

# **CERTIFICATE OF NEED REGULATION**

- **General Perspectives •**
- **Maryland Perspectives •**

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## **General Perspectives on CON**

**What is its value?**

**Why does it persist?**

**What can it be?**

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## **Value**

30 years ago, CON programs based on “comprehensive, community-based” health planning, operating at the state and regional level, were expected to:

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## **Value**

- improve health
- increase accessibility, acceptability, continuity, & quality of health services
- restrain increases in cost of providing health services
- prevent unnecessary duplication of health resources
- preserve and improve competition in the health service area

Source: National Health Planning and Resources Development Act

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## **Value**

### **“Reasonable Purposes” of a Health Planning/CON Program**

- 1. Establish and maintain open, participatory structure for articulating community health needs & desirable alternatives for meeting those needs, used to advise government & private sector decision makers who control resources**

Source: Health Planning in the U.S.: Selected Policy Issues, Institute of Medicine, National Academy of Sciences, 1981

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## **Value**

### **“Reasonable Purposes” of a Health Planning/CON Program**

- 2. Contribute to the redirection of the health care system through planning for a more effective, accessible, high quality & efficient configuration of facilities & services, more closely matched to basic health care needs of the population, including carefully thought out positions for introducing new technology**

Source: Health Planning in the U.S.: Selected Policy Issues, Institute of Medicine, National Academy of Sciences, 1981

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## **Value**

### **“Reasonable Purposes” of a Health Planning/CON Program**

**3. Contribute to the containment of health care costs (moderation in rise of health care expenditures) primarily by planning a more cost effective health system, promoting health, preventing disease, limiting unnecessary capital investment, & directing capital investment to more cost effective facilities & services**

Source: Health Planning in the U.S.: Selected Policy Issues, Institute of Medicine, National Academy of Sciences, 1981

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## **Value**

### **2 Types of Evaluation Questions for a Health Planning/CON Program**

**1. Is there a slowing (adjusted for inflation) in the rise of capital investment & operating expenses that can be attributed to the planning/regulation apparatus**

Source: Health Planning in the U.S.: Selected Policy Issues, Institute of Medicine, National Academy of Sciences, 1981

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## **Value**

### **2 Types of Evaluation Questions for a Health Planning/CON Program**

**2. Is capital being redirected in the health sector? Are the capital investments approved by the planning agency more cost-effective than those denied? In the aggregate, a substantial deceleration of new facilities and services should be occurring.**

Source: Health Planning in the U.S.: Selected Policy Issues, Institute of Medicine, National Academy of Sciences, 1981

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## **Value**

### **Early Problems Identified**

- 1. No way to determine or estimate need with some sense of what can be afforded**
- 2. Absence of technical certainty**
- 3. Limited knowledge concerning efficacy of treatment & appropriate supply of services**

Source: Health Planning in the U.S.: Selected Policy Issues, Institute of Medicine, National Academy of Sciences, 1981

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## **Value**

### **Early Problems Identified**

- 4. Limited planning technology and inadequate data make decisions complicated & ultimately the product of value judgments by decision makers**
- 5. Political bargaining is a major factor in CON decisions**

Source: Health Planning in the U.S.: Selected Policy Issues, Institute of Medicine, National Academy of Sciences, 1981

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## **Value**

**So, how are we doing, given this historical perspective?**

**Have we established and maintained open, participatory structures for articulating community health needs & desirable alternatives for meeting those needs – advising government and private sector decision makers?**

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## **Value**

How are we doing?

In general, no - certainly not as envisioned in the 1970s, through a comprehensive state health planning and regional health planning process with significant, coordinated community-level participation.

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## **Value**

How are we doing?

However, States have continued to engage in substantive health planning that supports efforts to improve access to medical care, reduce health status and service disparities, prevent disease, promote health, & improve health information technology

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## **Value**

How are we doing?

This planning tends to be fragmented, highly program-specific, and largely unlinked, in any direct way, with CON regulation. Government decision makers receive substantial advice from these State planning efforts - private sector decision makers do not.

