



New Technology

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Background:

Section 19a-634 requires OHCA to establish and maintain a state-wide health care facilities and services plan.

The Plan may include:

- An assessment of the availability of acute hospital care
- An evaluation of unmet need and vulnerable populations
- A projection of future demand for health care services

In Addition,

Sec. 19a-638. (Formerly Sec. 19a-154). Certificate of need. When required and not required. Request for office determination. Policies, procedures and regulations. (a) A certificate of need issued by the office shall be required for:

- (11) The acquisition of equipment utilizing technology that has not previously been utilized in the state**

Background:

- OHCA does not currently have a definition of what “new technology” is.
- Brief history of OHCA reviewing new technology related CONs:
 - 70's & early 80's (X-Ray Units)
 - 80's & 90's (PET, Lithotripsy, ESWT, HBOTs)
 - 90's & 00's (Robotic Surgery aka Da Vinci units)

OHCA's Historical CON Review:

- Certificate of Need applications (CON) are evaluated on a case-by-case basis.
- Assess the quality of the proposed new technology.
- Copies of federal approvals (FDA etc.).
- Use of the technology (target population).
- Need for the new technology for the Applicant (where are the patients currently going?).
- Are there alternatives/options to this technology? (for example: Proton Beam vs. Cyber Knife)
- Projections for the use (need the basis & demographics).
- Can the Applicant afford/absorb the cost of the new technology?
- Other statutory CON criteria .

Other States:

Staff researched several other states' health plans and guidelines including Alabama, Illinois, Maryland, Kentucky, North Carolina, Mississippi, and New York to see how they reviewed new technology.

General summary:

- Most states have not defined new technology and have no specific guidelines.
- However, two states Kentucky and New York appear to have information that this committee might find helpful.

State of Kentucky:

Definition

“New Technology” includes new technology equipment or services not previously provided in the Commonwealth and not otherwise covered in the Plan that involve a capital expenditure that exceeds the capital expenditure minimum or equipment that exceeds major medical equipment minimum, and has an annual operating cost greater than \$500K, or new technology where the medical literature indicates that certain utilization levels or procedural volumes are necessary to achieve desirable patient outcomes.

*underlined portion does not apply to OHCA, as there are no longer any capital expenditure thresholds in OHCA statutes.

Kentucky's Review Criteria:

- Document efficacy;
- Document equipment is certified through FDA;
- Preference given to proposal that involve multi-institutional arrangements;
- Preference given to proposals that place equipment in medical school/teaching and/or research facilities;
- Prior to acquiring the equipment, applicant(s) shall have complementary diagnostic and treatment services available to support the program;
- In cases specific professional standards have not yet been formulated, applicant(s) shall demonstrate that the personnel who will staff the new technology are qualified and adequately trained; and
- Applicant(s) shall report utilization and demographic data necessary to evaluate the technology and to facilitate state planning.

State of New York:

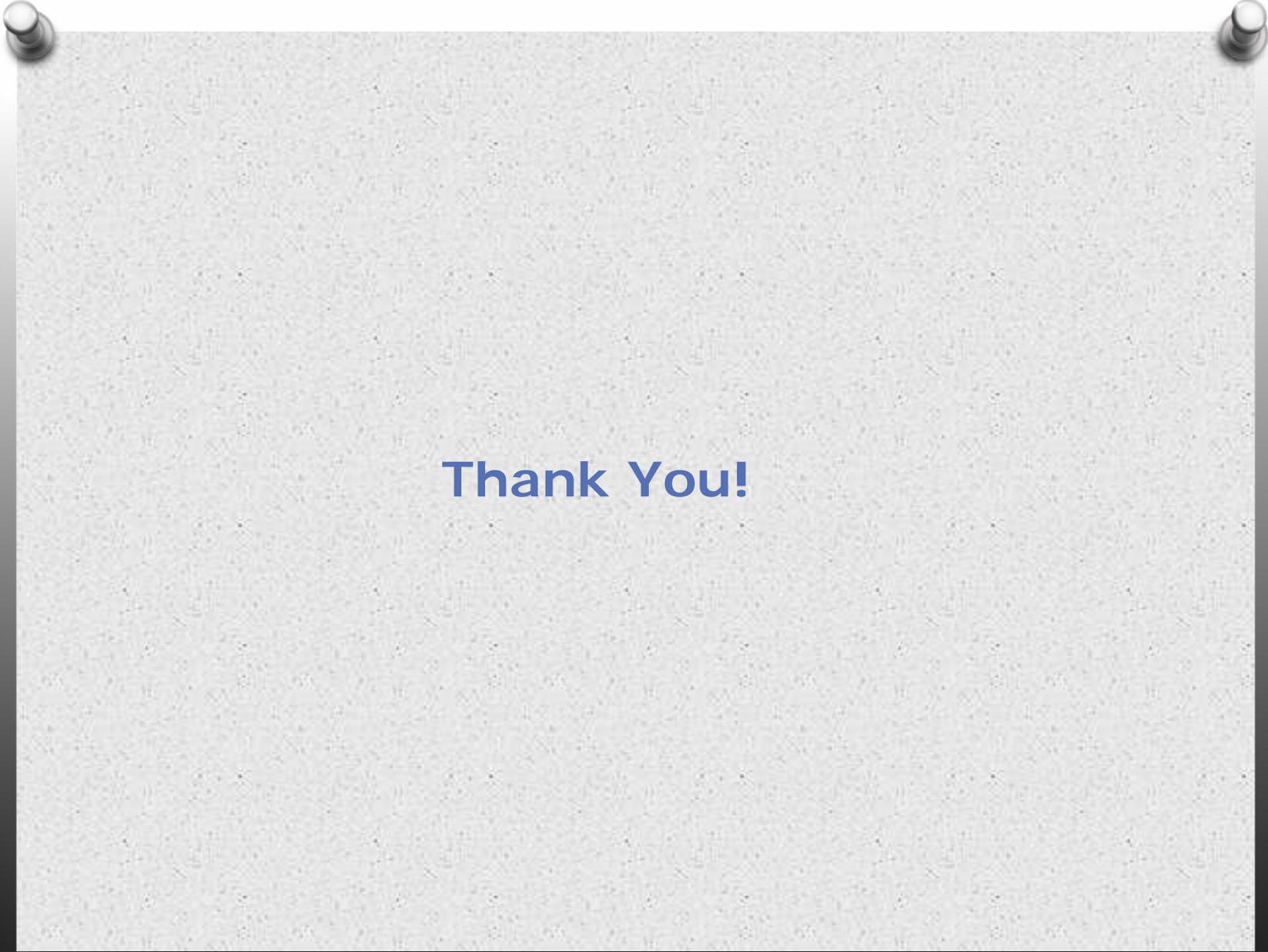
- Based on information gathered from a “memo” from the Division of Health Facility Planning to the Members of the State Hospital Review and Planning Council (March 11, 2010)
- Specific to Proton Beam (in anticipation of several applications)
- Very detailed and thorough and was drafted to help evaluate such applications.

Highlights from the NY Memo:

- Describes what the technology is;
- Provides a detailed background on the technology;
- Lists where its currently available (nationally & internationally);
- Discusses outcomes based on clinical studies;
- Cites professional journals;
- Discusses the comparative effectiveness;
- Evaluates public need, based on disease incidence rates;
- Discusses advantages and disadvantages of a consortium approach;
- Evaluates the cost and reimbursement aspects; and
- Option of a demonstration project;

Issues to consider:

- Define “new technology;”
- New Technology vs. Advancement in Technology;
- Evolution/proliferation of the new technology;
- Review criteria:
 - Clinical studies illustrating technology advantages and outcomes;
 - FDA approval; and
 - Additional criteria (see items listed in KY slide).



Thank You!