

# **Certificate of Need Project Report**

Prepared for the  
**Maine Department of Human Services**

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## Maine Department of Human Services Certificate of Need Project

### Executive Summary

#### Introduction

Certificate of need (CON) refers to statutory requirements for hospitals, nursing homes and other health care providers to obtain the formal approval of a state regulatory body for construction and renovation of health care facilities, for purchase or lease of medical equipment and for changes in certain health care services. When CON programs began in the 1970s, their primary purpose was to reduce increases in health care costs by reducing unnecessary duplication of health care facilities and services.

The value of state CON programs has been widely debated in the state of Maine and across the country. With changing healthcare technology and increasing healthcare costs many states are struggling with the role of CON in striking a balance between competition and preventing duplication of costly services. Concerns about the efficacy of Maine's CON program were renewed with the recent statewide controversy over the expansion of invasive cardiology services in community hospitals. As part of the cardiology need/demand (CVD) study conducted by the Public Health Resource Group (PHRG) on behalf of the Department of Human Services (DHS), PHRG evaluated the CON process as it relates to invasive cardiology or cardiac surgery. PHRG made several recommendations on ways to strengthen the program.

As a follow-up to the CVD study, DHS asked PHRG to more closely evaluate the Acute Care CON program in Maine, compare Maine's CON program to CON in other states, and recommend specific legislative changes to the program so that it better meets the needs of Maine people.

The CON report that follows is based on a series of interrelated tasks spelled out by DHS to PHRG. Specifically, PHRG was contracted to:

1. Analyze and describe the relationship between CON, health planning, cost control, and healthcare quality;
2. Compare the Acute Care CON program in Maine to CON in other states;
3. Review current program strengths and weaknesses and objectives for the future;
4. Interview stakeholders to understand perceptions of the current CON process and get feedback on proposed changes; and
5. Develop a template of legislative changes for CON in Maine.

#### Certificate of Need in Maine and Other States

Maine enacted its initial certificate of need law in 1977 in response to the federal requirement. The law has been amended several times. The most recent change to the law was in 1998 when the largely procedural recommendations of the Commission to Study the Certificate of Need Laws, 118th Maine Legislature, were adopted.

Despite several changes over the years, the type of services that are subject to CON in Maine are very similar to those specified in the initial legislation. CON is required for: i) acute care services, such as new inpatient and outpatient hospital services, ambulatory surgery centers and diagnostic and therapeutic medical equipment, and ii) nursing home services. CON approval is required for changes in ownership, original licensure, new construction or renovation, the purchase or lease of major medical equipment and the initiation of new services that meet certain dollar thresholds.

The purposes of the CON program as specified in the law are as follows:

- ◆ Support effective health planning;
- ◆ Support the provision of quality health care in a manner that ensures access to cost-effective services;
- ◆ Support reasonable choice in health care services while avoiding excessive duplication;
- ◆ Ensure that state funds are used prudently in the provision of health care services;
- ◆ Ensure public participation in the process of determining the array, distribution, quantity, quality and cost of these services;
- ◆ Improve the availability of health care services throughout the State;
- ◆ Support the development and availability of health care services regardless of the consumer's ability to pay; and
- ◆ 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.

In summary, the Maine CON program attempts to address the central challenge of health care policy, the balancing of health care cost, quality and access.

Comparing Maine CON program goals and procedures to CON programs in other states allows for greater insight into how to develop a more effective CON program in Maine. All six New England states have CON programs that, with the notable exception of Massachusetts, are fairly extensive. The variation among states is great when considering the relationship of CON with health planning and the balancing of health care costs, quality and access issues. Some states have developed particular administrative structures to address these health issues while others have little or no formal structure to do so. A careful review of the CON law in Maine and 10 other states (see Section I of the full report for details of the other states reviewed) yields the following strengths and weaknesses of the Maine CON program:

#### Program Strengths:

- ◆ Scope of services covered by CON appropriate for Maine;
- ◆ Well-defined procedures to establish the record for approving/disapproving applications; and
- ◆ Structured forum for affected party input into decision-making.

#### Program Weaknesses:

- ◆ CON decision-making without the benefit of effective system-wide health planning;
- ◆ Reactive rather than proactive regarding the development of needed services;
- ◆ Weak linkage with health care quality;
- ◆ Focus on medical care therapeutic & diagnostic services versus health care prevention & health care promotion activities;

- ◆ Lack of monitoring and enforcement; and
- ◆ Administrative procedures regarding the role of the Commissioner in decision-making.

The following four objectives for CON were developed based on the strengths and weaknesses of the current program:

1. CON to Take Place in the Context of Renewed DHS Health Planning Functions
2. Incentives/Requirements for Community Health Benefits
3. Coordination of CON and Licensure/Certification
4. Improved Administrative Procedures

### **Stakeholders' Perceptions of the Proposed Changes**

As part of the study, PHRG conducted interviews with 17 representative stakeholders (providers, consumers, and government officials) who have interest in or knowledge about the CON program in Maine (See Section II of the full report for details of the interview process and findings). Interviewees were asked to give their opinion on how CON should function within the State and critique the proposed changes to the program outlined in Section III of the full report.

The interviewees tend to endorse the intent of the language appearing in Section III of the full report. However they reserve the right to examine and debate the final product. As always, “the devil is in the details.” Emphasizing health planning, quality, prevention, and health status resonates well in the minds of those with whom we discussed these topics. A continuation of the CON program in Maine is overwhelmingly supported so long as there are better mechanisms to proactively involve interested parties in the process. This implies a reorganization of the CON program within the Department of Human Services so that health planning, data analysis, quality oversight, and CON program administration are well connected and coordinated. This will require attention to sufficient staffing of the program and sustained funding so that the public interests are maintained over time.

### **Synopsis of Suggested Changes to the CON Law**

The Maine Department of Human Services wishes to strengthen and improve the CON program to better serve the needs of the people of Maine. The objectives of PHRG's recommended changes include:

1. Improving administrative procedures governing the CON review process.
2. Strengthening health planning and health policy development within the CON program and the State.
3. Linking local health care prevention services to CON new services/new technology approvals.
4. Monitoring CON approved services through volume and quality indicators and linking them to licensure and certification.

PHRG proposes the following specific changes to the Maine Acute Care CON program to address these objectives (See Section III of the full report for a more complete description of the changes):

- ◆ Require applicants to explain and demonstrate how their proposal will improve the health status of their communities using valid and quantifiable measures of “public” health need;

and to define their quality assurance process for the service including how they will disseminate anticipated quality of care outcomes information.

- ◆ Clarify and expand the definition of and opportunities for input from directly affected persons.
- ◆ Enable the Department to hold an otherwise complete application for up to 180 days if it finds that a public necessity exists to carefully evaluate a new service or technology. The need, mechanisms, and communication protocols for conducting such an evaluation shall be prescribed.
- ◆ Grant the Commissioner authority to hold a public hearing on a specific application rather than the Certificate of Need Advisory Committee and the authority to appoint an independent ad hoc committee to conduct the hearing with the Commissioner as the chair.
- ◆ Grant the Commissioner the ability to communicate with his staff during the course of a review and after he has received a report of findings from staff on the application.
- ◆ Require that applicants include prevention services as part of their application for a new service or technology. A specified percentage (eg.5%) of the operating expense would be dedicated to preventative measures.
- ◆ Require the applicant to issue periodic (e.g. annual or longer) reports, following CON approval on the impact that the services have had in addressing matters of health status, quality of care, health need and health outcomes.
- ◆ Change and expand the role of the CON Advisory Committee to a body more engaged in health planning and policy development; permitting the committee to convene meetings and request studies on important and relevant health care issues, and eliminating recommending approval or denial of specific CON applications.
- ◆ Clarify scope of services, thresholds, and grouping of projects that will come under the purview of CON review. Require the department to justify their decision based on public health need.
- ◆ Establish organizational mechanisms to unify language, standards, and guidelines affecting CON and Licensure and Certification activities on a service or program specific basis.
- ◆ Establish an effective monitoring process for enforcement of quality and volume standard and conditions.

## **Maine Department of Human Services Certificate of Need Project**

### **Introduction**

Certificate of need (CON) has been widely debated not only in the State of Maine, but across the country. With changing healthcare technology and increasing healthcare costs many states are struggling with the role of CON in striking a balance between competition and preventing duplication of services. Evidence of the CON debate in Maine can clearly be seen in the recent statewide debate over the expansion of cardiology services in community hospitals. In June 2000, the Department of Human Services (DHS) contracted the Public Health Resource Group (PHRG) to conduct a study of need/demand for cardiology services in Maine after receiving 7 applications to develop cardiac catheterization laboratories and 1 application to develop an open-heart surgery program. As part of that study, PHRG also evaluated the CON process as it relates to invasive cardiology or cardiac surgery.

In the cardiology services need/demand study, PHRG concluded that CON should continue to oversee developments in the healthcare delivery system, and that the thresholds for triggering certificate of need reviews for invasive cardiology or cardiac surgery programs are not unduly restrictive. PHRG also noted several weaknesses in the Maine CON process, and recommended ways to strengthen the program that centered on the review process and linking CON to health planning for the State.

As a follow-up to that study, DHS has asked PHRG to more closely evaluate the history of the Acute Care CON program in Maine, compare the Maine Acute Care CON program to CON in other states, and recommend changes to the program so that it better meets the needs of the State. The following report is our response to that request.

### **Objectives**

The CON follow-up study involves a series of interrelated tasks spelled out in the charge to the consultant. Specifically, PHRG has been contracted to:

1. Study and document current program strengths and weaknesses and objectives for the future;
2. Analyze and describe the inter-relationship between CON, health planning, cost control, and healthcare quality;
3. Compare the Acute care CON program in Maine to CON in other states;
4. Interview stakeholders to understand perceptions of the current CON process and get feedback on proposed changes; and
5. Evaluate new CON initiatives/proposals.

Section I of this report presents an assessment of the Acute Care Certificate of Need (CON) program in Maine. The acute care component of CON in Maine applies to

facilities for acute, rehabilitation, psychiatric and ambulatory surgery services, new services, medical equipment and other certain services in hospital and community settings. This assessment addresses the relationship of the CON program with health planning, health care costs, health care quality, and health care access.

Section II reports on the findings of the interviews of stakeholders conducted as part of the study process. Interviewees were asked to comment on the proposed changes to the CON and what they felt the role of CON should be in Maine.

Section III contains recommended changes to CON legislation based on the findings presented in sections 1 and 2 of this report.

## **Section I: Assessment of the Acute Care Certificate of Need Program in Maine**

### **The Development and Evolution of Certificate of Need Programs**

Certificate of need refers to statutory requirements for hospitals, nursing homes and other health care providers to obtain the formal approval of a state regulatory body for construction and renovation of health care facilities, for purchase or lease of medical equipment and for certain changes in the array of health care services provided. When certificate of need programs began in the 1970s, their primary purpose was to reduce increases in health care costs by reducing unnecessary duplication of health care facilities and services.

Certificate of need was one of several responses to the rapid rise in health care costs in the early and mid-1970s. While inflation in the economy as a whole was a major issue during this era oil price shocks and "stagflation" (the previously unseen combination of high inflation and high unemployment rates), health care costs were rising even more dramatically. With the benefit of hindsight, the extraordinary health care cost inflation of the era can attributed to in substantial measure to the effects of i) the significant increases in health care capacity that was necessary to address the increased access for the elderly and the poor brought about by establishment of the Medicare and Medicaid programs in the mid-1960s, and ii) the widespread use of cost-based reimbursement as the method for paying health care providers.

