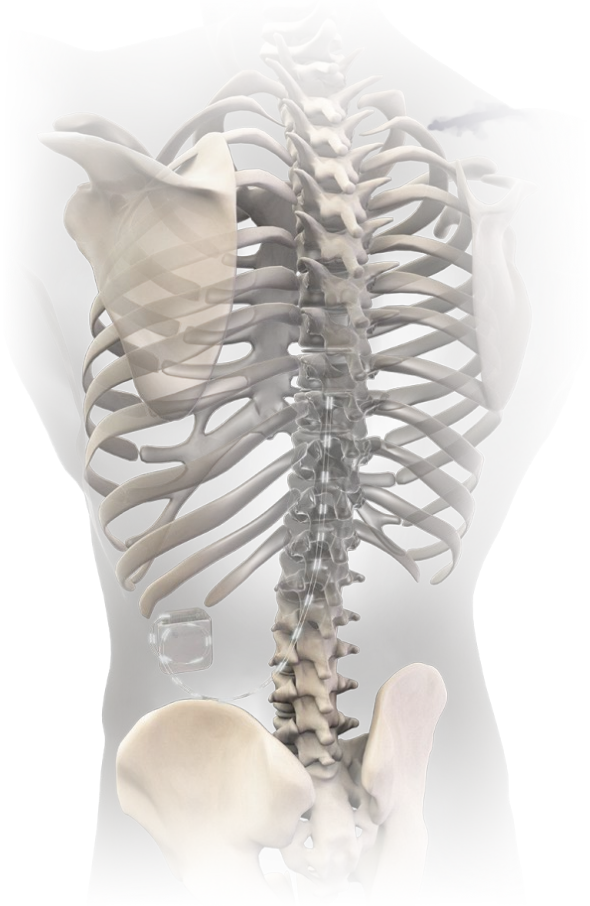

Practice Expansion

Outside of Fee for Service

Sean Li, MD
Premier Pain Centers,
Affiliate of National Spine and Pain Centers
Shrewsbury, NJ
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AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
THE VOICE OF INTERVENTIONAL PAIN MANAGEMENT

NJSIPP

NATIONAL Spine & Pain CENTERS

Disclosure

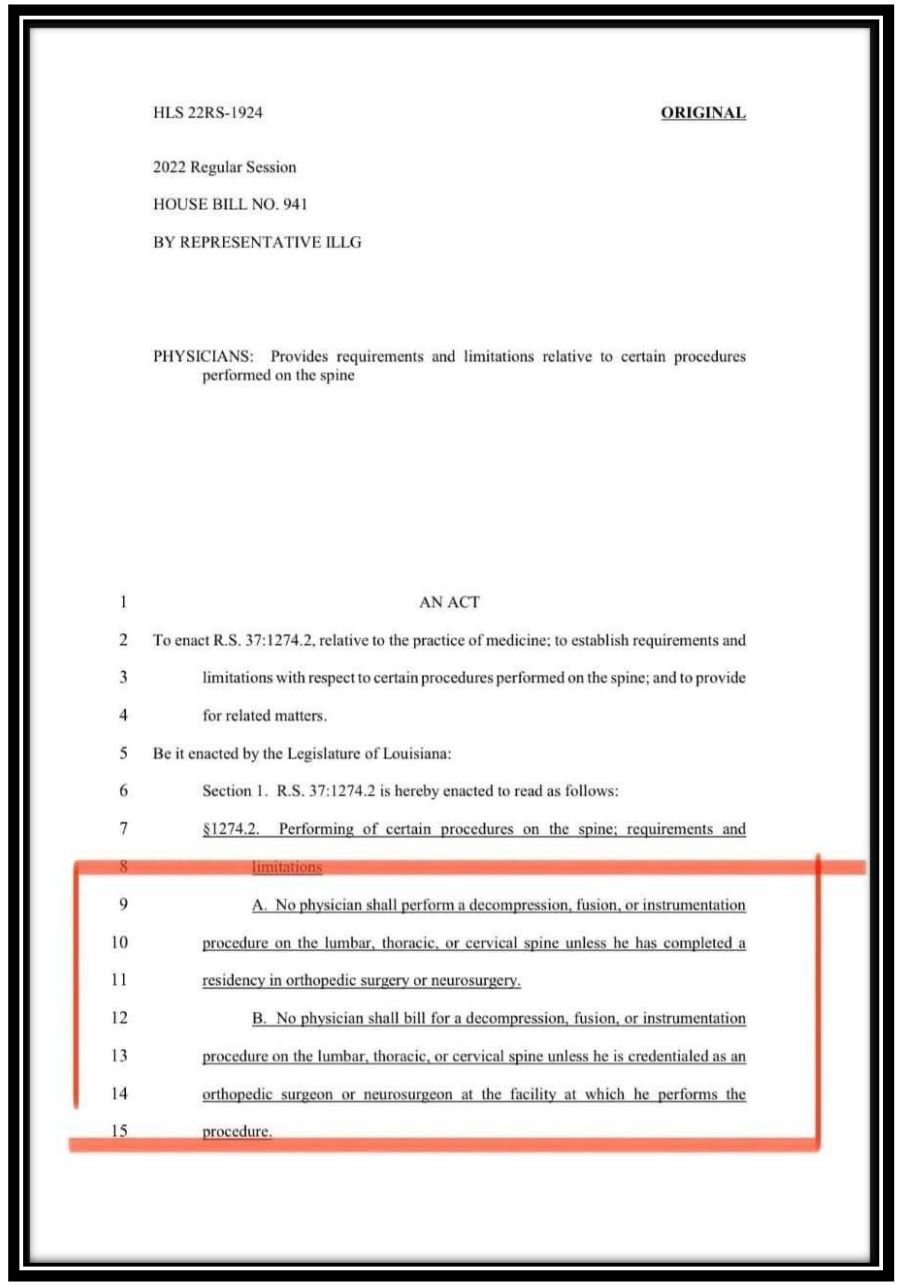
- Consultant/Independent Contractor: Abbott, Avanos, Averitas Pharm, Biotronik, Boston Scientific, Nalu, Nevro, PainTeq, Saluda, SPR Therapeutics, Vertos Medical
- Grant/Research Support: Avanos, Biotronik, Boston Scientific, SGX Medical, Nalu, PainTeq, Saluda, SPR Therapeutics
- Advisory Board: Abbott, Saluda
- Equity: Nalu, National Spine and Pain Centers

