COMMISSION TO STUDY THE CERTIFICATE OF NEED LAWS 118th MAINE LEGISLATURE

FINAL REPORT

February 18, 1998

Members:

Rep. Michael Quint, chair
Sen. Betty Lou Mitchell
Richard Batt
Elise J. Bolda
John Bouchard
Cathy Cobb
Eleanor Duffy
David Finlay, Ph.D.
Daniel Fishbein, M.D.
Jud Knox
Mark A. McAuliffe
Donald L. McDowell
Michael T. McNeil
Lisa Harvey-McPherson
Christopher Nolan

Staff:
Diane Arbour, Bureau of Medical Services
Department of Human Services
Augusta, Maine 04333

Table of Contents

Executive Summary

The Commission to Study the Certificate of Need Laws was established by Resolve 1997, chapter 82 and charged with the duty to study 1) the effectiveness of the certificate of need laws in ensuring access to health care and in controlling costs, 2) the need for modifications to address the changing health care system, and 3) alternative methods of meeting the goals of the laws.

The commission is pleased to forward to the Legislature the following recommendations, most of which reflect the agreement of all members but some of which were not unanimous. Legislation to accomplish these recommendations will be printed during the Second Regular Session under the title, "An Act to Implement the Recommendations of the Commission to Study the Certificate of Need Laws." The recommendations are:

Certificate of Need (CON) process issues

⇒ Amend the CON purpose statement to update it and focus it more on the development and availability of care, access to care, supporting choice while avoiding duplication, ensuring public participation in the CON process and seeking a balance, to the extent it is consistent with the purposes of CON, between competition and regulation in the provision of health care.

⇒ Change the CON Advisory Committee provisions: require the committee to review and comment on criteria for the CON process and the state health plan, review the CON process, provide advice to the Commissioner of DHS, review an annual report on CON from DHS. Delete outdated provisions on staggered membership. Delete the provision on serving until the successor is confirmed. Limit service to 2 4-year terms. Separate the CON Advisory Committee provisions from §307, the review process.

⇒ Add a community informational meeting to the CON process, convened by DHS, within 30 days from filing the application, to provide information to the public on the application.

⇒ Streamline the CON process and timeframes. Allow for re-application 1 year from the prior application.

⇒ Extend the time period for subsequent review for activities from 1 to 3 years.

⇒ Separate nursing facility provisions from § 307, the review process.

CON applicability issues

⇒ Require that all monetary thresholds be reviewed by DHS each year and adjusted to reflect changes in the Consumer Price Index medical index.

⇒ Combine the provisions on transfer of ownership, acquisition by lease, donation and transfer and acquisition of control.

⇒ Exempt from CON review acquisitions of major medical equipment that is replacement equipment or equipment used on a temporary basis in the case of a natural disaster, major accident or equipment failure.

⇒ Allow ambulatory surgical units licensed on 1/1/98 to use capacity in existence on 1/1/98 without CON review.

⇒ Apply CON to health care facilities, including diagnostic and treatment centers, excluding physicians' practices. Apply CON to nursing facilities in separate provisions.

⇒ Apply CON to nursing facilities, to the extent of capital expenditures above $500,000 or 3rd year operating costs at or above $350,000, and for increases in nursing beds.

⇒ Retain the threshold for major medical equipment at an aggregate cost of $1,000,000 (exempt temporary and replacement equipment, and cases of natural disaster, major accident or equipment failure).

⇒ Retain the threshold for capital expenditures for facilities at $2,000,000 (exempt temporary and replacement equipment and cases of natural disaster, major accident or equipment failure and exempt expenditures for parking lots and garages, information systems, communications systems and physician office space).

⇒ Require review of new health services provided by facilities that cost over $100,000 or with 3rd year operating costs at or above $350,000. Exempt extensions of current services, within the defined service area, through the purchase of new equipment costing in the aggregate within 1 year less than $1,000,000.

⇒ Exempt discontinuance of a health service from CON review.

⇒ Apply CON to increases in licensed bed count in facilities and nursing facilities and to increases in licensed bed category.

Other issues

⇒ Require DHS to convene meetings on the CON process and to report on CON to the Health and Human Services Committee by January 1, 2001.

⇒ Require DHS to adopt, through rulemaking under Title 5, chapter 375, all rules, standards and criteria required for the CON process. All existing rules to be redone at the same time.

I. Introduction

Resolve 1997, chapter 82, established the Commission to Study the Certificate of Need Laws and charged the commission with the duty to study the certificate of need laws, specifically:

* Their effectiveness in ensuring access to health care and in controlling costs;
* The need for modifications to address the changing health care system; and
* Alternative methods of meeting the goals of the laws.

The resolve directs the commission, in examining these issues, to consult with the public, providers of health care and insurers and other 3rd party payors.

The resolve directs the commission to submit a report with any accompanying legislation to the Joint Standing Committee on Health and Human Services and to the Second Regular Session of the 118th Legislature by December 1, 1997.

A copy of the authorizing legislation is included as **Appendix A**. The membership of the commission is included as **Appendix B**.

The commission requested an extension of the December 1 reporting date because delays in the making of appointments caused the commission to begin its meetings very late. Once appointed, commission members were diligent in their work, meeting October 28, November 4, November 13, November 18, December 4, December 9, December 19, and December 29, 1997 and January 23, 1998.

II. The Commission Process

The Commission to Study the Certificate of Need Laws began its work with an overview of certificate of need (CON) in Maine. Through a review of literature and presentation by representatives of the Department of Human Services, the entities regulated by certificate of need and other interested parties, the commission learned of the philosophical basis for certificate of need and the practical effects of certificate of need laws.

As of early 1997, 37 states and the District of Columbia had certificate of need laws, 13 states had repealed their laws and a few others had narrowed the scope of their laws. The federal laws that required states to have certificate of need laws, the certificate of need provisions of Section 1122 of the Social Security Act and the National Health Planning and Resources Development Act, Public Law 93-641, were repealed in 1987. During their heyday certificate of need laws regulated health care capital projects, services, and expenditures including long-term care services and facilities through a state planning process that balanced need, costs and consumer protection. Proponents of certificate of need laws hold to the view that the laws help to control health care costs and assist in ensuring quality of care and access to care by limiting large expenditures and acting as a participant in the

health planning process. Detractors hold to the view that the laws were ineffective in limiting costs or the construction of hospital beds and that managed care will address the issues of cost, quality and access. Commission members studied these arguments, focusing on their application to the Maine certificate of need laws and the experience of the Department of Human Services, regulated entities and interested parties with the laws.

The Certificate of Needs laws, which were first enacted in 1977, state the findings of the Legislature and the purposes of the laws in 22 MRSA, chapter 103. Current law on the findings and purposes reads as follows:

> **Findings:**
> The Legislature finds that unnecessary construction or modification of health care facilities and duplication of health services are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services.
>
> **Purposes.:**
> The purposes of this chapter are to:
> A. Promote effective health planning;
> B. Assist in providing quality health care at the lowest possible cost;
> C. Avoid unnecessary duplication in health facilities and health services and ensure that only those facilities that are needed will be built or modified;
> D. Assure that state funds are not used to support unnecessary capital expenditures made by or on behalf of health care facilities;
> E. Provide an orderly method of resolving questions concerning the need for health care facilities and health services which are proposed to be developed;
> F. Permit consumers of health services to participate in the process of determining the distribution, quantity, quality and cost of these services; and
> G. Provide for a certificate of need program which meets the requirements of the National Health Planning and Resources Development Act of 1974, Public Law 93-641 and its accompanying regulations.

The commission examined these purposes and agreed to recommend revisions to address changes in the health care field as follows:

- repeal of the Maine Health Care Finance Commission,
- the repeal of the federal certificate of need requirements,
- the current state of the delivery of health care services,
- the payment for health care through insurance, health benefit programs, carriers and health maintenance organizations,
- the changes in the health care system as a result of managed care, and
- the current status of the Medicaid program.

During its work the commission accepted information from and spoke with members of the public, representatives of hospitals and physicians' offices in their capacities as regulated entities, representatives of state agencies, representatives of interest groups and representatives of insurers, managed care entities and 3rd party payors in their respective

capacities. Formal presentations to the commission were made by the HMO Council, the Maine Medical Association, the Maine Hospital Association, Blue Cross Blue Shield of Maine, the Muskie School of Public Service, University of Southern Maine, the Office of the Attorney General, and the Department of Human Services.

The commission accepted and took into consideration materials pertaining to the certificate of need process in Maine and in other states. **Appendix C** is an overview of the scope and monetary thresholds of certificate of need-regulated services in 38 states completed in 1997 by the Missouri certificate of need program. **Appendix D** is a chart comparing certificate of need laws in the 50 states. This chart compares review criteria for capital and equipment thresholds, new health care services and review of non-hospital equipment acquisitions. **Appendix E** is a flow chart of the certificate of need review process within the Department of Human Services. **Appendix F** contains a summary of certificate of need activities in Maine from 1979 to 1995. **Appendix G** is a guide to the Maine certificate of need process compiled for the American Health Planning Association in December, 1996. **Appendix H** contains a statement of the Maine Medical Association, entitled "The Case Against Certificate of Need" and prepared for the commission in December, 1997. The BNA Health Law Reporter published a report on certification of need in September, 1997 entitled "Few Alternatives Seen as CON Laws Are Threatened by Rise of Managed Care," a copy of which is included as **Appendix I**. The National Association for Home Care completed a telephone survey and report on certificate of need in September, 1995, a copy of which is included as **Appendix J**. **Appendix K** contains a paper entitled "Effects of the Deregulation of Certificate of Need (CON) Requirements" completed by the Health Care Advisory Board of the Advisory Board Company in November, 1996. **Appendix L**, entitled "Pros and CONS: Is There Still A Need for Certificate of Need?" was published in the May/June, 1992, issue of HealthCare Alabama. "A National Look at CON Laws," published in Michigan Hospitals, February, 1989, is contained in **Appendix M**.

III. Commission Recommendations

The commission makes the following recommendations to the 118th Legislature and to the Joint Standing Committee on Health and Human Services. These recommendations will be contained in legislation to be printed later this session under the title "An Act to Implement the Recommendations of the Commission to Study the Certificate of Need Laws." The recommendations of the commission include the following:

CON process issues

⇒ Amend the CON purpose statement to update it and focus it more on the development and availability of care, access to care, supporting choice while avoiding duplication, ensuring public participation in the CON process and seeking a balance, to the extent it is consistent with the purposes of CON, between competition and regulation in the provision of health care.

⇒ Change the CON Advisory Committee provisions: require the committee to review and comment on criteria for the CON process and the state health plan, review the CON process, provide advice to the Commissioner of DHS, review an annual report on CON from DHS. Delete outdated provisions on staggered membership. Delete the provision on serving until the successor is confirmed. Limit service to 2 4-year terms. Separate the CON Advisory Committee provisions from §307, the review process.

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⇒ Require DHS to adopt, through rulemaking under Title 5, chapter 375, all rules, standards and criteria required for the CON process. All existing rules to be redone at the same time.

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APPENDIX A

RESOLVES 1997, CHAPTER 82

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H7 (1)

APPROVED
JUN 12'97
BY GOVERNOR

CHAPTER
82
RESOLVES

STATE OF MAINE

IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND NINETY-SEVEN

H.P. 734 - L.D. 998

Resolve, to Establish the Commission to Study the Certificate of Need Laws

Emergency preamble. Whereas, Acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, a study of the State's certificate of need laws is necessary to enable the State to plan for changes in the delivery of health care; and

Whereas, at least 6 months are required for a study of the State's certificate of need laws to be completed in a thorough manner; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore, be it

Sec. 1. Commission established. Resolved: That the Commission to Study the Certificate of Need Laws, referred to in this resolve as the "commission," is established; and be it further

Sec. 2. Membership. Resolved: That the commission consists of 15 members appointed as follows:

A. Eight members appointed by the Governor as follows:

(1) Three representatives of the Department of Human Services, one each from the Bureau of Elder and Adult Services, the Bureau of Medical Services and the Audit, Contracting and Licensing Service Center;

(2) One member of the public;

(3) One representative of the Maine Hospital Association, representing large hospitals;

(4) One representative of the Maine Health Care Association;

(5) One representative of a nonprofit hospital and medical service organization; and

(6) One representative of physicians, representing members of the Maine Medical Association; and

B. Seven members appointed jointly by the President of the Senate and the Speaker of the House of Representatives, as follows:

(1) One representative of physicians, representing members of the Maine Osteopathic Association;

(2) One member of the public;

(3) Two Legislators, one representing the majority party and one representing the minority party;

(4) One representative of the Maine Hospital Association, representing small hospitals;

(5) One representative of a health insurer licensed under the Maine Revised Statutes, Title 24-A; and

(6) One representative of the Home Care Alliance of Maine; and be it further

Sec. 3. Appointments. Resolved: That all appointments must be made no later than 30 days following the effective date of this resolve. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. When the appointment of all members is complete, the Chair of the Legislative Council shall call and convene the first meeting of the commission no later than August 1, 1997. The commission shall select a chair from among its legislative members; and be it further

Sec. 4. Duties. Resolved: That the commission shall study the application of the State's certificate of need laws, their effectiveness in ensuring access to health care and in controlling costs, the need for modifications to address the changing health care system and alternative methods of meeting the goals of the laws. In examining these issues, the commission shall consult with the public, providers of health care and insurers and other 3rd-party payors; and be it further

Sec. 5. Staff assistance. Resolved: That the Department of Human Services shall provide staffing and clerical services as requested by the commission; and be it further

Sec. 6. Reimbursement. Resolved: That the commission members who are Legislators are entitled to receive the legislative per diem, as defined in the Maine Revised Statutes, Title 3, section 2, and reimbursement for travel and other necessary expenses for attendance at meetings of the commission. Other members are not entitled to compensation or reimbursement of expenses; and be it further

Sec. 7. Report. Resolved: That the commission shall submit its report with any accompanying legislation to the Joint Standing Committee on Health and Human Services and to the Second Regular Session of the 118th Legislature by December 1, 1997; and be it further

Sec. 8. Appropriation. Resolved: That the following funds are appropriated from the General Fund to carry out the purposes of this resolve.

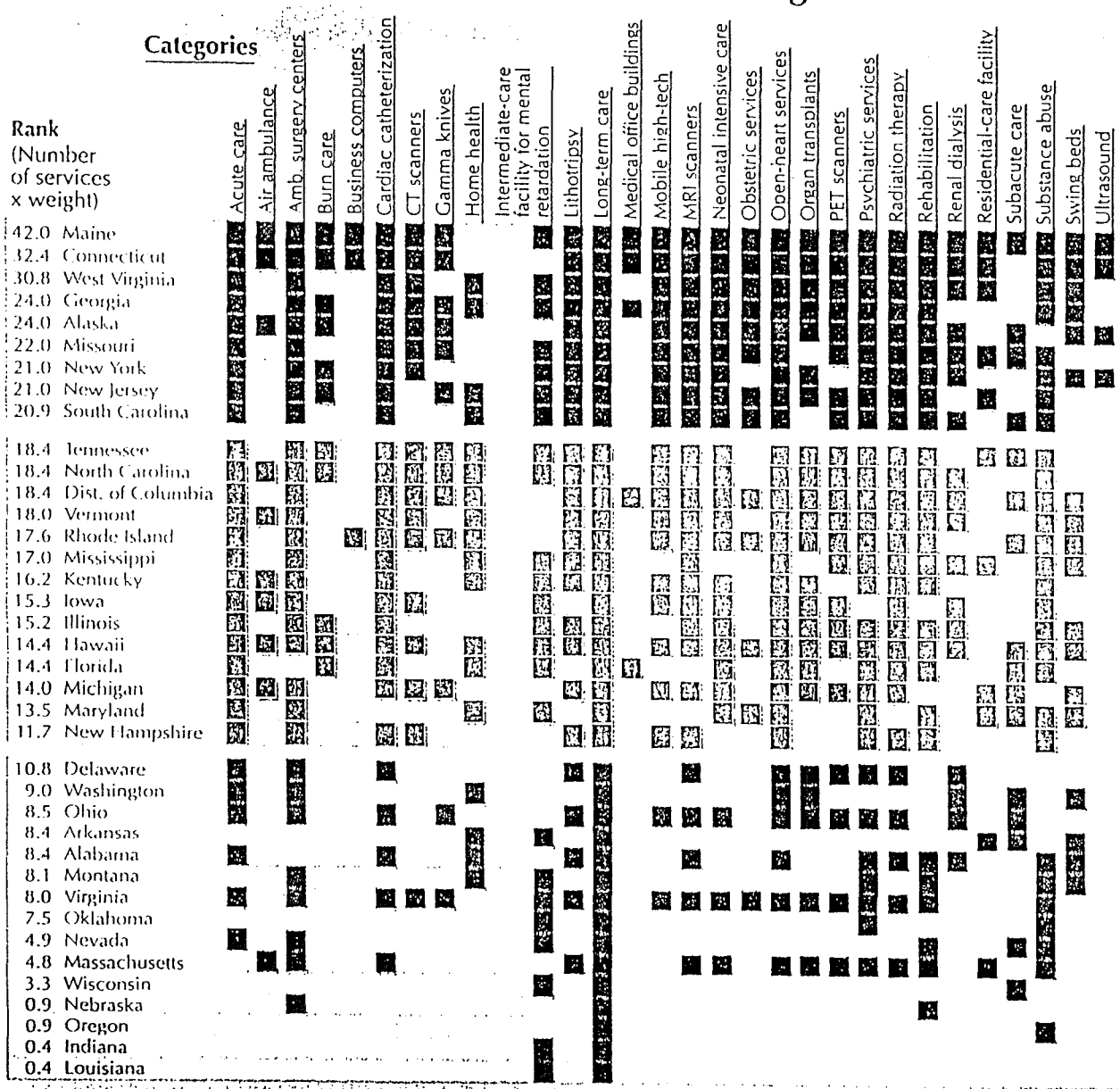
	1997-98
LEGISLATURE	
Commission to Study the Certificate of Need Laws	
Personal Services	$550
All Other	500
Provides funds for the per diem and expenses of the legislative members of the Commission to Study the Certificate of Need Laws.	
LEGISLATURE TOTAL	$1,050

Emergency clause. In view of the emergency cited in the preamble, this resolve takes effect when approved.