Under cost-based reimbursement, providers of health care were essentially guaranteed to receive their actual costs of providing health care services, including full capital, education and operating costs. This payment method provided strong financial incentives for providers to increase facilities and to services. While producing increases in health care service capacity, its inherently inflationary nature caused significant problems. In 1974, Congress passed and President Nixon signed the National Health Planning and Resources Development Act of 1974. This law required states to implement health planning and certificate of need programs as a condition of receipt for a variety of federal health funds. Under the law, certificate of need was one component of an integrated health planning system that included local health planning and statewide health planning, for which substantial federal funds were available.

Following the election of President Reagan in 1980, the federal role in regulating various aspects of the economy decreased, as did federal funding for health planning and CON programs. In 1987, the federal requirement for states to operate CON programs formally ended. Several states eliminated CON and others substantially reduced the scope of the program. As of February 2000, fourteen states had repealed their CON laws entirely. (See Exhibit 1) All thirty-six states with CON apply CON to nursing home services and twenty-eight of the thirty-six cover hospital and to varying degrees related services. (See Exhibit 2)

Most of the fourteen states that repealed CON entirely did so in the mid-to-late 1980s. In the last five years, only four states (North Dakota, Pennsylvania, Indiana and Minnesota) have repealed CON. (Minnesota actually repealed it for the second time, after initially repealing it in 1986 and then reinstating it in 1990.) In other states, proposals to eliminate or significantly scale back CON have been unsuccessful.

The track record of the cost effectiveness of state CON programs is decidedly mixed. In some states, the lack of effectiveness is at least partially attributable to deficiencies in program operations and to political environments in which legislative or high-level executive branch intervention alters or affects CON decision-making. On the other hand, there are states where CON is an integral and effective component of the operation of the health care marketplace, such as in Maryland.

The national perspective on certificate of need programs is thus one of substantial variation. This variation in CON program structures and effectiveness in large part reflects the diversity of health care and regulatory environments in the country. What makes sense for a CON program in one state may not be appropriate in another, including whether to have a CON program at all.

### **The Development and Evolution of the Certificate of Need Program in Maine**

Maine enacted its initial certificate of need law in 1977 in response to the federal requirement. The certificate of need law in Maine has been amended several times. The most recent change to the law was in 1998 when the recommendations of the Commission to Study the Certificate of Need Laws, 118th Maine Legislature, were adopted.

Although there have been several changes over the years, the type of services that are subject to CON in Maine are very similar to the type of services specified in the initial legislation. The program applies to i) acute care services, such as inpatient and outpatient hospital services, ambulatory surgery centers and diagnostic and therapeutic medical equipment, and ii) nursing home services. CON approval is required for changes in ownership, original licensure, new construction or renovation, the purchase or lease of major medical equipment and the initiation of new services.

While the type of services subject to CON in Maine have not changed substantially over the years, fewer projects and new services are now subject to CON review. This is due to the increases that have been made regarding the capital cost and operating cost "review thresholds". The thresholds are the minimum expenditure levels that must be incurred by a covered provider in order for the certificate of need to be required. The current threshold for capital expenditures is \$2,000,000. The current threshold for medical equipment is \$1,000,000. All new services require CON review regardless of cost. The 1998 amendments to the CON law in Maine made substantive changes to the thresholds and also included a provision specifying that the department shall annually adjust the thresholds for inflation, based on changes in Consumer Price Index medical index.

In addition to the changes in review thresholds, there have been several other changes that have significantly affected the CON program in Maine. The formal end of the

federal mandate for states to have CON programs in 1987 also meant the end of the federal dollars to support CON and health planning in states. State budget constraints and priorities have resulted in fewer resources devoted to health planning and certificate of need. For example, the Office of State Health Planning, which at one time had eight health planners, was eliminated. State health planning initiatives have been focused on particular issues such as chronic disease and cancer services in the State Bureau of Health. The type of planning on which the CON program was based simply no longer exists in Maine. Analysts in the CON program (both acute and nursing home), have been reduced from six (four program analysts and two financial analysts) to two program analysts in the acute care unit and one program analyst in the nursing home unit.

While the CON program has been a part of the Department of Human Services (including its predecessor, the Department of Health and Welfare) since its inception, the program has been organized in various ways in DHS. For most of its history, the CON program was part of DHS's Office of Health Planning, which no longer exists. The CON program is currently split into the acute care and nursing home units. The Acute Care CON Unit is part of the Division of Financial Services of the Bureau of Medical Services (BMS), while the Nursing Home Unit is part of the Bureau of Elder and Adult Services (BEAS). In addition to the two program analysts, the Acute Care CON Unit includes the Assistant Manager of the Division of Financial Services, a portion of whose time is allocated to the CON unit, and an Administrative Assistant.

### **The Maine CON Law**

As in the rest of the country, the health care environment in Maine has substantially changed since the enactment of Maine's CON law in 1977. The intervening years have seen dramatic changes in what, where and how health care services are delivered and financed in Maine. The changes range from the growth of ambulatory surgery and home based services to the emergence and growth of managed care to the mergers/sales/affiliations/conversion of numerous health care providers and insurers.

The health care regulatory structure has also changed in Maine during this period, including the development and demise of the Maine Health Care Finance Commission (MHCFC) that had regulated hospital budgets. While containing health care costs remains a primary purpose of the program, health care quality and access are also part of CON review process. The Maine CON law, 22 MSRA §301-325, reflects both the original focus on cost control and additional roles. The "Findings" section of the Maine CON law which has remained unchanged, is as follows: "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." The Purposes section, however, has been substantially revised, most recently by implementation of the recommendations of the CON Study Commission.

The "Purposes" as specified in the CON law are as follows:

- Support effective health planning;

- Support the provision of quality health care in a manner that ensures access to cost-effective services;
- Support reasonable choice in health care services while avoiding excessive duplication;
- Ensure that state funds are used prudently in the provision of health care services;
- Ensure public participation in the process of determining the array, distribution, quantity, quality and cost of these services;
- Improve the availability of health care services throughout the State;
- Support the development and availability of health care services regardless of the consumer's ability to pay; and
- 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.

As evidenced by these purposes, CON in Maine attempts to address the central challenge of health care policy, the balancing of health care cost, quality and access.

### **Services Subject To CON & Review Thresholds**

The current Maine CON law applies to acute care and specialty hospitals, nursing homes, ambulatory surgery centers, several types of specialty providers (e.g., kidney treatment centers), major medical diagnostic and therapeutic equipment and transfers of ownership of health care facilities. The law, however, also establishes review cost thresholds under which services are not subject to review. Exhibit 3 on the next page presents the type of health care facilities and services that are subject to CON and their associated review thresholds.

### **Administrative Procedures**

In addition to the type of services and review thresholds, the Maine CON law specifies in detail the administrative processes that govern the program. These processes are further specified in the written procedures that the Department of Human Services has developed to implement the CON law. (See Maine Certificate of Need Procedures Manual for Health Care Facilities (other than Nursing Care Facilities).)

The procedures manual addresses the full range of administrative issues and policies ranging from the scope of the CON program to the application process to the principles governing reviews to appeals of the CON decision. For purposes of this report, we are focusing on the application and review processes, with a particular emphasis on type and form of input into the DHS Commissioner's decision to approve or deny a proposed project.

The administrative processes regarding CON applications can vary among projects depending on the nature of the project and the degree to which the proposed project enjoys or lacks the support of parties other than the applicant provider. The vast majority of CON projects in Maine do not trigger the additional procedures when proposed projects are challenged by interested parties or when there are competing applications for similar services.

A summary outline of the steps in the administrative process for an applicant, the acute CON program staff, interested parties and the Commissioner of DHS follows. In this summary, *italics* indicate the additional administrative procedures that are related to projects in which either i) there are competing applications, or ii) a public hearing is conducted. Time limits for steps, where applicable, are shown in brackets after the description of the step. The specified time limits can usually be extended by mutual agreement of the parties. (NOTE: This summary outline does not include all of the administrative procedures that are specified in the Procedure Manual. The purpose of the outline is to convey an overall sense of the application and review process for both uncontested and contested projects.)

1. Prior to filing a CON application, the applicant submits a letter of intent regarding the project to the Director of the Acute CON Unit.
2. The Director advises the applicant in writing either i) that the proposed project requires a CON review, or ii) that additional information is necessary to make this determination. [Within 15 business days.]
3. If the project requires a CON, the applicant and unit staff meet prior to the filing of the application to i) assist the unit's staff in understanding the application, and ii) for the applicant to receive technical assistance from the unit's staff regarding the type and form of documentary evidence, statistical and financial data required. [Within 30 days from date of receipt of letter of intent.]
4. The applicant files a formal CON application following an application format and includes a filing fee that ranges from \$1,000 to \$25,000 depending on the size of the capital expenditure.
5. CON staff conducts a public informational meeting regarding the proposed project in which the applicant presents information about the project. The public information meeting must be held within 30 days of the filing of the CON application in a location convenient to the proposal location.
  - *Prior to the information meeting and up to 10 days after the informational meeting, a "registered directly affected person" can request that the CON Advisory Committee conduct a public hearing regarding the proposed project. (See Step 11)*
6. CON staff reviews the application for completeness and advises the applicant in writing either i) that the application is complete and the type of review it will conduct (see Step 7), or ii) that the applicant must submit additional information to complete the application. [Within 15 business days of the filing of the application.]
  - Applicants must respond to one set of requests for additional information. [Within 30 business days, or longer if the unit staff and applicant mutually agree.]
  - *In competitive reviews, within 30 business days or longer if the unit staff and all competing applicants agree.*

- CON staff may request, but cannot require applicants to respond to additional information requests. Such additional requests are restricted to being directly related to the prior request or to the applicant's response to the prior request.
7. For completed applications, CON staff determines which type of review will be required, the effective date of the beginning of the review cycle and notifies the applicant in writing.
    - Most applications are subject to "full review" [90 days]. Under specified circumstances applications may be subject to "extended review" [150 days], "simplified review" [60 days] or review can be waived.
    - There are twelve review cycles per year, with review cycles beginning on the first day of each calendar month. Applications are placed in the next scheduled review cycle that begins after the date that application is determined to be complete.
    - *CON staff may hold applications for up to 90 days if the unit expects, based on one or more letters of intent, that it will receive an application for a similar project in the same health service area within the additional time period.*
  8. For completed applications, the unit also provides public notification of the beginning of the review through newspaper notices.
    - *The public notice includes the procedures for "directly affected parties" to request that the Certificate of Need Advisory Committee hold a public hearing on the proposed project.*
  9. Unit staff reviews the application taking into account, among other criteria, sixteen factors that are identified in the procedure manual and the unit's space and need guidelines.
  10. Following its review, the unit staff issues a preliminary written report which is distributed to the applicant and interested parties.
    - *If a public hearing had not been previously requested, within 10 days of the submission of the preliminary staff report, an affected party can request that the CON Advisory Committee conduct a public hearing on the project.*
  11. If No Public Hearing Had Been Requested:
    - Interested or affected parties may submit comments to the unit [within 10 days of the submission of the staff report].
    - If the unit staff decide that additional information from any source is required, the unit staff may seek the additional information but the staff must also either i) provide all registered affected persons the opportunity to respond to the additional information [within 3 business days], or ii) convene a public meeting.

