THE REGULATION OF CONNECTICUT'S ACUTE CARE HOSPITALS

INTRODUCTION

Government has a profound effect on the acute care hospital industry through its roles as payer, purchaser, and regulator. Hospitals are increasingly dependent upon government revenue; in Connecticut during FY 1999, government reimbursements accounted for 50% of total hospital revenues.[1] All aspects of hospital operations are also affected by government regulations including physical plant maintenance and construction, waste disposal, staffing levels, and patient care. An industry focus group held during the summer of 2000 to discuss hospital regulations developed a draft list of seventy-five regulatory areas that affect Connecticut's acute care hospitals (See Exhibit 9). Within these areas, there are specific requirements that hospitals must understand, monitor for changes, include in operational policies, and, oftentimes, report back to the regulatory body.[2]

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Health care regulations are developed for a variety of purposes including ensuring access to care, establishing standards for care, containing cost, and protecting the safety of patients and staff. Whatever their intent, regulations create financial, structural, and procedural requirements for hospitals. Some regulations also govern non-hospital aspects of the health care market, such as HMOs and other payers that indirectly affect hospital operations and profitability; hospitals thus must address these requirements as well.

Areas in which regulatory requirements are felt most acutely, according to an industry focus group, are discussed in detail below. However, a more general review of all health care regulations may be needed in the future to ensure that regulations are sufficient, appropriate, timely, and relevant. In order for public officials to make well-informed decisions affecting the hospital and health care industry, it is important to understand the regulatory requirements that currently exist, why these regulations are in place, and whether they achieve their purpose in light of the evolving health care environment. While most would agree that some form of regulation is necessary to ensure the quality and accessibility of care for Connecticut's residents, the challenge is to ensure that these regulations are cost effective and not duplicative or contradictory.

THE STATE REGULATORY ENVIRONMENT IN CONNECTICUT

Hospitals are regulated by several state agencies including the Departments of Revenue Services, Social Services, Labor, Environmental Protection, Public Health, and the Office of Health Care Access. Other agencies, such as the Department of Insurance, also have a regulatory effect on hospitals. According to an industry focus group convened for input on this study topic and on-site interviews of hospital personnel, three primary areas of the Connecticut regulatory environment—Certificate of Need, licensure, and data collection—have the most immediate effect on hospital operations and finances. These areas and their impact are discussed below. It should be noted that focus group participants also mentioned that increased regulation should be developed in the area of timely payments for claims made to private insurance

companies. Since the focus group discussion was held, the Department of Insurance has issued a clarification of its "prompt payment law" which is expected to address many of the concerns raised regarding this issue.

Certificate of Need and Rate Setting

Prior to the mid-1990s, health care facilities, particularly hospitals, were so extensively regulated that competition in the health care field was very limited. In 1973, federal legislation mandating that states establish Certificate of Need programs to reduce fragmentation and duplication of health care services, control rising health care costs, ensure access to care, and maximize the utilization of limited health care resources,[3] led to creation of the state Commission on Hospitals and Health Care (CHHC). In FY 1974, the CHHC began administering Connecticut's Certificate of Need process, a mandatory examination of all health care institutions' proposed acquisitions or divestments of significant medical equipment (over a certain dollar amount) or services. The agency also reviewed and approved hospital rate schedules, capital budgets, gross and net operating revenue, and net expenses.

Rate-setting regulations were intended to ensure hospitals a certain level of revenue and, therefore, financial stability. It did permit some limited competition between hospitals on the basis of quality and amenities, if not price.[4] Furthermore, by trying to control costs and guarantee the financial stability of hospitals, the regulatory environment attempted to ensure people's access to acute care services. Despite these efforts, several hospitals faced severe budgetary crises and the number of acute care hospitals declined during the 1990s from 37 to 31. In addition, some areas of the regulatory framework restricted the ability of hospitals to respond autonomously to new trends in the delivery of and payment for care.