APPENDIX C

1997 SCOPE AND REVIEW THRESHOLDS OF CON-REGULATED SERVICES

1997 scope and review thresholds of CON-regulated services



Thirty-seven states and the District of Columbia have some form of certificate of need. Here they are listed in descending order by degree of regulation

Count (Number of services)	Review thresholds: Capital	Review thresholds: Medical equipment	Review thresholds: New services	Weight
28	$ 500,000	$1,000,000	$ 155,000	1.5
27	1,000,000	400,000	Any	1.2
22	750,000	300,000	N/A	1.4
24	1,035,096	575,054	N/A	1.0
24	1,000,000	1,000,000	1,000,000	1.0
22	1,000,000	1,000,000	Addl LTC	1.0
21	1,000,000	1,000,000	Any	1.0
21	1,000,000	1,000,000	Any	1.0
19	1,000,000	600,000	400,000	1.1
23	2,000,000	1,000,000	Any	0.8
23	2,000,000	750,000	N/A	0.8
23	2,000,000	1,300,000	600,000	0.8
20	1,500,000	500,000	300,000	0.9
22	2,000,000	1,000,000	750,000	0.8
17	1,000,000	1,000,000	Any	1.0
18	1,567,500	1,567,500	N/A	0.9
17	1,500,000	300,000	500,000	0.9
19	2,474,063	1,240,318	Any	0.8
24	4,000,000	1,000,000	Any	0.6
16	1,260,000	1,260,000	Any	0.9
20	2,130,000	0	0	0.7
15	1,250,000	N/A	N/A	0.9
13	1,500,000	400,000	Any	0.9
12	1,500,000	1,500,000	N/A	0.9
10	1,202,000	N/A	Any	0.9
17	5,000,000	2,000,000	N/A	0.5
7	500,000	N/A	Home health	1.2
14	3,200,000	1,500,000	Any	0.6
9	1,500,000	750,000	150,000	0.9
20	5,000,000	N/A	N/A	0.4
5	500,000	N/A	Any beds	1.5
7	2,000,000	N/A	N/A	0.7
16	8,668,395	N/A	Any	0.3
3	1,000,000	600,000	Any LTC	1.1
3	LTC/rehab	N/A	LTC/rehab	0.3
3	Any LTC	N/A	Any LTC	0.3
2	Any LTC	N/A	Any LTC	0.2
2	LTC/MR	N/A	LTC/MR	0.2

Source: Prepared July 18, based on mid-1997 information

Compiled by Thomas R. Piper, Missouri CON program, Jefferson City 573-751-6403

Disclaimer: Rank order relates to volume of items reviewed, NOT severity of analysis or conclusions based on criteria and standards and decisions

APPENDIX D

STATUS OF CERTIFICATE OF NEED BY STATE

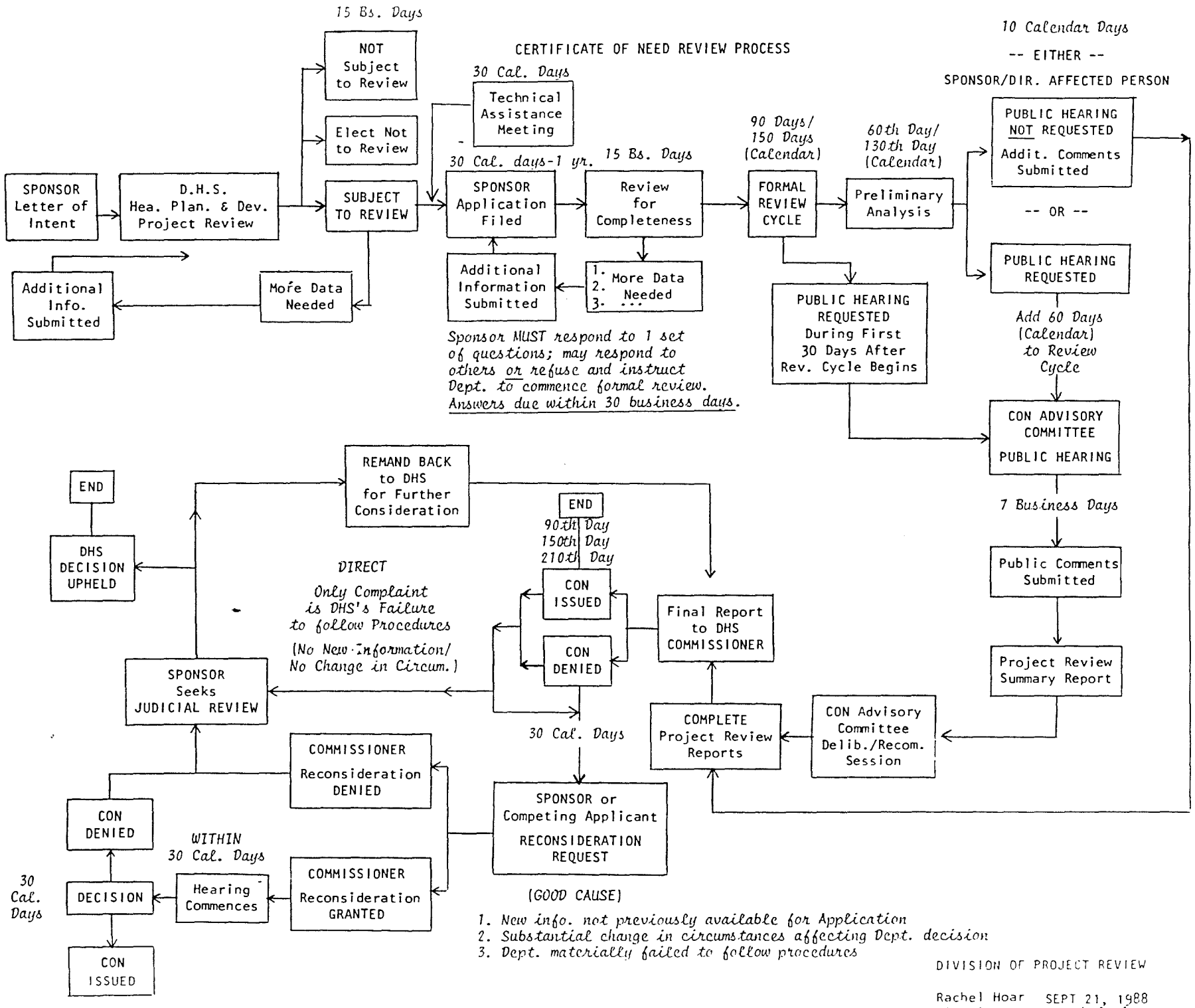
STATUS OF CON BY STATE

State	CON	Thresholds		New Serv.	Non-Hosp. Equip. Review
		Cap.	Equip.		
Alabama	Y	$3.2M	$1.5M	Y	Y
Alaska	Y	1.0	1.0	Y-$1.0	Y
Arizona	N	-	-	-	-
Arkansas	Y, LTC Only	-	-	-	-
California	N	-	-	-	-
Colorado	N	-	-	-	-
Connecticut	Y	1.0	.4	Y	Y
Delaware	Y	.75	.75	Y-.25	Y
Florida	Y	1.1	1.1	Y	N
Georgia	Y	1.0	.5	Y	Y
Hawaii	Y	4.0	1.0	Y	Y
Idaho	N	-	-	-	-
Illinois	Y	2.4	1.2	Y	Y
Indiana	Y, LTC Only	-	-	-	-
Iowa	Y	.8	.3	&-.3	Y
Kansas	N	-	-	-	-
Kentucky	Y	1.5	1.5	N	Y
Louisiana	Y, LTC Only	-	-	-	-
Maine	Y	2.0	1.0	Y-155	Y
Maryland	Y	1.2	-	N	N
Massachusetts	Y	8.5	.45	N	N
Michigan	Y	2.0	-	N	Y
Minnesota	N	-	-	-	-
Mississippi	Y	1.0	1.0	Y	Y
Missouri	Y	.6	.4	Y	Y
Montana	Y, LTC. psych. ASC's	-	-	-	-
Nebraska	Y	1.4	1.0	Y	Y
Nevada	Y	2.0	-	N	N
New Hampshire	Y	1.5	.4	Y	Y
New Jersey	Y	1.0	1.0	Y	Y
New Mexico	N	-	-	-	-
New York	Y	.4	.4	Y	Y
North Carolina	Y	2.0	.75	Y	Y
North Dakota	N	-	-	-	-
Ohio	Y	5.0	2.0	N	Y
Oklahoma	Y, LTC, psych only	-	-	-	-
Oregon	Y, LTC only	-	-	-	-
Pennsylvania	Y	2.0	-	N	Y
Rhode Island	Y	.8	.6	Y	Y
South Carolina	Y	1.0	.6	Y	Y
South Dakota	N	-	-	-	-
Tennessee	Y	2.0	1.0	Y	Y
Texas	N	-	-	-	-
Utah	N	-	-	-	-
Vermont	Y	.3	.25	Y-.15	Y
Virginia	Y	1-2.0	-	N	Y
Washington	Y	1.2	-	Y	N
West Virginia	Y	.75	.30	N	Y
Wisconsin	Y	1.0	.60	N	N
Wyoming	N	-	-	-	-

APPENDIX E

CHART OF CERTIFICATE OF NEED REVIEW PROCESS

CERTIFICATE OF NEED REVIEW PROCESS



DIVISION OF PROJECT REVIEW

Rachel Hoar SEPT 21, 1988
Planning & Research Assistant

APPENDIX F

SUMMARY OF CERTIFICATE OF NEED ACTIVITIES 1979-95

DEPARTMENT OF HUMAN SERVICES

DIVISION OF PROGRAM ANALYSIS AND DEVELOPMENT

SUMMARY OF CERTIFICATE OF NEED ACTIVITIES 1979-95

REVIEW ACTIVITY	No	1991	No	1992	No	1993		1994		1995		1996
TOTAL PROJECTS PROPOSED	88	$59,759,900	102	$62,327,966	120	$78,151,529	100	$147,505,010	116	$54,667,263	0	$0
LETTERS OF INTENT												
Withdrawn												
1. Not subject to review	48	$8,282,948	63	$16,394,921	64	$27,433,643	56	$7,171,471	58	$3,200,520		
2. Elected not to review* (N.A.)												
3. Waiver A**			2	$30,000	2	$41,510	0	$0	6	$48,093		
4. Waiver B** (N.A.)												
5. Waiver E**	4	$4,778,654	12	$5,602,334	14	$18,945,911	12	$9,044,057	11	$5,343,500		
SUBTOTAL, Letters of Intent/waivers	52	$13,061,602	77	$22,027,255	80	$46,421,064	68	$16,215,528	75	$8,592,113	0	$0
APPLICATIONS REVIEWED	36	$46,698,298	25	$40,300,711	40	$31,730,465	32	$131,289,482	41	$46,075,150	0	$0
6. Approved	25	$40,208,146	19	$33,234,133	11	$20,488,161	15	$9,731,683	37	$42,525,150		
7. Approved with modification							9	$92,512,722				
8. Elected not to review (N.A.)												
SUBTOTAL, Approved	25	$40,208,146	19	$0	11	$20,488,161	24	$102,244,405	37	$42,525,150	0	$0
Operating costs avoided												
9. Capital costs reduced from #7 above							-9	$2,449,549				
10. Disapproved			1	$1,531,962	3	$7,906,398	1	$0	1	$1,350,000		
11. Withdrawn pending recommendation to disappr	11	$6,490,152	3	$4,112,862	3	$83,475	5	$26,595,528	3	$2,200,000		
12. Expired/Inactive (failure to respond to requests for necessary documentation)					22	$2,452,431	0		0			
13. Withdrawn for reasons not directly related to CON standards			2	$1,421,754	1	$800,000	2	$0	0			
14. TOTAL capital costs avoided as a direct result of CON standards: Items 9-12	11	$6,490,152	4	$5,644,824	28	$10,442,304	15	$29,045,077	4	$3,550,000	0	$0

Cumulative capital costs, 1991-95:	Proposed:	$402,411,668	Reviewed:	$296,094,106	Avoided:	$55,172,357
Cumulative capital costs, 1979-95:	Proposed:	$1,293,223,460	Reviewed:	$1,029,033,958	Avoided:	$194,961,849

* ENTR - equivalent to an approval.

** WAIVER A - Hospital new health services; no adjustment to financial requirements for additional operating costs; WAIVER B - Hospital minor projects; individual hospital development account used for adjustment to increase financial requirements; WAIVER E - Nonacute services/projects with no significant new costs to health care system.

(N.A.) - No longer applicable.

APPENDIX G

INFORMATION ON THE MAINE CERTIFICATE OF NEED PROGRAM

Maine

Topical Contact Info

	Key State Contact	State Health Plan Contact
Name/Title:	John Dickens, Director	Warren Bartlett, Director
Organization:	Div of Prog Analysis and Dev, Off of Hlth Plng/Res/Dev, Dept of Human Svcs	Office of Health Data & Program Mgmt, Bureau of Health, State House Sta #11
Address:	35 Anthony Ave, State House Sta #11	151 Capital Street
City/State/Zip:	Augusta, ME 04333-0011	Augusta, ME 04333
Phone/E-mail:	207/624-5424	

	Data Contact	Certificate of Need Contact
Name/Title:	Ellen Naor,	John Dickens, Director
Organization:	Off of Data, Resources & Vital Stats Dept of Human Svcs	Div of Prog Analysis and Dev, Off of Hlth Plng/Res/Dev, Dept of Human Svcs
Address:	35 Anthony Ave, State House Sta #11	35 Anthony Ave, State House Sta #11
City/State/Zip:	Augusta, ME 04333-0011	Augusta, ME 04333-0011
Phone/E-mail:	207/624-5445	207/624-5424

Planning Info

Health Plans? **Statewide:** ○ Yes ◉ No **Local:** ○ Yes ◉ No *Date(s) of latest plan(s)?*

Are there any local health planning entities such as HSAs; business, labor or other health coalitions, or other entities: ○ *Yes* ◉ *No*

Publications: ☐ Facility Plan ☐ Specific Svc. Plan ☒ Year 2000 ☒ Other: Small Area Variation on Hlth Status In Maine

Public Data: ☐ Ambulatory Care ☒ Hosp. Discharge ☐ Mental Health ☒ Vital Statistics ☐ Costs/Charges ☒ Long Term Care ☐ Quality ☐ Other:

◉ *Yes* ○ *No* *Has this state experienced any legislative changes in health planning, data or regulation of services and facilities in the last year? If yes, please briefly explain:*
Statutory mandate for a State Health Plan by 1/97, nursing homes may bank beds for up to 4 years

◉ *Yes* ○ *No* *Any "health reform" legislation? If so, who is the contact person including address/phone?*
SHP (contact person above)

Other Plng Info or Plng Efforts: LTC (Nursing Homes) CON Rev. admin. transferred to: Cathy Cobb, Bur. Elder & Adult Svcs, DHS #11, 35 Anthone Ave, Augusta, ME 04333; Prog Coord by John Dickens

Cert. of Need Info

CON Impact: ○ Yes ◉ No Does this state measure the **influence and impact** of CON?

Reports: ☒ Monthly ☐ Quarterly ☒ Yearly Frequency of reports produced about state activities.

Guidance: ☒ Legislation ☒ Rules and Regs ☐ Criteria and Standards ☒ Other

Review Period: 120 Enter average number of days in 1995 to process applications from when it is deemed complete to the occurance of the final decision.

Process Chart: **Letter of Intent**: 15 days to review and determine if CON is required (if incomplete, may ask for additional information. **Application** can be submitted 30–365 days after letter of intent. **Completeness** check: 15 days, applicants have 30 days to respond. **Public Notice** with 30-day period when interested individuals may request a public hearing. **Analysis** and recommendations within 90 days, may be extended 60 days (add 60 more if public hearing called). **Decision** is made by the Commissioner within 90 days. **Judicial review** of the decision is made after 30 days if applicant, competitor, or public appeals (reconsideration by Commissioner is also possible). **Further appeal** would progress to the court system. (detailed CON flow chart available upon request).

compiled by the Missouri Certificate of Need Program for the American Health Planning Association on December 24, 1995

Maine

Contact Info

Certificate of Need (CON) Contact Information

Name/Title: John Dickens, Director
Organization: Div of Prog Analysis and Dev, Off of Hlth Plng/Res/Dev, Dept of Human Svcs
Voice Phone: 207/624-5424 Fax: 207/624-5431 E-mail:

Address/City/State/Zip/Phone:

35 Anthony Ave, State House Sta #11
Augusta, ME 04333-0011

If not "Certificate of Need" . . .
what is your alternate name?

FY96 CON Budget? $250,000

CON staff size? 5

Operational Specifics

Fac. changes: ◉ Yes ○ No Review **changes of owners or operators** for **nursing homes** or **hospitals** or **others** (specify): all health care facilities & operators

Population: 1,065,066 **(under age 65)** + 162,862 **(65 and over)** = 1,227,928 **Total Pop.**
(unless otherwise noted, the 1990 census data is used for this state; it is used as the common denominator to develop comparative rates among states for capacity and resources)

No. of Facilities: Number of **facilities** this state currently has in the following categories:
40 Hospitals 169 Nursing Homes _____ Resid. Care Fac. 4 Psychiatric

Bed capacity: Number of **beds** in health facilities in this state currently includes the following:
4,376 Hospitals 9,437 Nursing Homes _____ Resid. Care Fac. 558 Psychiatric

High tech eqpt: Number units of **equipment** in this state currently includes the following categories:
0 Gamma Knives 9 MRIs 2 Lithotriptors 0 PETs 17 CTs 8 Linear Accel.

FY96 Activity:	Hospitals	Nursing Homes	Freestanding	Mobile Svcs	TOTAL
Total Dollar					$49,917,886
Approved Dollars					$39,475,582
No. Applications					56

Cert. of Need Info

CON Fees: $1,000 per $1 million of capital expenditures

Thresholds: **Capital:** $500,000 **Equipment:** $ 1,000,000 **New Service:** $ 155,000

Final Decision: Commissioner, Dept. of Human Services

New Bed Moratoriums: ☐ Hospital ☒ LTC ☐ Other *General Notes:*

Major Med Eqpt Review: ☒ Hospital-based ☒ Freestanding ☒ Mobile ☐ None

Hlth. services covered by CON:

☒ Acute Care	☒ Gamma Knives	☒ MRI Scanners	☒ Radiation Therapy	☒ Ultra-sound	
☒ Air Ambulance	☐ Home Health	☒ Neo-natal Int. Care	☒ Rehabilitation	☐ Other:	
☒ Ambul. Surg. Ctrs.	☒ ICF/MR	☒ Obstetrical	☒ Renal Dialysis		
☒ Burn Care	☒ Lithotripsy	☒ Open Heart	☒ Resid. Care Fac.		
☒ Cardiac Cath.	☒ Long Term Care	☒ Organ Transplant	☒ Subacute Care		
☒ Bus. Computers	☒ Medical Office Bldgs.	☒ PET Scanners	☒ Substance Abuse		
☒ CT Scanners	☒ Mobile High Tech	☒ Psychiatric Svcs.	☒ Swing Beds		

Comments: Guidelines instead of standards; criteria in statute

(most historical data is for FY96 [7/1/95–6/30/96] . . . fees/thresholds/moratoriums/other as of Sept. 1996)

compiled by the Missouri Certificate of Need Program for the American Health Planning Association on December 24, 199

APPENDIX H

"THE CASE AGAINST CERTIFICATE OF NEED"

Gordon H. Smith, Esq.
Maine Medical Association
December 4, 1997

The Case Against Certificate of Need

1. Certificate of Need was historically enacted to review capital expenditures in hospitals. A historical review of the development of Certificate of Need legislation at both state and federal levels indicates that neither statute contemplated extension of the Certificate of Need requirement to other than health care facilities. The reason for this is a very simple one. The purpose of Certificate of Need was founded on the reasonable cost reimbursement method which applied to hospitals and did not and does not apply to other health care providers. This reasonable cost reimbursement formula assured that hospitals would be reimbursed for the cost of all capital equipment for facilities and equipment regardless of use or need. Under reasonable cost formula, hospitals were reimbursed for all capital costs incident to those acquisitions, whether or not the facilities were ever opened or used or whether or not the equipment was ever used to provide a single service. Recognizing this reimbursement situation and in an effort to deter the development and duplication of unnecessary facilities and services, the United States Congress passed the first Certificate of Need Law in 1972. Maine's law has closely mirrored the Federal law, including changes in the Federal 1974 legislation entitled "The National Health Planning and Resources Development Act." Providers of services other than facilities and now hospitals as well, are reimbursed under a variety of methods, including capitation and through negotiated fees. This difference in reimbursement alone assures that today any facility purchasing significant major medical equipment or otherwise expanding, will be certain that the equipment or expansion is needed in the community before it is purchased or built. If they purchase the equipment and the need is not there, the provider will face financial loss. No one is guaranteeing their payment to them. In this age of market-driven managed care, CON is an anachronistic regulatory tool.

