

# American Health Lawyers Association

## 2016 in Review: Traveling the Road to Value-Based Payment in a Regulatory Enforcement Minefield, Part II: *Is Orange the New Black? The Role of Commercial Reasonableness in Government Enforcement Actions and Settlements*

October 25, 2016, 2:00 PM (EDT)

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This webinar is sponsored by the FMV Affinity Group of the Hospitals and Health Systems Practice Group, and also the Fraud and Abuse, Physician Organizations and In-House Counsel Practice Groups



# About the Webinar Series

*“Fair market value”* (FMV) and *“commercial reasonableness”* are increasingly the subjects of both controversy and scrutiny in health care arrangements. Together, ongoing changes in market practices and in the regulatory environment may further magnify both confusion about and consequences of non-compliance with these standards. With recognition that an understanding of the changing rules, payment models, and enforcement trends may be key to ensuring compliant FMV and commercially reasonable arrangements and transactions, this webinar series is intended to provide a forum for education and discussion regarding those events and developments of 2016 that may or should affect how parties evaluate and address FMV and commercial reasonableness.

This is Part II of this series. Our panel will discuss *“Is Orange the New Black? The Role of Commercial Reasonableness in Government Enforcement Actions and Settlements”*

# About the Webinar Series

- **Session I: October 18, 2016**  
Universal Health Services v. Escobar + The Yates Memo: What Do They Mean for Health Care Counsel, Compliance Officers, and Compensation Consultants?
- **Session II: October 25, 2016**  
Is Orange the New Black? The Role of Commercial Reasonableness in Government Enforcement Actions and Settlements
- **Session III: November 2, 2016**  
Medicare's New and Clarified Rules: Per Click and Lithotripsy—Why Does FMV Matter?
- **Session IV: November 15, 2016**  
Medicare's New and Clarified Rules—Provider-Based Payment, FY 2017 IPPS Final Rule, and Other Recent Changes
- **Session V: December 6, 2016**  
2016's Acronym Soup: CJR, BPCI, OCM, MIPS, and APMs—What Do They Mean for FMV and Reasonableness in Compensation?

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# General Disclaimer

*The views expressed in this presentation are those of the speakers and are intended to facilitate a general discussion regarding legal and valuation issues that may arise in the context of health care transactions.*

*This presentation contains general information only. It is not intended to be comprehensive and should not be relied upon as providing accounting, business, financial, investment, legal, tax, or other professional advice or services.*

# General Program Agenda

- I. Regulatory Environment of the Healthcare Industry
- II. Definition of Fair Market Value (FMV)
- III. Definition of Commercial Reasonableness
- IV. Recent Case Law Implicating FMV and Commercial Reasonableness
- V. Determining Commercial Reasonableness
- VI. The Potential Evolution of Commercial Reasonableness in a Changing Healthcare Reimbursement Environment
- VII. Conclusion

Part I:  
Regulatory Environment of the  
Healthcare Industry

# Regulatory Environment of the Healthcare Industry

- Anti-Kickback Statute
  - Prohibits:
    - Remuneration, solicited, offered, accepted or received, knowingly or willfully to induce or provider referrals or purchasing leasing or ordering a any item for which payment is made under a Federal healthcare program
  - Fines
    - \$25,000 fine and up to 5 years in prison
  - Scope of Statute
    - Very broad
    - Intent Requirements
    - One Purpose
  - Safe Harbors

# Regulatory Environment of the Healthcare Industry

- Stark Law
  - Federal Prohibition of Self-Referral
    - Referral
    - Physician
    - Designated Health Services
    - Financial Relationship w/Entity
  - Stark Law DHS
    - Various Categories
    - Inpatient and Outpatient Hospital Services
  - Stark Law Exceptions
    - Various Exceptions
    - Employment Exception Prominent in Recent Cases
  - Provider Self-Referral Disclosures

# Regulatory Environment of the Healthcare Industry

- False Claims Act
  - Elements
    - Knowingly
    - Presents or Causes to be Presented
    - False or Fraudulent
    - Claim to the Government
  - Fines
    - Treble Damages
    - \$10,781 or \$21,563 per False Claim
  - Whistleblower Provision
    - Qui Tam Provisions
  - State FCA

# Part II:

## Definition of Fair Market Value (FMV)

# Defining Fair Market Value

- Why Important?
  - Anti-Kickback Statute
  - Stark Law
  - IRS Private Inurement Guidance
- Stark Law
  - “Fair market value means the value in arm’s-length transactions, consistent with the general market value.”
  - Not Very Clear!

# Defining Fair Market Value

- Stark Law
  - “General market value” means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party . . .”
  - Emphasis: **“buyers and sellers who are not otherwise in a position to generate business for the other party”**

# Defining Fair Market Value

- Anti-Kickback Statute
  - “The OIG’s definition of “fair market value” excludes any value attributable to referrals of Federal program business or the ability to influence the flow of such business. See 42 U.S.C. 1395nn(h)(3). Adhering to the rule of keeping business arrangements at fair market value is not a guarantee of legality, but is a highly useful general rule.”
  - Even if fair market value not required, it **“is a highly useful general rule.”**

# Part III:

## Definition of Commercial Reasonableness

# Defining Commercial Reasonableness

- Why Important
  - Anti-Kickback Statute
    - Safe Harbors
  - Stark Law
    - Exceptions
  - Separate and Distinct From Fair Market Value
- If Fair Market Value, is it Commercially Reasonable?

