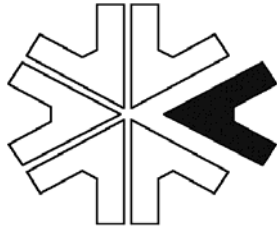


CERTIFICATE OF NEED REGULATION A NATIONAL OVERVIEW



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Overview of Presentation

- **History of State Health Planning & Certificate of Need ("CON") Regulation**
- **Current Status**
- **Recent Trends**
- **Unresolved Questions**

HISTORY

1940s -1960s

Voluntary city/regional hospital planning & regulation

1947 – 1973

Hospital Survey and Construction Act (Hill-Burton)

1966 – 1973

Regional Medical Programs

1967-1973

Comprehensive Health Planning

Establishment of State CON programs

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HISTORY

1972

Section 1122 Review of Capital Expenditures

1974 – 1986

National Health Planning and Resources Development
Act

1982 – Present

Continuation of State health planning and CON
regulation in most states and a limited number of
regions

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HISTORY

National Health Planning and Resources Development Act of 1974
Public Law 93-641

- Federal funding of State Health Planning and Development Agencies
- Federal funding of regional Health Systems Agencies (200+)
- Mandated comprehensive State Health Plans based on National Guidelines
- Mandated Certificate of Need programs (25 established prior to federal mandate) until 1982
- Repealed in 1986

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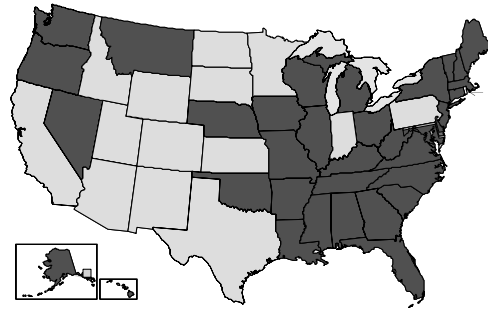
HISTORY

CON Regulation After P.L. 93-641

- 11 States eliminated CON programs between 1984-89
- 3 States eliminated CON programs between 1995-97
- Two states, Indiana and Wisconsin, eliminated their CON programs and revived them in some form – Indiana repealed its program for a second time in 1997
- CON programs continue to exist in D.C., Puerto Rico, and the Virgin Islands

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CON Regulation by State 2008



Source: AHPA

■ CON Program
□ No CON

CURRENT STATUS

- 36 States & D.C. have CON programs
- 7 States only regulate long-term care and/or home health care/hospice services
- 29 States regulate hospital and acute medical care facility services to varying degrees
- 27 States control the establishment and expansion of ambulatory surgical facilities under their CON programs

CURRENT STATUS

- 25 States regulate some types of major medical equipment
- Most States require review of the establishment of certain types of medical care facility and service regardless of the project capital cost
- Most States (31) employ project capital expenditure levels as one factor defining the need for CON review

CURRENT STATUS

New Facilities Subject to CON Regulation – Most Common

- Hospitals – General and Special
- Nursing Homes
- Intermediate Care Facilities/Mental Retardation
- Ambulatory Surgical Facilities
- “High End” Diagnostic Imaging Facilities (PET, MRI, CT)
- Radiation Therapy Facilities
- Renal Dialysis Facilities

CURRENT STATUS

New Services Subject to CON Regulation – Most Common

- Acute Inpatient Services – Pediatric, Obstetric, Psychiatric/Substance Abuse, Medical Rehabilitation, NICU
- Nursing Home Services
- Cardiac Surgery & Cardiac Catheterization (especially Angioplasty)
- Organ Transplantation
- “High End” Diagnostic Imaging Services (PET, MRI, CT)
- Radiation Therapy
- Renal Dialysis
- Swing Beds

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CURRENT STATUS

Service Capacities Subject to CON Regulation – Most Common

- Hospital (General and Special) and Nursing Home Beds
- Operating Rooms
- Cardiac Catheterization Laboratories
- “High End” Diagnostic Imaging Equipment Units (PET, MRI, CT)
- Radiation Therapy Equipment Units (Linear Accelerators. Gamma Knives)

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CURRENT STATUS

Other Facilities and Services Subject to CON Regulation – Less Common

- Home Health and Hospice
- Lithotripsy
- Assisted Living
- Air Ambulance
- Ultrasound
- Burn Care

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CURRENT STATUS

Capital Spending Thresholds

- Thresholds now in use nationally range from \$1 to \$15 million; national median is approximately \$2.3 million
- Usually come into play for health facility renovation & modernization projects; not applicable to bed expansion or new service projects in most states
- Most States have distinct equipment spending thresholds; ranging up to \$6.75 million; median is approximately \$1.4 million

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RECENT TRENDS

- Dissatisfaction with CON but no broad trend for elimination – a few states tend to have a perennial debate
- Incremental reduction in scope of regulation
- Incremental increases in capital spending thresholds
- Substitution of CON with other regulatory regimes – moratoria, licensure, lotteries, fraud and abuse oversight

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UNRESOLVED QUESTIONS

Is CON Regulation Effective or Beneficial?

- Academic Reports
- Consultant Reports
- Empirical Analyses
- Federal Trade Commission, 1982-84 & 2004

What are the true costs of CON regulation?

- No consensus among analyses
- Few disinterested studies
- Exaggerated claims

The policy maker's quandary is who and what to believe.

UNRESOLVED QUESTIONS

Macroeconomic Studies Attempting to Use Multivariate Regression and Correlation Techniques are Problematic

- Unreliable data
- Lack of appropriate quantitative tools
- The wrong questions being asked
- Inappropriate doctrinal assumptions
- Lack of accounting for empirical evidence (e.g., experience of U.S. automobile manufacturers)
- Extraneous and ignored factors (e.g., intrastate variations greater than interstate variations)

FTC Reports

- Based on assertions of doctrine rather than facts
- Cost, Quality, Access
- Innovation, Efficiency

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