2. As noted by Stephen Wessler in his recent presentation to the Commission, the Certificate of Need Law is a franchising mechanism that can not be reconciled with the competitive aspects of health care happening in some markets in Maine presently. The trend nationally is in favor of repealing Certificate of Need Laws which franchise inefficient providers and inhibit innovation and competition. Many states, including Arizona, Kansas, Minnesota, Idaho, Utah, New Mexico, Louisiana and California, Colorado, Wyoming, South Dakota, Texas, Florida, Montana and West Virginia, have repealed their Certificate of Need Laws as they apply to hospitals, and, in recent history, no state has extended the requirement to a physician's office. In the last year alone, 32 states have changed their CON laws and four more states, North Dakota, Ohio, Pennsylvania and Nebraska, repealed their laws altogether. For example, Wisconsin now subjects only nursing homes to CON review and Indiana's CON program has been limited to psychiatric hospitals and long-term care facilities.

3. Care delivered within a hospital is care delivered in the most expensive setting. The Federal Government, business and labor groups, as well as private insurers have all taken active steps to remove the provision of health care from the hospital setting when this can be done without compromising the quality of care. Require non-institutional providers to go through a Certificate of Need process puts them in a non-competitive position relative to hospitals with respect to ability to devote the necessary time, money and personnel to the Certificate of Need process. Time and cost associated with achieving a Certificate of Need can be as much as a year and tens of thousands of dollars with no assurance of success. In the meantime, necessary medical services may be denied to patients.

4. The Department of Human Services retains within its Certificate of Need Law the ability to grant the Certificate based upon certain conditions. The granting of such conditions can be very arbitrary as pointed out by John Dickens in his presentation to this Commission last meeting.

5. State regulators should not be permitted to restrict equipment or services, thus preventing its use by any and all patients when the State's share of the cost of the Medicaid program represents only a fraction of health care expenditures in Maine. The physician portion of Medicaid, for instance, represents less than 4% of the Medicaid budget!

6. Over the past two years, a Commission authorized by the Legislature has examined the issue of competition and regulation in health care and did not recommend expanding CON. Neither did the CON study conducted by the Human Resources Committee in 1986. In fact, three study Commissions in the past 12 years have rejected this approach. This Legislature itself has defeated similar proposals at least four times since 1978.

7. Maine patients should have a choice with respect to surgical locations. All over the country, patients are finding out-patient surgical facilities convenient to use, of high quality, and frequently pay less for the service then when it is offered in a hospital. Patients throughout Maine are being denied this choice by a highly restrictive CON law. A recent national publication (Orthopedic Practice Management, Oct. 1997) stated that Maine's CON laws were the most inclusive of all such laws in the country.

8. Several efforts have been made to assess the impact of CON review on health care costs. A number of studies have utilized sophisticated regression analysis techniques in attempts to compare various measures of hospital utilization and costs in states before and after enactment of CON reviews or between states with and without CON programs. A review of these studies was prepared by the US Congressional Budget Office in 1982. In general, studies that examined the relationship between CON review and hospital unit costs (e.g., cost per admission) have found no solid evidence that the presence of such programs has reduced such costs. (Sloan, 1981 and Policy Analysis, Inc., and Urban Systems Research and Engineering, Inc., 1980). Other studies examining the extent to which CON programs controlled growth in hospital use either found only a very tenuous relationship between the presence of a CON program and reduced hospital use (Salkever and Bice, 1979) or no relationship at all (Sloan, 1981). This report, sponsored by the Federal Department of Health and Human Services concludes that hospital CON programs may actually have increased hospital costs from 1968 to 1972 by increasing the rate of growth in assets per bed.

In 1987, the Federal Trade Commission found the CON requirements actually increased hospital prices by 4%. In addition, the study found that hospital expenses were higher in states that have CON laws. According to the study conducted at the request of the FTC's Bureau of Economics, there is "no evidence that CON laws have resulted in the resource savings they were purportedly designed to promote." According to the Bureau, "recent plans and decisions to repeal CON laws in some states should increase consumer welfare."

Given overwhelming evidence against the efficacy of the CON process in controlling costs, it is not surprising that the trend across the country is to repeal CON laws.

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APPENDIX I

"FEW ALTERNATIVES SEEN AS CON LAWS ARE THREATENED BY THE RISE OF MANAGED CARE"

Certificate of Need

FEW ALTERNATIVES SEEN AS CON LAWS ARE THREATENED BY RISE OF MANAGED CARE

Certificate-of-need laws may be slipping away in a number of states, but there is no consensus yet as to what should take their place, according to interviews with regulators, industry officials, and researchers.

The trend, while sometimes overstated, is clear. Certificate-of-need (CON) laws, originally intended to bring health care costs under control by preventing facilities from expanding unnecessarily, have been abolished in 13 states and whittled back to a shell in others.

Thirty-seven states and the District of Columbia still have CON laws in some form, but they range from broad regulation in Maine, Connecticut, and West Virginia to nearly nothing in states like Louisiana, according to an analysis by Thomas R. Piper, executive director of Missouri's CON program.

Critics say CON laws are no longer needed, that the rise of managed care has kept costs under control far more successfully without the burden of government regulation.

Some critics, like Nebraska Sen. Kate E. Witek (I), one of the leaders of the successful drive earlier this year to phase out virtually all of the state's CON laws, say little else is necessary now that managed care is firmly in place.

Others, like Georgia Rep. E.M. "Buddy" Childers (D), sponsor of the unsuccessful attempt earlier this year to repeal Georgia's CON laws for hospitals (6 HLR 427, 3/20/97), said any problems that arise after CON repeal can be handled through other means, such as funding pools to support indigent care and teaching hospitals.

Others say the future lies in community-level efforts that fall short of active regulation. Some, like Piper, believe in striking a balance between CON and managed care, with government acting as a watchdog to provide "checks and balances" in the new market-driven system.

Is CON Out Of Date?

The general idea of CON laws is to hold health costs down by keeping hospitals and other health care facilities from expanding unnecessarily and buying equipment they do not need. To prevent this, the facilities must show why they need new capital projects, equipment, and expensive services.

Starting in 1974, states were required by federal law to have CON programs to qualify for certain health care funds, but the federal mandate was repealed in 1987 and the rollbacks began.

Some CON critics argue that the laws simply do not work very well. In Nebraska, there never was a high rejection rate to begin with, but the process was undermined over the years because lawmakers regularly pushed through exemptions for hospitals in their districts, according to Witek.

In Texas, which abandoned its CON program in 1985, a similar history of favoritism and ineffectiveness has made it hard to stir up any interest in reviving the program, according to Lisa McGiffert, a senior policy analyst with the Southwest Office of Consumers Union.

"It was extremely influenced by money and politics. There was a lot of controversy about who got approved and who didn't," McGiffert said of the old CON program. Moreover, the commission that ran the program did not do what it was charged to do, which was to hold down costs, she said.

In addition, few economists believe CON laws had any significant role in keeping hospitals from adding unnecessary beds and many believe the laws have been used by existing hospitals to keep new facilities out of the market, according to Paul Ginsburg, president of the Washington, D.C.-based Center for Studying Health System Change.

Defenders of CON laws disagree. Dean Montgomery, executive director of the Northern Virginia Health Systems Agency, said CON laws are "not a panacea," but a planning tool that has had some effect on costs, quality, and access where the laws have been applied consistently.

The rise of managed care has changed the picture, however, achieving success in containing costs that CON never achieved.

"I think [CON laws] did work, but now they're out of date with the managed care environment," said Childers.

One significant exception has been long-term care. Even states that have ended virtually all CON reviews, such as Louisiana and Ohio, have left the process in place for long-term care, largely as a way of controlling Medicaid costs. Medicaid pays for more than half of all nursing home bills in the country and long-term care services accounted for 35 percent of all Medicaid expenditures in 1994, according to the Kaiser Commission on the Future of Medicaid.

In Ohio, legislators agreed to protect CON for long-term care because building sprees in non-CON states like Arizona, Utah, and Colorado "almost bankrupted Medicaid in those states," according to Bob Thimmes, president and chief executive officer of the Miami Valley Health Improvement Council in Huber Heights, Ohio.

Although Wyoming dropped its CON requirement in 1985, the state continues to limit construction of "swing beds" and nursing home beds, Dan Perdue, vice president of the Wyoming Hospital Association, told BNA. "It's kind of a quasi-CON law," he added.

Costs, Access, And Quality

Those who support CON laws say the laws are not just about controlling costs but are intended to guarantee quality and access as well. It is these goals that are in jeopardy, they say, as CON laws are scaled back or repealed outright.

In Nebraska, where Gov. E. Benjamin Nelson (D) signed a law earlier this year that will end virtually all CON regulation within about two years, CON supporters worry that ambulatory surgical centers will threaten the survival of community hospitals by entering markets and "cherry-picking" the best cases. That would leave the community hospitals to treat the people with more severe illnesses and less ability to pay for the treatment, they say.

"They didn't even feign an alternative" to CON, Nebraska Sen. Don Wesely (I), chairman of the Senate Health and Human Services Committee and a defender of CON, said of the critics who pushed for the repeal. "It was as if nobody had any worries about that."

The Nebraska law includes a two-year moratorium on new hospital and nursing home beds and phases out the CON review of ambulatory surgical centers by the end of 1999. Like Ohio and Louisiana, Nebraska will keep long-term care under CON review. Other than that, however, there will be "essentially no state regulation" of new health facility construction and equipment purchases after two years, Wesely said.

When run correctly, CON programs ask the right planning questions, Piper of Missouri said. He noted that managed care supporters promise not just lower costs but improved access and improved quality. But they also want total deregulation, "which essentially means, 'Don't watch us,'" he said.

"That's the wrong promise," Piper said. "We shouldn't be in the honesty game. We're in the checks and balances game."

Supporters of CON laws believe the critics have little to offer other than ideological arguments against government regulation and in favor of letting the market sort out the problems of the health care system. "If you oppose it, that's the only argument you really have," Montgomery said.

Some Constraints Considered

Still, not all of the critics would suggest letting the markets operate with no safety net at all. Childers would set up funding pools for indigent care and teaching hospitals, in which hospitals either would offer the services or pay the equivalent amount into the pools to be redistributed to other facilities.

And although Columbia/HCA Healthcare Corp. had lobbied heavily in Georgia and some other states to repeal CON laws outright, Columbia/HCA spokesman Jeff Prescott said the company now is "taking a more cooperative approach" to work out solutions in those states that could involve a balance between market forces and government regulation.

Witek, however, said there was no need for a continued government role in Nebraska other than the reviews for long-term care and the moratorium on new hospital beds, which she said were intended mainly to keep the repeal effort from getting bogged down by too many issues.

"There are constant changes in the health care market. Taking care of every eventuality is impossible for everybody," Witek said. "I'm much more comfortable letting the market handle the change in a flexible way than leaving it to a government-run system that is inflexible."

Community-Level Health Planning

Other analysts say the alternative, which may be evolving on its own rather than as part of a conscious effort, is scattershot health planning efforts that will be run at the community level and vary from county to county.

That has been the aftermath in Ohio, where CON review is being phased out for most services, according to Gretchen McBeath, a partner in the law firm of Bricker and Eckler in Columbus. Since the phase-out began, there have been building sprees in some communities, but others have seen no change and there appears to be no pattern that would allow people to predict where health planning is needed, she said.

As a result, some Ohio communities are starting to talk about setting up health planning mechanisms, generally involving the city council or a local health planning agency, while others have seen no need for them, McBeath said.

One Ohio community where health planning has continued is Miami Valley, which includes Dayton and Springfield. There, the Miami Valley Health Improvement Council has been taking a more low-key approach to health planning. It monitors the construction of new facilities, reports data to the community, brings players together to resolve disputes over proposed expansions, and coordinates volunteers who report access problems and other trouble spots.

Thimmes, the president of the agency, said he sees it as a model for other communities to examine and adjust to their needs if they are trying to set up local health-planning mechanisms.

Checks And Balances

Others say the answer is to find ways for CON and managed care to work together.

Piper said many people falsely see the situation as a "teeter-totter" pitting CON against managed care, when in fact CON or some variation of it is necessary to make sure managed care fulfills its promises of lower costs, greater access, and greater quality.

"Whether you call it CON or something else, the government has to have a role in the delivery of health care services," Piper said. "We inspect restaurants to see if the kitchens are safe. In the same way, we should be inspecting and monitoring health care to make sure the access and quality are there."

Left alone, the overall drive toward for-profit health care has led to mergers, closures, and buyouts that have restricted competition in some areas, Piper said. Still, he credited managed care with achieving control over the rise of health costs, something CON review was unable to do for many years.

"That's why we need to work hand in hand, rather than at each other's throats," Piper said.

—By David Nather, with contributions from Kurt Fernandez and Tripp Baltz

1084-2137/97/$0+$1.00

APPENDIX J

REPORT OF THE NATIONAL ASSOCIATION FOR HOME CARE ON CERTIFICATE OF NEED FOR HOME CARE AGENCIES AND HOSPICES

Introduction

This report reflects information gathered by the National Association for Home Care (NAHC) from a telephone survey of NAHC's Forum of State Associations. The survey was compiled in September, 1995.

Included in this report is a state-by-state listing on licensure and certificate of need (CON) information for Medicare-certified home care agencies, non-Medicare certified home care agencies, paraprofessional providers (home care aid, personal care aide, homemaker), Medicare certified hospices, non-Medicare certified hospices, temporary staffing agencies, IV therapy providers, and home medical equipment providers.

A brief summary of the survey findings follow.

Of the 50 states, Puerto Rico and the District of Columbia:

40 states require Medicare-certified agencies to obtain licensure;
37 states require non-Medicare-certified agencies to obtain licensure;
18 states require home care providers (home care aide, personal care aide, homemaker) to obtain licensure;
39 states require Medicare-certified hospices to obtain licensure;
37 states require non-Medicare-certified hospices obtain licensure;
12 states require temporary staffing agencies to obtain licensure;
18 states require providers of IV therapy to obtain licensure; and
5 states require home medical equipment providers to obtain licensure.

Of the 50 states, Puerto Rico, and the District of Columbia:

21 states require Medicare-certified agencies to obtain CON;
11 states require non-Medicare-certified agencies to obtain CON;
4 states require home care providers (home care aide, personal care aide, homemaker) to obtain CON;
11 states require Medicare-certified hospices to obtain CON;
4 states require non-Medicare-certified hospices to obtain CON;
2 states require temporary staffing agencies to obtain CON.
3 states require providers of IV therapy to obtain CON; and
0 states requires home medical equipment providers to obtain CON.

Summary of States

State		1 Medicare-Certified HHA	2 Non-Medicare-Certified HHA	3 Paraprofessional Provider*	4 Medicare-Certified Hospice	5 Non-Medicare-Certified Hospice	6 Temporary Staffing Service	7 IV Therapy Provider	8 Home Medical Equipment Provider
Alabama	Licensure	No	No	No	Yes	Yes	No	No	No
	CON	Yes	Yes	No	No	No	No	No	No
Alaska	Licensure	Yes	No	No	Yes	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Arizona	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Arkansas	Licensure	Yes	Yes	Yes	Yes	Yes	Yes	No	No
	CON	Yes	Yes	Yes	No	No	Yes	No	No
California	Licensure	Yes	Yes	No	Yes	Yes	No	Yes	No
	CON	No	No	No	No	No	No	No	No
Colorado	Licensure	No	No	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Connecticut	Licensure	Yes	Yes	Yes	No	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Delaware	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No

* home care aide, personal care aide, homemaker

Summary of States

State		1 Medicare-Certified HHA	2 Non-Medicare-Certified HHA	3 Paraprofessional Provider*	4 Medicare-Certified Hospice	5 Non-Medicare-Certified Hospice	6 Temporary Staffing Service	7 IV Therapy Provider	8 Home Medical Equipment Provider
D.C.	Licensure	No	No	No	No	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Florida	Licensure	Yes	Yes	Yes	Yes	Yes	Yes	Yes†	No
	CON	Yes	No	No	Yes	No	No	No	No
Georgia	Licensure	Yes	No	Yes	Yes	No	No	No	No
	CON	Yes	No	Yes	No	No	No	No	No
Hawaii	Licensure	Yes	No	No	Yes	No	No	No	No
	CON	Yes	No	No	Yes	No	No	No	No
Idaho	Licensure	Yes	Yes	No	No	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Illinois	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Indiana	Licensure	Yes	Yes	Yes	Yes	Yes	No	Yes †	No
	CON	No	No	No	No	No	No	No	No
Iowa	Licensure	No	No	No	Yes	Yes	No	No	No
	CON	Yes	No	No	No	No	No	No	No

* home care aide, personal care aide, homemaker

† only if nursing services are provided

Summary of States

State		1 Medicare-Certified HHA	2 Non-Medicare-Certified HHA	3 Paraprofessional Provider*	4 Medicare-Certified Hospice	5 Non-Medicare-Certified Hospice	6 Temporary Staffing Service	7 IV Therapy Provider	8 Home Medical Equipment Provider
Kansas	Licensure	Yes	Yes	No	No	No	No	Yes	No
	CON	No	No	No	No	No	No	No	No
Kentucky	Licensure	Yes	Yes	No	Yes	Yes	Yes	Yes	No
	CON	Yes	Yes	No	Yes	Yes	Yes	Yes	No
Louisiana	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Maine	Licensure	Yes	Yes	No	Yes	Yes	No	Yes	No
	CON	Yes	Yes	No	Yes	No	No	No	No
Maryland	Licensure	Yes	Yes	No	Yes	Yes	Yes †	Yes †	Yes †
	CON	Yes	Yes	No	Yes	Yes	No	No	No
Massachusetts	Licensure	No	No	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Michigan	Licensure	No	No	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Minnesota	Licensure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes ∂
	CON	No	No	No	No	No	No	No	No

* home care aide, personal care aide, homemaker
† as residential service agencies

∂ yes, if accompanied by the provision of services defined by law as a home care service

Summary of States

State		1 Medicare-Certified HHA	2 Non-Medicare-Certified HHA	3 Paraprofessional Provider*	4 Medicare-Certified Hospice	5 Non-Medicare-Certified Hospice	6 Temporary Staffing Service	7 IV Therapy Provider	8 Home Medical Equipment Provider
Mississippi	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	Yes	Yes	No	No	No	No	No	No
Missouri	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Montana	Licensure	Yes	No	No	Yes	Yes	No	No	No
	CON	Yes	No	No	No	No	No	No	No
Nebraska	Licensure	Yes	Yes	Yes	No	No	Yes †	Yes	No
	CON	No	No	No	No	No	No	No	No
Nevada	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
New Hamp.	Licensure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	CON	No	No	No	No	No	No	No	No
New Jersey	Licensure	Yes	Yes	Yes	No	No	Yes	No	No
	CON	Yes	No	No	No	No	No	No	No
New Mexico	Licensure	Yes	Yes	No	Yes	Yes	No	Yes	No
	CON	No	No	No	No	No	No	No	No

* home care aide, personal care aide, homemaker
† # staff provided to home health