# Defining Commercial Reasonableness

- CMS/Stark
  - An arrangement that is “a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.”
  - “An arrangement will be considered “commercially reasonable” in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.”
  - Must Make **Commercial Sense** and **Not Based on Potential Referrals**

# Part IV: Recent Case Law Implicating FMV and Commercial Reasonableness

# Recent Case Law

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System*
  - *Facts and Allegations*
    - It All Started With a Surgery Center . . .
    - Local Physicians and Part Time Employment
    - Multiple Opinions Received
    - Compensation Arrangements
      - Excess of 90<sup>th</sup> Percentile
      - Packages in Excess of Professional Collections
      - Valuation Calculated Based Upon Lost Referrals

# Recent Case Law

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System*
  - *Arguments*
    - Claimed Exceptions
    - Exceeding Fair Market Value
    - Commercial Reasonableness of Arrangements
    - Compensation Takes Into Account Referrals

# Recent Case Law

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System*
  - *Key Takeaways*
    - Multiple opinions questioning the strategy and/or physician relationships should immediately be a red flag
    - Organizations should ensure that the arrangement is actually what it purports to be (i.e., employment = actual employment)
    - Opinions and arrangements must be scrutinized (data, salaries, employment relationships, and all moving parts)

# Recent Case Law

- *U.S. ex rel. Reilly v. North Broward Hospital District*
  - *Facts and Allegations*
    - The relator alleged that Broward Health compensated physicians employed by the health system
    - Relator alleged that Broward Health purposely tracked referrals from physicians to the hospital for ancillary services and technical component (ASTC) in “*Contributive Margin Reports,*” which were then used to cover the “*massive direct losses*” from excessively compensating physicians in violation of the AKS and Stark Law
    - The complaint alleged that these reports track “*the revenue from every admission, every ancillary, anything that’s done to patients of employed physicians*”

# Recent Case Law

- *U.S. ex rel. Reilly v. North Broward Hospital District*

- *Key Takeaways*

- The relators alleged impermissible payments to employed physicians for referrals by separating the professional component of physician services (albeit, personally performed) from the associated ASTC services
- Based on this separation, the relators based their allegations on the profitability (or lack thereof) of the physicians' professional services, *independent* of the economic performance of the *vertically integrated* health system, of which those professional services were an integral part
- The case reflects how government regulators, as well as qui tam relators, are interpreting the threshold of *commercial reasonableness* to include consideration of the profitability of the professional services of employed physicians

# Recent Case Law

- *U.S. ex rel. Payne v. Adventist Health System*
  - *Facts and Allegations*
    - It all started with employee concerns . . .
      - Multiple individuals in various roles/locations
    - Questionable Arrangements Occurred in Various Adventist Systems
      - Failure to Meet Group Practice Exception
    - Compensation Based on Referrals, Not Personally Performed Services
    - Compensation Exceeded FMV
      - Compensation Far Exceeded Production
    - Financial Losses in Many of the Arrangements

# Recent Case Law

- *U.S. ex rel. Payne v. Adventist Health System*
  - *Arguments*
    - Non Personally Performed Services
    - Payments in Excess of FMV
    - Financial Losses Not Commercially Reasonable
    - Referral Driven Models
    - Unreasonable Benefits
      - Car payments . . .

# Recent Case Law

- *U.S. ex rel. Payne v. Adventist Health System*
  - *Key Takeaways*
    - Financial Losses Represent Viable Arguments for Non-Commercially Reasonable Decisions
      - Take into Account Referrals
      - Compensation Should be Adjusted to Reflect the Opportunity for Profit
    - Non-Personally Performed Services Cannot be Compensated for Under Stark and it is not Commercially Reasonable
    - Contribution Margin Reports Must be Analyzed Separate From Compensation Analyses

# Recent Case Law

- *U.S. ex rel. Barker v. Columbus Regional Healthcare System*
  - *Facts and Allegations*
    - An Administrative Director of the Medical Oncology Service Line Has Concerns . . .
    - Columbus Regional Oncology Treatment Center Owned by Columbus Regional Health System
    - Excessive Salary to Andrew Pippas – Medical Director
    - Organization Utilized Many Medical Directors

# Recent Case Law

- *U.S. ex rel. Barker v. Columbus Regional Healthcare System*
  - *Arguments*
    - Compensation Above Fair Market Value
    - Compensation Not Based Upon Personally Performed Services
      - NPs and PAs
    - Compensation for Referrals
    - Compensation Not Commercially Reasonable
    - High Upcoding Rates

# Recent Case Law

- *U.S. ex rel. Barker v. Columbus Regional Healthcare System*
  - *Key Takeaways*
    - Incriminating Internal Communications Key
    - Productivity and Compensation Must be Based Upon Actual Services Performed
    - Medical Directorships Must be Necessary and Fair Market Value
    - Physicians Themselves Can be Liable - \$425,000 Settlement for Andrew Pippas

