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Navigating the Briar Patch: Addressing Regulatory Compliance in an Alternative Payment World

Business of Healthcare Symposium, March 5, 2018

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COMMITMENT

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Conflict of Interest

Barry S. Herrin, JD

Has no real or apparent conflicts of interest to report.

Agenda

- Types of alternative payment model (APM) arrangements
- State regulation of APM structures
- Federal antitrust compliance issues
- Federal income tax issues for collaborations between taxable and tax-exempt providers
- Dialogue

Learning Objectives

- State at least one insurance law or regulation that might affect the choice of relationship in alternative payment model strategies, particularly those devolving risk from the insurer to the provider
- Discuss antitrust statutes and regulations that might affect the assembly of provider networks and the negotiation for payment in certain alternative payment models, especially those that do not require the sharing of risk
- Share information about restrictions on taxable entities and tax-exempt public entities collaborating to provide patient care and the treatment of revenue received from such collaborative treatment episodes

Types of Alternative Payment Model Arrangements

- For our purposes, any type of arrangement other than strict “fee for service”
- “Upside risk” only, or shared savings/bonus arrangements
- “Holdback” or “earnout” arrangements keyed to reaching goals
- Upside and downside risk for provider
- Global risk, including “sub-capitation” for other providers
- Bundled payment or case rate arrangements
- Can be insured or self-funded and TPA-administered

State Regulation of APM Structures

- Varies widely state to state
- Common regulatory issues:
  - Whether there is a direct contract between a regulated entity and the provider accepting risk
  - Whether there is delegation or “sub-capitation” of risk
  - What services the contracting entity is responsible for beyond patient care
  - Whether the payor is an insurer or a self-funded employer, union, or individual patient
- The spectrum runs from high regulation to virtually no regulation at all

State Regulation of APM Structures

- General principles:
  - When there is a direct contract between a licensed payor and a licensed provider compensating the provider for its own services, bonus/holdback arrangements are permitted almost without exception
  - When there is a direct contract between a licensed provider and a self-funded employer health plan for the provider's own services, shared savings arrangements are permitted almost without exception
  - Indirect risk (i.e., risk subcontracted to other entities by the entity with the direct payor/plan relationship) are regulated almost without exception

State Regulation of APM Structures

- California – High Regulation
- Tennessee – Low Regulation
- North Carolina – Intermediate Regulation

Don’t Forget ERISA Pre-Emption

- ERISA enacted in 1974 and pre-empted most state laws and regulations governing employer-sponsored health benefit plans, whether self-insured or insured
- Statutes and regulations solely governing “the business of insurance,” which was exempted from federal oversight in the 1945 McCarran-Ferguson Act, survive
- ERISA prohibits states from classifying self-funded employer health benefits plans as insurers
- Direct contracts between plans and individual providers for services offered by those providers cannot be prohibited or regulated by states

Regulation of APM Structures - California

- Knox-Keene Health Care Service Plan Act of 1975
  - California Department of Managed Health Care requires a license for entities that assume global financial risk for the provision of both physician and hospital services
  - Limited license requirement if the entity does not collect insurance premiums or directly market to consumers or employers
  - No license is required if the entity markets only its own services (consistent with ERISA pre-emption)

Regulation of APM Structures - California

- Risk-Bearing Organizations
  - "Lawfully organized group of physicians that delivers, furnishes, or otherwise arranges for or provides health care services."
  - Contract directly with a Knox-Keene Act licensee or "arranges for the provision of health care services" for licensee's enrollees
  - Is paid a capitated fee or "fixed periodic payment" of any kind
  - Adjudicates claims against the capitated or fixed periodic fee

Regulation of APM Structures - Tennessee

- Limited to regulation of HMOs
- "Health maintenance organization" (HMO) means any person that undertakes to provide or arrange for basic health care services to enrollees on a prepaid basis. The HMO may provide physician services directly through physician employees or under arrangements with individual physicians or a group or groups of physicians. The HMO may also provide or arrange for other health care services on a prepayment or other financial basis.

Regulation of APM Structures - Tennessee

- An HMO may provide or arrange for basic health care services on a prepayment or other financial basis with physician-hospital organizations; “by so doing, the physician-hospital organization is not deemed to be an insurer or HMO”
- “Physician-hospital organization””means an organization formed to allow hospitals and physicians to jointly obtain provider contracts with HMOs and other payers of health care benefits.
- In the event the HMO enters into an agreement with any physician-hospital organization on a prepayment basis, the DOI may not disallow the agreement on the basis that it transfers risk to the physician-hospital organization; however, the HMO remains responsible for the provision of the services contracted for

Regulation of APM Structures – North Carolina

- HMO Act - "Health maintenance organization" or "HMO" means any person who undertakes to provide or arrange for the delivery of health care services to enrollees on a prepaid basis except for enrollee responsibility for copayments and deductibles.
- 11 NCAC 20.0101(b)(6) - "Network plan carrier" means an insurer, health maintenance organization, or any other entity acting as an insurer … that provides reimbursement or provides or arranges to provide health care services; ***and*** uses increased copayments, deductibles, or other benefit reductions for services rendered by non-network providers to encourage members to use network providers.