*If a Public Hearing Had Been Requested:*

- *The CON Advisory Committee will conduct a public hearing about the project to obtain the comments about the project. The CON Advisory Committee consists of 10 members, 9 of who are appointed by the governor representing particular constituencies and one ex officio, non-voting member designated by the DHS Commissioner.*
- *Any person can present oral or written arguments at the hearing; persons who make "relevant factual allegations" are subject to questioning by directly affect parties.*
- *Members of the committee may also conduct questioning during the hearing.*
- *Interested or affected parties may submit written comments after the hearing [during the 7 business days following the hearing].*
- *If the unit staff decides that additional information from any source or contact with a registered affected party is required, it may do so but is required to either i) provide all registered affected persons the opportunity to respond [within 3 business day] or ii) convene a public meeting.*
- *Following receipt and review of any comments, the CON Advisory Committee makes a recommendation that the application be approved, be approved with conditions or be disapproved.*

12. The unit staff completes its review and issues a final staff report.

13. The Commissioner of Human Services issues a decision to either issue a certificate of need or deny the application. The Commissioner may issue the certificate of need with conditions. The Commissioner's decision must be based on the informational record developed during the course of the review.

### **Relationship of CON with Health Planning and the Balancing of Health Care Costs, Quality and Access**

**Health Planning:** As in other states, the CON program in Maine was an integral part of the health planning infrastructure that was effectively mandated by the federal National Health Planning and Resources Development Act of 1974. CON decisions were made in the context of a comprehensive state health plan that was the responsibility of a state office of health planning with the input of local health planning agencies. With the combined effect of the withdrawal of federal monies to support system-wide health planning and state budget pressures, the CON Program is the only structure from the original design to continue. The Maine CON program therefore currently operates without the benefit of system-wide health planning to provide a basis for assessing the need for a particular project. However, to a certain degree, specific health planning does occur in various departments and bureaus of the State. For example, the Maine Consortium for Comprehensive Cancer Control recently released *The Maine Comprehensive Cancer Control Plan 2001* to address cancer planning for Maine for the next five years. What is lacking in Maine is the authoritative body needed to organize and disseminate the results of these planning efforts, and a method for CON to use these plans in the decision-making process.

**Balancing Health Care Cost, Quality & Access:** The CON program in Maine is effectively charged with attempting to strike a balance among health care costs, quality and access in its decision-making. The CON program is currently the only entity in state government that is charged with evaluating changes in medical services from a system perspective and for all payers.

As it has been since the beginning of CON programs, the primary focus of the Acute Care CON Unit's health care cost considerations is whether the proposed project is needed or whether approval of a proposed project would result in unnecessary duplication of health facility or service. CON staff also reviews the method of financing the project. Projects are sometimes approved on the condition that the applicant use a different source for funding some or all of a project to reduce project costs, such as requiring the use of internal versus borrowed funds.

Health care quality considerations are addressed in part by reviewing whether the proposed project complies with the unit's *Health Care Facility/Agency Space and Needs Guidelines*. These guidelines incorporate criteria for square footage, staffing, staff training, organizational relationships, etc. for the facilities and services subject to CON. For proposed projects that involve the construction or renovation of physical space, staff from the Bureau of Medical Service's Division of Licensure and Certification provides technical assistance to the CON Unit staff to assess compliance with the CON guidelines.

Health care access considerations are supposed to be addressed in part by reviewing whether the proposed project complies with the need components of the *Health Care Facility/Agency Space and Needs Guidelines*. The guidelines include utilization standards for the various types of hospital units (medical/surgical, obstetrics, etc.) and diagnostic and therapeutic services. As with health care costs the CON program is the only state entity charged with evaluating changes in the health care delivery system from an access perspective although it does so largely in a vacuum. The demise of health planning brought along the end of development of standards for accessing and monitoring access to health care services.

### **Comparison with Selected Other States**

As noted earlier, whether CON programs exist and the details of the CON programs that do exist vary substantially across the country, with particularly wide variations among the various geographic regions of the country. All six New England states have CON programs that, with the notable exception of Massachusetts, are fairly extensive programs. Please see Exhibit 4 for a summary of the CON-covered services and review thresholds for the New England states.

The variation among states is even greater when considering the relationship of CON with health planning and the balancing of health care costs, quality and access issues. Some states have developed particular administrative structures to address these health issues while others have little or no formal structure to do so.

Exhibit 1 provides summary information about the CON programs and the relationship of CON with health care planning and health care cost, quality and access issues in a table format for Maine and ten other states. The ten other states consist of the five other New England states and New York, New Jersey, Maryland, North Carolina and Washington. These states were selected to provide a context for the Maine CON program based on geographic region (New England states, Northeast states), design approaches (Maryland) and other characteristics (North Carolina and Washington). North Carolina and Washington were included as, like Maine, they are large coastal states with population distributions that are skewed to the coastal areas. The information was gathered from materials available from the web sites of each of the states, primarily the laws and regulations governing CON and related programs.

Several conclusions can be drawn from the information presented in Exhibit 1 with its documentation of the range of administrative structures and state approaches to addressing these issues. These conclusions include i) that there are a variety of ways in which these issues can be addressed, including some methods that may have utility in Maine, and ii) that while some states, like Maine, have no state level health planning, other states have maintained a significant role for state health planning.

#### **Assessment of the Strengths & Weaknesses of the Maine CON Program**

A careful review of the CON law in Maine and 10 other states yields the following strengths and weaknesses of the Maine CON program.

#### **Program Strengths:**

**Scope of Services:** The services that are subject to CON in Maine are fairly extensive by current norms for CON programs. This breadth of covered services, however, is appropriate in a state such as Maine given i) the size of its population, ii) the distribution of its population, iii) its geography and topography, iv) the current status of health care market forces in Maine, and v) the role that state government has traditionally played in the health care marketplace.

The development of strong (cost competitive) health care market forces in Maine is significantly impaired by the combination of the size and distribution of the population and Maine's geography and topography. With the possible exception of the greater Portland area, the demographics of Maine make it difficult for multiple providers of services to survive. This means that most local markets are served by only one provider. Adding providers usually means increases in costs. Managed care companies have not created the competition and lower cost solutions originally expected of them. Limited regulation of the health care market through CON has the potential to keep costs in line, especially with the changes offered as part of this report. A broad range of services that are subject to CON is therefore appropriate and one of the program's strengths.

While the program has a broad range of covered services, it also has substantive review thresholds that exempt smaller projects from review. The combination of a broad range of covered services and a broad range of review thresholds strikes an appropriate balance regarding the competing interests involved in deciding when is government intervention

into the marketplace appropriate. The review thresholds were updated in 1998 as part of the implementation of the recommendations of the CON Study Committee. On a negative note, the provision regarding annually updating cost review thresholds for inflation (Section 305-A), adopted in 1998, has not been implemented. Such a situation, however is easily remedied.

**Well-defined Procedures:** The administrative procedures of the CON units are specified in detail in the *Procedures Manual*. In large measure, the Procedures Manual repeats the provisions that are quite explicitly laid out in the CON law itself. The statutorily-defined procedures are then occasionally supplemented by procedures that had been adopted through regulatory action.

As a program that has been in existence in Maine for over twenty years, the Acute Care CON Unit's administrative procedures are well-established. The length of time that the program has been operating assists in enhancing provider knowledge of the process and enhancing the development of refinements to the administrative process over time. At the same time, the application review process is cumbersome and out-of-date given the lack of the health planning component of the system and reductions in CON program staff.

**The Development And Use of the Informational Record:** A specific strength of the CON administrative procedures is its focus on the development of the "informational record developed in the course of review" that is the required basis for the decision on a CON application by the Commissioner. This informational record includes the recording of all CON Advisory Committee hearings and proceedings upon which the Commissioner bases his/her decision. The development and use of the informational record enhances the integrity of the entire CON process.

**Structured Forum For Affected Party Input Into Decision-making:** The CON administrative procedures provide a structure for the views of parties other than the applicant to be solicited and considered by the staff during the application review period. These procedures include the public notice and public meeting provisions, the opportunity for affected parties to request and participate in a public hearing conducted by the CON Advisory Committee, and the opportunity to submit written comments for review by the CON staff.

The public meeting process is a routine component of all applications subject to review. While the actual number of attendees at public informational meetings is generally small, the existence of this forum provides the opportunity for identifying and educating interested parties. Similarly, the actual number of public hearings conducted by the CON Advisory Committee has been small, but these hearings provide a formal structure for affected parties to express their views. The public hearings also provide a forum for the questioning of participants by persons with contrary views that has the potential to enhance understanding of the issues in a way that written comments simply cannot provide. By itself this component is a strength of CON; however, the time frame for input for informational and public hearings make it a limitation as well.

### **Program Weaknesses:**

**CON Decision-making In The Absence of Effective Health Planning:** The effectiveness of the CON program is greatly undermined by the lack of effective system-wide healthcare planning in Maine. Certificate of need was developed in the context of health planning and the many changes in the health care system since the 1970s have not affected the essential relationship of certificate of need and effective healthcare planning. Certificate of need can simply not be done well without health planning at the service level, the system level or regionally.

Healthcare planning that does occur is concentrated in the private sector with some planning at the service level by the state. For example, the state recently released *The Maine Comprehensive Cancer Control Plan 2001*, a plan for cancer care services in Maine. However, these planning efforts to date have been ineffective for CON in part because there is no authority that reviews these planning efforts for appropriateness and policy direction. Service level planning by the state serves only as a guide to those who wish to take advantage of it. There is no state body with the power to review and recommend the adoption of service specific plans. Additionally, there is no body to initiate or coordinate the plans developed by various sectors of state government or the private sector.

These inefficiencies in the planning process in Maine adversely affects the ability of the CON program to strike an appropriate balance among considerations regarding health care costs, quality and access in its decision-making. Decisions regarding the need for a particular proposed project as well as the implications of that project require a statewide perspective that is currently beyond the scope and resources of the current CON program.

### **Reactive Rather Than Proactive Regarding The Development Of Needed Services:**

The current design of the CON program in Maine results in a program that is entirely reactive to the actions of proposals by health care providers. CON activity is triggered by the submission of a letter of intent by providers. While this is and remains a common feature of many CON programs, the reactive nature of CON in Maine is not a necessary feature. It is possible for the state to be much more proactive in influencing the distribution and delivery of health care facilities and services, as discussed in more detail below.

**Weak Linkage With Health Care Quality:** As noted earlier, the CON program in Maine incorporates some aspects of health care quality in the form of guidelines regarding space and needs and receives assistance from BMS's Division of Licensure & Certification in reviewing some facility applications. These activities, however, have both design and operational limitations. The CON program's space and need guidelines have not been updated in at least several years. Almost all of the guidelines that do exist are essentially based on inputs to the delivery of health care services. Both the CON program and the Division of Licensure and Certification would be well served by incorporating health care outcome criteria for those services where relevant outcome-based measures are available.

**Focus On Medical Care Therapeutic & Diagnostic Services Versus Health Care Prevention & Health Care Promotion Activities:** One implication of both the reactive nature of the design of the CON program in Maine noted above and the scope of services that are subject to CON is that little attention is currently given to health care promotion and health care prevention activities. The program's activities are almost entirely devoted to medical care therapeutic and diagnostic services. Through its review criteria and with its authority to attach conditions to approvals to projects, the CON program has the potential to link health prevention and health promotion activities with medical care services and technologies.