Outline

- Obstacles in private practice model
- Ancillary services
- Alternative revenue streams
- Practice modification

Obstacles and Challenges in IPM

- COVID-19 Pandemic
- Increasing overhead expenses
- Decreasing reimbursement
- ***Un***-Affordable Care Act
- Insurance denials: LCDs, NCDs
- Changing insurance policies
- Emerging tuff war in scope of practice



HLS 22RS-1924 **ORIGINAL**

2022 Regular Session

HOUSE BILL NO. 941

BY REPRESENTATIVE ILLG

PHYSICIANS: Provides requirements and limitations relative to certain procedures performed on the spine

AN ACT

To enact R.S. 37:1274.2, relative to the practice of medicine; to establish requirements and limitations with respect to certain procedures performed on the spine; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1274.2 is hereby enacted to read as follows:

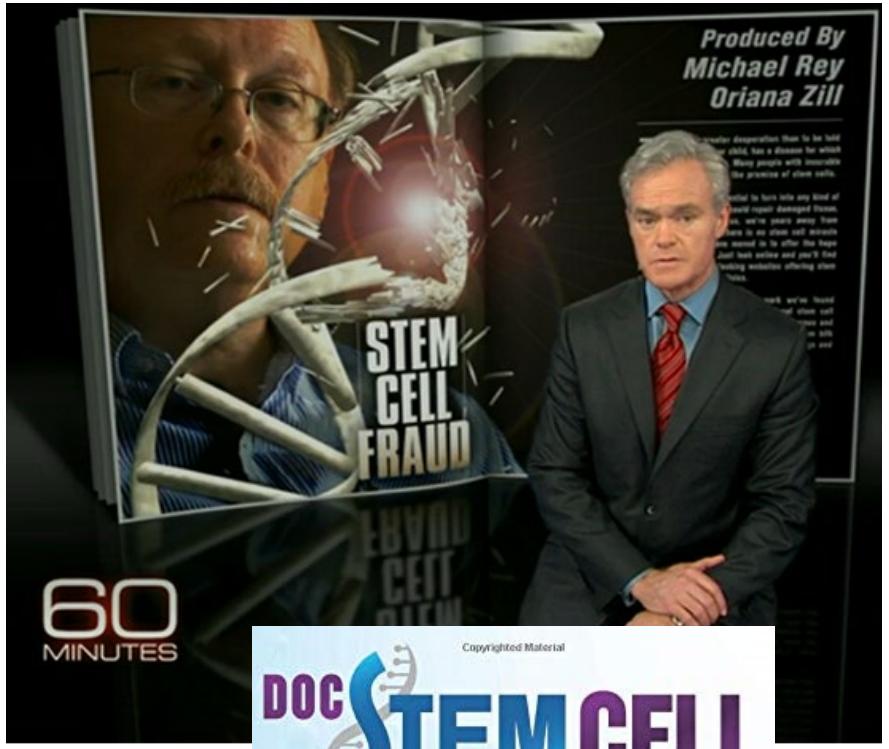
§1274.2. Performing of certain procedures on the spine; requirements and limitations