Summary of States

State		1 Medicare-Certified HHA	2 Non-Medicare-Certified HHA	3 Paraprofessional Provider*	4 Medicare-Certified Hospice	5 Non-Medicare-Certified Hospice	6 Temporary Staffing Service	7 IV Therapy Provider	8 Home Medical Equipment Provider
New York	Licensure	No	Yes	Yes	No	Yes	Yes	Yes	No
	CON	Yes	No	No	Yes	No	No	No	No
N. Carolina	Licensure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
	CON	Yes	No	No	Yes	No	No	No	No
N. Dakota	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Ohio	Licensure	No	No	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Oklahoma	Licensure	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
	CON	No	No	No	No	No	No	No	No
Oregon	Licensure	Yes	Yes	No	No	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Pennsylvania	Licensure	Yes	Yes	No	No	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Rhode Island	Licensure	Yes	Yes	Yes	Yes	Yes	Yes	No	No
	CON	Yes	No	No	Yes	No	No	No	No

* home care aide, personal care aide, homemaker

Summary of States

State		1 Medicare-Certified HHA	2 Non-Medicare-Certified HHA	3 Paraprofessional Provider*	4 Medicare-Certified Hospice	5 Non-Medicare-Certified Hospice	6 Temporary Staffing Service	7 IV Therapy Provider	8 Home Medical Equipment Provider
S. Caroline	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	Yes	Yes	No	No	No	No	No	No
S. Dakota	Licensure	No	No	No	No	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Tennessee	Licensure	Yes	Yes	Yes	Yes	Yes	No	Yes †	Yes
	CON	Yes	Yes	Yes	Yes	Yes	No	Yes †	No
Texas	Licensure	Yes	Yes	Yes	Yes	Yes	No	Yes †	No
	CON	No	No	No	No	No	No	No	No
Utah	Licensure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
	CON	No	No	No	No	No	No	No	No
Vermont	Licensure	No	No	No	No	No	No	No	No
	CON	Yes	Yes	No	No	No	No	No	No
Virginia	Licensure	Yes	Yes	Yes	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Washington	Licensure	Yes	Yes	Yes	Yes	Yes	No	Yes †	No
	CON	Yes	No	No	Yes	No	No	No	No

* home care aide, personal care aide, homemaker
† if they provide nursing in the home

Summary of States

State		1 Medicare-Certified HHA	2 Non-Medicare-Certified HHA	3 Paraprofessional Provider*	4 Medicare-Certified Hospice	5 Non-Medicare-Certified Hospice	6 Temporary Staffing Service	7 IV Therapy Provider	8 Home Medical Equipment Provider
West Virginia	Licensure	No	No	No	Yes	Yes	No	No	No
	CON	Yes	Yes	Yes	Yes	Yes	No	No	No
Wisconsin	Licensure	Yes	Yes	No	Yes	Yes	No	No	No
	CON	No	No	No	No	No	No	No	No
Wyoming	Licensure	No	No	No	No	No	No	No	No
	CON	No	No	No	No	No	No	No	No
Puerto Rico	Licensure	Yes	Yes	No	No	No	No	No	No
	CON	Yes	Yes	No	No	No	No	No	No

* home care aide, personal care aide, homemaker

APPENDIX K

"EFFECTS OF DEREGULATION OF CERTIFICATE OF NEED (CON) REQUIREMENTS

THE ADVISORY BOARD COMPANY

600 New Hampshire Avenue, N.W. • Washington, DC 20037 • Telephone: 202-672-5600 • Fax: 202-672-5700

000-043-013

EFFECTS OF THE DEREGULATION OF CERTIFICATE OF NEED (CON) REQUIREMENTS

NOVEMBER 1996

- Research Methodology
- Executive Summary
- Source Information
- Cost
- Charity Care
- Occupancy Rates
- Managed Care

FACT BRIEF

This project was researched and written to fulfill the specific research request of a single member of the Health Care Advisory Board and as a result may not satisfy the information needs of other members. The Health Care Advisory Board encourages members who have additional questions about this topic to assign custom research projects of their own design. The views expressed herein by third party sources do not necessarily reflect the policies of the organizations that they represent.

THE ADVISORY BOARD COMPANY

600 New Hampshire Avenue, N.W. • Washington, DC 20037 • Telephone: 202-672-5600 • Fax: 202-672-57(X)

FACT BRIEF

Effects of the Deregulation of
Certificate of Need (CON) Requirements
November 18, 1996

RESEARCH METHODOLOGY

During the course of research, members of the Advisory Board staff contacted state agencies, hospital associations, consultants, hospitals and health systems in order to determine the impact of repealing certificate of need (CON) regulations. In addition, researchers searched the Medline, ProQuest Business Periodicals OnDisc and Lexis/Nexis databases, as well as the Advisory Board's internal library of previously completed reports and secondary sources.

EXECUTIVE SUMMARY

State CON programs vary greatly and little statistical evidence exists supporting the repeal or maintenance of CON. To illustrate the variety of CON legislation in existence, one source profiled within the following report noted, "If you have seen one state's CON program, you have seen one state's CON program." As a result of the diversity and little identifiable information supporting either side, CON has become a very politicized issue. Sources contacted indicated that hospitals and other involved parties base their decisions regarding CON largely upon self-interest. For instance, a hospital that desires to purchase new magnetic resonance imaging (MRI) equipment may be in favor of repealing CON legislation, while a competing hospital that maintains MRI equipment will be opposed to repealing CON legislation.

A major problem with determining the impact of repealing CON is that the states that have repealed CON no longer track the statistical information necessary to determine the impact of the changes in legislation. The CON offices in many states previously tracked the information listed below.

- Access to care
- Charity care
- Health care costs
- Occupancy rates
- Quality of care

When CON was repealed, the statistical tracking halted as well. As a result, very little data exists concerning the impact of the deregulation of CON requirements.

Critics of CON regulation argue that managed care has taken the place of state tracking agencies. In a market that maintains high managed care penetration, competition among hospitals for managed care contracts forces the hospitals to lower costs and improve quality. As a result, managed care fulfills the original purpose of CON legislation, which was to prevent high health care costs through regulating high technology purchases and hospital expansions.

Proponents of CON requirements argue that despite managed care, quality is a major concern in states that no longer maintain CON. In addition to carefully monitoring high technology purchases, CON regulates the creation of high risk medical care departments like open-heart surgery programs. By limiting the number of high risk medical care departments, CON enables physicians to maintain high patient loads at those specialty departments, which provide the physicians with enough procedures to remain proficeint in that specialty. If many more hospitals expand into these high risk areas, patient volume per hospital will drop and quality may be diminished, as physicians will not be able to perform enough of these procedures to remain proficient.

Sources at the profiled organizations tended to agree that on most issues the effects of repealing CON legislation were difficult to determine. Journal literature suggests that building and expenditures increased immediately following the repeal of CON in most states; however, the increase may have been due to the simultaneous commencement of many projects waiting for CON approval. The effect of the deregulation of CON on quality has been difficult to determine, as researchers were unable to find any state agencies that tracked quality in states that have repealed CON.

Athough health care costs have increased and bed occupancy rates have decreased in states that repealed CON legislation, these two trends are nationwide phenomena that have occurred regardless of CON requirements. Therefore, the deregulation of CON requirements cannot be directly linked to these events other than through anecdotal evidence.

SOURCE INFORMATION

Information concerning organizations, associations, consultants and hospitals profiled within this report is listed, in pseudonym form, below.

- **Lewin VHI Inc.** is a Fairfax, Virginia-based consulting firm that specializes in CON regulation.
- **Department of Health B** is the agency that reviews CON requests in a state that maintains CON regulations. The state is located in the Midwest.
- **State Hospital Association C** is a hospital association located in a state that has recently repealed CON legislation. It is located in the Midwest.
- **Hospital D** is a 200-bed, not-for-profit hospital located in a large city in the Midwest, in a state that has repealed CON legislation.
- **Hospital E** is a 500-bed, not-for-profit hospital located in a medium-sized city in the Midwest, in a state that has repealed CON legislation.
- **State Hospital Association F** is a hospital association in a state that repealed CON legislation in the mid-1980s. The association is located in the Midwest.
- **Department of Health G** is a state-run agency that was formerly in charge of reviewing CON applications. CON legislation was repealed in this midwestern state in the mid-1980s.

COST

What is the effect of deregulation on the cost of health care?

According to journal literature, one of the original purposes of CON regulation was to help control health care costs by regulating the purchase of high technology equipment. Under CON, hospitals must show a need, prior to purchase, for equipment that amounts to a significant capital expendature. To those who argue against CON deregulation, the repeal of CON legislation would result in an increase of expensive high technology equipment purchasing by hospitals. Health care cost would rise as a result, as hospitals would have to make up the capital investment expended upon the new equipment. Increased purchasing would lead to an overabundance of expensive high technology services, and, consequently, lead to higher costs per procedure to recoup capital lost when patient demand decreased.

The impact of CON regulation on health care costs is at best inconclusive. According to the Winter 1993, *Spectrum* article entitled, "Certificate of Need Revisited," based on extensive empirical analysis of hospital costs between 1980 and 1989 the article states, "CON programs have not been successful in holding down hospital costs."

The director of legal services at **State Hospital Association C** agrees that CON regulations have not lowered hospital costs. He stated that his state has repealed CON legislation, reimplemented CON, and then repealed CON again. Throughout this process, health care costs have increased at the same inflation rate as national health care costs. As a result, rising prices and CON deregulation do not necessarily correlate.

However, the vice president of planning and business development at **Hospital E** stated that capital expenditure in the same state as State Hospital Association C increased dramatically when CON was first repealed. Athough, he added that this might have been due to a large number of projects waiting for CON approval that commenced at the same time due to CON repeal.

Additionally, an administrator at **Department of Health G** added that the CON process itself is an expensive one. Between hiring staff to create the applications for CON approval, application fees and legal cases, the CON process proves to be expensive for hospitals. The process is also costly for the state. According to a previously completed Advisory Board report entitled, "The Impact of Repealing CON Regulation at the State Level (12/94)," states spend between $300,000 and $1 million annually on CON regulatory bodies. The administrator at Department of Health G added that all of the regulation was meaningless, as, "CON rarely rejected building projects in our state, it just slowed them down. If you really wanted to get a project through, it was possible."

CHARITY CARE

Has deregulation affected charity care?

In many states, hospitals must demonstrate the amount of charity care its projects would provide as part of the application process for CON. Although the application process varied dramatically from state to state, literature suggests that repealing CON regulations may lead to a drop in charity care. If a hospital no longer is required to provide charity care in order to gain approval for skeptics believe that hospitals may cease to provide that care.

Sources contacted unanimously agreed charity care has not been noticeably affected by deregulation of CON legislation. The senior vice president of planning at **Hospital D** explained that other restrictions on hospitals maintain levels of charity care. Tax exemption through not-for-profit hospital status and moral and ethical standards prevent hospitals from lowering the levels of charity care provided.

A source at **Lewin VHI Inc.** commented that there is some anecdotal evidence that charity care may be increased by states that maintain CON requirements. For instance, the state of Pennsylvania negotiated CON applications with charity care levels. If a hospital wished to pass a borderline project, the hospital could gain approval from the CON committee by providing a greater amount of charity care. This stipulation increased the provision of charity care in the state.

OCCUPANCY RATES

Has deregulation effected occupancy rates?

Journal literature suggests that another purpose of CON regulations is to maintain hospital occupancy rates. CON controls the number of hospital beds in a given state. Opponents of deregulation argue that the repeal of CON legislation will result in a significant drop in occupancy rates as hospitals construct additional, unneeded hospital beds. Information obtained from sources at the profiled organizations indicated that the impact on occupancy rates as a result of CON repeal may be significant. Sources from the two states that repealed CON commented that those states have since passed moratoriums on nursing home beds to prevent an expansion in bed size as a result of CON repeal.

According to the senior vice president of planning at **Hospital D**, "Unless corresponding legislation restricts the number of acute and long-term beds, there can be a big problem when CON is gone." He commented that occupancy rates have dropped since CON was repealed.

The vice president at **State Hospital Association F** stated that the occupancy problem is not necessarily related to CON. "Market forces are moving away from inpatient care to an outpatient setting. This will lead to a drop in occupancy rates as patient length of stay decreases." Although his state has also passed a moratorium on nursing home beds, he added that population shifts from rural to urban areas has also added to lower occupancy rates at rural hospitals.

An anecdotal example of CON repeal lowering occupancy rates dangerously is illustrated in the September 24, 1989 article in *The Courier-Journal* entitled, "Certificate of Need Programs in Other States: Whether Repeals Have Helped or Hurt." The article states that the city and county-owned Las Cruces New Mexico-based Memorial General Hospital filled only 60 percent of its 286 beds in the late 1980s. Nevertheless, a Texas-based for-profit health system announced plans to build a 100-bed facility in the city in 1989. According to a hospital administrator, "The addition of 100 beds in this community would be ridiculous. We most likely will go into the red and become tax dependent." The city and state could do nothing to prevent this from happening because CON was repealed in New Mexico in 1983.

MANAGED CARE

Does the penetration of managed care impact the need for CON?

Proponents of CON repeal argue that managed care can create a marketplace in which hospitals will be self-regulated more efficiently. Managed care brings competition into the marketplace and forces hospitals to reduce costs and provide higher quality service. As a result, hospital administrators will not build additional beds or expend capital unnecessarily due to their attempts to attract managed care contracts. According to the argument, the higher the managed care penetration rate, the less need remains for CON regulations.

Despite maintaining a low statewide managed care penetration rate, an administrator at **Department of Health G** stated that managed care has had a major impact in urban areas and has discouraged construction and expenditures far more than CON. The senior vice president at **Hospital D** concurred by noting that hospitals operating in a state with a high penetration of managed care must be extremely wary of costs and market competition. He added, "If a hospital really wanted [to purchase new technology or add beds] it could get it approved by the CON committee easily. Under managed care, hospitals must be more fiscally responsible."

The vice president of planning and business development at **Hospital E** described CON regulations as "useless relics," explaining that CON is unnecessary in a managed care environment. In addition, the vice president at Hospital E explained that the inefficiencies in CONs administration in his state made it a detriment to the marketplace. CON regulations kept hospitals that needed to build or purchase technology from obtaining it, while it allowed inefficient hospitals to maintain their high technology and high costs due to its monopoly on available equipment. A source at **Lewin VHI Inc.** added, "One of the purposes of CON regulation was to create a rational plan for distributing technology. Managed care performs this role for the state."

What is CON's role in a managed care environment?

According to the director of the CON program at **Department of Health B**, CON does not need to be repealed; it needs to be revised. He explained, "CON needs to be updated to align with the current system. CON is in the perfect position to help managed care keep its promise of better quality of care at lower prices." He believes that completely abolishing CON is irresponsible as states that have repealed CON no longer track occupancy rates or capital expenditures, nor do they track quality of service. He thinks that CON can be utilized in a managed care environment as a "watchdog" for consumers.

A source at **Lewin VHI Inc.** added that changes in some states' CON regulations are needed. He explained that CON should concentrate on issues of access and quality. An example of this is illustrated in the Winter 1993, *Spectrum* article. According to the article, the Ohio Department of Health has denied access to CON applications that were likely to reduce health care access. One of those applications proposed an ambulatory surgery facility in the suburbs, designed to attract private patients who utilized an inner-city hospital that also served the poor. The article stated, "The application was rejected because it would have reduced the financial viability of the inner-city hospital."

An argument that many CON advocates pose is that CON helps maintain service quality, as CON limits the number of locations in which high risk medical procedures may be performed. For instance, according to the September 24, 1989, article in *The Courier-Journal*, within two years of repealing CON regulations, open-heart surgery programs in Arizona jumped from six to ten hospitals. Many proponents of CON are concerned that greater numbers of programs lead to less procedures performed per hospital. This could result in a drop in quality as physicians will not perform enough procedures to remain proficient in those procedures.

In contrast, the director of legal services at **State Hospital Association C** stated that strict regulation of CON may lead to a quality decline in service. He cited a April 28, 1988, study in *The New England Journal of Medicine* that examined patient mortality rates in 45 states. The study examined the influence of CON programs, competition, and hospital ownership on mortality rates for a variety of conditions. The study found significant associations between higher mortality rates among patients and the stringency of CON programs. Hospitals in states with the most stringent procedures for CON had ratios of actual to predicted death rates that were five to six percent higher that those states with less stringent CON programs. According to the director of legal services, this study shows that quality improvement cannot be claimed as an argument for CON regulation.

APPENDIX L

"PROS AND CONS: IS THERE STILL A NEED FOR CERTIFICATE OF NEED?"

Pros and CONS: Is There Still A Need for Certificate of Need?

ALABAMA'S CON PROGRAM GREW OUT OF FEDERAL MEASURES ENACTED IN THE 80'S. THE FEDERAL LAWS ARE GONE, BUT CON REMAINS. IS IT A CONCEPT WHOSE TIME HAS PASSED?

♦ ♦ ♦

Increases in healthcare costs have not sprung up overnight, nor has concern about trying to keep them in check. Because they are among the largest expenses incurred by healthcare providers, capital-related expenditures have been a favorite target of federal and state governments since the 1970s.

Today, the Certificate of Need process remains the weapon of choice for most states in trying to prevent duplication of services and unnecessary purchases. But critics, including many hospitals, say Alabama's health planning program is rigid, capricious in carrying out the State Health Plan and based as much on politics as the health needs of the state's citizenry. So is there still a place for CON, or is it a concept whose time has passed?

THE BACKGROUND OF CON

First, a quick history lesson. Alabama's Certificate of Need process developed out of a 1974 congressional measure, the National Health Planning and Resources Development Act, which was designed to rein in rising costs in the Medicare and Medicaid programs. NHPRDA required states to institute review systems, with federal funding assistance, and Alabama complied in 1979 when it created its CON process.

The Certificate of Need law created the State Health Planning Agency board, consisting of nine members appointed by the governor and responsible for review of CON applications. Applications were to be approved or denied based on standards set forth in the State Health Plan. The plan, a study of current services used by providers and the expected future health needs of Alabamians, was to be developed every three years by a separate board. That board, the State Health Coordinating Council, was also to be appointed by the governor.