# Recent Case Law - Summary

- Key Takeaways
  - Compensation was often above FMV
  - Compensation was tied directly or indirectly to referrals
  - The hospital or health system incurred financial losses related to the services for which the physicians were compensated
  - Compensation was sometimes paid for services not personally performed by the physicians
  - Multiple Opinions
  - Part-time and/or atypical employment structures
  - Inconsistencies with internal documentation

# Part V:

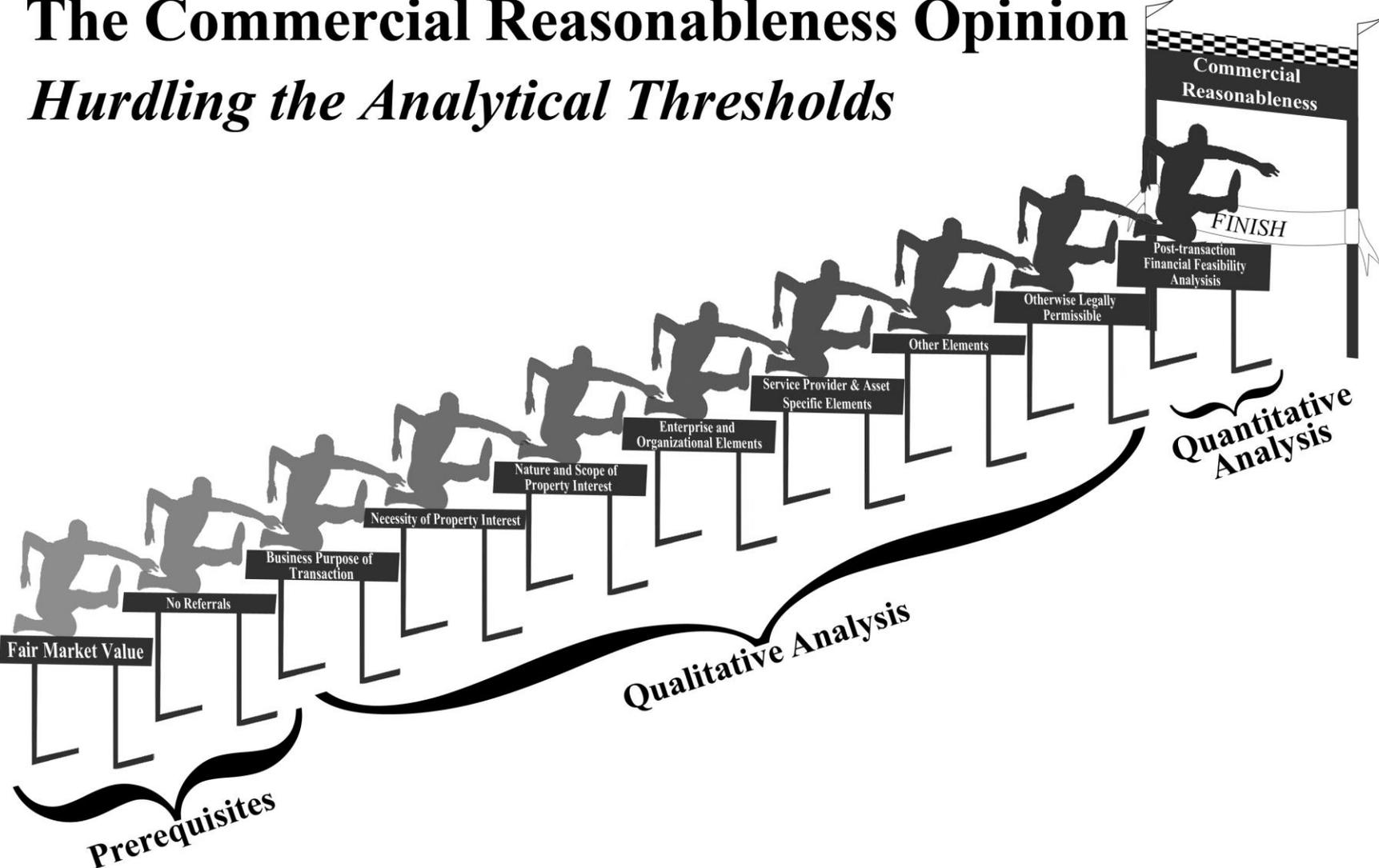
## Determining Commercial Reasonableness

# How Organizations Approach Commercial Reasonableness

- Internal vs. External Review
  - Do All Valuators Opine on Commercial Reasonableness?
  - Internally is there an Inherent Conflict of Interest?
  - Most Organizations Likely Approach Commercial Reasonableness in Risky Arrangements Only
- Who Within Organizations Can Analyze Commercial Reasonableness?
  - Operations Leader
  - Financial Leader
  - Legal Leader
  - Compliance Leader
  - ??????