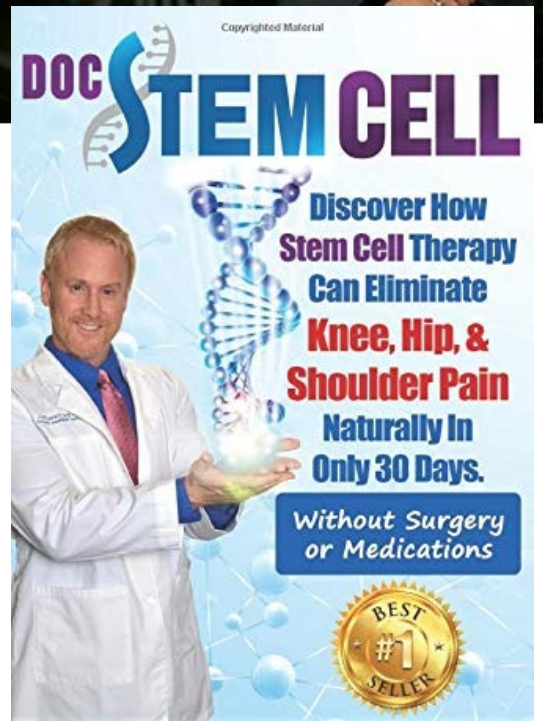
A. No physician shall perform a decompression, fusion, or instrumentation procedure on the lumbar, thoracic, or cervical spine unless he has completed a residency in orthopedic surgery or neurosurgery.

B. No physician shall bill for a decompression, fusion, or instrumentation procedure on the lumbar, thoracic, or cervical spine unless he is credentialed as an orthopedic surgeon or neurosurgeon at the facility at which he performs the procedure.

Meanwhile…

- Lack of business training in med school
- Bad press for pain management
- Fear of change, “creature of habit”
- Inefficient utilization of ancillary services
- Must think beyond operational



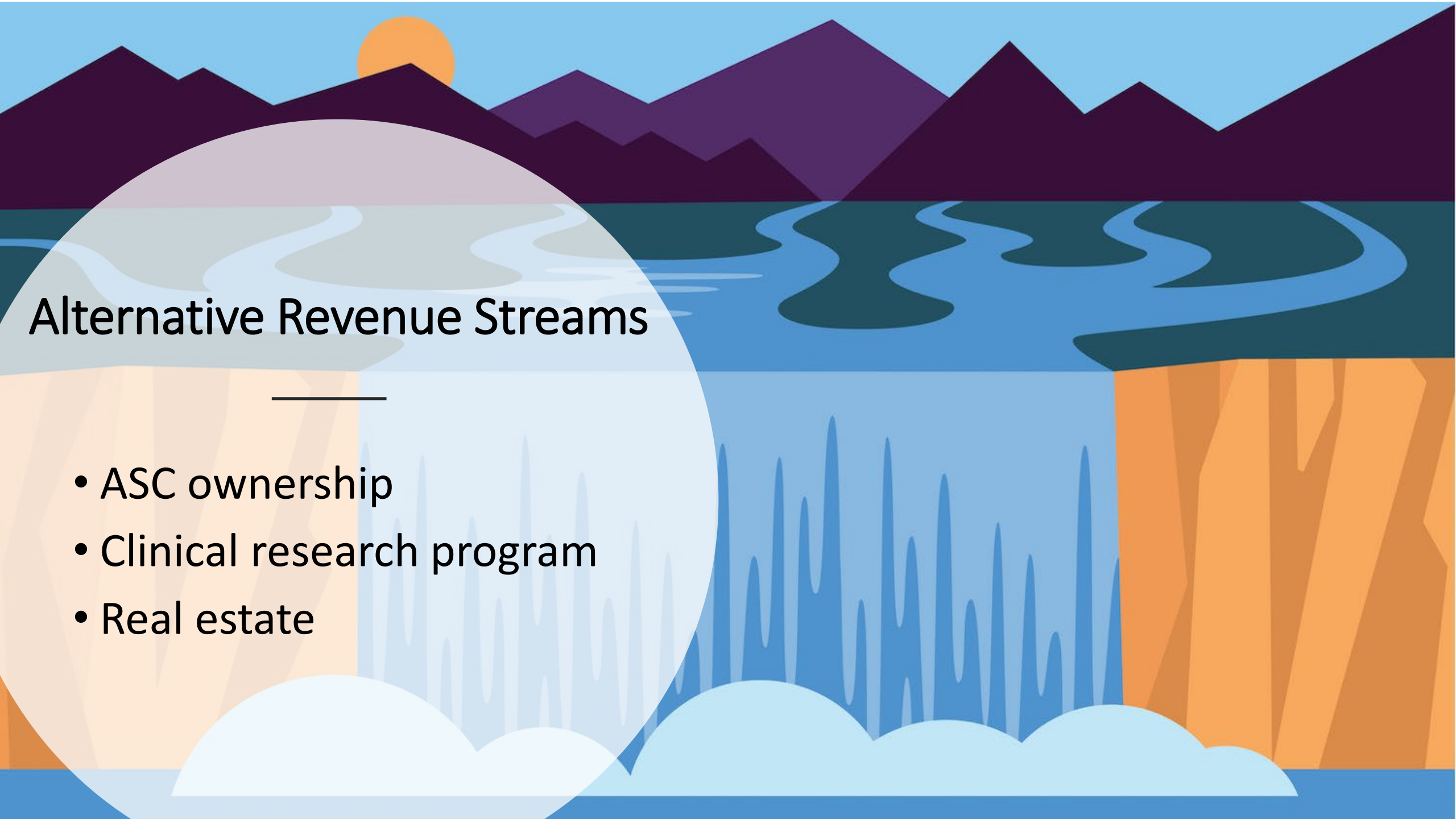


Growth Potentials in Private Practice

- Revenue cycle management
  - Digital marketing
  - Social media presence
  - *Practice modification*
  - *Ancillary services*
- *Alternative revenue streams*