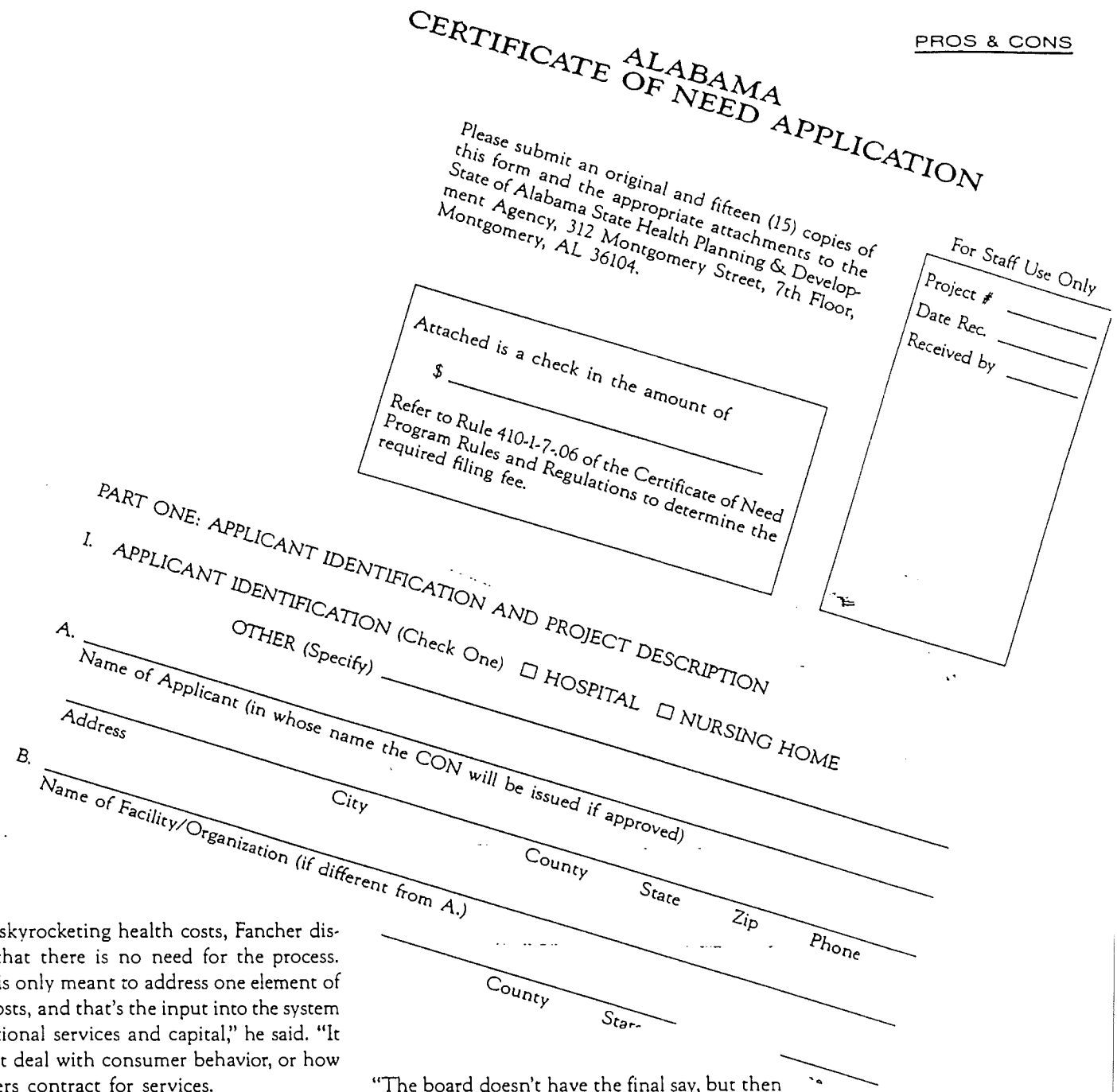
According to Derrell Fancher, executive director of the State Health Planning Agency, Alabama had instituted a review program prior to CON called Assurance of Need. "At the time, you could still make expenditures without an Assurance of Need, but you couldn't get Medicare or Medicaid reimbursement for it." Today, going forward with a project without the necessary CON approval can lead not only to unreimbursed costs for a hospital, but also to withheld licensure from the state and prevention from operating or building the desired facilities.

Strong deregulation efforts by the Reagan administration saw an end to new funding for state CON programs in 1982, and NHPRDA itself was repealed in 1986. While several states eventually did away with their federally required planning programs, Alabama maintained its own laws regarding Certificate of Need. However, with the support of the Alabama Hospital Association, the laws were amended in April 1990 to ease requirements on providers. The amendments raised the CON thresholds for new equipment and services to $500,000 and the threshold on other capital expenditures to $1.5 million. They also extended the exemption from CON application to certain replacement equipment items.

PROGRAM FACES CRITICISM

Opponents of CON contend that loosening restrictions on those providers seeking expenditure approval still are not enough. Currently, CON application must be made for establishment of new facilities or services; major equipment and other large capital purchases; and addition, elimination or transfer of beds. Many critics would reduce the scope of review to cover only bed capacity changes.

But while he says that CON cannot be the solu-



ALABAMA
CERTIFICATE OF NEED APPLICATION

Please submit an original and fifteen (15) copies of this form and the appropriate attachments to the State of Alabama State Health Planning & Development Agency, 312 Montgomery Street, 7th Floor, Montgomery, AL 36104.

For Staff Use Only
Project #
Date Rec.
Received by

Attached is a check in the amount of
$
Refer to Rule 410-1-7-.06 of the Certificate of Need Program Rules and Regulations to determine the required filing fee.

PART ONE: APPLICANT IDENTIFICATION AND PROJECT DESCRIPTION

I. APPLICANT IDENTIFICATION (Check One) ☐ HOSPITAL ☐ NURSING HOME
OTHER (Specify)

A. Name of Applicant (in whose name the CON will be issued if approved)
Address
City County State Zip Phone

B. Name of Facility/Organization (if different from A.)
County Stat-

tion to skyrocketing health costs, Fancher disagrees that there is no need for the process. "CON is only meant to address one element of rising costs, and that's the input into the system of additional services and capital," he said. "It does not deal with consumer behavior, or how employers contract for services.

"But especially now, the program is indispensable. Given the current status of Medicaid, the state can't afford to reimburse for unnecessary services."

Some opponents also point to the number of appeals processes available to those on the losing end of the review board's decision as further evidence of CON's impotence. Interested parties, either the applicant or those looking to prevent approval, may seek a hearing from an administrative law judge, an appeal by a fair hearing officer or reconsideration by the review board if they have additional facts pertinent to their request. If those efforts fail, the parties can also take their cases to state circuit court.

"The board doesn't have the final say, but then the state never does when the courts can get involved," said John Edge, chairman of the SHPA board. "A good number of applications are appealed, and they end up in litigation and cost both the agency and the hospital money. But we have a pretty good track record at having our decisions upheld."

"There have been very few cases in the past year that our agency has lost," Fancher agreed. "But the parties involved have the right of review on any administrative agency decision, as long as they can afford it."

Fancher said studying the effectiveness of Alabama's process is difficult. "It's not easy to

(continued on page 7)

Point/Counterpoint on CON

BARRY COLLINS

TERRY SMITH

The reasons for favoring or disagreeing with the continuation of Alabama's Certificate of Need process are numerous. Though they may not represent all the arguments for each position, here are two opposing viewpoints on CON:

CON OUR ONLY COST-CONTAINMENT PROCESS

by Barry Collins

The Certificate of Need process isn't perfect, but it's better than having no system for controlling capital related costs at all. What we have to do is ensure that CON remains a level playing field, and that the merits of each provider are judged when it comes to approving or denying an application.

The state's CON program is either an asset or a liability, depending upon how the review board's decision affects the applicant's interests. Although it has its flaws, this process is designed to provide systematic review of health projects, programs and resources based on demonstrated need at reasonable costs. Some will debate that the program should include all providers,-i.e., other licensed practitioners. Since CON is the only authoritative process we have, most providers work within the system.

The application, which must establish evidence of need, is the key. In my opinion the application information should be concise, accurate and reliable. Some applicants have attempted to influence the board by providing irrelevant information. Hopefully, this process will continue to provide substantive review and approval for those who demonstrate and prove a need versus those with the deepest pockets.

Two other advantages of the CON program are: (1) the notification of all affected providers in the geographical area; and (2) the provision, upon request, of information provided by the applicant. Having information about what competitors are seeking and having the capability to obtain this data is helpful and almost always interesting.

As I said, the system is not without its problems. But if we as providers are serious about cost-containment, then we don't need to completely scrap Certificate of Need.

Barry Collins is associate administrator of Eliza Coffee Memorial Hospital, Florence.

CON TOO LEGALISTIC, UNFAIR TO SMALLER HOSPITALS

by Terry Smith

The concept of the Certificate of Need program came from good intentions. But for all practical purposes, it has changed from a health care program to a complex legal system. Health care issues are seldom debated. Instead, the legality of regulations and procedures are interpreted by lawyers.

Health care providers with a number of assistants and substantial resources have a distinct advantage over those who do not. Many administrators, particularly those in smaller hospitals, do not have the staff or the time to apply to the CON program to justify a budget-neutral service that is needed by the community.

New services that will give the community a better health care system should not be reviewable by the program if the cost of providing the service is not a factor, and if the service will help the local health care provider continue its operation.

Out-of-county or state health care providers should not be allowed to replace the local providers or systems. Local providers generally serve the community's needs, while outside providers may only be interested in the profitable aspects of the health care system.

In conclusion, local health care providers know their own community and are able to provide a more personal and continuous care system.

Terry Smith is administrator of Bibb Medical Center in Centreville. ◇

PROS & CONS

(continued from page 5)

determine projects that weren't begun because no application was filed," he said. "But there have been some comparisons between states with CONs and those without using Social Security charge data. That data is not perfect, but it's a pretty good indicator of differentials among states.

"The studies have shown that, since 1980, costs for both groups have been about the same. But the information also suggests that the gap is beginning to widen, with non-CON states going up. Alabama ranks around the mid-point in those charges."

Edge added, "If you review states that have removed Certificate of Need, many are going back and putting some restraints in place."

OTHER STATES ELIMINATE CON

According to the American Hospital Association's State Issues Forum, 39 states and Washington, D.C., had some type of CON process as of July 1991. Those that had eliminated CON were Arizona, California, Colorado, Idaho, Kansas, Minnesota, New Mexico, South Dakota, Texas, Utah and Wyoming.

Texas and Kansas repealed Certificate of Need under fairly similar circumstances, with similar results; both saw their laws eliminated by sunset committees in 1985, both experienced proliferation primarily of freestanding psychiatric facilities and both are considering reinstating some form of state control over capital expenditures.

"There were basically two factors that led to the repeal of our law," explained Richard Bettis, executive vice president of the Texas Hospital Association. "The first was that it was just an ill-conceived law, basically a lawyers' employment act. The review committee consisted of three people who knew very little about capital reimbursement, and the process allowed all imaginable due processes for discovery. Most parties had legal representation, and so they might pay millions to get a CON.

"The second factor was that the chairman of the House committee in charge of sunset review was a conservative Republican, and he took it upon himself to make sure the process was eliminated. And [the Texas Hospital Association] supported it at the time, because it was such a poorly run effort, and the decisions made by the CON board were so arbitrary."

Tom Bell, vice president and legal counsel of the Kansas Hospital Association, said the anti-government attitudes of the 1980s also spelled doom for his state's CON law. "During the Reagan years, there just wasn't a lot of funding for federal initiatives, including health planning. And people here who were involved thought the measure wasn't serving its purpose."

Bell said that in addition to psychiatric facilities, Kansas had experienced some other problems with duplication of services. "There were some

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complaints in Wichita, for example, because they had seven MRIs, and there was a dispute in Topeka over radiation therapy units. But the thing is, we just don't know that it wouldn't have happened under CON."

While there has been discussion in both states about returning to Certificate of Need or some other type of health spending oversight, neither KHA nor THA are jumping on the bandwagon yet. "There's some frustration in the Legislature about controlling costs, and they know that CON would be a pretty simple solution, but whether there would be some modification of the process, I'm not sure.

"We are opposed to reinstating CON, but we are looking at some alternatives for health planning, probably something that would take a community focus."

Bettis said THA was also considering "some type of system-oriented approach that may be influenced by AHA reform initiatives. But we're not pushing anything just now."

THE FUTURE

Back in Alabama, Derrell Fancher and John Edge agree that while there may be a few changes in this state's Certificate of Need program, the whole thing is not likely to simply disappear anytime soon.

"Some modifications to the system are probable, and there has been talk about doing away with CON altogether," Fancher said. "But there was no bill introduced this session to eliminate it. And some areas of the state would probably see their hospital closure rates increase, so I think people are a little careful about making drastic changes."

Edge agreed that other measures like the incorporation of capital projects under the Medicare Prospective Payment System might lessen the need for CON, but he added, "I don't think you'll see its elimination right away because some of the cost-control coalitions would probably oppose it. But I do believe there will be more items removed from review in the future and increases in the dollar thresholds, and it may eventually be limited to new services and beds."

WORKING WITHIN THE SYSTEM

Whether you agree or disagree with the usefulness of Alabama's Certificate of Need process, it is probably best to plan on working within the system, at least for the short-term. With cost containment at the forefront of virtually every discussion on health policy, measures like CON that are already in place may not disappear soon. As for new thresholds, exemptions and other changes — the future could prove very interesting. ◊

APPENDIX M

"A NATIONAL LOOK AT CON LAWS"

A national look at CON laws

by Dean V. Kimmith, MHSA

Michigan has not been alone in taking long and hard looks at their certificate of need programs in recent years. Major changes in the way health care in this society is financed and delivered have caused a substantial amount of rethinking in state capitols across the country. The fundamental role of capital expenditure regulation in the health care industry is now being carefully scrutinized.

The origins of CON

The concept of CON regulation of health facilities originally devised at the state level. New York established the first program in 1964. With the advent of Medicaid in the middle of the decade and potential cost liability for the states, interest in state CON programs quickly spread. By 1974, 27 states had some form of program in place, most of which focused on the hospital sector.

The federal presence in this form of regulation first made its appearance with the passage of the Section 1122 amendments to the Social Security Act in 1972. States were given the option of entering into contracts with the federal government to enact much more comprehensive review programs. All facilities receiving Medicare or Medicaid funds (not simply hospitals) could now be subjected to a community needs test.

The 1975 enactment of the National Health Planning and Resources Development Act represented the watershed of federal interest in CON regulation. States were now obliged to establish laws creating full blown CON programs; failure to comply meant the risk of losing federal financial assistance for a

wide variety of health care programs. By 1982, with the exception of Louisiana, all states had put together attempts at reaching compliance with the federal CON regulations.

New directions at the state level

By the early 1980s, federal support for state health planning and CON programs began to dwindle; the message from Washington was becoming more and more clear. The Reagan Administration made no secret of its disenchantment with regulatory approaches to addressing the perceived problems of the U.S. health care system. Federal dollars continued to flow for a number of years through continuing budget resolutions for the program. The repeal of PL 93-641 in January of 1987 and the subsequent termination of the Section 1122 program in September of that year effectively ended all federal involvement.

Most states have now taken this opportunity to reevaluate the extent to which CON may play a useful role in addressing their own unique situations and problems. CON today is no longer the monolithic cost containment tool originally envisioned by the federal government. States are now coming to grips with the need to assess how (and if) the regulation of capital expenditures fits in with the changing health care environment. State CON programs are being called upon to assist in overall policy efforts to manage health care costs while preserving access to quality services.

Total deregulation

By July of 1986, only four states had completely eliminated CON and 1122 controls over their health care industries. Utah ended its programs in 1984 and Arizona, Kansas and Texas followed suit in the following year. The demise of these programs, however, was not greeted with universal acceptance in some states. Concern continues to be raised that the deregulation of nursing home beds, for example, may create severe strains on state Medicaid budgets. Others have raised concern about the proliferation of psychiatric bed capacity and the ultimate impact on health care costs.

With the termination of Section 1122 and the federal health planning program in 1987, many more states undertook major revisions of their own programs. In that year, six additional states terminated all capital expenditure controls over health care facilities. These states included California, Wyoming, Colorado, Minnesota, New Mexico and Idaho.

South Dakota was the only state to completely eliminate its CON program during 1988. However, a number of states have established "sunset" dates for their CON statutes scheduled to go into effect during this year or in the near future. Four states will end their capital expenditure controls in 1989; they include Oklahoma, Florida, Montana, and Ohio. West Virginia's program is scheduled to terminate in 1991.

Efforts to streamline and refocus

At present, however, the vast majority of states have made decisions to streamline and refocus their CON programs in lieu of total deregulation. Michigan is certainly an example of a state that now views CON in the context of a number of regulatory and nonregulatory efforts to better manage the health care system. These states are now targeting CON on more specific areas where it is hoped to yield more tangible benefits.

Some states drastically limited the focus of their programs in 1987. Wisconsin now subjects only nursing homes to CON review. Indiana's CON program has been limited to psychiatric hospitals and long-term care facilities. Many observers believe that CON may ultimately come to focus exclusively on services such as institutional nursing homes and psychiatric care where state cost liabilities are high.

Arkansas substantially revamped its CON program in 1987 as well, restructuring it to require facilities to obtain "permits of approval" before undertaking major capital expenditures. Louisiana continues to maintain a review effort similar to the one it maintained under previous Section 1122 requirements: the program is now limited to health care facilities that participate in the state's Medicaid program.

One of the areas of greatest change has been in review thresholds for covered capital expenditures. Many states have come to the conclusion that it is no longer worth spending scarce regulatory resources on projects with relatively low capital costs. Such states have elected to focus their time and energies on the "big ticket" projects that have the greatest potential impact on their treasuries.

At the time of the demise of the federal program in 1987, the "required" threshold levels were $760,495 for capital expenditures, $400,000 for major medical equipment, and $316,873 for new institutional health services. By the mid-1980s, however, many states were already beginning to go their own way in terms of thresholds and other review requirements. Even by then the federal presence was weakening and the watchword was flexibility.

By last year, twenty states had capital expenditure review thresholds that were at least $1,000,000. Thresholds ranged from a low of $300,000 in Vermont to $4,000,000 in Hawaii. Some states have also begun making distinctions between categories of projects and are establishing dual thresholds. In Michigan's case, separate thresholds of $750,000 and $1,500,000 were established last year based on whether clinical or nonclinical service areas were involved. These levels are scheduled to increase to $850,000 and $1,700,000 in October of 1991. New York's project review thresholds have been set at $300,000 for "substantial" projects and $3,000,000 for "administrative" projects. Many other state CON programs are also now using liberalized definitions of substantive versus nonsubstantive projects.

Similarly, review thresholds for major medical equipment have been increasing across the country. Two states, Maryland and North Carolina, have completely deregulated medical technology from their CON programs. Some states continue to exempt major medical equipment if it does not serve inpatient populations or is owned and operated by private physicians. Many other states continue to grapple with the thorny problem of developing standards and plans for new medical technology. Even states such as California and Utah, which repealed their CON programs, are undertaking efforts to study the impact of deregulation in selected areas. California will specifically be examining the status of its open heart surgery and cardiac catheterization services with a report due in 1990.

Many states have come to the conclusion that it is no longer worth spending scarce regulatory resources on projects with relatively low capital costs. Such states have elected to focus their time and energies on the "bit ticket" projects that have the greatest potential impact on their treasuries.

States are also taking the initiative in reexamining the types of health care facilities and services that are appropriate for CON coverage. Since 1987, only a handful of states have retained coverage of all the provider types previously mandated by federal CON law and regulations. Many states, such as Michigan, have revised their statutes to specifically identify providers subject to review. A prime example of where deregulation has been common is in the area of home health care and residential care facilities. CON has been changing to reflect revised state priorities of where expansion in the health care industry should be encouraged.

The selective use of moratoria as a short-term means of restraining capital spending continues to be used in a number of states. Arkansas, Mississippi, Missouri, and Minnesota all have moratoria in place for certain types of health care facilities. States have often used these periods of time to revise their criteria and plans, especially when experiencing increased expenditures.

The status of local planning agencies with formalized input into state CON programs remains poor. With the absence of federal funding and a general reluctance of states to pick up the tab, only around 40 local health planning agencies are still in operation nationwide (compared to 204 in 1981). Among the states, only New York and Florida appear committed both programmatically and financially to keeping these local agencies afloat. As in Michigan, local units of government and the business community are being looked to more and more often for the support of such efforts.

Many observers believe that CON may ultimately come to focus exclusively on services such as institutional nursing homes and psychiatric care where state cost liabilities are high.

What's ahead for CON?

It's fair to predict that states will continue to refine their CON programs in the years ahead and that regulatory controls over capital will occupy a smaller place in the overall scheme of things. As more major payers move toward incorporating capital costs into prospective reimbursement systems, the question of the future role of CON will remain high on the agendas of state legislatures across the country.