**Lack Of Monitoring And Enforcement:** Due to both design and operational issues, the CON program is almost entirely focused on the up-front decision regarding the review of a project. Monitoring and enforcement currently are not a priority. This circumstance can result in project implementations that are not in compliance with the CON decision. During its existence, the Maine Health Care Finance Commission (MHCFC) provided a mechanism for monitoring compliance with the financial aspects of an approved project. The demise of MHCFC was not accompanied by a replacement for its role in monitoring compliance with CON actions.

In addition to the monitoring and enforcement of the scope of the project, the current structure of licensure and certification in Maine limits the ability to monitor health care quality on a continuing basis. The Division of Licensure and certification reviews CON construction and renovation projects for compliance with quality guidelines regarding physical dimensions and layout prior to the commencement, but ongoing monitoring and enforcement of health care quality standards, such as procedure volume minimums for cardiac catheterizations and open heart surgery services, does not exist.

**Administrative Procedures Regarding Input To The Commissioner's Decision:** Under the current administrative provisions governing CON decisions, the information available to the DHS Commissioner for decision-making is restricted to written materials that had been developed during the course of the staff's review of a proposed project—he/she must rely upon the record yet there is almost no input by the Commissioner in building the record such as gathering additional information after a staff report. Such a system can result in circumstances where information that the Commissioner would have found extremely relevant to decision-making is available but not attainable at the stage when a decision needs to be rendered. This is in stark contrast to normal agency operations in which the Commissioner has the ability to request staff or others to provide specific information to assist in a decision as well as having the benefit of discussions with staff regarding various issues that are identified during the course of a project.

### **Objectives for the Future of CON in Maine**

The assessment of the strengths and weaknesses of the Maine CON program facilitate the development of objectives for the future of the CON program. Section I of the report concludes with the presentation and discussion of four objectives for changes in the Maine CON program. Specific proposals to carry out these objectives are presented and discussed in detail in Section III.

## **1. CON to Take Place in the Context of Renewed DHS Health Planning Functions**

The single most important objective for the Maine CON program of the future is to reinstitute the key design feature from the Maine CON program's past, viz., and the integration of health planning and certificate of need. As noted earlier, certificate of need simply cannot be done well in the absence of health planning. Without health planning the CON program is put in the difficult position of needing to make decisions regarding specific proposals without a roadmap on the direction of the health care delivery system. Such a circumstance impairs the program's ability to develop clear standards for assessing the need for a particular project. This impaired ability can easily lead to decision-making that is difficult for the CON applicants and interested parties to understand, which in turn can significantly affect both provider and public support for the program.

CON should take advantage of community health plans in the review process. A renewed health planning function for the DHS would also permit the CON program to take a much more proactive role in the development of the health care delivery system. If, for example, health planning identifies certain priority areas that would help improve the health status of the citizens of Maine, the CON program could institute a request for proposals for the identified services. The state, for example, could engage in an RFP process to solicit and identify potential providers of services that a state health plan identifies as priority services to be developed, such as positron emission tomography (PET) scanners. Through its CON and licensure powers, the state can confer the right to licenses that have economic value. This RFP process could be used both for new technologies as well as for existing technologies and services that a current provider may not be offering. Such an RFP process could be used to encourage competitive forces in the process of enhancing the delivery system.

## **2. Incentives/Requirements for Community Health Benefits**

With a strong health planning basis, the Maine CON program should also be a vehicle to more directly address health care costs, quality and access issues through a system of incentives and/or requirements for applicants to address community health needs. Potential community health needs include enhanced health promotion and disease prevention programs, services for uninsured and underinsured residents, underserved populations, support for community outreach programs, etc. The particular community health needs to be addressed through a community health benefits provision will vary by community and over time.

A community health benefits provision recognizes the significance of the role that a hospital plays in the communities it serves and builds on that role to further enhance the health of those communities. Community health initiatives have the potential to reduce health care costs through their focus on health promotion and health prevention activities. Such programs also can increase access to existing health resources by addressing specific barriers to care, including barriers due to language, cultural factors and transportation. Any such provision should draw upon the existing resources and initiatives in place to enhance the coordination of community resources.

### **3. Coordination of CON and Licensure/Certification**

The health care quality standards of the CON program should be the same as the health care quality standards of BMS's Division of Licensure & Certification. Attainment of this objective would require changes in DHS's licensure and certification statute to authorize the Division of Licensure and Certificate to develop and implement service-specific licensure as needed. The integration of CON and licensure standards ensures that i) the capital and operating costs approved by the CON program are sufficient for compliance with health care quality standards, and ii) that there is ongoing monitoring and enforcement of the quality standards by the Division of Licensure and Certification. Under such a provision, for example, the Division could develop and implement licensure standards for the operation of cardiac catheterization labs. Currently, the CON program has quality standards for approval of cath labs, including the minimum procedure volume standards. The Division, however, has no such standards, so it is possible for a program to be approved by CON based on projected procedure volume that, in practice, was not achievable. By implementing licensure by service, the Division would have the authority to suspend or revoke the license for that particular service without affecting the status of hospital's license as a whole.

In addition to the enhanced monitoring of health care quality, the integration of CON and licensure standards would protect hospitals and other health care providers from the potential of inconsistent health quality standards from two state programs.

### **4. Improved Administrative Procedures**

The current administrative procedures should be refined to facilitate the consideration of perspectives and activities of entities other than the applicant to ensure that CON decisions are made with the best available information. The CON program's recent experience with multiple proposals for cardiac catheterization labs and for an open heart surgery service helped identify some areas for improvement in CON administrative procedures. It is very reasonable to assume the CON program will be faced with similar circumstances for other services as the health care system continues to evolve. This objective would build on the current administrative procedures regarding interested parties and similar/competing applications.

Similarly the administrative procedures should be refined regarding the type of communications that the Commissioner of DHS may engage during the course of a project review. This refinement would provide the Commissioner with an enhanced ability to ensure that the type of information that is needed for decisionmaking is available.

## Section II. Findings of the Interview Process

### Overview and Method

As part of the study, PHRG conducted interviews with representative stakeholders who have interest in or knowledge about the CON program in Maine. A listing of potential interviewees was drawn from among categories of constituents identified in the existing *Certificate of Need Procedures Manual* and include providers, consumers of health care, state agencies, insurers, and managed care entities, Certificate of Need Advisory Committee, and other interested parties.

In consultation with DHS officials, a listing of potential interviewees was prepared and interviews were scheduled with 17 individuals. A listing of individuals interviewed is attached as Exhibit 5. Ronald Deprez and/or James F. Phalen conducted the interviews on behalf of PHRG. The interviews were conducted in person whenever possible, or by telephone if circumstances so warranted due to factors of timing, scheduling, or distance.

The content of the interviews was described in a letter sent to each person to be interviewed. This letter, a copy of which is attached as Exhibit 6, served both to introduce the individuals to the topics and as an interview guide in the discussions. Additionally, participants were shown early draft versions of the proposed changes in the CON program outlined in Section III of the full report. This document along with a brief summary of proposed changes in the CON program, which appears as Exhibit 3 and is discussed elsewhere in this report, was prepared by PHRG in consultation with Department of Human Services officials. It was emphasized in the interviews that these changes should be regarded as ideas and possibilities and that further discussion, debate on and refinement is expected as the legislation process proceeds. Participants were therefore encouraged to freely comment on the intent and direction of these proposed changes. Interviewees were also advised that reporting of the interviews would emphasize themes discussed and would not attribute particular comments to an individual. The interviews thus covered a wide range of subject areas reflecting the focus of the topics identified in the written material and those that interviewees felt should be addressed.

Described following is a summation of the themes discussed and viewpoints expressed by the participants.

### Philosophical Orientation

At some point in the discussions, each interviewee commented on his or her philosophy of certificate of need as an effective health policy pool. For the most part, participants believe that CON is a necessary instrument of public policy and should continue. The overwhelming majority of providers, legislators and consumers interviewed expressed this opinion. This belief stems from observations that health care as a scarce social resource can be subject to many excesses by differing participants in the system, providers -- physicians, hospitals, or entrepreneurial enterprises and by health plans that may be driven by organizational and economic interests rather than a focus on public

health of the people. As one of the interviewees stated "if not government, then who can curb the excesses of the industry?"

There also is a countervailing argument that free market forces are very important and should be preserved. The strongest of these views holds that market competition, not regulation, holds the key to the ultimate success in a capitalist system of which health care services are a part. Accordingly, opponents of regulation cite figures (see Section I) that many states have eliminated certificate of need altogether and that there are few comprehensive or authoritative studies that prove that health care delivery (cost, quality, and access) is any better or worse off because of CON.

This philosophical debate in Maine is not new. The debate has continued since the inception of the program in the late 1970s. In fact, much of the record of the 1998 Study Commission deals with this question. The overriding viewpoint expressed by those who have studied the question and favor CON point to some of the characteristics of the State of Maine. These include its large size, distinct geographic regions, and sparse population with a mixture of rural and urban communities, and many small providers with a few dominant provider hospital/health systems. Many people commented on the high-cost of hospital care, the weakness of managed care plans and their well publicized financial losses, and poor health status indicators among Maine's population that in themselves constitute reasons that some form of continued government oversight is needed. The legislation passed in 1998 affirms certificate of need (with the modifications that are on record in the current law) as an important health policy tool to be maintained.

### **Regard for the CON and Program in Maine**

As to the question of the effectiveness of the CON program in Maine, people are of many minds. On the positive side, are the viewpoints that capture such sentiments as "On balance, the CON and program in Maine has worked rather well", and "The program has served as an effective deterrent to uncontrolled development and excess duplication." Proponents also comment "the program exists, has funding mechanisms in place, and is a part of the accepted culture in Maine".

However, as is pointed out in Section One of this report, there are some wide and strongly held criticisms of the program, especially as it is currently administered. The most often mentioned points were: 1) the perceived high rates of approval of submitted applications (in the words of one interviewee – there is the perception of a 98.6 % track record of approvals in the state); 2) the lack of government initiated health planning; and 3) different standards and criteria that are causes for delay and unneeded expense. The primary concern of many providers, however, was the shortcomings of the administration of the program. It is a reactionary process that encounters frequent delays and missed deadlines, subject to staffing limitations, operates with a dearth of meaningful planning criteria and guidelines, and a lack of post application approval monitoring and follow-up activities. The lack of health planning that constitutes the basis for CON rulings was a consistent theme.

Many participants commented on the strong emotional impact that the recent open heart and cardiac cath lab rulings have had on the process. One provider made the point that “the CON program is no longer credible and should be either changed or terminated” in light of this controversy.

Several individuals voiced particular concern about weaknesses in the ability of CON to aid in cost containment challenges. They mentioned that costs are expressed in many ways -- higher health insurance premiums for both employers and individuals, taxes reflected in the costs of Medicare and Medicaid, or which appear in all form of cost shifting among payers and which ultimately result in out-of-pocket costs borne by the consumer. Others pointed out the competition in health care in Maine at the acute care level almost never leads to costs savings to consumers, employers and health plans.

Despite these shortcomings and while there are some who favor abolishing CON altogether, the preponderance of sentiment of those interviewed holds that the program should continue but that reform is needed.

