North Carolina regulates "Operating Rooms"

Certificate of Need required (economic)
Facility licensure required (safety)
Operating Rooms

• Definition - “...a room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room.”

• CON always required, regardless of cost.
• CON availability controlled by need formula.
• Facility license always required.
• Must have CON to get a facility license.
• Facility fee is paid to licensed facilities only.
Procedure Rooms

• Not defined in statute or rule
• No CON required
• No facility license required
• No limitations on types of procedures

BUT...

• Facility fee is paid for surgery performed in procedure rooms located in licensed facilities (hospitals and ASCs).
What is a Procedure Room?

• Until November 27, 2012...
• Any surgical room that failed to meet at least one of the regulatory minimums for an OR and cost less than $2 million was a “procedure room.”
  – Examples: lighting, square footage, medical gasses, ventilation, ceiling height, etc.
Legal Challenge

• Surgical Care Affiliates v. DHHS challenged this approach.
• Result: On November 27, 2012, DHHS lifted the requirement that hospitals and ASCs only build procedure rooms that fall below the safety standards for ORs.
• Procedure rooms can now be built to full OR standards.
Observations

• Since November 27, 2012, DHHS does not apply the CON law to procedure rooms built by hospitals or ASCs for less than $2 million.
  – Creates a strong incentive to build and use procedure rooms rather than ORs.

• DHHS does apply the CON law to procedure rooms built by physician offices.

• Surgery performed in procedure rooms is not reported to DHSR nor is that surgery volume used in the OR need formula.
  – This artificially suppresses new need determinations for ORs