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## **Value**

How are we doing?

Is the health care system being redirected through CON to be more effective, accessible, of higher quality & more efficiently configured?

Only on a limited basis and only marginally

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## **Value**

How are we doing?

CON has had an impact on the supply & distribution of medical care facilities

However, a clear and consistent contrast between States with & without CON regulation and among States with a varying scope & “rigor” of CON regulation that unambiguously demonstrates an association between

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## **Value**

CON regulation &

- effectiveness of medical care
- better access to medical care
- higher levels of quality of medical care
- more efficient medical care delivery

has not been shown in the research literature

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**Impact of CON  
on the supply & distribution of medical care  
facilities**

**Compared with non-CON states, most states with a  
broad scope of CON regulation have:**

- **Significantly fewer specialty hospitals**
- **Fewer physician-owned surgery centers and  
diagnostic imaging centers**
- **Fewer cardiac surgery and organ transplant  
programs**

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**Value**

**How are we doing?**

**Does the health care system more  
closely match basic health care needs  
of the population?**

**No**

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## **Value**

How are we doing?

The enormous levels of variation in health care resource use that cannot be explained by differences in population health status or population needs & the evidence of counter-productive resource use do not support the view that the health care system is more closely matching with the basic health care needs of the population in recent decades

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## **Value**

How are we doing?

Have CON programs established carefully thought out positions for introducing new technology?

For the most part, no

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## **Value**

How are we doing?

Some states have had limited success in using CON to regulate proliferation of new medical care technology more rationally than would be likely without controls.

However, reimbursement policy, the availability of physician specialists, & the prevailing zeitgeist concerning what is “state of the art” & what are reasonable “patient expectations”

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## **Value**

tend to overpower the ability of CON to systematically plan and control the introduction of new technology on the basis of technology assessment, sound economic analysis, & considerations of quality assurance

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## Value

How are we doing?

Has CON contributed to the containment of health care costs (moderation in the rise of health care expenditures) through

- planning
- promoting health/preventing disease
- limiting unnecessary capital investment
- directing capital investment to more cost effective facilities & services

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## Value

How are we doing?

The research literature does not clearly demonstrate that CON moderates the rise in health care expenditures

However

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## **Value**

Analysis of specific states & cases can plausibly demonstrate some effectiveness in limiting unnecessary capital investment

More generally, the ability to proactively redirect capital investment to more cost effective facilities & services is not a strength of CON programs

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## **Value**

How are we doing?

Is there a slowing (adjusted for inflation) in the rise of capital investment & operating expenses that can be attributed to the planning/regulation apparatus?

The research says no

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## **Value**

How are we doing?

Is capital being redirected in the health sector by CON programs?

Not directly or systematically

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## **Value**

How are we doing?

Are the capital investments approved by CON programs more cost-effective than those denied?

Arguably, in many cases, yes. But rigorous use of cost effectiveness analysis is usually limited to the project review level – not used for macro-level systems planning

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## **Value**

**How are we doing?**

**In the aggregate, is CON leading to a substantial deceleration of new facilities and services?**

**No - CON is weak compared to other factors affecting investment in new facilities and services – it can assist in rationalizing the contraction of facility and service sectors**

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## **General Perspectives on CON**

**What is its value?**

**Why does it persist?**

**What can it be?**

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**Because Americans Love Centralized  
Government Planning &  
Command & Control Regulation?**



### **Persistence**

**Probably not, however**

1. The underpinnings of CON regulation are, in general, sound
  - Demand & supply are not balanced in medical care delivery by what is traditionally understood as a competitive market structure in which consumers have the ability to make consumption choices based on a meaningful appraisal of the relationship between value & price

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## **Persistence**

- Quality of care and better outcomes for some services can best be achieved by limiting the number of service providers, so that programs can achieve high volume and high-level proficiency

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## **Persistence**

- The medical care sector in the U.S., including the facility resource base, is too expensive relative to the health status being achieved by the American population. The evidence provided by the rest of the developed world on this point is overwhelming. The amount of medical care we consume, as a nation, is detrimental to our economic well being and, as individuals, detrimental to our health.