### **History and Organization of the CON Program**

Several of the interviewees point to program shortcomings being a product of some of the organization and development changes that have occurred during the past decade. That is, those with "institutional memories" comment that the CON program was developed and administered in a more comprehensive and integrated manner when funding for the program and its related components was more plentiful. However, as fiscal pressures mounted, regulatory oversight programs have been eliminated, reduced or combined in various ways among different agencies within the Department of Human Services. These include dividing certificate of need oversight among acute care and elder care services as well as placing the program under the jurisdiction of the Medicaid program. These measures along with staff reductions have hampered the agency’s ability to combine planning, data analysis and certificate of need administration. The composite impact of these changes has in words of one interviewee “eviscerated the strength of the program”.

At the same time the current program has not taken advantage of resources available in the form of better health data with which to measure health need, quality and outcomes of care. In the words of one CON proponent, “demonstrating volumes does not indicate service need, particularly when the same or related services are being offered by nearby providers.” Several also noted the lack of analysis in CON decisions. As one interviewee stated: “CON reports simply state back what was in the application, 90% of which are direct quotes. There is no staff analysis to justify the decision”.

In addressing the question of possible program changes, most of the interviewees are favorably disposed to finding ways to better integrate functions of planning, data analysis and CON program administration. The draft language contained in the proposed changes outlined in Section III begins to address these concerns.

### **Statewide and Regional Planning**

The notion of establishing effective mechanisms for statewide and regional planning strikes a very positive cord among virtually all constituencies. Time and again, interviewees cited the need for an effective context for evaluating any certificate of need application that emerges. As one participant commented, using a “Yogi Berra” metaphor “if we don't know where we are going, we might wind up some where else.” Particular concern holds that the applicant dominates current planning. Other interested parties including the state must react, often as adversaries to a proposal without the benefit of a meaningful regional planning context. Several individuals comment on the need to develop very specific and definitive guidelines that will allow all participants to address a project using a well-defined “scorecard”.

Just how to develop such a planning framework however, sparks an interesting intellectual debate. One approach in getting at this issue suggests development of a comprehensive statewide planning document, which appropriately addresses contemporary health planning issues and presents quantitative information appropriate to addressing factors of need, demand, quality and cost effectiveness. Such an undertaking is a formidable task, requiring “person years” of effort and involving massive documentation requirements. Individuals are quick to point out that this approach was tried during the 1970s and '80s resulting in publication of a “book” which was either ignored (placed on the shelf) or was used by the applicant (and their attorneys) as a hurdle to overcome, circumvent or litigate in their institutional interests.

Others comment that most of the planning resides at the institutional level, focusing on the needs of the institution and its immediately surrounding communities. This orientation can be used by the applicants to buttress their arguments in favor of local access to care and may enable them to gain public relations support within their communities. Other providers that might be affected by the application likewise might argue against the application having a negative impact on their institution. What is lacking, as many interviewees point out is an effective means of balancing statewide, regional, and local planning initiatives.

Virtually all participants commented that the speed, complexity, and wide ranging clinical and technological changes require focused attention to specific areas of inquiry. These dynamics “defy government's ability to manage health care planning” using standards, formulae or prescriptive solutions”. Rather what is needed is administration of processes that promote conduct of ad hoc investigations and which convene knowledgeable task forces in order to inform policymakers on the impact of a potential new service or technology. In this regard, most interviewees are positively disposed to finding ways to periodically conduct these special studies on an as needed basis. The language used in Section III seems to communicate this intent and represents a rational way of addressing these matters.

### **Health Status Quality and Prevention**

Interviewees for the most part are very supportive of the concept of strengthening CON legislation as a means of improving matters of health status, quality and outcome

measurement, and preventive services. There is ample evidence that these topics offer an invaluable means of improving the health of the people without necessarily focusing exclusively on high cost capital development initiatives. Therefore, it is regarded as appropriate to link preventative and health status initiatives to a government supported health planning initiative. Here participants acknowledge that quantitative data exists within the State and affecting many areas of medical interest such as heart, cancer, stroke, mental illness etc. that should be addressed in the CON program in a more effective way.

The idea of linking certificate of need to licensure and certification of specific programs receives mixed reviews, although most favored it. At issue for proponents and opponent was “Who will administer the program?” A common expression was “I like the idea in theory but am concerned with how it will be implemented on a day to day basis”. On the one hand, it makes eminent sense to have consistency of regulatory language governing a particular program or service. However, the intricacies and details of enforcement can be quite involved and interviewees caution that creating bureaucratic hurdles that may be very difficult to monitor and enforce. Also, several individuals commented on the need to distinguish between certificate of need applications affecting clinical services from those that may trigger a capital cost threshold (example given – replacement of a boiler) but which is unrelated to care programs and services. Notwithstanding these concerns, the idea of imposing higher standards and consistency of criteria strikes a positive chord, which places real “teeth” into certificate of need oversight in ways that will cause all parties to pay attention to the importance of addressing the total impact of the proposed application.

### **Certificate of Need Advisory Committee**

Considerable discussion was held on the topic of the role of the Certificate of Need Advisory Committee. Participants acknowledge that the Committee has been an integral part of the legislative framework in Maine for a number of years. Designed primarily as an adjudicating body, the committee is only called upon when there is an application or group of applications that are hotly contested and are subject to public hearing review. However, virtually all interviewees commented on the inactivity of the Committee and questioned its impact over the years. Several individuals point out that the committee has only met once or twice in the past decade. Apparently, applicants and interested parties have been reluctant to engage in these kind of public hearing controversies because of the negative publicity and emotional arguments that they stir up.

Most of the individuals agree that the role of the Certificate of Need Advisory Committee could be greatly expanded and enhanced. In fact there is considerable support to change its name and role—that it be a health policy or planning committee with responsibility beyond that of simply adjudicating and recommending a particular decision following a public hearing. The idea of having an advisory body to proactively involve itself in health policy questions is regarded by many as central to addressing the health planning void existing within the State. Several participants mentioned the recommendation within the recent Governor’s *Blue Ribbon Committee* report that calls for creation of a health policy oversight body. When asked to comment on the advisability of linking the CON Advisory Committee with some form of a health policy oversight initiative group,

there was strong support. As one participant stated "it would be crazy not to join these two ideas as a single body". Such a body can serve as an organizational mechanism to address some of the statewide, and regional planning issues impacting the public necessity for a particular project or service delivery initiative. Particular importance is placed on establishing mechanisms for evaluating the post approval impact of a given project over time.

### **Program Administration and Procedural Matters**

Interviewees have mixed evaluations of the current mechanisms in place to administer the CON program. Critical comments were voiced that the program is too detailed, intricate and focused on procedural matters rather than on the public health, prevention, and cost-containment purposes of the legislation. Accordingly, some believe there is a need to loosen some of the thresholds so that there are fewer applications for review and that emphasis on minutiae and procedural matters are reduced. As one interviewee stated "why would government want to become so involved in projects of minor stature". However, the question of due process and the ability of consumers to have meaningful input into the planning and review process are deemed essential. Apparently there has been an "overlay" all of the Administrative Procedures Act (APA) language on the CON law and its enabling rules and regulations. Rather, more focus on substantive planning is more appealing. Therefore, the idea of convening a CON Advisory Committee around specific health issues and insisting upon wide ranging consumer, provider, and payer input (prior to becoming enmeshed in their details of an application after it is filed and deemed complete) is regarded as a progressive change.

Interviewees emphasize that any CON program must be effectively funded and staffed so that timely review of applications occurs and the uncertainty facing applicants and all affected parties are mitigated.

### **Summary**

In summary, the interviewees tend to endorse the intent of the language appearing in the Section III. However they reserve the right to examine and debate the final product. As always, "the devil is in the details." Emphasizing health planning, quality, prevention, and health status resonates well in the minds of those with whom we discussed these topics. A continuation of the CON program in Maine is generally supported so long as there are better mechanisms to proactively involve interested parties in the process. This implies a reorganization of the CON program within the Department of Human Services so that health planning, data analysis, quality oversight, and CON program administration are well connected and coordinated. This will require attention to sufficient staffing of the program and sustained funding so that the public interests are maintained over time.

### **Section III: Proposed Changes to the CON Law**

#### **Synopsis of Suggested Changes to the Maine CON law**

The Maine Department of Human Services wishes to strengthen and improve the CON program to better serve the needs of the people of Maine. The changes in the CON program detailed in below have as their objective:

- Improving administrative procedures governing the CON review process.
- Strengthening health planning and health policy development within the CON program and the state.
- Linking local health care prevention services to CON new services/new technology approvals.
- Monitoring CON approved services through volume and quality indicators and linking them to licensure and certification.

To accomplish these objectives, PHRG proposes the following changes to the Acute Care CON program in Maine:

- Add language to the CON statute defining access to care, health planning, health status, health need and primary and secondary prevention.
- Require applicants to explain and demonstrate how their proposal will improve the health status of their communities using valid and quantifiable measures of “public” health need; and to define their quality assurance process for the service including how they will disseminate anticipated quality of care outcomes information.
- Require the Department of Human Services to issue a letter and/or checklist in writing advising the applicant on specific informational requirements needed in the application.
- Clarify and expand the definition of and opportunities for input from directly affected persons.
- Enable the Department to hold an otherwise complete application for up to 180 days if it finds that a public necessity exists to carefully evaluate a new service or technology. The need, mechanisms, and communication protocols for conducting such an evaluation shall be prescribed.
- Grant the Commissioner authority to hold a public hearing on a specific application rather than the Certificate of Need Advisory Committee and the authority to appoint an independent ad hoc committee to conduct the hearing with the Commissioner as the chair.
- Grant the Commissioner the ability to communicate with his staff during the course of a review and after he has received a report of findings from staff on the application.
- Require that applicants include prevention services as part of their application for a new service or technology. A specified percentage (eg.5%) of the operating expense would be dedicated to preventative measures. The

Department would be required to issue guidelines that will assist applicants to meet this requirement.

- Require the applicant to issue periodic (e.g. annual or longer) reports, following CON approval on the impact that the services have had in addressing matters of health status, quality of care, health need and health outcomes.
- Change and expand the role of the CON Advisory Committee to a body more engaged in health planning and policy development. This permits them to convene meetings and request studies on important and relevant health care issues. This eliminates them from recommending approval or denial of specific CON applications.
- Clarify scope of services, thresholds, and grouping of projects that will come under the purview of CON review. Require the department to justify their decision based on public health need.
- Establish organizational mechanisms to unify language, standards, and guidelines affecting CON and Licensure and Certification activities on a service or program specific basis.
- Establish an effective monitoring process for enforcement of quality and volume standards and conditions.

In order to make the changes to the CON program outlined above, the law that governs CON, Chapter 103: the "Maine Certificate of Need Act of 1978," must be changed. The following table outlines the specific language to be added to the CON statute and what that language is intended to accomplish.