# The Commercial Reasonableness Opinion

## *Hurdling the Analytical Thresholds*



# Transactional Prerequisites

- Fair Market Value

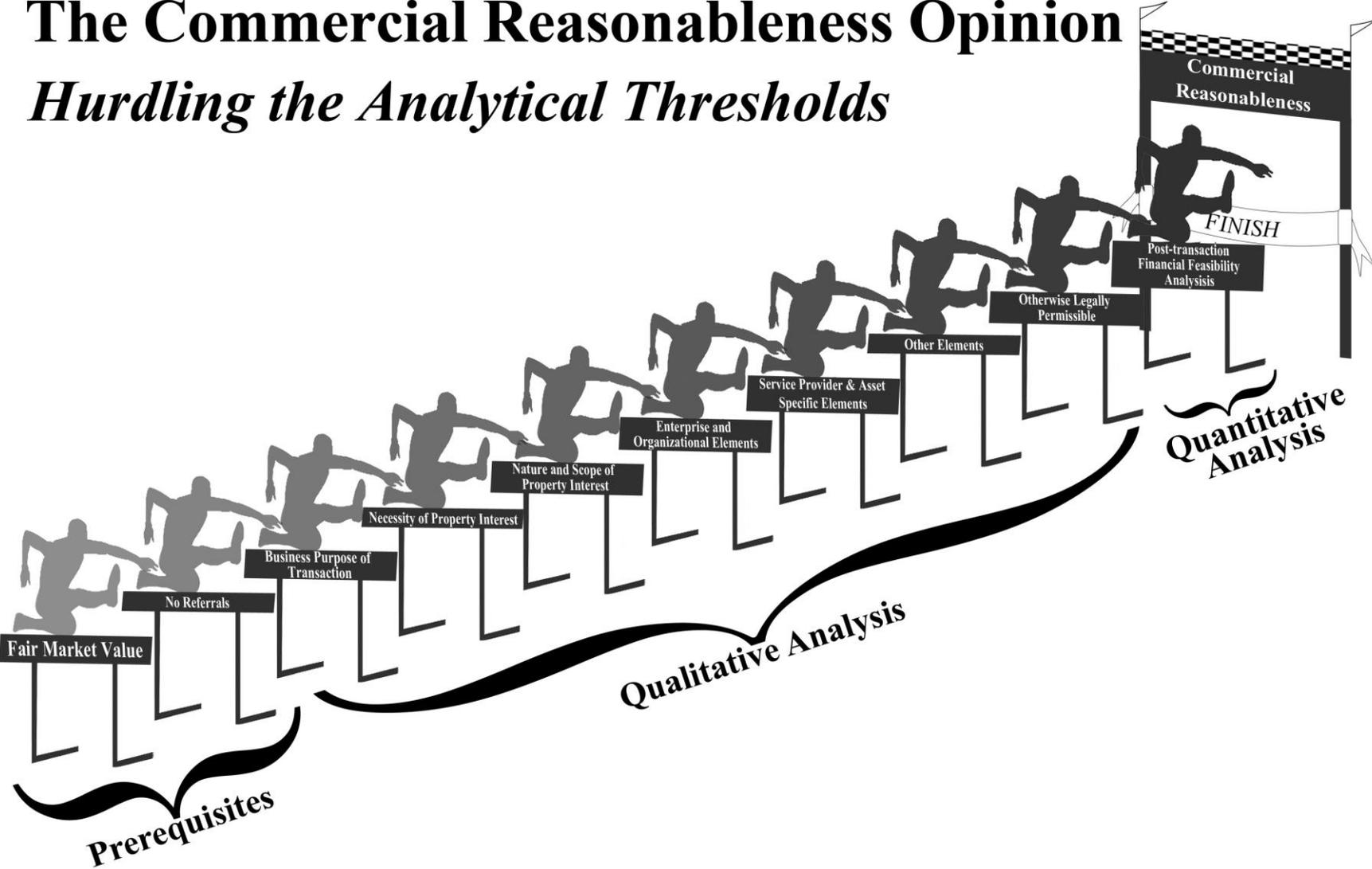
- Consideration paid for all aspects of the transaction must be at fair market value
- FMV is implicated by three distinct bodies of law that fall under the federal Fraud & Abuse laws:
  - Internal Revenue Code
  - Stark Law
  - Anti-Kickback Statute
- An FMV analysis will need to be completed by the appraiser to support the *Commercial Reasonableness* opinion