Concerned with the rising health care costs of the early 1990s, the Connecticut General Assembly created a more competitive health care market by reducing

the state's regulatory role. Public Act 94-9 terminated the state's authority to set hospital rates and abolished net revenue limits, thus giving hospitals authority to set their own prices and to assume greater financial risk, particularly in negotiating managed care discount agreements. Public Act 94-3 abolished the Commission on Hospitals and Health Care and replaced it with the Office of Health Care Access (OHCA). With an eye toward oversight rather than control, the role of the new agency included evaluating hospitals' financial results, maintaining an inpatient database, carrying out health care research and planning, and managing the Certificate of Need (CON) program.

The overall purpose of CON review is to ensure an orderly introduction of new

and expensive health care services, and to guarantee that services needed by the community remain available. Sections 19a-638 and 19a-639 of the Connecticut General Statutes require CON authorization for the acquisition of new services or termination of services by a health care facility. CONs are also required for capital expenditures in excess of $1 million or $400,000 for acquisitions of medical/imaging equipment by a health care facility, including ambulatory care centers and outpatient behavioral health programs —except those specifically exempted in Section 19a-639a.[5]

A common concern raised by health care providers has been the complexity of the process and the length of time required for CON authorization. In 1998, the General Assembly approved OHCA's request (P.A. 98-150) to streamline the CON process to make it a less stringent and more flexible health system planning tool suited to the evolving health care market.[6] This law also exempted and created the option to waive certain types of activities from the CON process. As a result of streamlining, the time between CON application filing and receipt of the average CON application decision was reduced from 19 weeks to seven weeks, or 45 percent.

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However, issues related to CON still persist. For example, thresholds for capital expenditures continue to generate a great deal of discussion. The expenditure thresholds, last revised in 1987, for major medical equipment and major capital projects are $400,000 and $1,000,000, respectively. Three quarters of the states that maintain CON programs have established their thresholds in excess of $1 million for capital expenditures. While some feel that Connecticut's thresholds should be adjusted upward for inflation, others are concerned that medical equipment with costs falling under the current threshold are being placed in service without CON review. Issues have arisen regarding the quality provided by less expensive, sometimes older, rebuilt equipment, as well as the "unbundling" of equipment purchases so that some equipment is obtained in piecemeal fashion at a cost of less than $400,000. Raising the medical equipment threshold may actually exacerbate the potential for use of lower quality equipment that falls below state thresholds.

In addition, recent advances in medical technology and the reduction in acquisition costs for major medical and imaging equipment have allowed physician practices to provide health care services and to acquire equipment within an office setting that were previously available only at health care facilities. Under current CON law, services provided in some locations receive CON review, while the same service provided in a different location, e.g., some physician practices, does not. This situation undermines the overall community protections intended by CON regulation.

There is disagreement about whether CON should continue to be a regulatory requirement in Connecticut. On a national level, the CON program did not effectively control the rising cost of health care but has been shown to have slowed the spread of certain new technology. The federal government repealed its CON requirements and subsequently 14 states also abolished their CON programs. Most others modified their CON programs by either increasing capital expenditure thresholds or exempting non-clinical service areas from review. Control of health care costs now appears

more dependent on the effects and influences of the managed care industry, rather than CON.

Stakeholders and organizations in Connecticut that are firmly opposed to any type of CON laws argue that these regulations preserve inefficiencies and prevent entry into the marketplace of competition for the hospitals and other health providers. They would prefer that the law be repealed, allowing market forces to work and if necessary, allow the inefficient providers to fail.

Supporters of CON feel that the current law has contributed to the existence of a high quality, primarily non-profit, Connecticut health care system that facilitates access to acute care services. According to CON supporters, without CON laws a wide variety of new providers could enter Connecticut without sufficient scrutiny, bringing an uncertain outcome for the quality and quantity of care provided. In addition, many CON supporters believe that the process contributes to health care delivery system planning for the state. However, even CON supporters agree that additional streamlining and modification of the process should occur and that it should be modified to include all services among competing providers, not just a portion of providers, and to encourage adoption of cost effective technologies.