**Table of the Proposed Changes To The Maine CON Program**

<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
<p>22§303 <b>Definitions</b></p>	<p>Access to Care is defined as the timely use of needed personal health services to achieve the best possible health outcomes balanced by the health system’s resource limitations. Access means being able to obtain needed services and may be influenced by many factors, including travel distance, waiting time, available financial resources, availability of a source of care and health status of the population to be served.</p> <p>Health Planning is concerned with improving health, whether undertaken comprehensively, for a whole community or for a particular population, type of health services, institution or health program. The components of health planning include data assembly and analysis, goal determination, action recommendation, and implementation strategy.</p> <p>Health status is defined by patient and/or population measures of good and poor health practices, rates of death and disease (chronic and infectious) and the prevalence of symptoms/ conditions of illness and wellness.</p> <p>Health Need is defined by a situation or condition of people (expressed in health outcome measures such as mortality, morbidity or disability) that is considered undesirable and is likely to exist in the future.</p> <p>Primary prevention services are defined as health care services including health education that seek to prevent the occurrence of disease or injury, generally through reducing exposure or risk factor levels that cause disease.</p> <p>Secondary prevention services are defined as health care services that seek to treat and control the severity of disease processes in their early stages before the onset of acute symptoms and events.</p>	<p>Adds definitions to the statute thus providing more specificity to the statute (and program).</p>

<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
<p>22§306-A <b>Information required in the application</b></p>	<p>Measures of health status relevant to the services/technology of the application in the service area of the applicant. Such measures shall to the extent possible be the same as those contained in the USDHHS Healthy People 2010 Report.</p> <p>Valid and replicable quantitative measures of public health need relevant to the new service/technology in the service area of the applicant for the service. The department may adopt a specific set of measures for certain services where there is consensus in the literature. The CON advisory committee shall review and comment on any measures developed by the department for this purpose.</p> <p>Quality assurance process including measures to be used to assess the new service/technology. The applicant shall specify the quality assurance process including the measures to be used, the time period for reporting and the mechanism that will be used to disseminate quality assurance information to the state and the public. Quality assurance information that the applicant does not consider appropriate for public dissemination needs to be justified. When possible quality measures shall be similar to those required by hospital accreditation organizations such as JCAHO.</p> <p>Current and planned prevention programs relevant to the service/technology of the application and the population to be served. To the extent possible such information shall contain effectiveness measures for existing and planned programs.</p> <p>Information as to how the proposed service/technology fits into any published state health planning report.</p> <p>The department shall develop specific guidelines as appropriate for this requirement as part of the CON Procedure Manual, Chapter 6, 2D &amp; 2E. This shall be updated periodically.</p>	<p>Requires applicants to provide measures of health status for the services/technology they are applying a CON for the population/geography they will be providing the service to.</p> <p>Similar requirements for prevention programs, quality of care measures and measures of public health need.</p> <p>It also permits the department to adopt a set of standard measures of public health need for specific services, subject to the review by the CON Advisory Committee.</p> <p>The applicant’s plan for collecting and reporting quality assurance information for the service/technology is also requested. This will permit the department to review the quality assurance program and measures suggested and comment on their appropriateness and validity. This will also result in the dissemination of results/outcomes (defined below under monitoring and follow-up), which will be public unless the applicant makes the case that there is reasonable cause, for example confidentiality would be violated, that the results should not be made public.</p>

<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
<p>22 § 306-A 2. <b>Application filed</b></p>	<p>The department shall issue a letter and/or checklist to the proposed applicant following receipt of the applicant’s letter of intent to file a CON that stipulates and clarifies what will be required in the application.</p>	<p>Provides standardized application for specific services/new technology –will clarify what data and information will be required in the application.</p>
<p>22 § 307. <b>Review process</b>  1. F (addition)</p>	<p>1. F. Directly affected persons includes but is not limited to the state Department of Business Regulation, the Department of Mental Health, Mental Retardation and Substance Abuse, the Department of Human Services, the Maine Health Policy Advisory Committee, affected cities and towns, and such other agencies and/or persons as may be deemed appropriate in the context of an individual application. Directly affected persons shall be afforded an opportunity to provide written comment with respect to each application submitted. Any comment so initiated must be received by the state agency within fifty (50) days, when practicable, from the date of notification of affected persons except in the case of:</p> <ul style="list-style-type: none"> <li>a) expeditious reviews or accelerated reviews when comments must be received within twenty (20) days, when practicable, of the date of notification of affected persons, or</li> <li>b) Public meetings shall be held in accordance with this statute. The commissioner may modify the period for comments in order to establish the official record.</li> </ul>	<p>Clarifies who directly affected persons are and when they may comment on an application.</p>

<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
<p>22 § 307.  <b>Review process</b>                      1. F (addition)                      (Continued from previous page)</p>	<p><b>Holding an application:</b>                      The department may hold an otherwise complete application for up to 180 days from the time of the beginning of its normal review cycle if it finds that a public necessity exists.                      In order to hold an application, the department shall find that a public necessity exists if:                          The proposed application represents a new service or technology not previously provided within the State;                          The proposed application represents a potential significant impact on healthcare system costs; or                          The proposed application represents a new service or technology for which a healthcare system need has not been previously established.                      The department shall notify the applicant, any registered affected and directly affected persons, and the Certificate of Need Advisory Committee of its decision to hold an application. Public notice of the department's decision to hold an application shall be given by publication in the Kennebec Journal and in a newspaper of general circulation in the area in which the proposed application or other action will occur.</p> <p>Content of Public Notice. This notice shall include:</p> <ul style="list-style-type: none"> <li>(1) A brief description of the proposed application or other action, including:                             <ul style="list-style-type: none"> <li>a. Sponsor,</li> <li>b. Project name and address, and</li> <li>c. Estimated capital cost;</li> </ul> </li> <li>(2) The duration of the time for which an application is being held; and</li> <li>(3) A statement as to the reason the application is being held.</li> </ul>	<p>Permits the Department to hold CON applications for "public necessity". Tied to language later on the revised role of the CON Advisory Committee.</p>

<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
<p>22 §307-2.B. <b>Public Hearing</b></p> <p>B. (repeal and replace)</p> <p>H. (repeal)</p> <p>I. (repeal)</p> <p>J. (repeal and replace)</p>	<p>Replace language giving the Commissioner authority to hold a public hearing on a specific application rather than the Certificate of Need Advisory Committee. Grant the Commissioner the authority to appoint an independent ad hoc committee to conduct the hearing with the Commissioner as the chair.</p> <p>B. Findings, recommendations, reports, analyses and related documents prepared by the staff of the agency in their most complete form shall be made available to affected persons at least 5 business days prior to a hearing.</p> <p>J. During the course of a hearing, the department may not 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 or after the conclusion of a public hearing pursuant to paragraph G.</p>	<p>Removes the Certificate of Need Advisory Committee from holding a public hearing on a specific CON application and gives that power to the Commissioner.</p> <p>Change section B to reflect the role of commissioner and to reflect the fact that the hearing may take place at any time during the process</p> <p>Repealing subsection H. is consistent with the change in 2B. Essentially it removes the need for a recommendation to the commissioner by the Certificate of Need Advisory Committee. It therefore permits the public hearing to be an information exchange adding to the record.</p> <p>Repealing subsection I. permits the Commissioner to accept comments up to his/her decision and makes this information part of the record.</p> <p>Clarifies the changes in the public hearing process and acknowledges the authority of the commissioner and his staff to obtain additional information after a hearing is completed and before a final decision is made.</p>

<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
<p>22 §307-5 <b>Decision by the department.</b></p> <p>B. (repeal and replace)</p> <p>C. (repeal and replace)</p>	<p>5. 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. This notice must incorporate written findings that state the basis of the decision, including the findings required by section 309, subsection 1.</p> <p>5. C. The Staff report of the agency and the preliminary staff report of the department.</p>	<p>Changes the section to reflect the enhanced role of the commissioner and the new role of the CON Advisory Committee.</p> <p>Reflects the new role of the CON Advisory Committee.</p>
<p>22§309-2 A (public need requirement)</p>	<p>Insert the word “health” between the words “public need” in this section.</p> <p>Adds the following language:</p> <p>In its preliminary and final findings on the application the department must state how the applicant meets the public health need requirements.</p>	<p>Current CON says application for services will be based on public need; public need is a vague term not defined anywhere in the statute. This section changes the term to public health need and requires the department to state in its findings how the service/technology meets a public health need.</p>



<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
<p><b>22 § 306-B. 2.</b>  <b>Certificate of Need Advisory Committee</b>            (Continued from previous page)</p>	<p>D. request studies, informational meetings or public hearings if they deem it necessary to further the purposes of the CON program.</p> <p>E. review, comment upon or make specific health policy or service specific recommendations to the department based on their review of the findings of such studies.</p> <p>F. hold by-monthly meetings open to the public to further the purposes of this chapter and to promote rational and coordinated health planning and health policy development in Maine.</p>	
<p>22 § 304-A.  <b>Certificate of need required</b>            Scope of services</p>	<p>CON is needed only if the increase is greater than 10% of the existing bed complement or bed category</p>	<p>For hospitals, this section establishes a threshold regarding increases in licensed bed complement or licensed bed category, viz., that a CON is needed only if the increase is greater than 10% of the existing bed complement or bed category. CON shouldn't be dealing with minimal changes that are more properly addressed by licensure.</p>
<p>22 § 304-A.  <b>Certificate of need required</b>            Scope of services</p>	<p>Any project or grouping of projects if taken in the aggregate in terms of scope, or timing are subject to review-----etc..... [ Establish a review threshold for one project that is related to two applications.] The department may make this finding for projects for which it receives letters of intent within 24 months of each other.</p>	<p>Give the department the authority to determine the threshold to be met for capital costs if it finds that two or more projects, which the hospital had presented as separate projects, are in fact related projects.</p>

<b>Section:</b>	<b>Language to be added to the CON statute:</b>	<b>What the language is intended to do:</b>
NEW (CON Law)	Add a requirement for the Department to revise the CON Health Care Facility/Agency Space & Needs Guideline for any hospital service for which the License & Certification Unit has established service specific licensure requirements. "CON guidelines are required to be identical to License & Certification Unit's licensure requirements."	In combination with parallel language in the Licensing of Hospitals & Institutions statute, provides ongoing monitoring and enforcement of the health quality standards that an applicant was required to meet to obtain a CON approval. This is also intended to eliminate conflicting requirements for applicants, one for CON and another for licensing.
22§1811 (Licensing of Hospitals & Institutions)	Authorizes the Department to establish service-specific licensure requirements for those services for which it determines that the health care quality will be enhanced by establishing licensing requirements for services for which the specialized nature of the service and/or the equipment warrant targeted monitoring and enforcement.	Give the department the authority to enhance health care quality by increasing the review by the licensing and certification unit. If necessary, the Department will be able to suspend or terminate the license for a specific service, rather than for the facility as a whole as under current law. The current law's remedy to quality of care issues regarding the entire facility's license is so broad as to be essentially unusable. The change would permit the Department to address specific quality of care issues in a facility that otherwise is providing appropriate quality of care.

**New Hampshire  
CON Scope of Coverage**

Services subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
All new health services  Ambulatory Surgery Centers  Acute Care Cardiac Catheterization Chemotherapy CT Lithotripters Long Term care Mobile Technology MRI Open Heart Surgery Psychiatry Radiation Therapy Substance Abuse	Any Purchase of equipment in excess of \$400,000  Any expansion of an existing Acute Care facility costing \$1,759,512 or more.  Any expansion to a nursing home, Ambulatory Surgical Unit, Specialty Hospital Project or Nursing Home costing \$1,173,008 or more	None	Yes  CON issues a request for new services when a need is identified by the Health Services Planning and Review Board.	Indirectly  The Office of Community and Public Health monitors quality (CON is within this Office)	Yes  Cost control is the main function of CON.	Yes  CON applicants must identify the population that does not have access to care due to medical indigency, low income, geographic location, or the unavailability of specialized service.  Applicants must ensure that no resident of NH shall be refused services because of race, color, creed, age, gender, sexual orientation, disability, or ability to pay.