Regulation of APM Structures – North Carolina

- Bulletin 97-B-1 removes direct regulation of “insurance intermediaries” and now places the burden of compliance on the contracting insurer, HMO, or “network plan carriers”
    - 11 NCAC 20.0204(b)(6) - Intermediary organizations may assume risk
    - 11 NCAC 20.0204(b)(3) Intermediary organizations may not subcontract for risk without written approval of the insurer or HMO, who will remain financially responsible for any subcontracted services

Regulation of APM Structures – North Carolina

- 2012 NCDOI Position Statement (unpublished) permits integrated delivery systems (hospitals that employ physicians directly or in a wholly-owned subsidiary) to offer capitated or pre-paid physician and hospital services directly to employers' self-insured health benefit plans without licensure as an HMO
- NCGS Section 58-67-5(h) expressly exempts from coverage of the Act individual providers and professional associations, who remain free to offer prepaid or capitated payment services directly to individuals or self-insured employer plans (see the Durham County Hospital Corp. legal opinion at *http://www.ncdoj.gov/About-DOJ/Legal-Services/Legal-Opinions/Opinions/278.aspx*

Antitrust Issues in APMs

- Federal Trade Commission (FTC) and US Department of Justice (DOJ) are concerned about
  - Price fixing
  - Monopolization/predatory pricing
  - Tying arrangements that lessen competition
- Insurance companies are currently exempt from these restrictions, though that may change
- Providers are not exempt generally

Antitrust Issues in APMs

- Keys to antitrust enforcement (other than naked price fixing or tying) are the definition of the applicable **market** and the **power** held in that market
- Geographic markets and product markets
- Healthcare providers have both, and they may differ
    - Acute care hospital services may have a smaller market than pediatric oncology services
    - Primary care markets are usually smaller than specialty physician markets due to consumer behavior

Antitrust Issues in APMs

Two ways to look at potential antitrust violations:

- Per se – conduct that is always illegal without any need for analysis
  - Price fixing and agreements to divide markets (competition free zones) are always illegal
- "Rule of reason"
  - Requires an analysis of market power and any significant pro-competitive benefits
  - Any proposed restraint of trade must be "reasonably necessary to produce the claimed efficiency"
  - FTC and DOJ ultimately want costs to the ultimate consumer to decrease

Antitrust Guidance Applicable to APM Activities

- Otherwise competing businesses must be either financially or clinically integrated to avoid per se price fixing
- US Supreme Court held in *Arizona v. Maricopa County Medical Society* (1982) that physicians in independent practices are supposed to compete with one another; such providers can avoid a price fixing charge by "pooling capital and ***sharing risks of loss as well as the opportunities for profit***"
- This admonition is important when evaluating APMs that have no downside risk

Antitrust Guidance Applicable to APM Activities – ACOs

Medicare Shared Savings Program Accountable Care Organizations (ACOs)

- Groups of providers "meeting the criteria specified by [HHS] may work together to manage and coordinate care for Medicare . . . beneficiaries through an [ACO]" and "may receive payments for shared savings if the ACO meets certain quality performance standards"
- "Deemed clinical integration" at establishment, but must work towards actual clinical integration
- Track 1has no requirement to share downside risk – **99% of ACOs fit here**

Antitrust Guidance Applicable to APM Activities – ACOs

- The FTC and the Antitrust Division of the Department of Justice established guidelines in October 2011 for both MSSP participants and commercial ACOs.
- The guidelines established a safety zone for participants in the MSSP and indicated other ACO providers would be evaluated under the rule of reason.
- The rule of reason evaluates whether the ACO's potential pro-competitive effects are likely to outweigh those anti-competitive effects.

Antitrust Guidance Applicable to APM Activities – ACOs

Four other circumstances likely to raise concerns of anticompetitive behavior relate to provider-payor relationships inside ACOs:

1. Preventing or discouraging private payors from incentivizing patients to choose certain providers, including providers not participating in the ACO.
2. Linking the sales of ACO services to the private payor's purchase of other services from providers outside the ACO. For example, an ACO should not require a payor to contract with all of the hospitals under the same system of the hospital participating in the ACO.