# Transactional Prerequisites

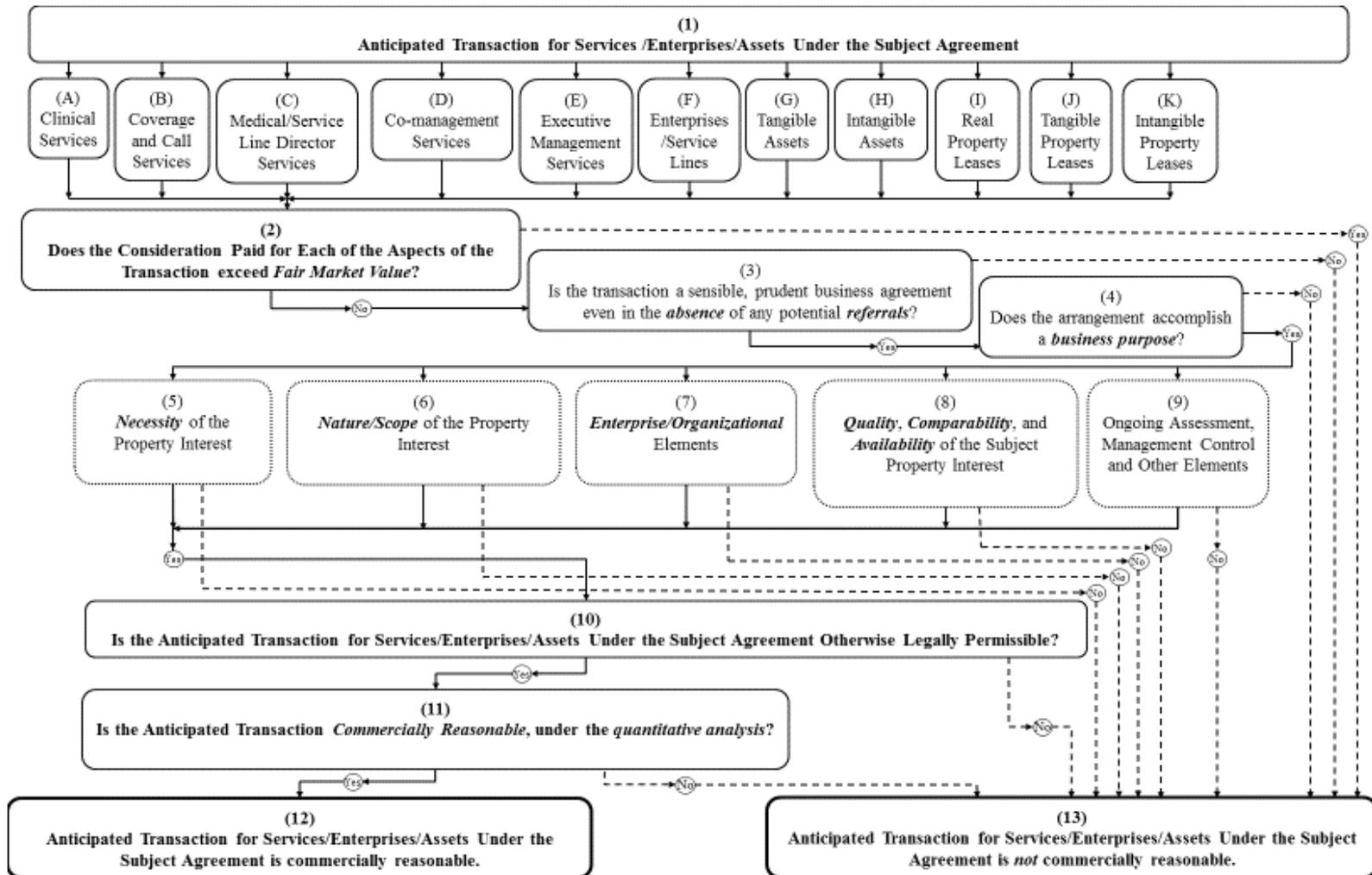
- *“Sensible, Prudent Business Agreement in the Absence of Referrals”*
  - Applies in the areas of:
    - *“rental of office space”*
    - *“rental of equipment”*
    - *“bona fide employment relationships”*
    - *“personal service arrangements”*
    - *“physician incentive plans”*
    - *“physician recruitment”*
    - *“isolated transactions, such as a one-time sale of property”*
    - *“certain group practice arrangements”*

# The Commercial Reasonableness Opinion

## *Hurdling the Analytical Thresholds*



# Qualitative Analytical Steps in Commercial Reasonableness Threshold



# Qualitative Analysis

- Business Purpose
  - The net economic benefits generated from the invested capital may **not** be the **sole business purpose** of the anticipated transaction
    - Includes focus on:
      - » Expansion into new geographic areas
      - » Expansion into new business lines
      - » Diversification benefits (e.g., diversifying payor mix, geographically)
      - » Increased asset utilization
      - » Improved research and development

# Qualitative Analysis

- Necessity of the Property Interest
  - The IRS requires a determination of whether the consideration paid for the property interest is “ordinary,” i.e., “common and accepted in trade or business;” and “necessary,” i.e., “helpful and appropriate for the trade or business;”, in light of the “the volume of business handled” by the acquirer, e.g., the number of “beds, admissions, or outpatient visits;” “the complexities of the business;” and/or, the “size of the organization.”