**New Hampshire  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>CON is located in the Office of Community and Public Health within the Department of Health and Human Services. The Health Services and Planning Review Board administer the CON program.</p>	<p>Affected parties and the general public are informed of formal review of an application via letters and notices in newspapers. The review board must hold a public hearing during the review period where any person can testify (and is cross-examined by the applicant). (VI-XIII of 151-C:8) A public hearing to argue the final decision of the board can be called by anyone with relevant information not previously considered by the board, changes in information used by the board to make its decision, or proof that the board failed to follow the adopted procedures.</p>	<p>Multiple applications are reviewed simultaneously and considered in Related to each another.</p>	<p>90 Calendar days with the option to extend the process 30 days at the board's discretion. No review is allowed to exceed 120 calendar days.</p>	<p>Standards of need are outlined for each request for applications issued by the state. Section 4 Part A of the general application outlines how the applicant should address demonstration of need. Items to be covered include:                      Project location within service area and service area map.                      Site plan                      Services included.                      Description of current health system                      Description of target audience.                      Utilization rates of services in service area by payor category.</p>	<p>Quality assurance plan required element of application. No indication of any follow-up by CON.</p>

**Connecticut  
CON Scope of Coverage**

Services subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
All new health services  Ambulatory Surgery  Acute Care Air Ambulance Burn Business Computers Cardiac Catheterization Chemotherapy CT Gamma Knives Lithotripters Long Term care Medical Office Blding Mobile Technology MRI Neonatal ICU Obstetrics Open Heart Surgery Organ Transplants PET Psychiatry Radiation Therapy Residential Care Facilities Substance Abuse Swing Beds	Any expansion costing over \$1,000,000.  Equipment Costing over \$400,000.	Indirectly if at all  The Bureau of Community Health exists within the DPH and is responsible for promoting health behaviors and providing resources to the public.	No  Health planning is a function of the Bureau of Health, which is separate from the Office of Health Care Access.	No  The Bureau of Community Health within the DPH regulates quality through the Bureau of Regulatory Services.  It consists of: <ul style="list-style-type: none"> <li>◆ The Division of Health Systems Regulation;</li> <li>◆ The Division of Community Based Regulation;</li> <li>◆ The Division of Environmental Health, and;</li> <li>◆ A legal office</li> </ul>	Yes  CON is designed to focus on cost issues.	Yes  The Office of Health Care Access oversees data collection, health planning, the CON program, and implementation of and oversight of health care reform as enacted by the general assembly.  OHCA carries out an annual statewide study. Goal is to improve efficiency, lower costs, coordinate use of facilities and services, and expand availability.

**Connecticut  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>CON is located within the Office of Health Care Access. It is separate from the Department of Health.</p>	<p>If the CON application is for transfer of ownership the board may decide to hold a public hearing during the review process.</p> <p>If the CON application is for approval of capitol expenditure the board will hold a public hearing in the area to be served.</p>	<p>During the review process, the board may hold public hearings on applications of a similar nature.</p>	<p>90 days with provisions for a 30-day extension granted at the Commissioners request if additional information is required.</p>		<p>Health care providers are required to submit a compliance assessment and data required for a budget review. The follow-up process relates to cost control only.</p>

**Maine  
CON Scope of Coverage**

Services subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services Ambulatory Surgery Acute Care Air Ambulance Burn Cardiac Catheterization Chemotherapy CT Gamma Knives ICF/MR Lithotripters Long Term care Mobile Technology MRI Neonatal ICU Obstetrics Open Heart Surgery Organ Transplants PET Psychiatry Radiation Therapy Renal Dialysis Substance Abuse Swing Beds Ultrasound	Medical equipment that costs \$1,000,000 or more Hospitals: Any capitol expenditure of \$2,000,000 or more Nursing homes: Any capitol expenditure of \$500,000 or more	None	Indirectly	Indirectly  The department may consider whether or not the quality of any health care provided by the applicant in the past meets industry standards.	Yes  Cost control is the main function of CON.	Indirectly  The department may consider whether or not the proposed services will be accessible to all residents of the service area

**Maine  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>The CON program is divided between two programs. The Nursing Home division of CON is located within the Bureau of Elder Adult Services within the Department of Human services. The CON program for health care facilities other than nursing homes is located within the Bureau of Health within the Department of Health and Human Services</p>	<p>Public notice of review of an application is published in the Kennebec Journal and other papers circulated in the affected area. A public hearing is held if requested by persons directly affected by the review.</p>	<p>There are provision by which the department can obtain additional information should competing applications be filed. Provisions to allow concurrent review of competing applications.</p>	<p>90 days with the option for a 60 day extension. A public hearing adds 60 days to the 90-day review process.</p>	<p>None  Applicants are required to show a need for the proposed services/expenditures exists, but there are no guidelines for how need is to be measured</p>	

**Massachusetts  
CON Scope of Coverage**

Services subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New Technology, as determined by the Department of Public Health (DPH) <sup>1</sup>	N/A	Primary/preventive health care services and community contributions are required.	Projects must be the "product of a sound health planning process", including consultation with affected state agencies such as Department of Mental Health, Department of Elder Affairs and the Department of Public Welfare.	Projects must comply with applicable operational standards. The Division of Health Care Quality licenses health care facilities and has service-specific licensure requirements for numerous services.	Objective of CON program includes "adequate health care services are made available to every person ... at the lowest reasonable aggregate cost."	Applicants are routinely required as condition of approval to provide service to patients regardless of ability to pay.
Innovative Services, as determined by DPH <sup>2</sup>	N/A	A "rule of thumb" is that applicant provide 5% of the capital expenditure for new or incremental community initiatives.	Projects must satisfy, in whole or in part, health care requirements of proposed population.  There is no state health plan.		Requirements for efficiently and effectively operated services and for reasonable capital and operating costs.	Guidelines for specific new technology or service may include access criteria.

<sup>1</sup> New technology is medical or surgical services equipment that i) has been approved by the FDA or authorized for physician use by appropriate professional societies, and ii) has been determined by DPH not to be in general use in the state for patient care by physicians qualified to use the equipment. A list of such technology is published by DPH annually.

<sup>2</sup> Innovative service that DPH determines to be innovative for reasons of quality, access or cost, such as dialysis, neonatal intensive care, and transplant services. A list of innovative services is published by DPH annually.

**Massachusetts  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>CON program (called the Determination of Need (DoN) program) is a part of the Department of Public Health's Division of Health Care Quality, which also is responsible for health care facility licensure and certification.</p>	<p>Extensive public participation process that includes "parties of record" and general public.</p> <p>Parties of record include relevant state agencies and ten taxpayer groups.</p> <p>General public may comment in writing or at a public hearing, if one is held.</p> <p>A public hearing may be requested by parties of record or may be convened by the program director if he/she believes a public hearing will assist the staff in carrying out its duties.</p>	<p>"Comparable applications" are defined as those that i) are filed within the same filing period, or, at discretion of the program director's discretion, in different filing periods in the same filing year, and ii) are for projects for "similar or reasonably interchangeable health services for applicable services areas which are the same in whole or in significant part."</p> <p>Special procedures apply for comparable applications.</p>	<p>No specific period of review is specified.</p>	<p>DoN program operates with guidelines for specific new technologies and innovative services which specify measures of need.</p>	<p>A mandatory condition on project approvals is that authorization if for a three year period. If "substantial and continuing process" is not made during the three years, the authorization expires, but can be continued of good cause.</p> <p>Condition also requires reporting to the Program Director regarding various aspects of the project and the process for immaterial, minor and major changes to the project.</p>

**Rhode Island  
CON Scope of Coverage**

Services Subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services Ambulatory Surgery Acute Care Cardiac Catheterization Chemotherapy CT Gamma Knives Long Term care Mobile Technology MRI Neonatal ICU Obstetrics Open Heart Surgery Organ Transplants PET Psychiatry Radiation Therapy Rehabilitation Services Renal Dialysis Substance Abuse Swing Beds	An Expansion costing \$2,000,000 or more Any Equipment costing \$1,000,000 or more Any new services costing \$750,000 or more	Not related to CON	NO	Yes  The Division of Facilities Regulation is responsible for ensuring quality. (CON is located within this division.)	Yes  The Primary function of CON is cost control.	Not directly

**Rhode Island  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>The CON program is located within the Division of Facilities Regulation within the Department of Health.</p>	<p>CON is required to give written notification of receipt of an application to “affected parties” at the beginning of the review cycle. Notification is also published in a newspaper having wide circulation throughout the state. A public hearing is held at an “affected person’s request. CON also accepts written comments from the public, the manner in which these comments are to be accepted is also published in newspapers.</p>	<p>Competing applications are reviewed concurrently.</p>	<p>120 days</p>	<p>Yes</p> <p>Applicants are required to define the population served and delineate the health needs of that population. They need to inventory the facilities currently serving the targeted population and determine the portion of need not satisfied. They also need to identify and evaluate alternative proposals to satisfy unmet needs and provide justification for the proposal submitted for review.</p>	

**Vermont  
CON Scope of Coverage**

Services Subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services  Ambulatory Surgery  Acute Care Air Ambulance Burn Business Computers Cardiac Catheterization Chemotherapy CT Gamma Knives Home Health Lithotripters Long Term care Mobile Technology MRI Neonatal ICU Obstetrics Open Heart Surgery Organ Transplants PET Psychiatry Radiation Therapy Renal Dialysis Substance Abuse	New Services costing \$300,000 or more.  Hospitals: capital expenditures of \$1,500,000 or more  Other Health Facility: Capital expenditures of \$750,000 or more.  Equipment costing \$500,000 or more	Indirectly if at all.  The Department of Health oversees prevention programs through the Division of Community Public Health and the Division of Health Improvement. The connection to CON is unclear.	Yes  The Commissioner is required to consider the goals and recommendations of the health resource management plan or the state health plan in, whichever is applies.	Indirectly if at all	Yes  Cost control is the main function of CON.	Yes  Access to care is a consideration in the CON process. Generally assessed by the Department of Health

**Vermont  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>CON is located within the Department of Health, which is located within the Department of Human Services.</p>	<p>The commissioner shall provide “interested parties” the information necessary to participate in the review process.</p> <p>The public oversight commission must hold a public hearing after it has decided to argue for or against the application.</p> <p>After the Commissioner has made a final decision, any party aggrieved may appeal to the supreme court.</p>	<p>Competing applications are reviewed concurrently.</p>	<p>120 days with the option for the commissioner to extend the review for 30 days with written consent from each applicant.</p>	<p>None</p>	<p>Not directly related to CON</p>

**Maryland  
CON Scope of Coverage**

Services Subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services  Ambulatory Surgery  Acute Care Burn Cardiac Catheterization Chemotherapy Home Health ICF/MR Lithotripters Long Term care Neonatal ICU Obstetrics Open Heart Surgery Organ Transplants Psychiatry Radiation Therapy Substance Abuse	Any expansion costing \$1,305,000 or more	Not tied to CON	Yes  CON uses the state health plan as a guide.	Yes  Only during review process-no follow-up.	Yes  Cost control is the main function of CON.	Yes  Access to care is a consideration in the state health plan and CON approval.