Licensure

The Department of Public Health (DPH) evaluates the public health and safety of Connecticut's residents, in part through hospital licensure and inspections. DPH also works with the Health Care Financing Administration (HCFA) to ensure compliance with federal standards. According to the industry focus group, DPH licensing requirements have a significant impact on hospitals.

Licensing requirements apply to such matters as minimum staffing levels, staff qualifications, a mandatory 24-hour emergency department, physical plant, and various fire and safety regulations. Hospitals reapply for licensure every two years and are subject to a full inspection every four years. Interim inspections are made in response to complaints filed against a facility or as follow-up to violations. As is the case with many other states, Connecticut's hospital licensing and patient care regulations are predominantly process-based, focusing on evaluating policies and procedures and patient care documentation, rather than on quality outcomes. While the licensing process assists in evaluating the quality of the staffing and operations of the hospital services, it does not monitor the outcomes of the care provided.

As is the case with many other states, Connecticut's hospital licensing and patient care regulations are predominantly process-based.

Connecticut's licensing requirements for acute-care hospitals have not been amended in 20 years, and the pace of change in medicine is rapid. An industry focus group convened in summer of 2000 suggested that Connecticut's licensing requirements be reviewed to ensure that they adequately reflect needed protections to the process, scope, and outcomes of hospital services. For example, current licensing requirements for staffing preclude hospitals from providing sub-acute care, which is a level of treatment between chronic and acute care.[7] This category allows hospitals to serve patients who no longer require acute care but do not qualify for admission to a skilled nursing facility. Sub-acute beds typically require lower levels of staffing and have a correspondingly lower rate of reimbursement. Such services might provide more flexibility in balancing bed capacity and patient

need, while also assisting in hospital discharge planning and case management.

Current licensing standards exist to ensure that hospitals maintain qualified patient care staff. Routine inspections help to monitor the quality of care. A concern is that quality issues may go undetected as inspections are only regularly performed by the state every four years as part of the licensing process. Another concern is that there are disincentives for self-reporting of incidents in which the quality of care was compromised. If hospitals detect quality concerns within their medical staffs, they often find it difficult (due to legal and other constraints) to discipline physicians and, if necessary, to remove practice privileges. Hospitals are not currently involved in the board certification process, and therefore cannot provide feedback regarding the performance or quality of physicians.

Hospital representatives must track regulatory and legislative changes, assess their effects, and adapt to maintain compliance with the law.

A major staffing concern in the industry is the growing nursing shortage, and this issue is discussed in detail in a later section of this report. These concerns are being studied in detail by the Department of Public Health as of the writing of this report. Stakeholders participating in this Hospital Study indicated that staff licensing categories potentially could be modified to increase and broaden the available workforce.

Data Collection

Hospitals are required to report a significant amount of data to state agencies such as OHCA, DPH, and the Department of Social Services (DSS). Based on hospital interviews and focus group discussions, the data collection and reporting process requires significant resources. Advances in technology and some streamlined data reporting mechanisms are improving the efficiency of the process, and one category, inpatient discharge data, is transmitted to OHCA by the Connecticut Hospital Association as a subset of data it already collects from the hospitals.

Some stakeholders have discussed the need to broaden data collection to include outpatient data as patient care has moved, and continues to move, to outpatient settings. In addition, some particularly sensitive and costly services, such as adult and children behavioral health care, require analysis in order to understand and plan for care trends. This data is not currently being collected on a statewide basis. Finally, many stakeholders have suggested that data collection and analysis need to target the increased need for statewide information on health services for consumers and for system planning for all populations.

Legislative reforms in the mid-1990s loosened the regulatory strictures upon Connecticut's acute care hospitals and established the framework for a more competitive health care market. Hospitals gained the ability to competitively set their prices and, with recent CON reforms, they achieved greater control over their range of services. Thus at this time, hospitals can compete with each other and other health care facilities on the basis of their quality of care, rates, and range of services. Hospitals also gained control over their revenues, including complete autonomy in negotiating discount agreements with all types of payers. They assumed greater financial risk and, while this generated incentives for the delivery of more efficient and less expensive care, it also increased financial and management pressures on the industry.