Antitrust Guidance Applicable to APM Activities – ACOs

Four other circumstances likely to raise concerns of anticompetitive behavior relate to provider-payor relationships inside ACOs:

3. Contracting exclusively with ACO physicians, hospitals, ambulatory surgery centers and other providers to prevent those providers from contracting with payors outside the ACO.
4. Restricting a private payor's ability to share enrollees information on its health plan cost, quality, efficiency and performance to help enrollee choose providers – if that information is similar to the cost, quality, efficiency and performance measures used in MSSP.

Antitrust Guidance Applicable to APM Activities – Other APMs

FTC and DOJ Statements on Antitrust Enforcement Policy in Health Care

- Statement 9 addresses multi-provider networks
- "Ventures among providers that jointly market their health care services to health plans and other purchasers"
- Because the providers in these networks are otherwise competitors, agreements that fix prices or allocate markets may result in antitrust violations

Antitrust Guidance Applicable to APM Activities – Other APMs

FTC and DOJ Statements on Antitrust Enforcement Policy in Health Care

- Efficiencies often are achieved through providers sharing substantial financial risk **OR** through clinical integration of the providers in the network
- However, a qualified clinically-integrated joint arrangement is not required to involve the sharing of financial risk
- Participants must participate in active and on-going programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided

Antitrust Guidance Applicable to APM Activities – Other APMs

FTC and DOJ Statements on Antitrust Enforcement Policy in Health Care

- The arrangement must create a high degree of interdependence and cooperation among the participants
- Any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement

Antitrust Guidance Applicable to APM Activities – Other APMs

FTC and DOJ Statements on Antitrust Enforcement Policy in Health Care

- Advisory Opinions - FTC and DOJ are looking for utilization review, quality assurance, and medical management programs in clinically integrated networks without financial risk that:
  - Will be implemented
  - Will have a strong probability of reducing utilization and costs, and increasing quality significantly
  - Include strong monitoring, reporting, correction, and "enforcement" (meaning financial penalties and exclusion from the network) mechanisms

Antitrust Guidance Applicable to APM Activities – Other APMs

Examples of Clinically Integrative Activities

- Establishing network goals regarding quality of patient care and utilization review – not just individual goals
- On-going case management
- Review of inpatient stays at hospitals
- Review of clinical practices at the individual provider level and for the network as a whole
- Development and enforcement of practice standards and treatment protocols

Antitrust Guidance Applicable to APM Activities – Other APMs

Clinical Integration Must Be Real – No "Deemed Status" for Non-MSSP Networks

- Regardless of how the efficiencies are achieved, the primary determination is whether the efficiencies are actually achieved and, if so, whether collective agreement and negotiation regarding price terms are necessary to create and maintain such efficiencies
- It is not enough to achieve efficiencies if the collective agreement and negotiation were not necessary in order for them to be achieved

Tax Issues for APM Joint Ventures

- Many APMs create joint ventures between tax-exempt public hospitals and for-profit physician organizations
- March 2011 IRS issues guidance for tax-exempt organizations participating in ACOs operating within the Medicare Shared Savings Program
    - Such participation generally linked to the charitable purpose of “lessening the burdens of government”
    - Participation in the MSSP should not result in unrelated business taxable income (UBTI) for tax-exempt organizations

Tax Issues for APM Joint Ventures

- March 2011 IRS issues guidance (Notice 2011-20) for tax-exempt organizations participating in ACOs operating within the Medicare Shared Savings Program
  - All transactions among participants must be at fair market value and the tax-exempt's share of benefits should be proportional to its contributions to the ACO
    - So the physicians can't get an outsized payment of the shared savings
    - So contributions of technology, staff, and start-up capital have to be recognized in ownership percentages?

Tax Issues for APM Joint Ventures

- March 2011 IRS issues guidance (Notice 2011-20) for tax-exempt organizations participating in ACOs operating within the Medicare Shared Savings Program
  - What about payments for NOT taking care of patients?
  - What about payments received for patients NOT treated by tax-exempt hospital?
  - UBTI for part of the revenue paid by the ACO to the tax-exempt entity?
    - Can the ACO even be a tax-exempt entity if it's owned partially by community (for profit) physicians?

Tax Issues for APM Joint Ventures

IRS Private Letter Ruling 2016-15-022 (1/15/16)

- ACO formed for commercial contracting is not entitled to tax-exempt treatment
  - Doesn't lessen the burdens of government
  - "Triple Aim" means nothing to the IRS
  - ACOs negotiating with commercial payors are treated as provider organizations that more than incidentally benefit the providers rendering services to the public and therefore are not charitable (Rev. Rul. 86-98)
  - More than 50% of ACO participants are for-profit providers

Questions?

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