**Maryland  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>CON is located within the Office of Licensing and Certification within the Department of Health and Mental Hygiene.</p>	<p>Dependant on the level of review. When applicants have not been exempted from CON review (3<sup>rd</sup> level). Those who qualify as interested parties have the right to request oral argument or evidentiary hearing, submit written arguments and argue before Commission, request reconsideration, and appeal the decision in circuit court.</p>	<p>The Commission designates a single commissioner to act as reviewer for competing applications</p>	<p>90 days if there is no public hearing.  150 days if there is a public hearing.</p>	<p>Yes</p>	

**New York  
CON Scope of Coverage**

Services Subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services Ambulatory Surgery Acute Care Burn Cardiac Catheterization Chemotherapy CT Gamma Knives Home Health ICF/MR Lithotripters Long Term care Mobile Technology MRI Neonatal ICU Open Heart Surgery Organ Transplants Psychiatry Radiation Therapy Rehabilitation Services Renal Dialysis Substance Abuse Swing Beds Ultrasound	Any capital expenditure of \$3,000,000 or more  An Equipment purchase of \$3,000,000 or more		Yes	Yes	Yes.	Yes Access to care is an important part of demonstrating need.

**New York  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>The CON program is located within the Bureau of Project Management within the Division of Health Facility Planning, within the Department of Health.</p>	<p>For transfer of ownership and establishment: The State council or the health systems agency can request a public hearing to be held during the review process. If the public council proposes to recommend against the application, it must afford the applicant the opportunity for a public hearing.</p> <p>All Applications are posted on the DHS web site and the public is invited to submit comments on the posted applications</p>		<p>2 review cycles for transfer of ownership per year. Applications received between January 1<sup>st</sup> and June 30<sup>th</sup> shall be reviewed and presented to the state hospital and planning council before June 30<sup>th</sup> of the following year. Application received July 1<sup>st</sup> and December 31<sup>st</sup> shall be presented before December 31<sup>st</sup> of the following year.</p>	<p>Yes</p> <p>Detailed methodology to be used to determine need is outlined in section 709.2</p>	

**New Jersey  
CON Scope of Coverage**

Services Subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services  Acute Care Burn Cardiac Catheterization Chemotherapy Home Health ICF/MR Long Term Care Neonatal ICU Open Heart Surgery Organ Transplants Psychiatry Rehabilitation Residential Care Facilities	Capital expenditures of \$1,000,000 or more  Equipment purchases of \$1,000,000 or more			Yes to the extent that it is related to licensure	Yes	Not directly

**New Jersey  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>The CON program is located within the Division of Health Care Systems Analysis within the Department of Health and Senior Services.</p>	<p>Different review processes for different services.</p> <p>Transfer of ownership-a public hearing is held within 60 days after the date an application is deemed complete</p>		<p>Different review processes for different services.</p> <p>Transfer of ownership of a hospital--90 days</p>		

**North Carolina  
CON Scope of Coverage**

Services Subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services  Ambulatory Surgery  Acute Care Air Ambulance Burn Cardiac Catheterization Chemotherapy CT Gamma Knives Home Health Lithotripters Long Term care Mobile Technology MRI Neonatal ICU Open Heart Surgery Organ Transplants PET Psychiatry Radiation Therapy Radiation Therapy Renal Dialysis Substance Abuse Swing Beds	Capital expenditures of \$2,000,000 or more  Equipment purchases of \$750,000 or more	Not directly related to CON	Yes  The Medical Facilities Planning Section located within the Division of Facility Services provides support to the North Carolina Health Coordinating Council which makes recommendations to the DHHS and Governor regarding unmet need in the state.	Indirectly  The Licensure and Certification Section investigates complaints and conducts surveys on quality.	Yes  Cost control is the main function of CON.	Indirectly if at all

**North Carolina  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>The CON section is located within the Division of Facility Services within the Department of Health and Human Services</p>	<p>During the first 30 days of the review period any person may file written comments concerning proposals under review. A public hearing is not automatically part of the process. Under some circumstances a public hearing may be held in the affected service area no more than 20 days from the conclusion of the written comment period.</p>	<p>Competing applications are reviewed at the same time.</p>	<p>90-150 days</p>	<p>Yes</p>	<p>Yes</p> <p>During the implementation of the proposed services the applicant must submit progress reports. These reports are reviewed to ensure that the project is carried out in accordance with the approved proposal.</p>

**Washington  
CON Scope of Coverage**

Services Subject to CON	Cost Triggers	Incentives for Preventative Services	CON Related to Health Planning	CON Related to Quality/Regulation	CON Related to Cost Control	CON Related to Access to Care
New health services  Ambulatory Surgery  Acute Care Burn Home Health Long Term care Neonatal ICU Obstetrics Open Heart Surgery Organ Transplants Psychiatry Radiation Therapy Rehabilitation Services Renal Dialysis Subacute Care Swing Beds	Capital expenditures of \$1,202,000 or more.	Not related to CON	Yes  Decisions are required to be consistent with the current state health plan	Yes, but only during the implementation of the project.  The department is required to monitor the approved projects to ensure conformance with the issued CON. The department may require the applicant to submit progress reports.  There are no guidelines for follow-up after the project is complete.	Yes  Cost control is the main function of CON	Indirectly if at all

**Washington  
CON Administrative Process**

Organizational Map	Public Participation	Multiple Applications	Period of Review	Standards/Guidelines Measuring Need	Post-approval Monitoring and Enforcement
<p>CON is located within the Division of Facilities and Services Licensing within the Department of Health Systems Quality Assurance within the Department of Health.</p>	<p>Any affected health care organization or facility can submit written comments during the review process providing that the organization requested to be informed of the department's decision.</p> <p>If requested by an affected person, the department will conduct a public hearing.</p>	<p>Competing applications are reviewed concurrently.</p>	<p>90 days with provisions for two 30 day extensions if requested by the department.</p>	<p>The state health plan serves as a guide in determining need.</p>	<p>The department is required to monitor the approved projects to ensure conformance with the issued CON. The department may require the applicant to submit progress reports.</p> <p>There are no guidelines for follow-up after the project is complete.</p>



**MAINE  
Facilities & Services Subject To CON & Review Thresholds  
Acute Care CON Unit**

<b>Category of Health Care Facility or Services subject to CON</b>	<b>Review Triggers</b>	<b>Examples of Services Subject to CON (Non-Inclusive)</b>
<p><b>HEALTH CARE FACILITIES</b></p> <ul style="list-style-type: none"> <li>• Acute Hospitals</li> <li>• Ambulatory Surgery Centers</li> <li>• Substance Abuse Centers</li> </ul>	<p style="text-align: center;">Capital: \$2,000,000 or Any increase either in the number of licensed beds or in the licensed bed category</p>	<p>Construction or renovation of all or part of a facility.</p>
<p style="text-align: center;"><b>MAJOR MEDICAL EQUIPMENT</b></p>	<p style="text-align: center;">\$1,000,000</p>	<p>Diagnostic</p> <ul style="list-style-type: none"> <li>• CT Scanner</li> <li>• MRI</li> <li>• PET Scans</li> <li>• Mobile Technology</li> </ul> <p>Therapeutic</p> <ul style="list-style-type: none"> <li>• Lithotripsy</li> <li>• Gamma Knives</li> </ul>
<p><b>NEW HEALTH SERVICES</b> (Both hospital-based and independent)</p>	<p style="text-align: center;">Capital: \$100,000  OR Annual Operating Expenses of \$350,000</p>	<ul style="list-style-type: none"> <li>• Air Ambulance</li> <li>• Cardiac Catheterization</li> <li>• Chemotherapy</li> <li>• Organ Transplants</li> <li>• Open Heart Surgery</li> <li>• Renal Dialysis</li> <li>• Radiation Therapy</li> </ul>
<p style="text-align: center;"><b>OTHER</b></p> <ul style="list-style-type: none"> <li>• Transfer of ownership of health care facility</li> </ul>		

**COMPARISON OF CON-COVERED SERVICES & REVIEW THRESHOLDS  
IN MAINE AND OTHER NEW ENGLAND STATES**

<b>TYPE OF FACILITY OR SERVICE</b>	<b>MAINE</b>	<b>CONNECTICUT</b>	<b>MASSACHUSETTS</b>	<b>NEW HAMPSHIRE</b>	<b>RHODE ISLAND</b>	<b>VERMONT</b>
<b>HEALTH CARE FACILITY CONSTRUCTION Capital Cost Threshold</b>	<b>\$2,000,000</b>	\$1,000,000	Not Subject To CON	\$1,759,512	\$2,000,000	\$1,500,000
<b>MEDICAL EQUIPMENT Capital Cost Threshold</b>	<b>\$1,000,000</b>	\$400,000	CON Limited To "New Technology" (Annually updated list)	\$400,000	\$1,000,000	\$500,000
<b>NEW SERVICES (Capital Cost Threshold and/or Operating Cost Threshold)</b>	<b>\$100,000 Capital Costs or 350,000 Operating Costs</b>	ANY	CON Limited To "Innovative Services" (Annually updated list)	ANY	\$750,000	\$300,000

Sources: 1) State laws or regulations  
2) American Health Planning Association web site.

**Individuals Interviewed by PHRG as Part of The CON Project**

<b><u>Name</u></b>	<b><u>Affiliation</u></b>	<b><u>Date</u></b>
William Caron	Maine Health, President	2/5/01
Peter Chalke	Central Maine Medical Center, Chief Executive Officer	2/6/01
Bruce Cummings	Blue Hill Memorial Hospital, Chief Executive Officer	2/6/01
John Dickens	Past head of Certificate of Need	2/6/01
Joe Kozak	Lawyer	2/6/01
Ed McGeachy	Southern Maine Medical Center, Chief Executive Officer	2/6/01
Gordon Smith	Maine Medical Association, Executive Director	2/6/01
John LaCasse	Medical Care Development, President	2/7/01
Michael Michaud	Maine Senate President	2/7/01
James Pulia	Certificate of Need Advisory Committee Member	2/7/01
Joe Ditre	Consumers for Affordable Healthcare	2/8/01
Katherine Pelletreau	Maine HMO Council, State Director	2/8/01
Theresa Wood	Certificate of Need Advisory Committee Member	2/8/01
Norm Ledwin	Eastern Maine Healthcare, Chief Executive Officer	2/9/01
Mike McNeil	Certificate of Need Advisory Committee Member	2/13/01
Steven Michaud	Maine Hospital Association, Executive Director	2/13/01
Paula Valente	Maine Health Care Association, Executive Vice President	2/13/01

February 7, 2001

Dear ,

On behalf of PHRG and the Maine Department of Human Services, I am grateful that you have agreed to participate in an interview relating to the CON program. We have been charged by the State to examine possible changes that should be made in the CON program that will strengthen its ability to serve the needs of the people of Maine. While it is contemplated that Certificate of Need will continue in the State of Maine, it is recognized that the program should be strengthened in a number of ways.

Among the possible changes that Commissioner Concannon is considering and about which we would like to elicit your views include:

- Improving administrative procedures governing the CON review process
- Strengthening the health planning functions of the CON program.
- Linking local health care prevention services to CON new services/new technology approvals
- Monitoring CON approved services through volume and quality indicators and linking them to licensure and certification

In assessing these possibilities we would like to learn of your views on the CON program and discuss ways of making the program better respond to the public need. Specific topics that we would like to discuss are:

- Measures of health status and prevention
- Scope and thresholds for CON review
- Quality indicators impacting introduction of new technology
- Streamlining the review process
- Reporting utilization and quality experience after approval of CON
- Role of the CON Advisory Committee

We invite your candid views on these and other topics that you feel are relevant and look forward to our discussions. Your comments will be confidential.

Sincerely,

Ronald D. Deprez, Ph.D., MPH  
President