Ancillary Services

- Durable Medical Equipment (DME) Program
- High complexity drug testing
- In-office sedation (Pro-Nox)
- Regenerative medicine
- Ketamine infusion
- Medication dispensing
- Compounding pharmacy
- Aesthetics
- Wellness program
- Physical Therapy
- Diagnostic imagining and testing



Alternative Revenue Streams

- ASC ownership
- Clinical research program
- Real estate

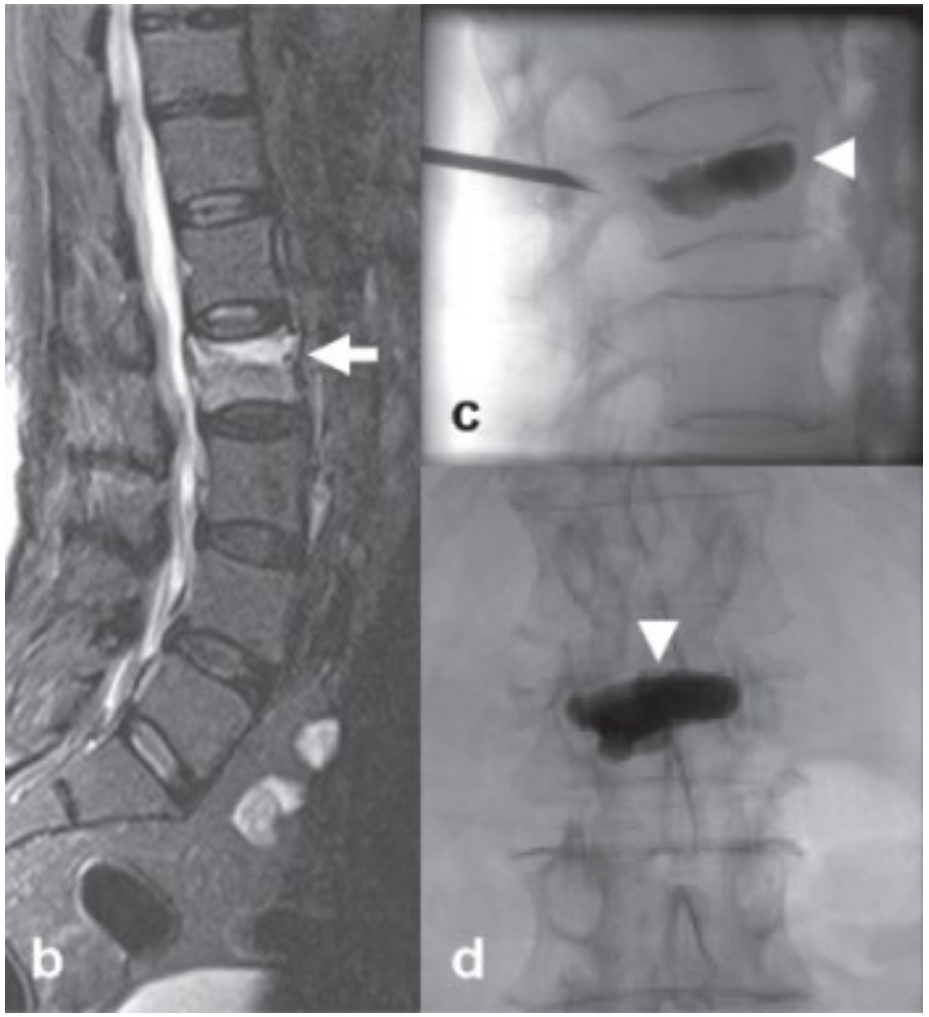
PRACTICE CHANGE

Practice Modification

- Advanced practice providers (PA, NP)
- High acuity IPM procedures
- Ancillary concierge practice
- Worker’s compensation
- Personal injury protection
- Sell practice to private equity

High Acuity Interventional Procedures

- Expansion of interventional practice
- Spinal cord stimulation
- In-office kyphoplasty
- Targeted drug delivery therapy
- Peripheral nerve stimulation
- MILD, interspinous spacers
- Minimally invasive lumbar fusion
- Posterior sacroiliac join stabilization
- Endoscopic discectomy



Merchandising

- Direct to patient sales
- CBD products
- Medical Foods
- Dietary supplements and vitamins
- Books (even your own!)
- Vending Machine

Medical Legal Consulting

- Develop relationships: attorneys, NCM
- PIP (Personal Injury Protection)
- Work Comp: Independent Medical Examinations
- Expert Witness
- Consulting work to state and federal agencies
- Medical Liability Work: plaintiff vs defense
- Case Reviews for Managed Care organizations

Consulting for Industry

- Becoming a “KOL” not an “influencer”