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## **Persistence**

2. Most Americans do not view medical facilities in the same way that they view other types of business firms.

- Unregulated capital investment by medical care facilities can lead to results that communities & their political institutions view as undesirable & unfair
- CON provides a means for empowerment or a tangible basis for the illusion of empowerment by individuals, communities, interest groups, & government

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## **Persistence**

3. Health care facilities are a politically powerful constituency that is often pro-CON

- Co-optation happens
- Change is scary
- Competition is great - for everyone else
- Inertia is powerful

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## **Persistence**

4. CON works in every state where it exists – in some ways & for some persons – tending to mute the debate over measurable costs & benefits

- Every state is unique – no state is “all states”
- CON has evolved & adapted over time – time has been on its side
- Inertia is powerful

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## **General Perspectives on CON**

What is its value?

Why does it persist?

What can it be?

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## **Being CON**

CON regulation of projects should be a validation of capital investments that are consistent with planning & policy guidance established by the program – it should usually be boring

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## **Being CON**

CON programs should connect project decisions & decision makers with “some sense of what can be afforded” or well-considered target levels of spending. The budgeting exercise has value even if there is no established budget target – try to see the “big picture” and put the program in context

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### **Being CON**

CON programs should connect project decisions & decision makers with an understanding of how use of medical care facilities & services in affected areas compares with use observed in other areas & the role that resource levels may play in patterns of excessive use.

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### **Being CON**

CON programs should refine & restructure the scope of their review programs when market entry & exit can be effectively regulated through market entry qualification & the monitoring of quality indicators, rather than traditional project review.

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## **Being CON**

Contract program scope and compress procedure wherever possible – Don't sweat the small stuff

Make the review process force more concentration on good planning by using RFPs whenever possible

Demand real cost effectiveness analysis from applicants – require that CEA consider opportunity cost and life cycle costs – demand that applicants quantify effectiveness measures whenever possible and analyze true alternative approaches rather than dummies

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## **Being CON**

### **Impact of Health Insurance Reform on CON**

- Disappearance of the hospital as “safety net”
- A more competitive health insurance market – greater market leverage by hospitals – what does a CON program do to promote competition?
- Alignment of physician and hospital financial incentives - opportunities for rationalizing facility and service infrastructure

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## Maryland Perspectives on CON

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### Maryland

- Population of 5.9 million (2010)
- Population growing about 1% per year
- Population aging – 600,000 aged 65+ in 2000  
1 million aged 65+ in 2020
- Geographically compact and heavily urbanized – most of population centered in metropolitan Baltimore and D.C. suburbs
- 47 general hospitals

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## Precedents

Maryland Health Care Commission was created 10 years ago through the merger of

### ❑ Maryland Health Resources Planning Commission

**Mission: Health systems planning and regulation of health facilities capital investment – 1970s-style government “command and control” – Direct intervention to compensate for market failure**

### ❑ Maryland Health Care Access and Cost Commission

**Mission: Overcome market failure by educating consumers and expanding health insurance coverage in small group market – 1980s-style government market reform – Help the market work better**

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## Health Regulation in Maryland

### Key Components

Practitioners –

DHMH  
Health Occupation  
Licensing Boards: Board  
of Physicians, Board of  
Nursing, etc.