In the short term, however, it is unrealistic to expect a major abandonment of CON as one of the many tools that states will call upon to restrain continuing increases in the cost of health care. We as a nation spent $500 billion on health care in 1987, up almost 10% from the previous year. It is hard to argue that the proliferation of expensive new medical technology isn't one of the driving forces behind this surge. We could also engage in

face. With managed care efforts still in relative infancy in this state and across the country, the emergence of a truly price competitive health care industry is still more of a promise than a reality. □

Dean V. Kimmith is a health planning consultant with the Office of Health and Medical Affairs, Michigan Department of Management and Budget. *The author would like to acknowledge the research assistance of Constance Thomas of the Intergovernmental Health Policy Project, George Washington University, Washington, DC.*

Next month in
Michigan Hospitals:
The malpractice crisis

APPENDIX N

PROPOSED LEGISLATION

FINAL DRAFT OF PROPOSED LEGISLATION (2/11/98)
Commission to Study the Certificate of Need Laws

PART A

Sec. A-1. 5 MRSA §12004-I, sub-§38 is amended to read:

38. Human Services Health Facilities	Certificate of Need Advisory Committee	$25/Day	22MRSA §~~307~~	306-B

Sec. A-2. 22 MRSA §253, sub-§3 is amended to read:

3. Public hearings; consultation with Certificate of Need Advisory Committee. Prior to adopting the state health plan and in reviewing the state health plan, the department shall conduct public hearings in different regions of the State on the proposed state health plan. Interested persons must be given the opportunity to submit oral and written testimony. Not less than 30 days before each hearing, the department shall publish in a newspaper of general circulation in the region the time and place of the hearing, the place where interested persons may review the plan in advance of the hearing and the place to which and period during which written comment may be directed to the department. Prior to adopting the state health plan and in reviewing the state health plan the department shall provide copies to and shall meet and consult with the Certificate of Need Advisory Committee as provided in section 306-B, subsection 2, paragraph A.

PART B

Sec. B-1.

22 § 301. Short title

This chapter may be cited as the "Maine Certificate of Need Act of 1978."

22 § 302. Declaration of findings and purposes

1. Findings. The Legislature finds that unnecessary construction or modification of health care facilities and duplication of health services are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services.

2. Purposes. The purposes of this chapter are to:

A. ~~Promote~~ Support effective health planning;

B. ~~Assist in providing~~ Support the provision of quality health care ~~at the lowest possible cost~~ in a manner that ensures access to cost-effective services;

C. ~~Avoid unnecessary duplication in health facilities and health services and ensure that only those facilities that are needed will be built or modified~~ Support reasonable choice in health care services while avoiding excessive duplication;

D. ~~Assure~~ Ensure that state funds are ~~not~~ used ~~to support unnecessary capital expenditures made by or on behalf of health care facilities~~ prudently in the provision of health care services;

~~E. Provide an orderly method of resolving questions concerning the need for health care facilities and health services which are proposed to be developed;~~

F. ~~Permit consumers of health services to participate~~ Ensure public participation in the process of determining the array, distribution, quantity, quality and cost of these services; ~~and~~

~~G. Provide for a certificate of need program which meets the requirements of the National Health Planning and Resources Development Act of 1974, Public Law 93-641 and its accompanying regulations.~~

H. Improve the availability of health care services throughout the State;

I. Support the development and availability of health care services regardless of the consumer's ability to pay; and

J. Seek a balance, to the extent a balance assists in achieving the purposes of this subsection, between competition and regulation in the provision of health care.

22 § 303. Definitions

As used in this chapter, unless the context otherwise indicates, the following words and phrases shall have the following meanings.

1. Ambulatory surgical facility. "Ambulatory surgical facility" means a facility, not part of a hospital, which provides surgical treatment to patients not requiring hospitalization. This term does not include the offices of private physicians or dentists, whether in individual or group practice.

2. Annual implementation plan.

2-A. Annual operating costs. For purposes of section 304-A, subsection 4, paragraph B, "annual operating costs" means the total incremental costs to the institution which are directly attributable to the addition of a new health service.

2-B. Appropriately capitalized expenditures. "Appropriately capitalized expenditures" means those expenditures which would be capitalized if the project were implemented.

3. Capital expenditure. "Capital expenditure" means an expenditure, including a force account expenditure or predevelopment activities, which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance and, for the purposes of this chapter, shall include capitalized interest on borrowed funds and the fair market value of any property or equipment which is acquired under lease or comparable arrangement or by donation.

~~**3-A. Commission.** "Commission" means the Maine Health Care Finance Commission established pursuant to chapter 107.~~

4. Construction. "Construction," when used in connection with "health care facility," means the establishment, erection, building, purchase or other acquisition of a health care facility.

5. Department. "Department" means the Department of Human Services, but does not include the Certificate of Need Advisory Committee.

6. Development. "Development," when used in connection with "health service," means the undertaking of those activities which on their completion will result in the offering of a new health service to the public.

6-A. Expenditure minimum for annual operating costs. The "expenditure minimum for annual operating costs" is:

~~A. For services commenced between January 1 and December 31, 1983, $125,000 for the 3rd fiscal year, including a partial first year;~~

~~B. For services commenced between January 1 and December 31, 1984, $135,000 for the 3rd fiscal year, including a partial first year;~~

~~C. For services commenced between January 1 and December 31, 1985, $145,000 for the 3rd fiscal year, including a partial first year; and~~

D. For services commenced after December 31, 1985, ~~$155,000~~ $350,000 for the 3rd fiscal year, including a partial first year, as adjusted pursuant to section 305-A .

6-B. Generally accepted accounting principles. "Generally accepted accounting principles" means accounting principles approved by the American Institute of Certified Public Accountants.

7. Health care facility. "Health care facility" means ~~hospitals, psychiatric hospitals, nursing facilities, kidney disease treatment centers including free-standing hemodialysis facilities, rehabilitation facilities and ambulatory surgical facilities~~ hospital, psychiatric hospital, nursing facility, kidney disease treatment center including free-standing hemodialysis facility, rehabilitation facility, ambulatory surgical facility, independent radiological service center, independent cardiac catheterization center, and cancer treatment center. The term does not include the office of a private physician or physicians, whether in individual or group practice.

8. Health maintenance organization. "Health maintenance organization" means a public or private organization ~~which~~ that:

A. Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health services: Usual physician services, hospitalization, laboratory, x-ray, emergency and preventive health services and out-of-area coverage;

B. Is compensated, except for copayments, for the provision of the basic health services to enrolled participants on a predetermined periodic rate basis; and

C. Provides physicians' services primarily through physicians who are either employees or partners of the organization or through arrangements with individual physicians or one or more groups of physicians.

9. Health services. "Health services" means clinically related services, that ~~is,~~ are diagnostic, treatment, ~~or~~ rehabilitative services or nursing services provided by a nursing facility, and includes alcohol, drug abuse and mental health services.

10. Health Systems Agency.

11. Health systems plan.

11-A. Home health care provider.

11-B. Hospital. "Hospital" means an institution which primarily provides to inpatients by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons or rehabilitation services for the rehabilitation of injured, disabled or sick persons. This term also includes psychiatric and tuberculosis hospitals.

11-C. Hospital swing bed. "Hospital swing bed" means acute care beds licensed by the Division of Licensure and Certification, Bureau of Medical Services for use also as nursing care beds. Swing beds may be established only in rural hospitals with fewer than 100 licensed acute care beds.

12. Intermediate care facility.

12-A. Major medical equipment. "Major medical equipment" means a single unit of medical equipment or a single system of components with related functions which is used to provide medical and other health services and which costs ~~$300,000~~ $1,000,000 or more. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services, if the clinical laboratory is independent of a physician's office and a hospital and has been determined under the United States Social Security Act, Title XVIII, to meet the requirements of Section 1861 (s), paragraphs 10 and 11 of that Act. In determining whether medical equipment costs more than ~~$300,000~~ $1,000,000, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to acquiring the equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

12-B. Nursing facility. "Nursing facility" means any facility defined under section 1812-A.

13. Modification. "Modification" means the alteration, improvement, expansion, extension, renovation or replacement of a health care facility or health maintenance organization or portion thereof, including initial equipment thereof and the replacement of equipment or existing buildings.

13-A. Obligation. An "obligation" for a capital expenditure is considered to be incurred by or on behalf of a health care facility:

A. When a contract, enforceable under Maine law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset;

B. When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or

C. In the case of donated property, on the date on which the gift is completed under applicable Maine law.

14. Offer. "Offer," when used in connection with "health services," means that the health care facility or health maintenance organization holds itself out as capable of providing or having the means to provide a health service.

15. Person. "Person" means an individual, trust or estate, partnership, corporation, including associations, joint stock companies and insurance companies, the State or a political subdivision or instrumentality, including a municipal corporation of the State, or any other legal entity recognized by state law.

16. Predevelopment activities. "Predevelopment activities" means any appropriately capitalized expenditure by or on behalf of a health care facility made in preparation for the offering or development of a new health service for which a certificate of need would be required and arrangements or commitments made for financing the offering or development of the new health service; and shall include site acquisitions, surveys, studies, expenditures for architectural designs, plans, working drawings and specifications.

17. Project. "Project" means any acquisition, capital expenditure, new health service~~, termination~~ or change in a health service, predevelopment activity or other activity which requires a certificate of need under section 304-A.

17-A. Rehabilitation facility. "Rehabilitation facility" means an inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent professional supervision.

17-B. Replacement equipment. "Replacement equipment" means a piece of capital equipment that replaces another piece of capital equipment that performs essentially the same functions as the replaced equipment.

~~**18. Secretary.** "Secretary" means the United States Secretary of Health and Human Services and any other officer or employee of the United States Department of Health and Human Services to whom the authority involved may be delegated.~~

19. Skilled nursing facility.

20. State Health Coordinating Council.

21. State health plan.

22. State medical facilities plan.

22 § 304. Certificate of need required
(REPEALED)

22 § 304-A. Certificate of need required

No person may enter into any commitment for financing a project that requires a certificate of need or incur an ~~obligation~~ expenditure for the project without having sought and received a certificate of need, except that this prohibition does not apply to ~~commitments~~ obligations for financing conditioned upon the receipt of a certificate of need or to obligations for predevelopment activities ~~of less than $150,000 for health care facilities other than hospitals or $250,000 for hospitals~~.

Except as provided in sections ~~304-D and~~ 304-E, a certificate of need from the department ~~shall be~~ is required for:

1. Transfer of ownership; ~~Acquisition~~ acquisition by lease, donation, transfer; acquisition of control. Any transfer of ownership or acquisition ~~by or on behalf of a health care facility~~ under lease or comparable arrangement or through donation~~, which would have required review if the acquisition had been by purchase~~ or any acquisition of control of a health care facility under lease, management agreement or comparable arrangement or through donation that would have required review if the transfer or acquisition had been by purchase, except in emergencies when such acquisition of control is at the direction of the department;

~~**1-A. Acquisition of control.** Any acquisition of control of a health care facility under lease, management agreement or comparable arrangement or through donation that would have required review if the acquisition of control had been by purchase, except in emergencies when such acquisition of control is at the direction of the department;~~

2. Acquisitions of certain major medical equipment. Acquisitions of major medical equipment with a cost in the aggregate of $1,000,000 or more, as adjusted pursuant to section 305-A. ~~There is a waiver for the~~ The use of major medical equipment on a temporary basis ~~as provided in section 308, subsection 4~~ in the case of a natural disaster, major accident or equipment failure and the use of replacement equipment does not require a certificate of need;

A.

B.

C.

D.

~~**2-A. Acquisitions of major medical equipment with a cost in the aggregate of $1,000,000 or more.** Acquisitions of major medical equipment with a cost in the aggregate of $1,000,000 or more by ambulatory surgical centers, independent cardiac catheterization centers, independent radiologic service centers and centers providing endoscopy, sigmoidoscopy, colonoscopy or other similar procedures associated with gastroenterology;~~

3. Capital expenditures. The obligation by or on behalf of a health care facility~~, except a hospital,~~ of any capital expenditure of ~~$500,000~~ $2,000,000 or more~~, except that any transfer of ownership is reviewable~~, as adjusted pursuant to section 305-A. Capital expenditures in the case of a natural disaster, major accident or equipment failure, for replacement equipment, and for parking lots and

garages, information and communications systems and physician office space do not require a certificate of need. Capital expenditures by nursing facilities are subject to review under subsection 8-A;

~~**3-A. Hospital capital expenditures.** The obligation, by or on behalf of a hospital, of any capital expenditure of $2,000,000 or more, except that:~~

~~A. A capital expenditure for the purpose of acquiring major medical equipment is reviewable only to the extent provided in subsection 2; and~~

~~B. Any transfer of ownership of a hospital is reviewable.~~

4. New health services. The offering or development of any new health service. For purposes of this section, "new health services" includes only the following:

A. The obligation of any capital expenditures by or on behalf of a health care facility of $100,000 or more, as adjusted pursuant to section 305-A, that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the facility within the 12-month period prior to the time the services would be offered; or

B. The addition of a health service that is to be offered by or on behalf of a health care facility that was not offered on a regular basis by or on behalf of the facility within the 12-month period prior to the time the services would be offered, and that, for the 3rd fiscal year of operation, including a partial first year, following addition of that service~~, absent any adjustment for inflation,~~ is projected to entail annual operating costs of ~~at least the expenditure minimum for annual operating costs~~ $350,000, as adjusted pursuant to section 305-A~~; or~~.

~~C. The addition of a health service that falls within a category of health services that are subject to review regardless of capital expenditure or operating cost and which category the department has defined through regulations promulgated pursuant to section 312.~~

~~This subsection does not prohibit a nursing facility from converting beds used for the provision of nursing services to beds to be used for the provision of residential care services. If such a conversion occurs, public funds are not obligated for payment of services provided in the converted beds;~~

A certificate of need is not required for a health care facility that extends a current service within the defined primary service area of the facility by purchasing within a 12 month time period new equipment costing in the aggregate less than $1,000,000, as adjusted pursuant to section 305-A;

~~**5. Termination of a health service.** The obligation of any capital expenditure by or on behalf of a health care facility other than a hospital that is associated with the termination of a health service that was previously offered by or on behalf of the health care facility; except, neither the conversion of licensed nursing facility beds to residential care beds nor a decrease in the licensed or certified bed capacity of a nursing facility may be considered a termination of a health service;~~

6. Changes in bed complement. Any ~~change~~ increase in the existing licensed bed complement or any increase in licensed bed category of a health care facility ~~other than a hospital; except that a decrease in the licensed or certified bed capacity of a nursing facility is not subject to review so long as any capital expenditure incurred in the decrease does not trigger review under subsection 3~~;

A.

B.

C.

~~**6-A. Increases in licensed bed capacity of a hospital.** Any change in the existing bed complement of a hospital, in any 2-year period, that:~~

~~A. Increases the licensed or certified bed capacity of the hospital by more than 10% or more than 5 beds, whichever is less; or~~

~~B. Increases the number of beds licensed or certified by the department to provide a particular level of care by more than 10% of that number or more than 5 beds, whichever is less;~~

~~**7. Predevelopment activities.** Any appropriately capitalized expenditure of $150,000 or more or, in the case of hospitals, $250,000 or more for predevelopment activities proposed to be undertaken in preparation for any project that would itself require a certificate of need;~~

~~**8. New health care facilities.** The construction, development or other establishment of a new health care facility; and~~

A.

B.

8-A. Nursing facilities. The obligation by a nursing facility, when related to nursing services provided by the nursing facility, of any capital expenditures of $500,000 or more, as adjusted pursuant to section 305-A.

A certificate of need is not required for a nursing facility to convert beds used for the provision of nursing services to beds to be used for the provision of residential care services. If such a conversion occurs, public funds are not obligated for payment of services provided in the converted beds;

9. Other circumstances. In the following circumstances:

A. Any proposed use of major medical equipment to serve inpatients of a hospital, if the equipment is not located in a health care facility and was acquired without a certificate of need, except acquisitions ~~waived under section 308, subsection 4~~ exempt from review under subsection 2 or 3; or

B. If a person adds a health service not subject to review under subsection 4, paragraph A or C and which was not deemed subject to review under subsection 4, paragraph B at the time it was established and which was not reviewed and approved prior to establishment at the request of the applicant, and its actual 3rd fiscal year operating cost, as adjusted by an appropriate inflation deflator promulgated by the department~~, after consultation with the Maine Health Care Finance Commission,~~ exceeds the expenditure minimum for annual operating cost in the 3rd fiscal year of operation following addition of these services.

22 § 304-B. Subsequent review

Where a certificate of need has been issued, and changes occur as specified in this section, a subsequent review is required.

1. Criteria for subsequent review. The following activities require subsequent review and approval, if the department has previously issued a certificate of need and if within ~~one year~~ three years after the approved activity is undertaken:

A. There is a significant change in financing;

B. There is a change affecting the licensed or certified bed capacity as approved in the certificate of need;

C. There is a change involving the addition or termination of the health services proposed to be rendered ~~by the facility~~;

D. There is a change in the site or the location of the proposed facility; or

E. There is a substantial change proposed in the design of the facility or the type of construction.

2. Procedures for subsequent review. Any person proposing to undertake any activity requiring subsequent review and approval shall file with the department, within 30 days of the time that person first has actual knowledge of the circumstances requiring subsequent review, a notice setting forth the following information:

A. The nature of the proposed change;

B. The rationale for the change including, where appropriate, an explanation of why the change was not set forth in the original application or letter of intent; and

C. Other pertinent detail subject to the procedures and criteria set forth in section 309.

The department shall, within 30 days of receipt of the information, advise that person in writing whether the proposed change is approved. If not approved, the application shall be treated as incomplete and reviewed in accordance with the application procedures in section 306-A, subsection 4. If approved, the department shall amend the certificate of need as appropriate.

22 § 304-C. Waiver of certificate of need review for projects for which hospital does not seek positive adjustment to financial requirements established by Maine Health Care Finance Commission (REPEALED)

~~**22 § 304-D. Waiver of certificate of need for certain minor projects**~~

~~**1. Categories of projects eligible for waiver.** A hospital may apply for a waiver of the certificate of need review requirements otherwise imposed by this chapter with respect to the following projects:~~

~~A. The offering or development of any new health services involving:~~

~~(1) No capital expenditure or a capital expenditure of less than $300,000; and~~

~~(2) Third year annual operating costs of less than $250,000.~~

~~B.~~

~~**2. Conditions of waiver.**~~

~~**3. Waiver process for certain new health services.** Any hospital may file a request for waiver under subsection 1, paragraph A, with the department describing the proposed project and its projected associated capital costs and projected operating costs, as appropriate. Within 15 days following receipt of the hospital's waiver request and other information, if requested, the department shall issue its waiver determination.~~

~~The department shall waive certificate of need review in all cases where the request demonstrates that:~~

~~A. The project meets the criteria of subsection 1, paragraph A; and~~

~~B. The hospital agrees to be bound by the conditions of subsection 2.~~

~~**4. Waiver process for certain minor projects.**~~

~~**5. Treatment of project by the Maine Health Care Finance Commission.**~~

22 § 304-E. Waiver of certificate of need review when review is unnecessary and serves no public purpose

1. Request for waiver. An applicant for a project requiring a certificate of need~~, other than a project related to acute patient care or a project that could affect the financial requirements of a hospital under chapter 107,~~ may request a waiver of the review requirements under this chapter. The applicant shall submit, with the request, sufficient written documentation to demonstrate that the proposed project meets the conditions of this section and that sufficient public notice of the proposed waiver has been given.