- “KOL”: **trusted, respected professional with proven experience and expertise**
  - Clinical excellence
  - Principal investigator
  - Peer reviewed publications
- “Influencer”: a person with the **ability to influence** buyers of a product/services

- Key Opinion Leaders Work Full-Time vs. Influencers Spend Their Work Time Online

https://influencermarketinghub.com/kols-key-opinion-leader/

https://www.definitivehc.com/resources/glossary/key-opinion-leader#

Safety in Numbers: Join a Larger Group

- Established HER
- Robust compliance and human resource department
- Negotiation power with insurance contracts
- Bundled multi-product industry contracts
- Sophisticated marketing strategy
- Diversified ancillary revenue streams
- Ambulatory surgery centers

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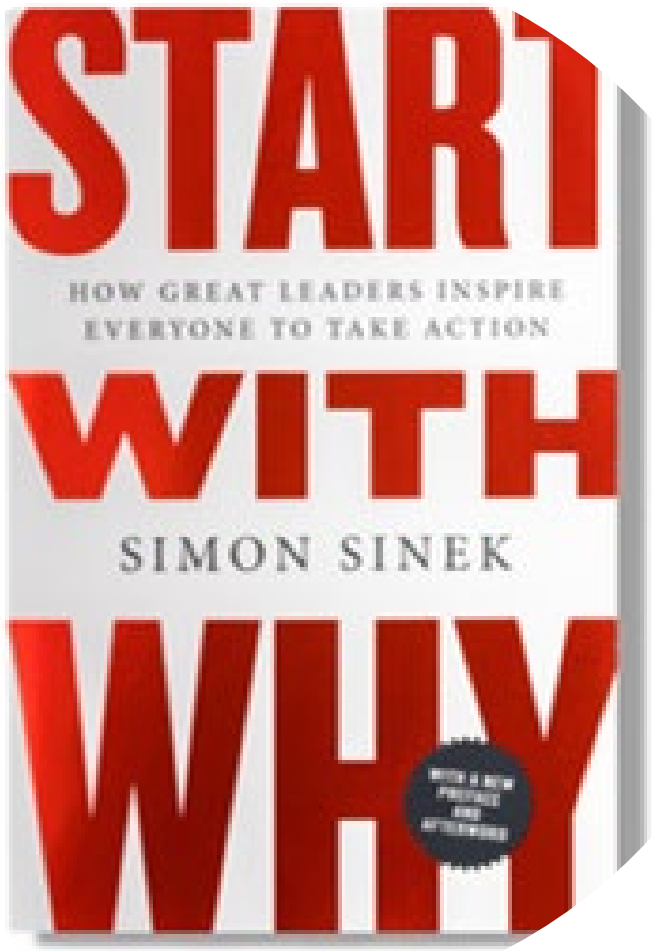
Selling Your Practice

- EBIDTA- Earnings Before Interest, Taxes, Depreciation and Amortization
- An approximate measure of a company's operational cash flow
- The measure by which a medical practice is valued for purchase
- Practices can sell for 5-8x EBIDTA
- Private equity groups
- Trade autonomy for work/life balance



Why clinical research?

