ASCs: Flexibilities and Pitfalls

Health Law Webinar

September 10, 2025

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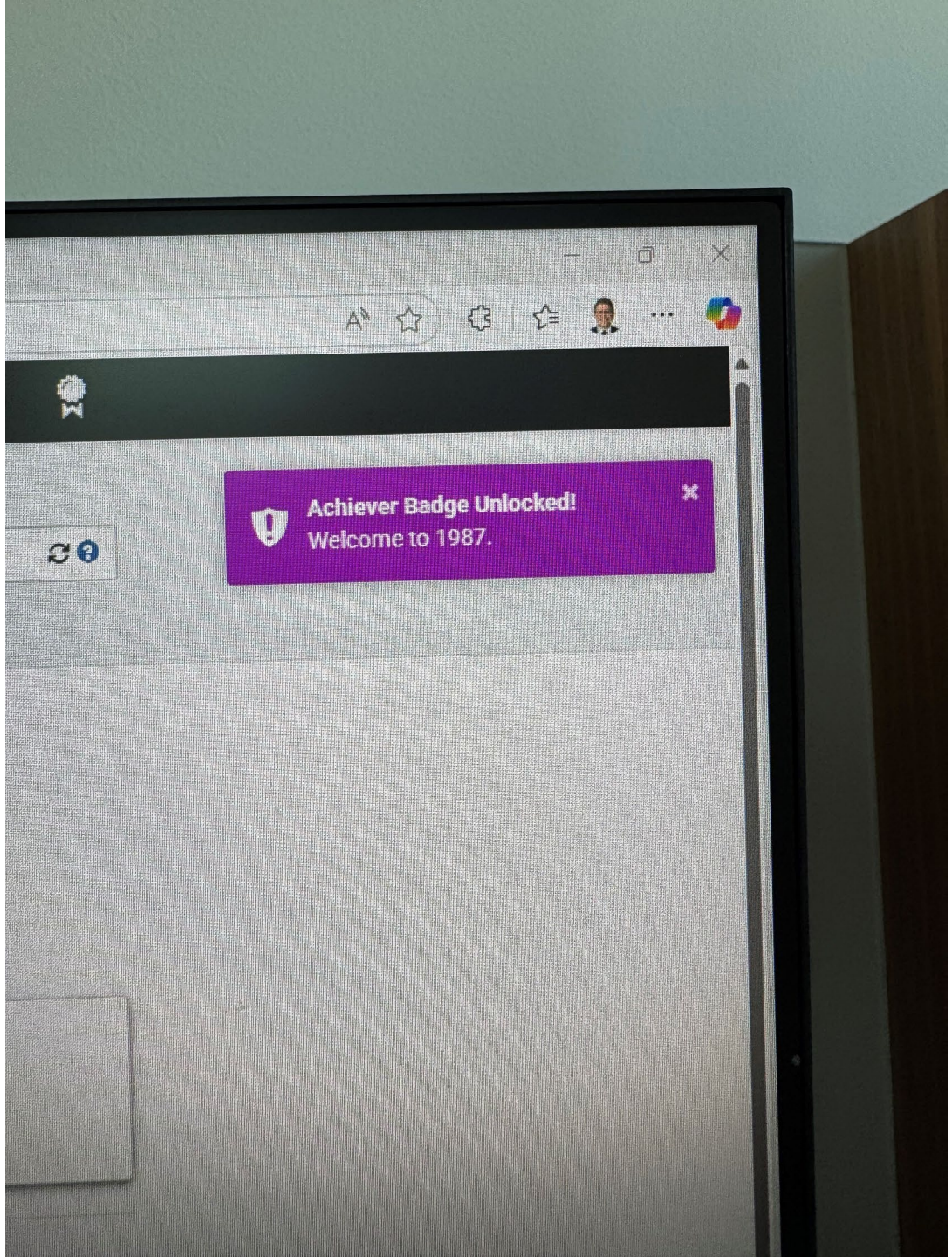

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Agenda

- The Legal framework around ASCs?
- Limits on relationships (antikickback etc.) and how they are misunderstood.
- How do you structure it?
- How do you allocate income?
- The perils of management contracts.
- Special issues with hospital/physicians JVs.
- Miscellaneous issues.