THE FEDERAL REGULATORY PRESENCE AND PRIVATE CERTIFICATION

Federal Regulation

In addition to states, hospitals are also regulated by several federal entities including the Health Care Financing Administration (HCFA), Occupational Safety and Health Administration (OSHA), Equal Employment Opportunity Commission (EEOC), U.S. Nuclear Regulatory Commission (NRC), Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention (CDC), and the Internal Revenue Service (IRS). Hospital representatives must track regulatory and legislative changes, assess their effects, and adapt to maintain compliance with the law. Some examples of federal agencies, laws and regulations that have an impact on hospitals are described below.

Health Care Financing Administration (HCFA)
HCFA, a part of the Department of Health and Human Services, plays a critical role in regulating Connecticut's acute care hospitals because it administers the Medicare program and establishes statutory and regulatory standards for Medicaid and the State Children's Health Insurance Program (SCHIP). It also performs quality-focused regulatory and data gathering activities such as:

- regulation of laboratory testing;
- surveying and certification of health care facilities;[8]
- tracking of emerging medical technologies and patterns of care to determine applicability of existing coverage policy;
- development of quality standards for health care organizations that participate in the Medicare and Medicaid programs;[9] and

- monitoring the standards of accrediting organizations recognized by HCFA such as the Joint Committee on the Accreditation of Health Care Organizations (JCHAO).

American with Disabilities Act
The American with Disabilities Act (ADA), enacted a decade ago and enforced by the Equal Employment Opportunity Commission, has numerous requirements for all service industries, including the hospital industry. All new construction and facility renovation projects must adhere to ADA physical plant requirements. Many Connecticut hospitals have buildings that require major upgrades in order to comply with local and state building and ADA requirements. The ADA addresses not only physical plant needs but also service provision and employment requirements that must be continuously monitored, as these carry significant penalties for non-compliance.

HIPAA
A federal law that is significantly affecting all hospitals is the 1996 Health Insurance Portability and Accountability Act (HIPAA). HIPAA was enacted to develop standards and requirements for maintenance and transmission of health information

identifying individual patients. It is estimated that the privacy requirements included in HIPAA will increase national costs for providers and health plans by $1.2 billion for the first year alone, and $3.8 billion over five years.[10] The administrative simplification requirements of HIPAA will increase net cost by $71 million annually. A recent study found that hospitals could pay three to four times as much in order to comply with HIPAA reporting requirements than they spent on the technology needed to prevent Y2K problems.[11] A detailed discussion of HIPAA and its impact on hospitals appears later in this section of the report.

Medicare

The federal government is the largest health care payer and thus strongly affects the hospital industry. In FY 1999, Medicare reimbursements were 45% of Connecticut's acute care hospitals' revenues.[12] Over the latter 1990s, the federal government sought to control increasing health care costs by introducing managed care programs to Medicare, and later, by reducing the overall amount of reimbursements through the Balanced Budget Act of 1997 (BBA). The BBA is projected to reduce Medicare payments for hospital inpatient services from FY 1998 through 2002 by more than $70 billion—about $20 billion more than anticipated at the time the law was enacted.[13] The Balanced Budget Refinement Act of 1999 (BBRA) has replaced some of those reductions. Government reimbursements influence the services that providers such as hospitals offer, because providers are reluctant to offer services that are not reimbursed by Medicare.

Private Certification

Hospitals must also comply with accreditation rules from private organizations, such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to be eligible for reimbursement under the Medicare program and other private insurers. JCAHO performs regular site visits to hospitals to ensure the facilities are complying with JCAHO standards, which range from organizational issues such as governance, to process standards such as documentation requirements. JCAHO's ORYX program is its attempt to begin monitoring outcomes. Obtaining and maintaining JCAHO accreditation is a significant cost to hospitals.

