Considerations for Structuring *Any* **OBL or ASC**

- Consider long-term goals when selecting a legal structure
- Plan your pro forma and syndicate before spending
- Enter into a letter of intent with investors
- Overcome physician reluctance to invest early on
- Avoid overbuilding
- Don't underestimate the competition
- Engage experienced professionals (consultants, architects, general contractors, attorneys and accountants)

<u>Unique Federal Considerations When Structuring OBL-ASC</u> <u>"Hybrids"</u>

- Stark Law DHS should not be provided in an OBL that is not a physician group practice
- Ensure that site of service selection is based upon clinical and staffing considerations, not remuneration differences (e.g., PAD services reimbursed at higher rates in an OBL)
- Critical to avoid gamesmanship and "cherry picking" in site selection when establishing dual ownership structures for affiliated OBLs and ASCs

<u>Unique Federal Considerations When Structuring OBL-ASC</u> <u>"Hybrids" (cont)</u>

- Temporal separation of operations is required
- Physical separation of patient records and drugs is required
- Non-interventionalist physician investment in ASCs will increases the degree of fraud and abuse risk, while noninterventionalist physician investment in OBLs may increase the degree of fraud and abuse risk
- MACs and commercial payors are implementing rules restricting certain types of procedures from being performed in ASCs and OBLs

<u>Unique State Law Considerations When Structuring OBL-ASC</u> <u>"Hybrids"</u>

- Hybrid model is permitted in many, but not all, states
- Procedure mix may be impacted by state CON, licensure, fraud and abuse laws, anesthesia requirements, Attorney General and Board of Medicine rules
- States are becoming increasingly active in regulating OBLs (e.g., Brazilian Butt Lifts)
- Important to evaluate state-specific "major artery" rules

THANK YOU!!!



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