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Ambulatory Surgical Centers

- SSA §1832(a)(2)(F).
- SSA §1833(i).
- 42 CFR §416.
- See the approved list of procedures. Note the proposed 3 year inpatient only list phaseout!
- State Operations Manual Appendix L.

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How Are ASCs Different from Outpatient Hospitals?

- Reimbursement.
- Licensure.
- Conditions of participation.
- ASCs can be anywhere, outpatient surgery must be on campus.
- Stark, or lack thereof.

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Limitations on Financial Relationships

- Not a DHS under Stark.
- The antikickback safe harbors are widely misunderstood.
- The safe harbors are NOT requirements.

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Important Reminder

- “Arrangements are not necessarily unlawful because they do not fit in a safe harbor. Arrangements that do not fit in a safe harbor are analyzed for compliance with Federal anti-kickback statute based on the totality of their facts and circumstances, including the intent of the parties.”

85 F.R. 77685

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Limitations on Financial Relationships

- The real question: Is anyone paying for referrals?
  - Is a hospital offering improper remuneration to encourage referral of hospital patients?
  - Are surgeons including referral sources such as internists/ family practitioners to obtain surgery referrals?
- The government wants active investors. If you have that, ASCs are very low risk.

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Safe Harbors: 42 CFR §1001.952(r)

- Four safe harbors:
  - Surgeon-owned ASCs.
  - Single-specialty.
  - Multi-specialty.
  - Hospital physician.

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Physician/Hospital Safe Harbor

- Investment terms can’t be related to referrals.
- Hospital can’t lend/provide guarantee to Drs. to finance the venture.
- Payout proportional to investment.
- No discrimination against federal beneficiaries.
- No use of hospital space/equipment w/o safe harbor-compliant lease.

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Physician/Hospital Safe Harbor

- All ancillaries to government pts. must be related to ASC services and services must be billed by ASC.
- Hospital can’t include costs on cost report.
- Hospital may not be in a position to make or influence referrals directly or indirectly to any investor.

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Active Investment: 1/3 Test

- 1/3 of each Dr. investor's medical practice income from all sources derives from the physician's performance of “procedures.”
- 1/3 of each Dr. investor’s “procedures” performed at the investment entity.

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Definitions are Important

- "For purposes of paragraph (r) of this section, procedures means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by the Department and group practice means a group practice that meets all of the standards of paragraph (p) of this section. Surgical group practice means a group practice that meets all of the standards of paragraph (p) of this section and is composed exclusively of surgeons who meet the requirements of paragraph (r)(1) of this section.

42 CFR 1001.952(r)(5)

Getting Practical

- It can be done.
- You won’t meet a safe harbor.
- In rural areas, you may be able to try a different approach, joint venturing the outpatient hospital services. This may result in better reimbursement.

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Getting Practical

- If a tax-exempt entity is involved, you must worry about tax exemption in addition to other rules.
- The law as leverage:
  - CON often creates most leverage.
  - The 1/3 tests.
  - The *Redlands and St. David's* cases.

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Tax-Exemption Issues

- Tax Issues.
  - EO must have formal or informal control over JV sufficient to ensure furtherance of charitable purposes.
    - *Redlands, St. David's, Rev. Rul. 98-15, Rev. Rule 2004-51, etc.*

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Getting Practical – Tax Exemption Issues

- Address Control Issues:
  - Governance Rights/Board Control.
  - Reserve Powers.
  - Dispute Resolution Provisions.
- Financial Arrangements:
  - Fair Market Value.
  - Equity, Management Agreements, Leases, etc.
- Sharing of Liabilities/Risks:
  - Proportionate to ownership.

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Getting Practical – Tax Exemption Issues

- Unwind/Separation Provisions.
- Address Charitable Purposes:
  - Open Medical Staff.
  - Charitable-Care Policy.
- Use of a For-Profit Subsidiary.

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Legal Framework – State Laws

- CON.
- Fee splitting.
- Antikickback laws.
- Financial interest disclosures.

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Assessing ASC Investment Options

- De novo vs. existing ASC.
  - Single-specialty.
  - Multi-specialty.
  - Hospital JV.
- Benefits of joint ventures.
- Consider exit strategies.