CONCLUSION

In its roles as payer and regulator, the government has a strong influence upon acute care hospitals. Many aspects of hospital operations are affected by federal and state regulations including physical plant maintenance and construction, waste disposal, staffing levels, and patient care. Regulations were developed for a variety of purposes including ensuring access to care, establishing standards for care, and protecting the safety of patients and staff. In Connecticut during the 1990s, the regulatory environment was reformed to create a more competitive health care market. Hospitals gained more flexibility and autonomy to respond to the new market forces and also realized more financial risk and variability. Several regulatory areas, especially CON and licensing, could be improved through modernization, elimination, and in some cases, expansion. A broader look at the entire health care regulatory environment is recommended to ensure adaptation to a quickly changing marketplace.

RECOMMENDATIONS

In summer 2000, OHCA convened a focus group consisting of industry and government regulatory personnel to discuss the impact of the regulatory environment on hospitals and to develop recommendations for future change. The following are recommendations from the Focus Group on Government Regulations and on-site hospital interviews.

General Recommendations

- Reconvene the focus group and expand other areas of concern and topics discussed.
- Continue monitoring Connecticut's health care industry. Ongoing focus groups with key industry and regulatory representatives could work together to maintain the focus of the health industry's issues.
- Improve coordination among the State's regulatory agencies.
- Identify statutory revisions to eliminate unnecessary requirements, such as setting net revenue limits, while maintaining and even expanding the data collection function. Improve the use of such data to inform the industry, the public and state policy makers.
- If the state is going to prevent providers from eliminating services that are losing money then the state should ensure that it pays for these services at rates that are sufficient to cover the financial requirements of effective and efficient providers. Financial requirements would include the cost of bad debt and charity care as well as the cost of providing care.
- Analyze the health care practices and regulations of other states. A comprehensive study and presentation of the findings would help evaluate how Connecticut compares to other states and identify successes and failures experienced by other states.

Recommended Changes to Certificate of Need Program:

- CON laws should not be repealed- but the CON process and regulations should continue to be modernized to reflect the current health care environment.
- Update CON laws to address current issues and trends that exist in today's health care marketplace and to

improve their effectiveness in influencing provider capacity.

- Update CON laws to "level the playing field" and have all providers of similar services abide by the same requirements.
- Implement a planning process to identify areas where the risk of health care shortages or access problems is evident, and address these issues. This will enable the CON process to become more proactive in planning to meet the health care needs within the state.

Recommended Changes to Licensure:

- Further evaluate quality monitoring and reporting to modify the disincentives for reporting and to encourage reporting of potential violations, in order to obtain better information regarding quality.
- Establish benchmarks at the state level to improve the quality of health care and move the regulatory framework to an outcomes focus.
- Examine other clinical/management systems that detect medication and related medical errors to help improve the monitoring of care, as improved information technology and reporting techniques could contribute to better consumer information about quality of care.
- Further consider changing regulatory requirements to allow hospitals and other health care employers to hire non-licensed staff to perform duties now carried out by licensed nurses.
- Clarify hospitals' role in coordinating patient care after discharge.
- Consider the advantages of having some hospital involvement in the board certification process of physicians who have hospital privileges.
- Look at alternative licensure options within hospital settings to encourage flexibility to meet varying patient care needs.
- Review and evaluate the recommendations included in the (DPH) nursing shortage study and report, scheduled for completion in December 2000.

Recommended Changes for Data Collection Efforts:

- Build and/or expand collaboration between the various state agencies that regulate health care and collect data. The Department of Insurance, OHCA, and the Department of Public Health could benefit from sharing information and drawing up recommendations and areas for improvement.
- Expand the collection of billing data to include outpatient data in order to improve meaningful information available to OHCA, the industry, the public, and state policy makers, while preserving the competitiveness of Connecticut's hospitals.
- Wherever possible, the State should streamline data collection efforts, including eliminating any duplicative collection efforts.
- Data analysis should focus more on planning.
- Data collection should increase in areas that are the most relevant in terms of volumes and cost of care.