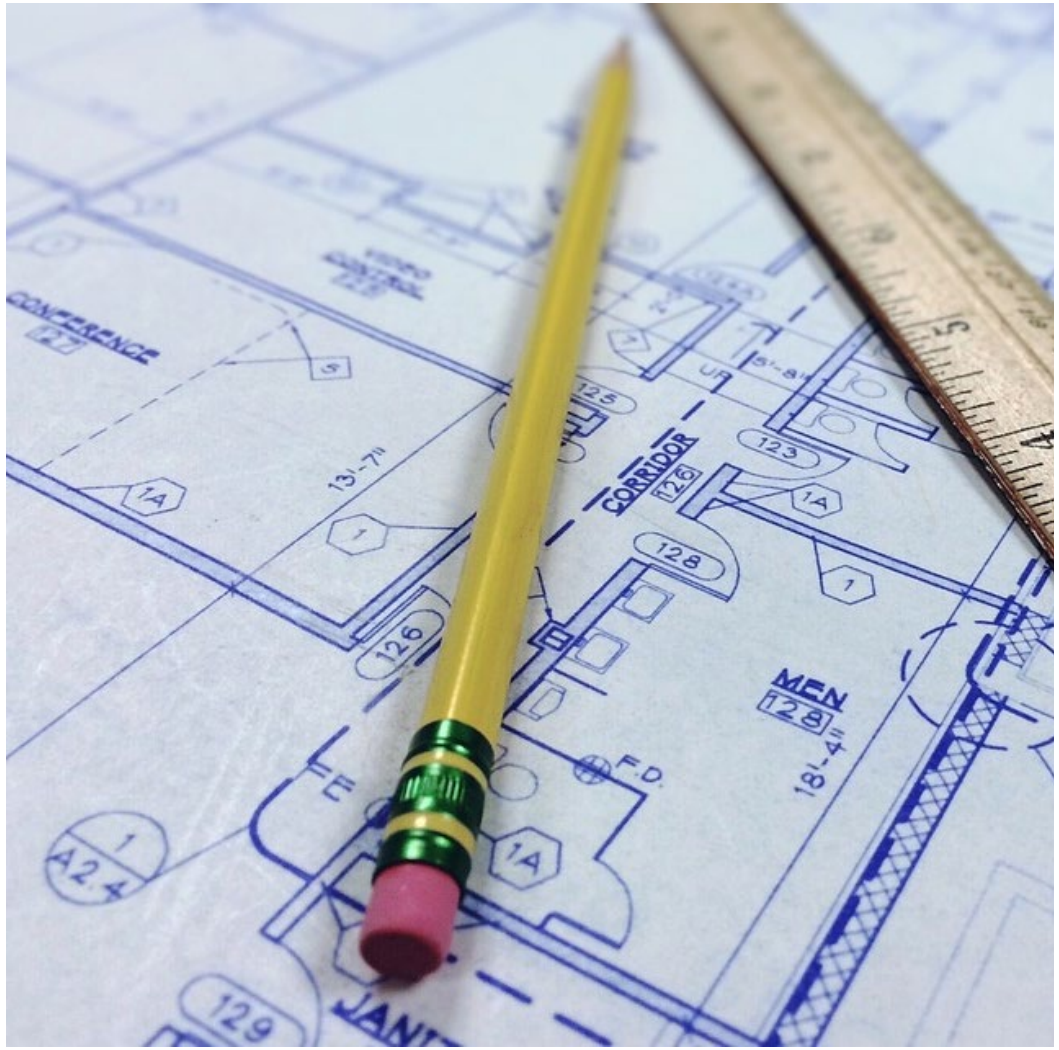
- ***Purpose and passion***
- Expand therapy options for patients
- Differentiate from competitors
- Rewarding and very exciting
- Advance the science
- New colleagues and friendships
- Clinical practice, research, and education
- Participate in ***publications***
- Podium presentation opportunities
- Become a key opinion leader (KOL)
- Can be financially **profitable**
- Not for everyone!

Types of Research

- Case report
- Case series
- Systematic review
- Investigator initiated
- Sub-investigator role
- Industry sponsored
- NIH RO1 study

Logistics and Infrastructure

- “The line between disorder and order lies logistics”, …Sun Tzu
- Time?
- Permission: partners, group, corporation
- Patient volume
- Office space: secured room, fireproof cabinet, exam room
- Research team
- Research budget and funding
- Time: office schedule, research meetings, site-visits
- No such thing as “academic time” in private practice



Research Team

- Principal investigator
- Research coordinator (CRC)
- Sub-investigator(s), optional
- Adv. practice provider(s)
- Medical assistant(s)
- Emergency coverage (partners)

- □ Non-Disclosure Agreement (NDA)
- □ Feasibility Questionnaire
- □ Protocol Synopsis Review
- □ Clinical Trial Agreement (CTA)
- □ Budget Review
- □ IRB Initial Submission
- □ Informed Consent Review (ICF)
- □ Financial Disclosures (FDF)
- □ Collection of CV’s, GCP’s, and Medical Licenses
- □ Site Qualification Visit (SQV)
- □ Site Initiation Visit (SIV)


Ambulatory Surgery and
Medical Procedures Center
4270 Plymouth

Ambulatory Surgery Center

- Distinct entity, exclusively for providing surgical services
- Duration of services < 24 hours without hospitalization
- First ASC 1970, now over 5,300 Medicare-certified ASC
- 2008-2011, ASC saved Medicare beneficiaries $7.5B
- Medicare reimburse ASC 58% of rate to HOPD
- Facility fee is 3-4x of professional fee
- Expensive to build, average $1-2 million/room
- Buying into an existing ASC is an option
- Quarterly distributions if the ASC is profitable