Payers -

1. Maryland Insurance Administration (MIA)
2. MHCC – small employer health insurance market
3. DHMH – Medicaid



Health Facilities -

1. Office of Health Care Quality, DHMH: hospitals, nursing homes, ambulatory surgical centers, home health, hospice, etc.
2. MHCC - Certificate of Need and State Health Plan
3. HSCRC - hospital rate setting

Consumers -

Appeals and Grievances law - MIA, Office of the Attorney General, Consumer Protection Division

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## Maryland Health Care Commission

### Information for Policy Development

- State Health Expenditures
- Health Insurance Coverage in Maryland
- Studies of Health Care Utilization and Financing

### Quality and Patient Safety

- Public Reporting of Performance
- Patient Safety

### Access to Health Care

- Small Group Market and Limited Health Benefit Plan
- Study of the Affordability of Health Insurance in Maryland
- Trauma Fund
- Maryland Health Insurance Plan

### Future Health Care Delivery System

- State Health Plan
- Forecasting Future Need for Health Facilities and Services
- Certificate of Need Approval of Major Capital Expenditures and New Health Care Facilities

### Technology Enhancement

- Accreditation of Electronic Health Networks
- HIPAA Education
- Electronic Health Records

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## Maryland Health Care Commission

### ■ Center for Hospital Services

- Integrates planning, CON, quality and outcomes reporting to improve hospital quality and value
- Includes specialty services, ambulatory surgery, hospital-based ambulatory care

### ■ Center for Long-term and Community-based Services

- Integrates planning, CON, quality and outcomes reporting to improve quality and value of nursing homes, HHAs, hospices, and other community services as appropriate

### ■ Center for Financing and Health Policy

- Analysis of health insurance markets, HMO/PPO reporting, and regulation of SGM
- Includes public sector health policy responsibilities as adopted

### ■ Center for Information Services and Analysis

- Analysis of Maryland health care expenditure data, national survey data
- Price transparency project
- Trauma fund policy
- Analysis of physician reimbursement and the market for physician services

### ■ Center for Health Information Technology

- Certification of electronic health networks
- Promotion of electronic data interchange
- Governor's Task Force on Electronic Health Records

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## **Required Considerations in CON Review**

- **Consistency with applicable State Health Plan standards**
- **Need for the project**
- **Cost-effectiveness of the project**
- **Financial viability of the project**
- **Compliance of applicant with terms and conditions of previous CONs**
- **Impact of the project on costs, charges, and other providers**

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## **Regulation of Hospital Charges in Maryland**

- **Health Services Cost Review Commission**
  - **All payor rate regulation – unique in U.S.**
  - **Target: Keep rate of growth in hospital charges below U.S. rate of growth in Medicare hospital payments**
  - **Coordinated with CON regulation – hospitals can avoid CON by taking the “pledge”**

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## Impact of CON and Hospital Rate Regulation

- Compared with U.S.A overall, Maryland has:
  - Low ratio of hospital beds to population – higher bed occupancy
  - Low average length of hospital stay
  - Until the middle of this decade, a low admissions rate
  - Highest number of outpatient surgery centers per capita in U.S.
  - High levels of non-surgical outpatient diagnostic and treatment centers

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## Recent Trends in Health Facilities Use

- A long-term decline in acute hospital inpatient census ended in the late 1990s

- From 2000 to 2007, average daily census of acute hospital patients in Maryland increased 12.2% (1,165 patients)

- Outpatient service demand in the hospital and freestanding setting has experienced strong growth and this trend continues

- A long-term decline in nursing home use rates continues

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## **Evaluating CON in Maryland**

**2000-2002**

**Comprehensive Legislatively Mandated Evaluation – Considered by Commission as a whole**

- **Validated scope of program and approaches used for each service, as it then existed**

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## **Evaluating CON in Maryland**

**2005**

**Issue-oriented review based on an explicit call for identification of issues and problems – Task Force with Commissioners and Regulated Industry Representatives developed report**

- **Raised capex threshold from \$1.5 million to \$10 million for hospitals and \$5 million for all others**

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## **Evaluating CON in Maryland**

- **Some Procedural Changes**
- **Task Force recommended elimination of hospice services from CON review – not accepted by Commission**

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## **Recent Evolutionary Steps – Maryland CON**

- **Restructuring regulation of angioplasty**
- **Rethinking regulation of home health care (hospice?)**

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