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Structure

- Choice of Entity.
- Investor Selection.
- Buy-Sell Provisions.
- Governance Issues.

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Structure: Investor Selection

- Business Considerations.
  - Want engaged, active investors who use the ASC as an extension of their practice.
- Regulatory Considerations.
  - AKS Safe Harbor.
    - Extension of practice (1/3rd test, not based or conditioned on referrals).

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Getting Practical – Investor Selection and Terms

- Don’t let individual non-surgeon physicians invest (except anesthesia/those who don’t refer).
  - An entire clinic investing is less troubling.
- Don’t allow a hospital to subsidize physicians.
- Antikickback issues are very fact specific.
  - The poorly worded memo/e-mail can bite.
  - Geography/participants can drive the analysis.
- Good antikickback analysis is seldom expensive.

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Buy-Sell Provisions

- For Cause.
  - Failure to Satisfy Extension of Practice Requirements or Other Investor Requirements.
  - Other Material Breaches.
- Without Cause.
- Redemption Price.
  - Adverse Purchase Price, Minority Discount, etc.

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Governance Issues

- Board Representation.
  - Single-specialty, multi-specialty, hospital JV.
- Member Approvals.
- Minority Owner Protections.
- Day-to-Day Control.

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Allocating Income and Expenses When Groups Own The ASC

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ASC Owned By The Group

- You can allocate money via the compensation formula.
- This offers strategic and legal benefits.
- The only downside? Liability. But how big is that?
- Favorable 2023 OIG Advisory Opinion
  - OIG Advisory Opinion No. 23-07, https://oig.hhs.gov/documents/advisory-opinions/1132/AO-23-07.pdf

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Group Invests in ASC

- Similar analysis.
- Antikickback protection isn’t quite as airtight, but seems strong.

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Can You Readjust Ownership Based on Use?

- The “active investor” policy supports it.
- Is forced redemption safer than “merely” reducing ownership?
- How often can it be done?

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Management Contracts

- Business Issues.
  - Term and termination, responsibilities, fees and expense reimbursement, restrictive covenants, performance criteria, ownership and perhaps most importantly, control.
- Regulatory Issue.

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Considerations in Hospital/Physician JVs

- Compete or Cooperate.
  - CON, Payer Contracting, Recruitment, etc.
- Benefits of JVs.

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Key JV Business Issues

- Scope of Joint Venture.
- Selection of Investors.
- Governance.
- Buy-Sell/Exit Provisions.
- Valuation.
- Restrictive Covenants.

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Miscellany

- Management Agreements.
  - Provided by tax-exempt partner, to the tax.
- Real Estate.
  - Leasing arrangements.
- Affiliated Service Group Issues.

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Antitrust

- Many antitrust issues associated with healthcare JVs.
  - Sherman Act, Clayton Act, Federal Trade Commission Act, state laws, etc.
  - DOJ/FTC Guidance.
- Today's Focus.
  - Sherman Act, Section 1.

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Sherman Act, Section 1

- Section 1 prohibits contracts, combinations or conspiracies in restraint of trade.
  - *Per se* violations: price-fixing, allocation of territories or customers, customer or other nonprice restraints, group boycotts and concerted refusals to deal, tying agreements, and exclusive dealing arrangements.
  - Rule of Reason.
    - Does the challenged agreement promote or suppress competition?
    - Does the challenged agreement unreasonably restrain trade?

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Sherman Act, Section 1

- Section 1 violation requires.
  - Agreement between two or more economic entities which has an anticompetitive purpose.
    - Parent/subsidiary relationships?
    - Joint ventures?

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Antitrust

- Can a member conspire with the joint venture in violation of the Sherman Act?
  - Examples: payor contracting, territory allocation, etc.
  - *Copperweld Corp. vs. Independent Tube Corp. (U.S. 1984)*
    - Involved a parent and wholly-owned subsidiary.
    - One entity for antitrust purposes if
      - Unity of economic interest.
      - Common, not disparate objectives.
      - Corporate actions guided by a single “corporate consciousness.”