2. Public notice. The applicant shall give public notice, on a form provided by the department, of its intention to seek a waiver of full review. This notice shall be given in the Kennebec Journal and in a daily newspaper of general circulation in the applicant's service area. The public shall be given 10 days from the date of publication within which to submit to the department any comments concerning the proposed waiver of review.

3. Criteria for waiver. The department may waive the requirement for a full certificate of need review of a project, if the department finds that the waiver, rather than full review, would best further the purposes of the Maine Certificate of Need Act, as set forth in section 302, subsection 2. When making this determination, the department shall consider a number of factors including, but not limited to:

A. Whether the proposed project would incur no or minimal additional expense to the public or to the health care facility's clients;

B. Whether the proposed project is or will be in compliance with other state and local laws and regulations;

C. Whether the proposed project primarily involves the maintenance of a health care facility as is; and

D. Whether the health and welfare of any person the health care facility is already serving will be significantly adversely affected if a waiver is not granted.

4. Other action by department. If the department finds that the proposal is not clearly eligible for a waiver of the review requirements, it may elect to conduct an emergency review, a simplified review pursuant to section 308, subsection 1, or a full review.

5. Notification of decision. The department shall notify the applicant of its decision in writing as soon as it determines whether to grant or deny the request for a waiver or decides to conduct a different review in accordance with subsection 4. The notice shall include a brief summary of the reasons for the department's decision.

6. Report to Legislature. The department shall submit an annual report to the joint standing committee of the Legislature having jurisdiction over health and human ~~resources~~ services matters on the implementation and operation of this section no later than February 15th of each year.

22 § 304-F. Procedures after voluntary nursing facility reductions

1. Procedures. A nursing ~~home~~ facility that voluntarily reduces the number of its licensed beds for any reason except to create private rooms may convert the beds back and thereby increase the number of nursing facility beds to no more than the previously licensed number of nursing facility beds, after obtaining a certificate of need in accordance with this section, provided the facility has been in continuous operation and has not been purchased or leased. To convert beds back to nursing facility beds under this subsection, the nursing facility must:

A. Give notice of its intent to preserve conversion options to the department no later than 30 days after the effective date of the license reduction; and

B. Obtain a certificate of need to convert beds back under section 309, except that if no construction is required for the conversion of beds back, the application must be processed in accordance with subsection 2.

2. Expedited review. Except as provided in subsection 1, paragraph B, an application for a certificate of need to reopen beds reserved in accordance with this section must be processed on an

expedited basis in accordance with rules adopted by the department providing for shortened review time and for a public hearing if requested by a directly affected person. The department shall consider and decide upon these applications as follows:

A. Review of applications that meet the requirements of this section must be based on the requirements of section 309, subsection 1, except that the determinations required by section 309, subsection 1, paragraph B must be based on the historical costs of operating the beds and must consider whether the projected costs are consistent with the costs of the beds prior to closure, adjusted for inflation; and

B. Conversion of beds back under this section must be requested within 4 years of the effective date of the license reduction. For good cause shown, the department may extend the 4-year period for conversion for one additional 4-year period.

3. Effect on other review proceedings. Nursing facility beds that have been voluntarily reduced under this section must be counted as available nursing facility beds for the purpose of evaluating need under section 309 so long as the facility retains the ability to convert them back to nursing facility use under the terms of this section, unless the facility indicates, in response to an inquiry from the department in connection with an ongoing project review, that it is unwilling to convert them to meet a need identified in that project review.

4. Rulemaking. Rules adopted pursuant to this section are major substantive rules as defined by Title 5, chapter 375, subchapter II-A.

22 MRSA §304-G is enacted to read:

§304-G. Addition of nursing facility beds

Nursing facility projects that propose to add new nursing facility beds to the inventory of nursing facility beds within the State may be grouped for competitive review purposes consistent with appropriations made available for that purpose by the Legislature. A nursing facility project that proposes renovation, replacement or other actions that will increase Medicaid costs may be approved only if appropriations have been made by the Legislature expressly for the purpose of meeting those costs, except that the department may approve, without a prior appropriation for the express purpose, projects to reopen beds previously reserved by a nursing facility through a voluntary reduction pursuant to section 304-F, if the annual total of reopened beds approved does not exceed 100.

~~**22 § 305. Periodic reports**~~

~~The department shall require health care facilities subject to the requirements of this chapter to maintain current health services and capital requirements' plans on file with the department. The department, in its rules and regulations, shall prescribe the form and contents of the health services and capital requirements' plans and shall require annual or other periodic reports updating the plans to be filed with the department. No application for a certificate of need made pursuant to this Act shall be accepted from any health care facility for which the current health services and capital requirements' plans are not on file.~~

22 MRSA §305-A is enacted to read:

§305-A. Inflation adjustment

Beginning July 1, 1999 and annually thereafter, the department shall adopt rules to adjust the monetary figures contained in this chapter to reflect changes in the Consumer Price Index medical index.

22 § 306. Application process
(REPEALED)

22 § 306-A. Application process for a certificate of need

1. Letter of intent. Prior to filing an application for a certificate of need, an applicant shall file a letter of intent with the department. The letter of intent shall form the basis for determining the applicability of this chapter to the proposed expenditure or action. A letter of intent shall be deemed withdrawn one year after receipt by the department, unless sooner superseded by an application; provided that the applicant shall not be precluded from resubmitting the same letter of intent.

2. Application filed. Upon a determination by the department that a certificate of need is required for a proposed expenditure or action, an application for a certificate of need shall be filed with the department if the applicant wishes to proceed with the project. Prior to filing a formal application for a certificate of need, the applicant is required to meet with the department staff in order to assist the department in understanding the application and to receive technical assistance concerning the nature, extent and format of the documentary evidence, statistical data and financial data required for the department to evaluate the proposal. The department shall not accept an application for review until the applicant has satisfied this technical assistance requirement unless waived in writing by both parties. The technical assistance meeting shall take place within 30 days subsequent to receipt of the letter of intent, unless waived in writing by both parties.

3. Additional information required. Additional information may be required or requested as follows.

A. If, after receipt of an application, the department determines that additional information is necessary before the application can be considered complete, the department may:

(1) Require the applicant to respond to one set of requests for additional information from the department. Applicants must submit additional information requested by the department within 30 business days or within a longer period of time, provided that the department and the applicant agree; and

(2) Request, but not require, the applicant to respond to additional sets of requests for information, provided that each request is directly related to the last request or to the information provided in response to the last request.

B.

C. Within 15 business days after the filing of an application or response to any information request, whichever is applicable, with the department, the department shall notify the applicant in writing that:

(1) The application contains all necessary information required and is complete; or

(2) Additional information is required by the department. If, after receipt of the applicant's response to the first or any subsequent request, the department determines that additional information is required, the notification shall also include a statement of the basis and rationale for that determination.

4. Review of incomplete application. Upon receipt of the 2nd or any subsequent notice described in subsection 3, paragraph C, subparagraph 2, the applicant must notify the department in writing that:

A. It will provide the additional information requested by the department. Following completion, it shall be entered into the next review cycle; or

B. That it is not able to or does not intend to provide the information requested and requests the application be entered into the next appropriate review cycle. In that case, the applicant shall be prohibited from submitting the information it had declined to provide into the record after the 25th day of the review cycle and the information shall not be considered in the determination to issue or to deny a certificate of need. If the applicant provides the information requested prior to the 25th day of the review cycle, the application may, at the discretion of the department, be returned to the beginning of the review cycle. Failure to submit additional information requested by the department may result in an unfavorable recommendation and may result in subsequent denial of the application by the department, as long as the denial is related to applicable criteria and standards.

5-A. Public informational meeting. Within 30 days of the filing of an application the department shall advertise and conduct in a location convenient to the proposal location a public informational meeting at which the applicant shall present information about the proposal.

5. Competitive reviews. In cases of competitive reviews, applicants shall submit additional information requested by the department within 30 business days or within a longer period of time, provided that the department and all competing applicants agree.

6. Automatic withdrawal. Any incomplete application is considered withdrawn if the applicant fails to respond to a request for additional required information within 180 days of the date the request was forwarded by the department.

7. Voluntary withdrawal of application. During the review period, prior to the date that staff submit a final report to the commissioner, an applicant may withdraw an application without prejudice. Written notice of the withdrawal must be submitted to the department. A withdrawn application may be resubmitted at a later date, as a new application, requiring a new letter of intent and new filing fees, docketing and review.

8. Filing fee. A nonrefundable filing fee must be paid at the time an application is filed with the department.

A. The department shall establish minimum and maximum filing fees, pursuant to section 312, to be paid per application.

B. If the approved capital expenditure or operating cost upon which the fees were based is higher than the initially proposed capital expenditure, then the filing fee must be recalculated and the difference in fees, if any, must be paid before the certificate of need may be issued.

C. Rules adopted pursuant to this subsection are ~~major substantive~~ routine technical rules as defined by Title 5, chapter 375, subchapter II-A.

22 MRSA §306-B is enacted to read:

§306-B. Certificate of Need Advisory Committee

The Certificate of Need Advisory Committee, established by Title 5, section 12004-I, subsection 38, shall participate with the department in the public hearing process under section 307, subsection 2-B.

1. Appointment. The Governor shall appoint the members of the Certificate of Need Advisory Committee according to this subsection.

A. The committee is composed of 10 members, 9 of whom are appointed by the Governor. The Commissioner of Human Services shall name a designee to serve as an ex officio, nonvoting member of the committee. The 9 members appointed by the Governor must be selected in accordance with the following requirements.

(1) Four members must be appointed as follows:.

(a) One member must represent the hospitals;

(b) One member must represent the nursing home industry;

(c) One member must represent major 3rd-party payors; and

(d) One member must represent providers.

In appointing these representatives, the Governor shall consider recommendations made by the Maine Hospital Association, the Maine Health Care Association, the Maine Medical Association, the Maine Osteopathic Association and other representative organizations.

(2) Five public members must be appointed as consumers of health care. One of these members must be designated on an annual basis by the Governor as chair of the committee. Neither the public members nor their spouses or children may, within 12 months preceding the appointment, have been affiliated with, employed by, or have had any professional affiliation with any health care facility or institution or nursing facility, health product manufacturer or corporation or insurer providing coverage for hospital or medical care; however neither membership in or subscription to a service plan maintained by a nonprofit hospital and medical service organization, nor enrollment in a health maintenance organization, nor membership as a policyholder in a mutual insurer or coverage under such a policy, nor the purchase of or coverage under a policy issued by a stock insurer may disqualify a person from serving as a public member.

B. Appointed members of the committee shall serve for terms of 4 years. Members are limited to 2 4-years terms.

C. Vacancies among appointed members must be filled by appointment by the Governor for the unexpired term. A vacancy in the office of the chair must be filled by the Governor, who shall designate a new chair for the balance of the member's term as chair. The Governor may remove any appointed member who becomes disqualified by virtue of the requirements of paragraph A, or for neglect of any duty required by law, or for incompetency or dishonorable conduct.

D. Each appointed member of the committee is entitled to compensation according to Title 5, chapter 379.

E. Five members of the committee shall constitute a quorum. Actions of the committee must be by majority vote.

2. Duties. The committee shall perform the following duties:

A. Review proposed rules, criteria, standards and procedures for the certificate of need process and the state health plan prior to their adoption, review the annual certificate of need report prepared by the department and advise the commissioner with regard to certificate of need; and

B. Conduct the public hearing required under section 307, subsection 2-B.

22 § 307. Review process

1. Notice. Upon determination that an application is complete, or upon receipt of a notice under section 306-A, subsection 4, paragraph B, or upon grouping of the application with other pending applications, the department shall provide for written notification of the beginning of a review. Public notice shall be given by publication in the Kennebec Journal and in a newspaper of general circulation in the area in which the proposed expenditure or other action will occur. The notice shall be provided to all persons who have requested notification by means of asking that their names be placed on a mailing list maintained by the department for this purpose. This notice shall include:

A. A brief description of the proposed expenditure or other action;

B. The proposed schedule for the review;

C. A statement that a public hearing will be held during the course of a review if requested by persons directly affected by the review and the date by which the requests must be received by the department;

D. A description of the manner in which public notice will be given of a public hearing if one is to be held during the course of the review; and

E. A statement of the manner and time in which persons may register as affected persons.

2. Public hearing.

~~**2-A. Certificate of Need Advisory Committee.** The Certificate of Need Advisory Committee, established by Title 5, section 12004-I, subsection 38, and created within the Department of Human Services, shall participate with the department in the public hearing process.~~

~~A. The committee is composed of 10 members, 9 of whom are appointed by the Governor. The Commissioner of Human Services shall name a designee to serve as an ex officio, nonvoting member of the committee. The 9 members appointed by the Governor must be selected in accordance with the following requirements.~~

~~(1) Four members must be appointed to represent the following.~~

~~(a) One member must represent the hospitals.~~

~~(b) One member must represent the long-term care industry.~~

~~(c) One member must represent major 3rd-party payors.~~

~~(d) One member must represent providers.~~

~~In appointing these representatives, the Governor shall consider recommendations made by the Maine Hospital Association, the Maine Health Care Association, the Maine Medical Association, the Maine Osteopathic Association and other representative organizations.~~

~~(2) Five public members must be appointed as consumers of health care. One of these members must be designated on an annual basis by the Governor as chair of the committee. Neither the public members nor their spouses or children may, within 12 months preceding the appointment, have been affiliated with, employed by, or have had any professional affiliation with any health care facility or institution, health product manufacturer or corporation or insurer providing coverage for hospital or medical care; however neither membership in or subscription to a service plan maintained by a nonprofit hospital and medical service organization, nor enrollment in a health maintenance organization, nor membership as a policyholder in a mutual insurer or coverage under such a policy, nor the purchase of or coverage under a policy issued by a stock insurer may disqualify a person from serving as a public member.~~

~~B. Appointed members of the committee shall serve for terms of 4 years. Members shall hold office until the appointment and confirmation of their successors. Of the members first appointed by the Governor, the member representing hospitals and 2 public members shall hold office for 4 years, the member from the nursing home industry and one public member shall hold office for 3 years, the member from the insurance field and one public member shall hold office for 2 years and the physician and one public member shall hold office for one year.~~

~~C. Vacancies among appointed members shall be filled by appointment by the Governor for the unexpired term. A vacancy in the office of the chair shall be filled by the Governor, who shall designate a new chair for the balance of the member's term as chair. The Governor may remove any appointed member who becomes disqualified by virtue of the requirements of paragraph A, or for neglect of any duty required by law, or for incompetency or dishonorable conduct.~~

~~D. Each appointed member of the committee shall be compensated according to Title 5, chapter 379.~~

~~E. Five members of the committee shall constitute a quorum. Actions of the committee shall be by majority vote.~~

2-B. Public hearing. A public hearing shall be held during the course of a review by the Certificate of Need Advisory Committee if requested by persons directly affected by the review pursuant to subsection 1. Nothing in this section may be construed to prevent the department from holding informational meetings with applicants and interested and affected persons prior to the conduct of the hearing. In the event no hearing has been requested prior to an informational meeting or receipt of the preliminary staff report, the applicant or any directly affected persons may request a hearing within 10 days of either circumstance, provided that the review period shall be extended by 60 days if such a hearing is requested. In the case of grouped applications, the extension shall apply to all competing applications.

A. The committee or agency shall provide notice of its hearings in accordance with the procedure described in subsection 1.

B. Findings, recommendations, reports, analyses and related documents prepared by the staff of the agency shall be in final form and be made available to affected persons at least 5 business days prior to its hearings. The department shall make its preliminary staff report available to the committee and affected persons at least 5 business days prior to a public hearing conducted by the committee.

C. In a hearing conducted by the committee, any person shall have the right to be represented by counsel or to present oral or written arguments and evidence relevant to the matter which is the subject of the hearing. Any person directly affected by the matter may conduct reasonable questioning of persons who make relevant factual allegations.

D. The chair serves as a voting presiding officer and, in consultation with the members of the committee, shall rule on the relevance of argument and evidence and make determinations as to reasonable questioning. The department's administrative hearing unit shall provide technical support to the committee for the conducting of hearings as necessary. Members of the committee may conduct reasonable questioning in the course of a hearing.

E. The department or agency shall record all hearings and any subsequent proceedings of the committee with respect to the application in a form susceptible to transcription. The department shall transcribe the recording when necessary for the prosecution of an appeal.

F. During the first 7 business days following the close of a public hearing conducted by the committee interested or affected persons may submit written comments concerning the review under consideration. The department shall provide copies of comments submitted in that manner to all persons registered as affected persons and to appointed members of the committee. In reviews where no hearing is held, interested or affected persons may submit comments 10 days after the submission of the preliminary staff report, but no later than the 70th day of a 90-day review cycle or the 130th day of a 150-day review cycle.

G. In the event that circumstances require the department to obtain further information from any source or to otherwise contact registered affected persons following the public hearing and submission of comments under paragraph F or, when no hearing is held, following the 80th day of a 90-day review cycle or the 140th day of a 150-day review cycle, the department shall:

(1) Provide written notice to all registered affected persons who shall have at least 3 business days to respond; or

(2) Convene a public meeting with reasonable notice with participation of the committee at its discretion and affording directly affected persons the opportunity to conduct reasonable questioning.

In either event, notwithstanding any other provision of this chapter, the time period in which a decision is required shall be extended 20 days. Any written comments shall be forwarded to the committee.

H. At its next meeting following the receipt of comments pursuant to paragraph F or G, or in the case of a public hearing pursuant to paragraph G, the committee shall make a recommendation of approval, disapproval or approval with conditions with respect to the application or applications under consideration. This meeting is open to the public; however, during the committee's deliberations, participation is limited to committee members. The recommendation must be determined by majority vote of the appointed members present and voting. Members of the committee may make additional oral comments or submit written comments, as they consider appropriate, with respect to the basis for their recommendations or their individual views. The committee recommendation and any accompanying comments must be forwarded to the commissioner. If the committee is unable to obtain a majority on a recommendation, the committee shall report to the commissioner the result of any vote taken.

I. At the time the staff submits its final report to the commissioner, a copy of the report shall be sent to the applicant and a notification shall be sent to all registered affected persons. No further comments may be accepted.

J. After a hearing commences, no appointed members of the committee or the department may communicate directly or indirectly in connection with any application with any affected party or anyone acting in their behalf, except upon notice and opportunity for all affected parties to participate. This paragraph shall not prohibit the department from communicating with any affected party or anyone acting on their behalf for the purpose of arranging a public meeting pursuant to paragraph G.

3. Reviews. To the extent practicable, a review shall be completed and the department shall make its decision within 90 days after the date of notification under subsection 1. The department shall establish criteria for determining when it is not practicable to complete a review within 90 days. Whenever it is not practicable to complete a review within 90 days, the department may extend the review period up to an additional 60 days.

Any review period may be extended with the written consent of the applicant. The request to extend the review period may be initiated by the applicant or the department. If the request is initiated by the department, it shall not be effective unless consented to by the applicant in writing. If the request is initiated by the applicant, the department shall agree to the requested extension if it determines that the

request is for good cause. The department shall acknowledge the extension of the review period in writing.

4. Review by Health Systems Agency.

5. Review by department.

5-A. Decision by the department. Decisions by the commissioner shall be made in accordance with the following procedures.

A. The department shall prepare its final staff report based solely on the record developed to date, as defined in paragraph C, subparagraphs (1) to (6).