# Qualitative Analysis

- Nature and Scope of the Property Interest
  - The IRS has advised that the nature and scope of services provided should be analyzed to determine as to whether their cost is:
    - a *“cost of carrying on a trade or business;”*
    - undertaken *“for the production of income from the sale of goods or the performance of services;”*
    - *“...paid or incurred during the taxable year”;*
    - *“...reasonable in terms of the responsibilities and activities...assumed under the contract;”* and,
    - *“...reasonable in relation to the total services received.”*

# Qualitative Analysis

- Enterprise and Organizational Elements
  - The IRS pronouncements on reasonable compensation for tax purposes offer analysts guidance that a determination should be made as to whether the consideration paid for the property interest is “...*a sensible, prudent business agreement...*” within the context of:
    - “*the pay compared with the gross and net income of the business;*”
    - “*business policy regarding pay for all employees;*” and,
    - “*the cost of living in the locality,*” based on an analysis of the “*national and local economic conditions*” including whether the acquirer is located in a “*...rural, urban, or suburban*” area

# Qualitative Analysis

- Quality, Comparability, and Availability of the Subject Property Interest
  - Based on the nature and scope of the services provided, the analyst should determine those attributes which speak to the nature and quality of the services, assets, and enterprises included in the anticipated transaction, including the education and specialized training of those individuals subject to the transaction

# Qualitative Analysis

- Management Control, Ongoing Assessment, and Other Elements
  - The following elements should also be kept in mind:
    - The “*quality of management and interdisciplinary coordination*”
    - “*consideration given and received [is paid] under materially different circumstances*”
    - The openness of the proposal process
    - The effects of patient care and market competition

# Qualitative Analysis

- Otherwise Legally Permissible
  - Antitrust Considerations
    - Additional factors to consider when assessing the legal permissibility of the anticipated transaction may be found in Antitrust pronouncements by the Federal Trade Commission
    - The IRS prohibits excess benefit transactions between tax-exempt organizations (such as a hospital) and other parties, in which *“the value of the economic benefit provided exceeds the value of the consideration received for providing the benefit.”*

# Qualitative Analysis

- Otherwise Legally Permissible
  - Stark Law Considerations
    - The Federal Physician Self-Referral, or “*Stark Law*,” prohibits physicians from referring Medicare or Medicaid patients to an entity for designated health services (“*DHS*,” defined by HHS) if the physician, or an immediate family member, has a financial relationship with that entity
    - However, there are numerous exceptions, notably:
      - Bona fide employment exception
      - Personal services exception