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Antitrust

- If *Copperweld* satisfied, arrangement analyzed under Section 2 of the Sherman Act.
  - Prohibits conduct that creates, sustains, or threatens monopolization.
    - More difficult to prove than Section 1 violations.
- *Copperweld* requirements not clear.
  - "Legal Control" test.
    - Could parent exert full control over subsidiary (JV) if failed to act in parent's best interest.
  - "Unity of Interest" demonstrated by preponderance of multiple factors.

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Miscellaneous Antitrust Issues

- Monopoly Power.
- Affiliated ASCs.

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Miscellaneous Issues

- Sharing Space.
- Multiple ASCs.
- Other Services in ASCs.
- In-Network or Out-of-Network.
- Prior Authorization Program.
- HIPAA Compliance.

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Sharing Space: Interpretive Guidelines

Distinct Entity - Physical or Temporal Separation

CMS's long-standing interpretation of the "distinct entity" requirement is that the ASC must be physically and administratively distinct (47 FR 34085) from any other entity. The ASC is not required to be housed in a separate building from other healthcare facilities or physician practices, but, in accordance with National Fire Protection Association (NFPA) Life Safety Code requirements (incorporated by cross reference at §416.44(b)), it must be separated from other facilities or operations within the same building by walls with at least a one-hour separation. If there are State licensure requirements for more permanent separations, the ASC must comply with the more stringent requirement.

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Sharing Space: Interpretive Guidelines

"An ASC does not have to be completely separate and distinct physically from another entity, if, and only if, it is temporally distinct. In other words, the same physical premises may be used by the ASC and other entities, so long as they are separated in their usage by time. For example:

Adjacent physician office: Some ASCs may be adjacent to the office(s) of the physicians who practice in the ASC. Where permitted under State law, **CMS permits certain common, non-clinical spaces**, such as a reception area, waiting room, or restrooms to be shared between an ASC and another entity, as long as they are never used by more than one of the entities at any given time,

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Sharing Space: Interpretive Guidelines

and as long as this practice does not conflict with State licensure or other State law requirements. In other words, if a physician owns an ASC that is located adjacent to the physician's office, the physician's office may, for example, use the same waiting area, as long as the physician's office is closed while the ASC is open and vice-versa. **The common space may not be used during concurrent or overlapping hours of operation of the ASC and the physician office**. During the hours that the ASC is closed, its records must be secure and not accessible by non-ASC personnel.

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Sharing Space: Interpretive Guidelines

- It is not permissible for an ASC during its hours of operation to “rent out” or otherwise make available an OR or procedure room, or other clinical space, to another provider or supplier, including a physician with an adjacent office.

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Can I Have Multiple ASCs?

- Yes, but…
- Creates havoc with the 1/3 test.
- If they have different ownership, consider price fixing issues.

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Other Services

- Imaging.
- Physical Therapy.

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Can I Adjust My Fees To Out-of-Network Patients To Mirror The Network?

- New Jersey court ruled against Health Net and for the physicians in an ASC dispute where ASC waived co-insurance. State law forbid dentists from waving co-insurance. Garcia v. Health Net of New Jersey, Inc., No. A-2430-07T3, 2009 BL 295398, 2009 WL 3849685 (N.J. Super. Ct. App. Div. Nov. 17, 2009.)

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Can I Adjust My Fees To Out-of-Network Patients To Mirror The Network?

- Compare this with North Cypress Medical Center Operating Co., Ltd. v. Cigna Healthcare, 781 F.3d 182 (2015)781 F.3d 182, 197, (5th. Cir. 2015), holding that limiting the patient's liability, limited the plan's liability in the same fashion.

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Prior Authorization Demonstration Project

- On December 15, 2025, CMS will start a five-year prior authorization demonstration for certain services provided in ambulatory surgical centers in California, Florida, Texas, Arizona, Ohio, Tennessee, Pennsylvania, Maryland, Georgia, and New York.
- The service categories targeted by the demonstration are blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation procedures.
- Providers can submit prior authorization requests beginning on December 1, 2025 for dates of service on or after December 15, 2025.

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HIPAA Compliance

- Recently Announced Ransomware Settlement with Syracuse ASC:
  - July 2025 Press Release; 2021 Incident.
  - $250K Settlement and two-year Corrective Action Plan.
  - Syracuse failed to perform an accurate and thorough risk assessment.
  - Failed to timely notify affected individuals and OCR.

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