CERTIFICATE OF NEED
OVERVIEW of DIAGNOSTIC CENTERS

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What is a Diagnostic Center?*

- Freestanding facility, program or provider, including, but not limited to:
  - Physician office
  - Clinical lab
  - Radiology center
  - Mobile diagnostic program

*As defined by the NC Certificate of Need (CON) Statute
Total cost of all the medical diagnostic equipment utilized by the facility which cost $10,000 or more exceeds $500,000. Cost includes:

- Cost of the equipment (fair market value or cost, whichever is greater)
- Studies, surveys, designs, plans, working drawings, specifications
- Construction
- Installation
- Other Activities essential to acquiring & making equipment operational
How are Diagnostic Centers Regulated?

- DHSR does not license or certify diagnostic centers, except:
  - DHSR Acute & Home Care Licensure & Certification Section does certify and provide oversight for:
    - Clinical labs – Clinical Laboratory Improvement Amendments (CLIA)
    - Portable x-ray supplier service
  - A clinical lab and portable x-ray service can be designated as diagnostic centers if they meet the criteria.
How Regulated Continued

- For health and safety, DHSR Radiation Protection Section requires:
  - Registration of ionizing radiation diagnostic equipment
    - CT
    - X-ray
    - Mammography
  - Training, shielding & installation oversight
- DHSR CON Section regulates diagnostic centers by requiring a facility to apply for a CON to become a diagnostic center when the total cost of all medical diagnostic equipment costing $10,000 or more totals $500,000.
Diagnostic Centers Reviewed Since March 1993*

- 310 diagnostic center applications reviewed
  - 63% Magnetic Resonance Imaging (MRI) Scanner
  - 3% Positron Emission Tomography (PET) Scanner
  - 34% Other equipment
    - Computed Tomography (CT) Scanner
    - Mammography
    - Bone density
    - Ultrasound
    - X-ray

*Through March 7, 2014
Diagnosis Centers Reviewed Continued

- 165 diagnostic center CON approvals
  - 51% MRI
  - 2% PET
  - 47% Other equipment
- 146 not approved
  - Part of competitive review, or
  - Withdrawn after approval