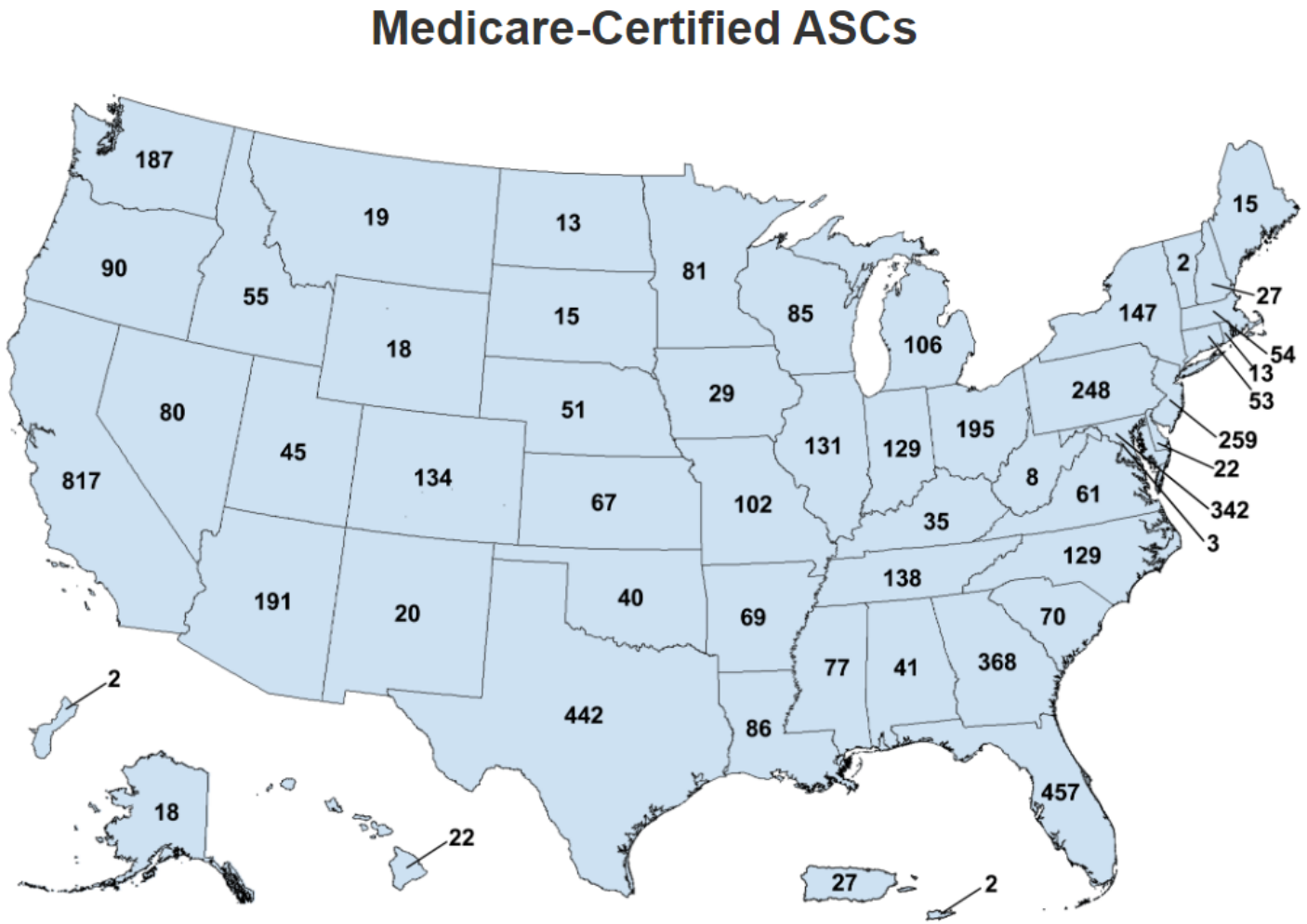
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/ASCs.html

https://www.ascassociation.org/advancingsurgicalcare/reducinghealthcarecosts/costsavings/medicarecostsavingstiedtoascs

Types of ASC Ownership Models

- Single room versus multi-room ASC
- Single specialty versus multi-specialty ASC
- 100% physician owned
- Joint physician/hospital system
- Physician/management organization
- Physician/hospital/management organization
- Hospital owned

Number of ASCs per State



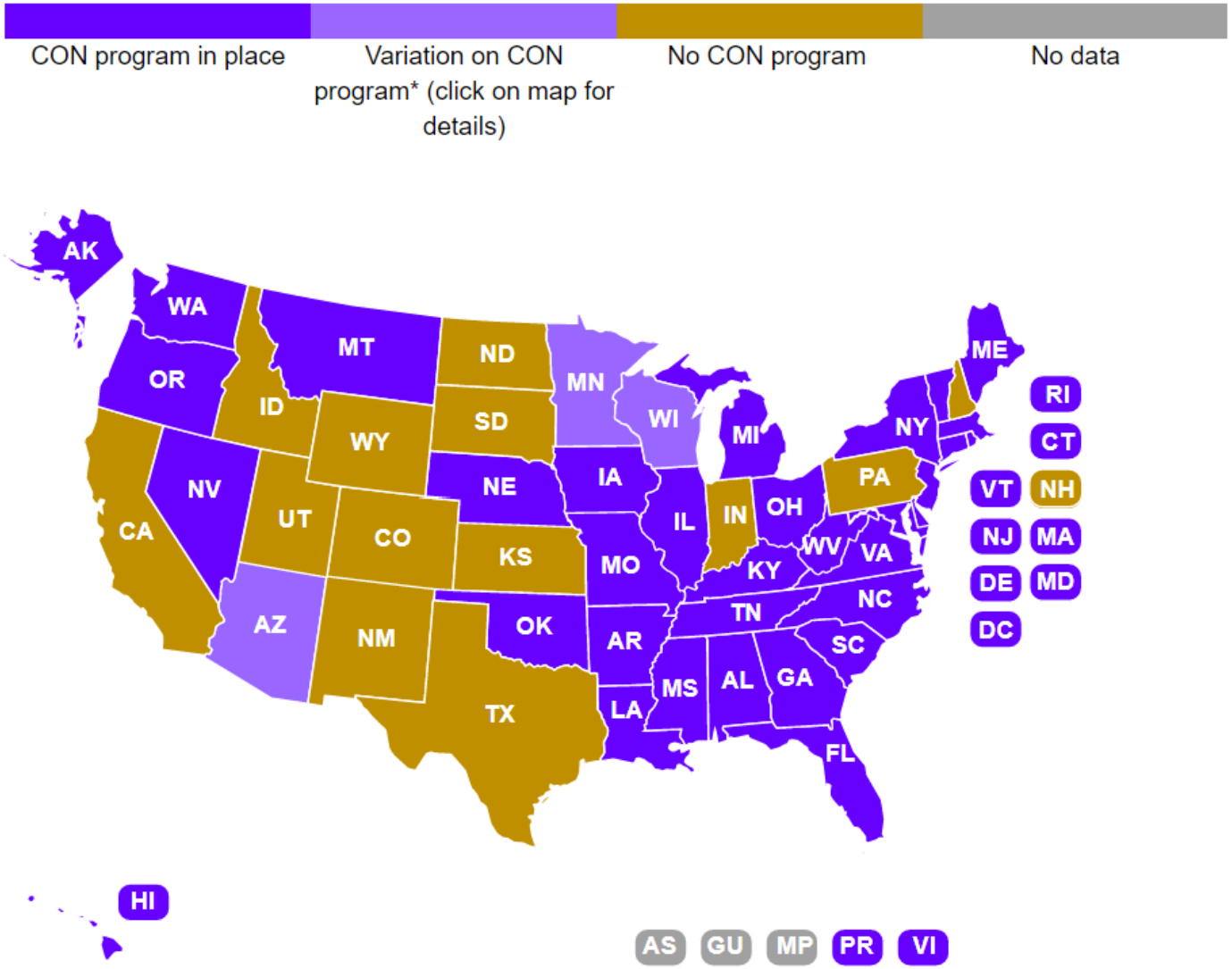
Based on data provided by the Centers for Medicare & Medicaid Services (CMS), March 2021