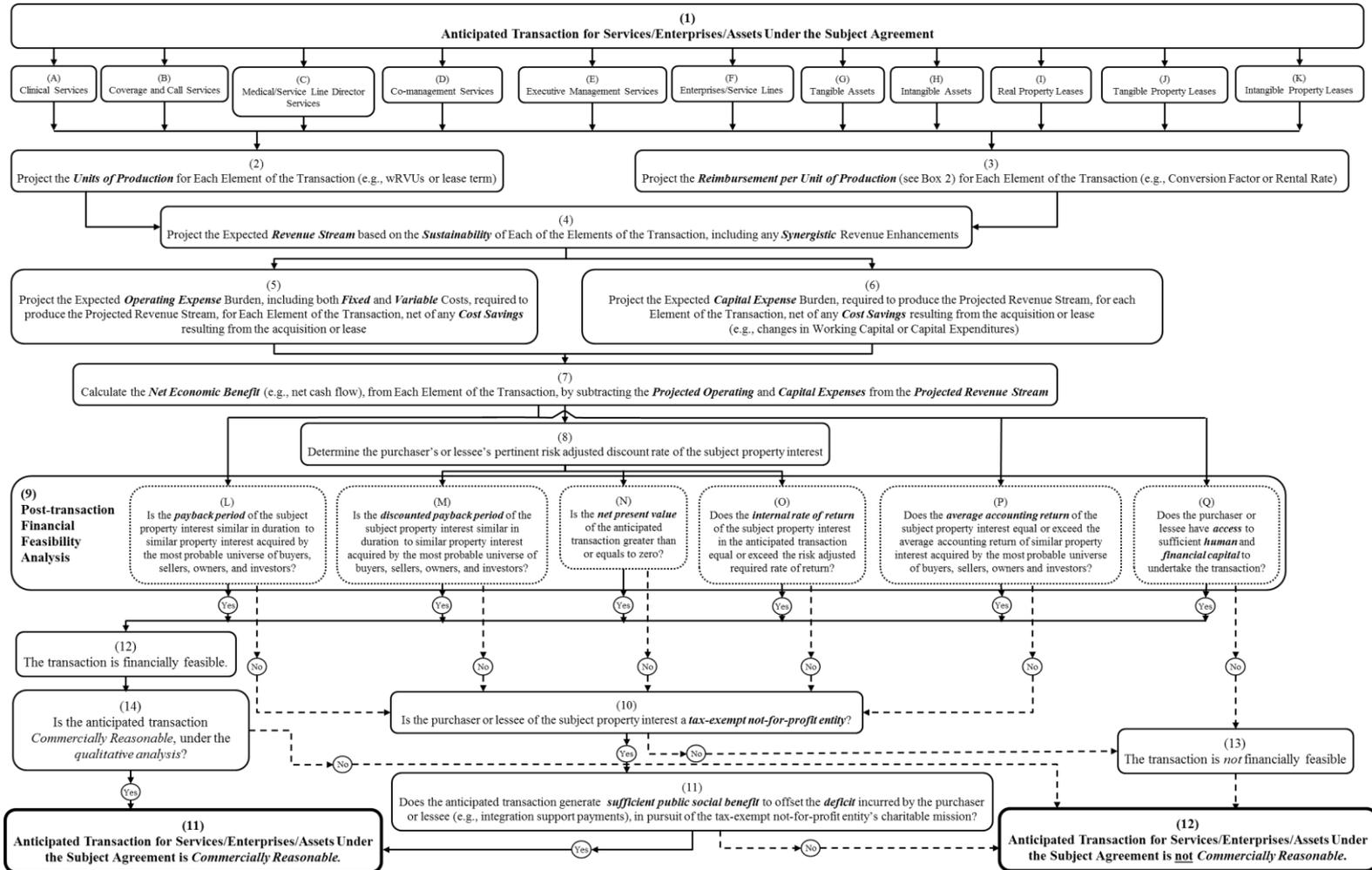
# Qualitative Analysis

- Otherwise Legally Permissible
  - Anti-Kickback Statute Considerations
    - The Anti-kickback Statute makes it illegal to:
      - *“knowingly and willfully solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.”*
  - However, there are safe harbors to the law, notably:
    - Employment safe harbor
    - Personal services and management contracts safe harbor

# Quantitative Analysis

- Post-Transaction Financial Feasibility Analysis
  - The analyst should also undertake a quantitative analysis as part of the determination of the *Commercial Reasonableness* of both the *discrete elements* and the *entirety* of the anticipated transaction
  - This post-transaction financial feasibility analysis takes into account all consideration to be paid by acquirers to sellers and lessors