B. After reviewing each application, the commissioner shall make a decision either to issue a certificate of need or to deny the application for a certificate of need. The decision of the commissioner must be based on the informational record developed in the course of review as specified in paragraph C. The commissioner may issue a certificate of need with specific conditions. Notice of the decision must be sent to the applicant and the committee. This notice must incorporate written findings that state the basis of the decision, including the findings required by section 309, subsection 1. If the decision is not consistent with the recommendations of the Certificate of Need Advisory Committee, the commissioner shall provide a detailed statement of the reasons for the inconsistency.

C. For purposes of this subsection, "informational record developed in the course of review" includes the following:

(1) All applications, filings, correspondence and documentary material submitted by applicants and interested or affected persons prior to the termination of the public comment period under subsection 2-B, paragraph F or, if no hearing is held, prior to the 80th day of a 90-day review cycle and prior to the 140th day of a 150-day review cycle;

(2) All documentary material reflecting information generated by the department prior to termination of the public comment period or, if no hearing is held, prior to the 80th day of a 90-day review cycle and prior to the 140th day of a 150-day review cycle;

(3) Stenographic or electronic recording of any public hearing or meeting held during the course of review, whether or not transcribed;

(4) All material submitted or obtained in accordance with the procedures in subsection 2-B, paragraph G;

(5) The staff report of the agency, the preliminary staff report of the department and the recommendations of the committee;

(6) Officially noticed facts; and

(7) The final staff report of the department.

Documentary materials may be incorporated in the record by reference, provided that registered affected persons are afforded the opportunity to examine the materials.

In making a determination on any pending application under the certificate of need program, the department shall not rely on the contents of any documents relating to the application when those documents are submitted to the department anonymously.

6. Review cycles.

6-A. Review cycles. The department shall establish review cycles for the review of applications. There must be at least one review cycle for each type or category of project each calendar year, the dates for which must be published at least 3 months in advance. An application must be reviewed during the next scheduled review cycle following the date on which the application is either declared complete or submitted for review pursuant to section 306-A, subsection 4, paragraph B. ~~Nursing home projects that propose to add new nursing home beds to the inventory of nursing home beds within the State may be grouped for competitive review purposes consistent with appropriations made available for that purpose by the Legislature. A nursing home project that proposes renovation, replacement or other actions that will increase Medicaid costs may be approved only if appropriations have been made by the Legislature expressly for the purpose of meeting those costs, except that the department may approve, without a prior appropriation for the express purpose, projects to reopen beds previously reserved by a nursing facility through a voluntary reduction pursuant to section 304-F, provided that the annual total of reopened beds approved does not exceed 100.~~ The department may hold an application for up to 90 days following the commencement of the next scheduled review cycle if, on the basis of one or more letters of intent on file at the time the application is either declared complete or submitted for review pursuant to section 306-A, subsection 4, paragraph B, the department expects to receive within the additional 90 days one or more other applications pertaining to similar types of services, facilities or equipment affecting the same health service area. Pertinent health service areas must be defined in rules adopted by the department pursuant to section 312.

22 § 308. Waiver of requirements; emergency certificate of need

1. Waiver of full review. The department may waive otherwise applicable requirements and establish a simplified review process for projects which do not warrant a full review. Procedures for conducting these reviews shall be established by the department in its rules. These procedures shall provide for a shortened review and for a public hearing to be held during the course of a review, if requested by any person directly affected by the review. In order to waive requirements for a full review, the department shall find that the proposed project:

A. Meets an already demonstrated need as established by applicable state health plans or by the rules of the department;

B. Is a part of a minor modernization or replacement program which is an integral part of an institutional health care facility's health services or capital expenditures plans required by section 305; and

C. Is required to meet federal, state or local life safety codes or other applicable requirements.

1-A. Acquisition of control. The department shall waive the requirements of section 309, subsection 1, paragraphs C and D and conduct a simplified review process in accordance with this section for an acquisition of control of health care facilities pursuant to section 304-A, subsection ~~1-A~~ 1, if the acquisition consists of a management agreement or similar arrangement and primarily involves day-to-day operation of the facility in its current form. The department shall complete its review of arrangements qualifying for simplified review within 45 days of the filing of a completed application.

2. Waiver of other requirements. In order to expedite the review of an application submitted in response to an emergency situation, the department may:

A.

B.

C. Establish a schedule for the review of an application which commences on a day other than the first day of an established review cycle.

3. Emergency ~~defined~~ certificate of need. The department shall determine that an emergency situation exists whenever it finds that an applicant has demonstrated:

A. The necessity for immediate or temporary relief due to natural disaster, fire, unforeseen safety consideration, major accident, equipment failure, foreclosure, receivership or action of the department or other circumstances as determined to be appropriate by the department;

B. The serious adverse effect of delay on the applicant and the community that would be occasioned by compliance with the regular requirements of this chapter and the rules and regulations promulgated by the department; and

C. The lack of substantial change in the facility or services which existed before the emergency situation.

In an emergency situation the department may waive in writing any penalties for failure to receive a certificate of need for an otherwise reviewable project. After the emergency is resolved the department shall review the action to determine whether any additional review is required.

~~**4. Waiver of review of acquisitions of major medical equipment.** The department may waive the review of an acquisition or proposed use of major medical equipment required pursuant to section 304-A if the equipment will be used to provide services to inpatients of a hospital only on a temporary basis in the case of:~~

~~A. A natural disaster;~~

~~B. A major accident; or~~

~~C. Equipment failure.~~

~~**5. Provision for expedited administrative reviews.** The department shall promulgate rules by January 1, 1988, to create a procedure for administrative reviews for at least the replacement of major medical equipment.~~

22 § 309. Principles governing the review of applications

1. Determinations for issue of certificate. A certificate of need shall be issued whenever the department determines:

A. That the applicant is fit, willing and able to provide the proposed services at the proper standard of care;

B. That economic feasibility of the proposed services is demonstrated in terms of: Effect on the existing and projected operating budget of the applicant; the applicant's ability to establish and operate the facility or services in accordance with licensure rules adopted under pertinent state laws; the projected impact on the facility's costs and rates the total health care expenditures in the community and the State; and the availability of State funds;

C. That there is a public need for the proposed services; and

D. That the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State, that the citizens of the State have the ability to underwrite the additional costs of the proposed services and that the proposed services are in accordance with standards, criteria or plans adopted and approved pursuant to the state health plan developed by the department.

2. Criteria for certificate of need.

2-A. Criteria for certificate of need. In determining whether to issue or deny a certificate of need under subsection 1, the department shall, among other criteria, consider the following:

A. Whether the project will substantially address specific problems or unmet needs in the area to be served by the project;

B. Whether the project will have a positive impact on the health status indicators of the population to be served;

C. Whether the services affected by the project will be accessible to all residents of the area proposed to be served. Accessibility is determined through analysis of the area including population, topography and availability of transportation and health services;

D. Whether there are less costly or more effective alternate methods of reasonably meeting identified health service needs of the project;

E. Whether the project is financially feasible in both an intermediate and long-term time frame;

F. Whether the project would produce a cost benefit in the existing health care system of the State and the area in which the project is proposed;

G. Whether the quality of any health care provided by the applicant in the past meets industry standards; and

H. Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project.

3. Health maintenance organizations.

4. Required approvals. Approval of proposed capital expenditures shall comply with the following:

A. Except as provided in paragraph B, the department shall issue a certificate of need for a proposed capital expenditure if:

(1) The capital expenditure is required to eliminate or prevent imminent safety hazards, as defined by applicable fire, building or life-safety codes and regulations; to comply with state licensure standards; or to comply with accreditation or certification standards which must be met to receive reimbursement under the United States Social Security Act, Title XVIII, or payments under a state plan for medical assistance approved under Title XIX of that Act; and

(2) The department has determined that the facility or service for which capital expenditure is proposed is needed; the obligation of the capital expenditure is consistent with the state health plan; and the corrective action proposed by the applicant is the most cost effective alternative available under the circumstances.

B. Those portions of a proposed project which are not required to eliminate or prevent safety hazards or to comply with licensure, certification or accreditation standards are subject to review in accordance with the criteria established under section 312.

5. Standards applied in certificate of need. The commissioner shall, in issuing a certificate of need, make ~~his~~ the decision, to the maximum extent practicable, directly related to criteria established under federal laws and standards or criteria prescribed in regulations promulgated by the department pursuant to subsections 1 to 4 and section 312.

The commissioner shall not deny issuance of a certificate of need, or make his decision subject to fulfillment of a condition on the part of the applicant, except where the denial or condition directly relates to criteria established under federal laws and standards or criteria prescribed in regulations promulgated by the department in accordance with subsections 1 to 4 and section 312, which are pertinent to the application.

~~**6. Hospital projects.** Projects that are carried forward shall compete equally with newly proposed projects. For the purposes of this subsection, a project may be held for a final decision beyond the time frames set forth in section 307, subsection 3.~~

7. Intermediate care facilities.

22 § 310. Reconsideration

Any person directly affected by a review may, for good cause shown, request in writing a hearing for the purposes of reconsideration of the decision of the department to issue or to deny a certificate of

need. The department, if it determines that good cause has been demonstrated, shall hold a hearing to reconsider its decision. To be effective, a request for the hearing shall be received within 30 days of the department's decision. If the Department of Human Services determines that good cause for a hearing has been demonstrated, the hearing shall commence within 30 days of receipt of the request. A decision shall be rendered within 60 days of the commencement of the hearing. The decision may be rendered beyond this time period by mutual consent of the parties. For purposes of this section, a request for a hearing shall be deemed to have shown good cause if it:

1. New information. Presents significant, relevant information not previously considered by the department;

2. Changes in circumstances. Demonstrates that there have been significant changes in factors or circumstances relied upon by the department in reaching its decision;

3. Failure to follow procedures. Demonstrates that the department has materially failed to follow its adopted procedures in reaching its decision; or

4. Other bases. Provides other bases for a hearing that the department has determined constitutes good cause.

22 § 311. Remedy

Any person aggrieved by a final decision of the department made under the provisions of this Act shall be entitled to review in accordance with Title 5, chapter 375, subchapter VII, of the Administrative Procedure Act. A decision of the department to issue a certificate of need or to deny an application for a certificate of need shall not be considered final until the department has taken final action on a request for reconsideration under section 310.

A decision by the department is not final where opportunity for reconsideration under section 310 exists with respect to matters involving new information or changes in circumstances. Where new information or changes in circumstances are not alleged by the applicant or other person aggrieved by the decision, a person aggrieved by a decision of the department may, at its option, seek reconsideration under section 310 or may seek direct judicial review under this section.

In civil actions involving competitive reviews of proposals to construct new nursing ~~home~~ facility beds, the court shall require the party seeking judicial review to give security in such sums as the court deems proper, for the payment of such costs and damages as may be incurred or suffered by any other party who is found to have been wrongfully delayed or restrained from proceeding to implement the certificate of need, provided that for good cause shown and recited in the order, the court may waive the giving of security. A surety upon a bond or undertaking under this paragraph submits ~~himself~~ the surety to the jurisdiction of the court and irrevocably appoints the clerk of the court as ~~his~~ the agent for the surety upon whom any papers affecting ~~his~~ liability on the bond or undertaking may be served. ~~His~~ The liability of the surety may be enforced on motion without the necessity of an independent action. The motion and such notice of the motion as the court prescribes may be served on the clerk of the court who shall forthwith mail copies to the persons giving the security if their addresses are known.

22 § 312. Rules ~~and regulations~~

The department shall adopt any rules, ~~regulations,~~ standards, criteria, ~~or~~ plans or procedures that may be necessary to carry out the provisions and purposes of this Act. The department shall, to the extent applicable, take into consideration recommendations contained in the state health plan ~~as approved by the Governor~~ and the recommendations of the Certificate of Need Advisory Committee under section 306-A, subsection 2, paragraph A. The department shall provide for public notice and hearing on all proposed rules, ~~regulations,~~ standards, criteria, plans procedures or schedules pursuant to Title 5, chapter 375. Unless otherwise provided by this Act, rules adopted pursuant to this chapter are routine technical rules as defined by Title 5, chapter 375, subchapter II-A. The department is authorized to accept any federal funds to be used for the purposes of carrying out this chapter.

22 § 313. Public information

The general public shall have reasonable access to all applications reviewed by the department and to all other written material pertinent to its review of these applications. The department shall prepare and publish at least annually a report on its activities conducted pursuant to this Act.

22 § 314. Conflict of interest

In addition to the limitations of Title 5, section 18, a member or employee of the Department of Human Services or Certificate of Need Advisory Committee who has a substantial economic or fiduciary interest which would be affected by a recommendation or decision to issue or deny a certificate of need, or who has a close relative or economic associate whose interest would be so affected shall be ineligible to participate in the review, recommendation or decision making process with respect to any application for which the conflict of interest exists.

22 § 315. Division of project to evade cost limitation prohibited

No health care facility or other party required to obtain a certificate of need shall separate portions of a single project into components, including, but not limited to, site facility and equipment, to evade the cost limitations or other requirements of section 304.

22 § 316. Exemptions (REPEALED)

22 § 316-A. Exemptions

Except as otherwise specifically provided, nothing in this Act shall be construed to preempt, replace or otherwise negate the requirements of any other laws or regulations governing health care facilities. The requirements of this Act shall not apply with respect to:

1. Health care facilities. Any health care facility:

A. Operated by religious groups relying solely on spiritual means through prayer for healing; ~~or~~

~~B. For which any construction, modification or other change subject to this Act has been reviewed and has received approval pursuant to the United States Social Security Act, Section 1122, from appropriate agencies prior to the effective date of this Act;~~

2. Activities; acquisitions. Activities or acquisitions by or on behalf of a health maintenance organization or a health care facility controlled, directly or indirectly, by a health maintenance organization or combination of health maintenance organizations to the extent mandated by the National Health Planning and Resources Development Act of 1974, as amended and its accompanying regulations; and

2-A. Assisted living. Assisted living programs and services regulated under chapter 1665.

2-B. Existing capacity. The use by an ambulatory surgical facility licensed on January 1, 1998 of capacity in existence on January 1, 1998.

3. Home health care services. Home health care services offered by a home health care provider ~~prior to 90 days after adjournment of the Second Regular Session of the 110th Legislature.~~

4. Home health care providers.

5. Hospice. Hospice services and programs.

22 § 317. Scope of certificate of need
(REPEALED)

22 § 317-A. Scope of certificate of need

1. Application determinative. A certificate of need shall be valid only for the defined scope, premises and facility or person named in the application and shall not be transferable or assignable.

2. Maximum expenditure. In issuing a certificate of need, the department shall specify the maximum capital expenditures which may be obligated under this certificate. The department shall, by ~~regulations promulgated~~ rules adopted pursuant to section 312, prescribe the method to be used to determine capital expenditure maximums, establish procedures to monitor capital expenditures obligated under certificates and establish procedures to review projects for which the capital expenditure maximum is exceeded or expected to be exceeded.

3. Periodic review. After the issuance of a certificate of need, the department shall periodically review the progress of the holder of the certificate in meeting the timetable for making the service or equipment available or for completing the project specified in the approved application. A certificate of need shall expire if the project for which the certificate has been issued is not commenced within 12 months following the issuance of the certificate. The department may grant an extension of a certificate for an additional specified time not to exceed 12 months if good cause is shown why the project has not commenced. The department may require evidence of the continuing feasibility and availability of financing for a project as a condition for extending the life of certificate. In addition if on the basis of its periodic review of progress under the certificate, the department determines that the holder of a certificate is not otherwise meeting the timetable and is not making a good faith effort to meet it, the department may, after a hearing, withdraw the certificate of need. The department shall in accordance with section 312 ~~promulgate the necessary procedures~~ adopt rules for withdrawal of certificates of need.

22 § 318. Withholding of license

No new health care facility or nursing facility, as defined in section 303, shall be eligible to obtain a license under the applicable state law, if the facility has not obtained a certificate of need as required by this chapter. The license of any facility shall not extend to include or otherwise be deemed to allow the delivery of any services, the use of any equipment which has been acquired, the use of any portion of a facility or any other change for which a certificate of need as required by this Act has not been obtained. Any unauthorized delivery of services, use of equipment or portion of a facility, or other change shall be deemed to be in violation of the respective chapter under which the facility is licensed.

22 § 319. Withholding of funds

No health care facility, nursing facility or other provider may be eligible to apply for or receive any reimbursement, payment or other financial assistance from any state agency or other 3rd party payor, either directly or indirectly, for any capital expenditure or operating costs attributable to any project for which a certificate of need as required by this Act has not been obtained. For the purposes of this section, the department shall determine the eligibility of a facility to receive reimbursement for all projects subject to the provisions of this Act.

22 § 320. Injunction

The Attorney General, upon the request of the department, shall seek to enjoin any project for which a certificate of need as required by this Act has not been obtained, and shall take any other action as may be appropriate to enforce this Act.

22 § 321. Penalty

Whoever violates any provision of this chapter or any rate, rule or regulation established hereunder shall be subject to a civil penalty payable to the State of not more than $5,000 to be recovered in a civil action. The department may hold these funds in a special revenue account which shall be used only to support certificate of need reviews, such as for hiring expert analysts on a short-term consulting basis.

22 § 322. Implementation reports

The holder of a certificate of need shall make a written report at the end of each 6-month period following its issuance regarding implementation activities, obligations incurred and expenditures made and any other matters as the department may require. A summary report shall be made when the service or services for which the certificate of need was issued becomes operational. For a period of one year following the implementation of the service or services for which the certificate of need was granted, the provider shall file, at 6-month intervals, reports concerning the costs and utilization. The department, in its rules, shall prescribe the form and contents of the reports. Any holder of a certificate of need which has been issued for the construction or modification of a facility or portion thereof shall file final plans and specifications therefor with the department within 6 months, or any other time that the department may allow, following the issuance of the certificate for review by the department to determine that the plans and specifications are in compliance with the certificate of need which has been issued therefor and are in compliance with applicable licensure, life safety code and accreditation standards. The department may revoke any certificate of need it has issued when the person to whom it has been issued fails to file reports or plans and specifications required by this section on a timely basis.

~~**22 § 323. Relationship to the United States Social Security Act, Section 1122**~~

~~**1. Administration of Section 1122 reviews.** The department shall, in reviewing those capital expenditures which require review under section 304-A and the United States Social Security Act, Section 1122, and regulations promulgated thereunder, allow the maximum flexibility permitted under the United States Social Security Act, Section 1122, consistent with this chapter.~~

~~**2. Thresholds for review.** The department shall waive review of proposed capital expenditures by health care facilities under the United States Social Security Act, Section 1122, and regulations promulgated thereunder, unless those expenditures are subject to review under section 304-A.~~

~~**3. Procedures.** The department shall, pursuant to section 312, modify its United States Social Security Act, Section 1122 Procedures Manual as required by this section, and shall promulgate the revised manual as a regulation on or before January 1, 1983.~~

22 § 324. Review

The department shall convene meetings of the public, providers and consumers of health care, state agencies, insurers and managed care entities, the Certificate of Need Advisory Committee and interested parties to examine the operation of the certificate of needs laws, rules, standards, criteria and procedures and shall report to the legislative joint standing committee having jurisdiction over health and ~~institutional~~ human services not later than January 31, ~~1999~~ 2001 on the continuing feasibility of this chapter.

PART C

Sec. C-1. Effective date. This Act takes effect October 1, 1998.

Sec. C-2. Adoption of rules, standards, criteria and procedures. Beginning November 1, 1998, the Department of Human Services shall adopt new rules, standards, criteria and procedures for the certificate of need process, consistent with Title 22, chapter 103, as amended, in accordance with the requirements of Title 5, chapter 375, subchapter II.

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