Certificate of Need (CON)

- Hill-Burton Act of 1946, control the increase of medical facilities
- 1964, New York first CON state
- Eventually all but Louisiana enacted similar laws
- 1987, federal mandate was repealed
- 14 states discontinued, (NH last to repeal 2016, GA pending)
- 34 states maintain CON status
- Including Puerto Rico, US Virgin Islands, District of Columbia

http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx

CERTIFICATE OF NEED STATE LAWS



Source: NCSL, August 2016

http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx

Potential Benefits of Physician ASC Ownership

- Patient access and convenience
- Accountability
- Enhanced delivery of care by specialty
- Efficiency
- Lower cost of service
- Improved overall patient experience
- Professional control over clinical environment
- Incentivized model of profit sharing
- OWNERS SPLIT PROFITS AFTER EXPENSES ACCORDING TO OWNERSHIP

Operational Challenges of ASC

- Maintaining case load…revenue cycle management
- Turbulence of healthcare reimbursement
- Constant scrutiny by accreditation agencies
- Patient satisfaction surveys…”Press Ganey”
- Addition of new surgeon: staffing, equipment
- Departure of surgeon: reduced case volume
- Share price can fluctuate
- Current shareholders: dilution of share value?
- Restrictive covenant
- Hospital employment restrictions

Regulatory Concerns of ASC Ownership

- **Stark Law**
- Federal law prohibits physicians from referring Medicare or Medicaid beneficiaries to an entity in which they (or family) have financial relationship for designated health services (DHS)

- **New York State's mini-Stark Law**
- More extensive, includes all practitioners, all referrals of health services, without the exemptions listed on the federal law

- **New Jersey Codey Law**
- The original prohibition on physician self-referral.

Federal Anti-kickback Statute

- Prohibits anyone from offering paying, soliciting, or providing anything of value in exchange for the referral of healthcare business
- **The ASC Ownership Safe Harbor**:

  1) surgeon-owned ASCs;
  2) single specialty ASCs;
  3) multi-specialty ASCs; and
  4) hospital/physician-owned ASCs

- **Fair Market Value (EBITDA)**
- Investment interest is not be related to volume of referrals (Stark Law)
- Entity must not loan or guarantee loan to investor
- Payment must be **proportional** to the capital invested
- **The "one-third" Test**
  - Must generate at least 1/3 of professional income (Medicare)
  - Must perform 1/3 of procedures at the invested entity

Red Flags in ASC Ownership

- Capital invested is disproportionately small compared to large returns
- Small nominal fee investment
- Investor allowed to “borrow” the capital through deductions from distributions
- Extraordinary returns
- Requirement to bring certain types of cases or volume

SUMMARY

- Private practice IPM must evolve with changing climate
- Traditional fee for service model no longer sustainable
- Incorporate non-traditional revenue sources
- Remain on the correct side of the law
- Expand your scope of practice and services
- Explore and expand symbiotic relationships

NATIONAL Spine & Pain CENTERS

REGISTRATION IS OPEN!
October 20-23, 2022

THE BUSINESS OF PAIN MEDICINE

Orlando World Center Marriott
Orlando, FL