# Quantitative Analytical Steps in the Commercial Reasonableness Threshold



# Post-Transaction Financial Feasibility Analysis

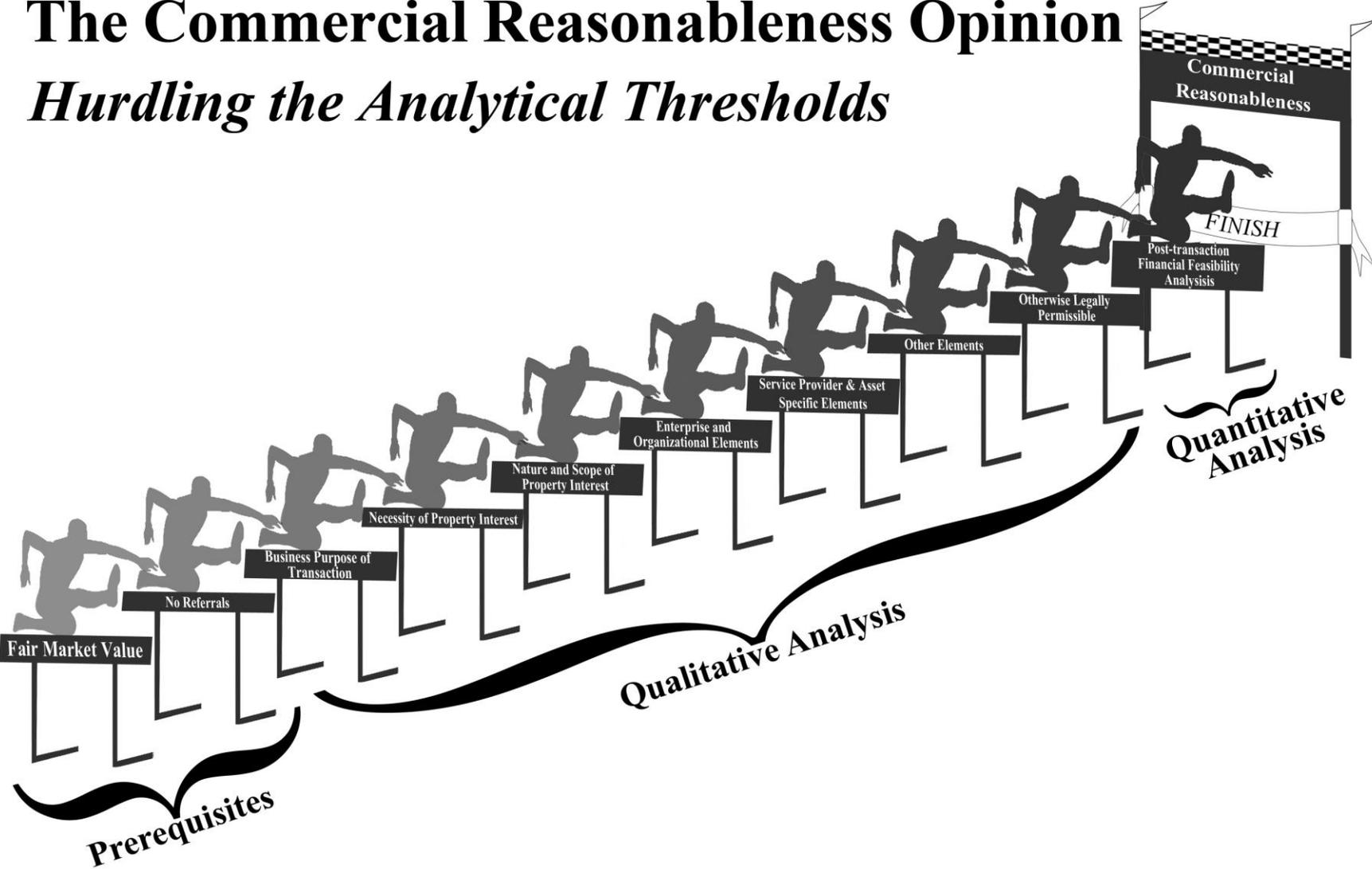
	TTM	Common Size		PAY 1	Common Size	PAY 2	Common Size	PAY 3	Common Size	PAY 4	Common Size	PAY 5
Revenue												
Professional Revenue (2)	\$10,978,453		(12)	\$11,921,167		\$12,225,054		\$12,536,685		\$12,856,213		\$13,183,937
wRVUs (3)	171,770		(13)	174,404		177,079		179,795		182,552		185,352
Reimbursement per wRVU (4)	\$63.91		(14)	\$68.35		\$69.04		\$69.73		\$70.42		\$71.13
with in Utilization Demand/Market Share			(15)	1.53%		1.53%		1.53%		1.53%		1.53%
Growth in Reimbursement			(16)	6.95%		1.00%		1.00%		1.00%		1.00%
Technical Revenue (5)	\$3,097,624		(17)	\$3,794,377		\$5,216,891		\$5,349,934		\$5,486,357		\$5,626,229
Units (6)	16,622		(18)	16,876		17,135		17,398		17,665		17,936
Reimbursement per Unit (7)	\$186.36		(19)	\$224.84		\$304.46		\$307.50		\$310.58		\$313.68
with in Utilization Demand/Market Share			(20)	1.53%		1.53%		1.53%		1.53%		1.53%
Growth in Reimbursement			(21)	20.65%		35.41%		1.00%		1.00%		1.00%
Total Revenue	\$14,076,077	100.00%	(8)	\$15,715,544	100.00%	\$17,441,945	100.00%	\$17,886,618	100.00%	\$18,342,570	100.00%	\$18,810,166
Total Non-MD Comp Expenses	\$8,453,719	60.06%	(22)	\$7,581,780	48.24%	\$7,775,066	44.58%	\$7,973,280	44.58%	\$8,176,521	44.58%	\$8,384,958
Physician Compensation Related Expenses												
Physician Shareholder Salaries (9)	\$5,315,152	37.76%	(23)	\$7,837,716	49.87%	\$7,957,930	45.63%	\$8,079,987	45.17%	\$8,203,887	44.73%	\$8,329,719
Physician Benefits	\$840,385	5.97%	(24)									
Health Care	\$0	0.00%	(24)	\$186,550	1.19%	\$186,550	1.19%	\$186,550	1.19%	\$186,550	1.19%	\$186,550
Taxes	\$0	0.00%	(24)	\$203,615	1.30%	\$208,769	1.33%	\$210,539	1.34%	\$212,335	1.35%	\$214,160
Pension	\$0	0.00%	(24)	\$156,754	1.00%	\$159,159	1.01%	\$161,600	1.03%	\$164,078	1.04%	\$166,594
CME & Meals	\$0	0.00%	(24)	\$49,000	0.31%	\$49,000	0.31%	\$49,000	0.31%	\$49,000	0.31%	\$49,000
Dues & Subscriptions	\$0	0.00%	(24)	\$24,250	0.15%	\$24,250	0.15%	\$24,250	0.15%	\$24,250	0.15%	\$24,250
Signing Bonus	\$0	0.00%	(25)	\$208,000	1.32%	\$208,000	1.19%	\$208,000	1.16%	\$208,000	1.13%	\$208,000
Quality Incentive Bonus	\$0	0.00%	(26)	\$416,000	2.65%	\$416,000	2.39%	\$416,000	2.33%	\$416,000	2.27%	\$416,000
Total MD Comp Related Expenses	\$6,155,537	43.73%		\$9,081,885	57.79%	\$9,209,658	52.80%	\$9,335,926	52.20%	\$9,464,100	51.60%	\$9,594,273
Total Operating Expenses (10)	\$14,609,256	103.79%		\$16,663,665	106.03%	\$16,984,724	97.38%	\$17,309,206	96.77%	\$17,640,621	96.17%	\$17,979,231
Net Operating Income Before Adjustments (11)	(\$533,179)	-3.79%		(\$948,121)	-6.03%	\$457,222	2.62%	\$577,412	3.23%	\$701,949	3.83%	\$830,935
Cumulative Cash Flow			(29)	(\$2,748,121)		(\$2,290,899)		(\$1,713,487)		(\$1,011,538)		(\$180,603)
Initial Investment			(27)	(\$1,800,000)								
Payback Period	5.17											

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# The Commercial Reasonableness Opinion

## *Hurdling the Analytical Thresholds*



Part VI:  
The Potential Evolution of Commercial  
Reasonableness in a Changing Healthcare  
Reimbursement Environment

# Potential Evolution of Commercial Reasonableness in a Changing Reimbursement Environment

- *Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)*
  - Alternative Payment Model (APM) program
  - Merit-Based Incentive Payment System (MIPS)

Conclusion

Questions  
and  
Answers

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