EKRA) that prohibits knowingly and willfully soliciting, paying or receiving remuneration, directly or indirectly, in return for a referral to a recovery home, clinical treatment facility or laboratory. 18 U.S.C. Section 220.
 - Penalties include fines and imprisonment up to \$200,000 and 10 years, respectively, for each occurrence.
 - Statutory safe harbors; no regulations yet
 - Part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Community Act

Anti-kickback Statutes

- Washington State Anti-Kickback Statute (AKS)
 - Prohibits any person from soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind for the referrals of services, goods, or leases for which payment may be made under the Medicaid program. RCW 74.09.240
 - Penalties include the possibility of a felony conviction and fines.

Physician Referral Laws

- Federal Physician Self-Referral or “Stark Law”
 - Civil statute that prohibits physicians from making referrals of designated health services (DHS) to entities with which a physician (or immediate family member) has a financial relationship (i.e., direct or indirect ownership, compensation or both), unless the financial relationship meets an applicable exception. 42 U.S.C. Section 1395nn(g)(1)
 - Strict liability statute in which intent is irrelevant
 - Statutory and regulatory exceptions required to avoid violation of law.
 - Note: Waivers during the Public Health Emergency for certain activities

Physician Referral Laws

- State Physician Self-Referral
 - Prohibits physicians from making referrals of designated health services (DHS) to entities with which a physician (or immediate family member) has a financial relationship (i.e., direct or indirect ownership, compensation or both), unless the financial relationship meets an applicable exception. RCW 74.09.240
 - Applies to the State Medicaid Program
 - Exceptions mirror federal Stark law exceptions

Anti-Rebating Statute

- Washington statute prohibiting paying or offering, directly or indirectly, a rebate, refund, commission, unearned discount or profit in connection with referral of healthcare services by persons licensed under state law. RCW 19.68
 - Conduct that would not violate the federal AKS is exempted
 - Violation is unprofessional conduct under licensing statutes and a criminal misdemeanor
 - Limited statutory exceptions; several AGO advisory opinions exist and a handful of WA state cases to aid in interpretation

Civil Monetary Penalties Law (CMPL)

- Federal CMPL authorizes penalties against persons for an array of conduct, including but not limited to the below. 42 U.S.C. Section 1320a-7a
 - Presenting a claim that person knows or should know is false
 - Services not provided as claimed or while an excluded provider
 - Violating Medicare assignment agreements
 - Providing false or misleading statements influencing discharge decisions
 - Contracting with an excluded provider
 - Violating the federal AKS
 - Knowingly submitting an improper claim under federal Stark law

OIG Special Advisory Bulletin for Contractual Joint Ventures

- OIG has expressed concern regarding “contractual joint ventures” in which a health care provider in one line of business expands into a related healthcare business through contracting with an existing provider of services
 - Concern is relationships between those in a position to refer federal healthcare program business
 - OIG provides examples of “suspect” arrangements

Antitrust – Federal

- **Section 1 of the Sherman Act** - makes illegal “Every contract, combination, . . . or conspiracy, in restraint of trade or commerce.” The statute prohibits agreements among competitors on any aspect of prices, group boycotts, customer or market allocations among competitors, and certain types of exclusive dealing arrangements and tying arrangements.
 - Requires that two or more independent entities be involved.
- **Section 2 of the Sherman Act** - unlawful to “monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize” trade or commerce.
 - Does not prohibit monopoly power. Makes illegal the abuse of monopoly power, for example, attempting to exclude competitors from a market. Section 2 may be violated by a single entity.

Antitrust – Federal

- **Section 5 of the Federal Trade Commission Act** - prohibits all “unfair methods of competition ... and unfair or deceptive acts or practices.” Broad prohibitions that cover activities prohibited by all of the other antitrust laws, as well as such practices as deceptive advertising.
- **Enforcement of the Antitrust Laws**
 - Criminal - substantial fines and prison terms brought by DOJ.
 - Civil –
 - Actions may be brought by the DOJ Division, the Federal Trade Commission, the Washington Attorney General, to obtain injunction and penalties.
 - Private party injured by the activity may recover 3 time damages plus attorney fees.

Antitrust – Washington State

- The State of Washington has antitrust laws that are similar to federal law.
- The Unfair Business Practices Consumer Protection Act (RCW 19.86) prohibits:
 - Unfair methods of competition; unfair or deceptive acts or practices; contracts or conspiracy in restraint of trade or commerce; attempts to monopolize or combine or conspire to monopolize trade; and leases or sales of goods and services conditioned upon the understanding that the purchaser will not substantially lessen competition or tend to create a monopoly
 - Civil penalties, damages (including attorney fees) and private right of action

Antitrust – Notice to WA AGO

- RCW 19.390 requires that prior notice be given to the WA Attorney General before the effective date of a proposed material change, such as a merger or acquisition, involving hospitals, hospital systems, and provider organizations.
 - <https://www.atg.wa.gov/healthcare-transactions-notification-requirement>

IRS Tax-Exempt Considerations

- IRS Tax-Exempt Considerations (i.e., use of charitable assets)
 - Unrelated business income
 - Private benefit; Private inurement
 - Excess benefit transactions
 - Commerciality doctrine
- Note: If a public entity – state, county, city or public hospital district – there may be similar considerations

Other Enforcement Statutes of Note

- Federal False Claims Act
 - Prohibits knowingly submission of a false claim, use of a false statement to get paid, decreases an obligation, or conspiracy to defraud government. 31 U.S.C. Section 3729(a)(1)
 - Significant case law around definition of knowingly, implied certifications, reverse false claims
 - Significant penalties with multipliers for damages and private right of action

Other Enforcement Statutes of Note

- State Medicaid False Claims Act – Civil
 - Civil - Prohibits any person from obtaining Medicaid benefits or payments through false statements, misrepresentations, concealments or generally fraudulent means. RCW 74.09.210
 - Penalties include recoupment and civil penalties
 - Criminal - Prohibits knowingly making false statements related to services reimbursed under and state medical program, including Medicaid. RCW 74.09.230
 - Penalties include Class C Felony and fines.

Other Enforcement Statutes of Note

- State law prohibits false claims and statements related to claims for healthcare payment. RCW 48.80.030
 - Prohibited conduct includes false statements to insurers, health maintenance organizations, healthcare service contractors and self-funded plans

Other Regulatory Considerations

- Depending on transaction, consider
 - EMTALA
 - Corporate practice of medicine
 - Certificate of need
 - State licensure
 - Accreditations/certifications
 - Reimbursement prohibitions
 - Standard of Practice
 - CMS Conditions of Participation
 - Emergency Rules relaxing Stark Law, Telemedicine and Site of Service Requirements

Key Take-Aways

- Continued complexity and uncertainty
- Opportunities exists – and so do regulatory risk
- Adopt successful disrupter strategies
- Know what needs to be done to support community needs, whether you can do alone, or need a partner to advance your strategy

Polsinelli PC provides this material for informational purposes only. The material provided herein is general and is not intended to be legal advice. Nothing herein should be relied upon or used without consulting a lawyer to consider your specific circumstances, possible changes to applicable laws, rules and regulations and other legal issues. Receipt of this material does not establish an attorney-client relationship.

Polsinelli is very proud of the results we obtain for our clients, but you should know that past results do not guarantee future results; that every case is different and must be judged on its own merits; and that the choice of a lawyer is an important decision and should not be based solely upon advertisements.

© 2020 Polsinelli® is a registered trademark of Polsinelli PC. Polsinelli LLP in California. Polsinelli PC (Inc.) in Florida.

[polsinelli.com](https://www.polsinelli.com)