Exhibit 9: Hospital Regulatory Areas

1. Hospital Employment
    - A. Safety/OSHA
    - B. Staff qualifications/background checks
    - C. Labor relations
    - D. Scope of practice
    - E. EEOC/Discrimination
    - F. Staffing levels/ratios
2. Waste Handling
3. Infection Control
4. Ancillary Departments
    - A. Lab (CLIA)
    - B. Radiology (NRC)
    - C. Pharmacy (FDA/DEA)
    - D. Other
5. Access to Care
    - A. Emergency Room access
    - B. Anti-dumping
    - C. Americans with Disability Act
    - D. Linguistic capacity
6. Patient Care Requirements
    - A. Restraints
    - B. Records
    - C. Other
7. Quality Assurance Programs
    - A. Physician credentialing
    - B. Event reporting/processing
    - C. Medical errors
8. State Medical Board
9. Building Codes/Zoning
    - A. Fire
    - B. Building standards
    - C. Other
10. Licensure and Accreditation
    - A. Inspections
    - B. Program standards
    - C. Provider types
    - D. Moratoria
    - E. Staff qualifications
11. Mergers and Acquisitions
    - A. Antitrust
    - B. For-profit to Not-for-profit Conversions
12. Disproportionate Share
13. 'Stark' Requirements
14. Data Reporting/Disclosure
    - A. Budget/finance
    - B. Quality/patient satisfaction
    - C. Nurse staffing
    - D. Inpatient/outpatient billing
15. HIPAA (discussed in a separate focus group)
16. Certificate of Need
    - A. Threshold limits
    - B. Process/criteria
    - C. Providers affected
17. Net Revenue Limits
18. "Ethics Areas"
    - A. Gene therapy
    - B. Research
    - C. End of life
19. Reimbursement
    - A. Documentation
    - B. F&A
    - C. Others
20. Managed Care
    - A. Risk sharing
    - B. Prompt payment
    - C. Minimum stays
    - D. Insurance Department
21. Fair Credit Reporting Act
22. Internal Revenue Service reporting and disclosure requirements
23. OEMS (ambulance system)
24. Drug and alcohol reporting
25. ERISA
26. Connecticut Department of Revenue Service requirements
27. Property taxes requirements
28. Insurance Department requirements

NOTES

[1]State of Connecticut Office of Health Care Access Hospital Budget Reporting System.

[2]Regulations are legal pronouncements (that have the force of law) by a state agency as to how that agency is implementing a specific statutory authorization. Each proposed regulation must be reviewed for legal sufficiency by the Office of the Attorney General and presented to the Legislative Regulation Review Committee. This Committee reviews all regulations sought by state agencies and may disapprove any regulation that contravenes the legislative intent, or conflicts with current state or federal laws, or state or federal constitutions.
Statutes are pronouncements by the legislature that have become law. Only legislators and committees can introduce legislation, which starts out as a bill. Each bill goes through a series of drafts and committee reviews. A bill becomes a Public Act when it passes both houses of the General Assembly and is signed into law by the Governor. Most Public Acts passed are then codified, or incorporated into the existing statutes, which are published on January 1, every two years.

[3]State of Connecticut Commission on Hospitals and Health Care, *Functions of the Commission on Hospitals and Health Care: Review, Issues, and Role Under Health Care Reform*, 1994.

[4]KPMG Peat Marwick Report *The 1994 Development of Recommendations and Plans for Health Reform in Connecticut.*

[5]Facilities exempted from OHCA's CON authority are outpatient clinics or programs operated exclusively for a municipality, residential facilities for the mentally retarded, outpatient rehabilitation service agencies operated exclusively on an outpatient basis, clinical laboratories, assisted living services agencies, outpatient services offering chronic dialysis, programs of ambulatory services established and conducted by a health maintenance organization, home health agencies, clinics operated by the Americares Foundation, nursing homes, residential care homes, and rest homes.

[6]CON reforms included exempting certain categories of providers, providing waivers for programs endorsed by other state agencies, creating waivers for certain other categories of equipment acquisitions, and reengineering the dynamics of the CON process itself.

[7]Subacute care is a comprehensive inpatient program for those have experienced serious illness, injury, or disease, but who do not require intensive hospital services. It may include infusion therapy, respiratory care, cardiac services, wound care, rehabilitation services, postoperative recovery programs for knee and hip replacements, as well as cancer, stroke, and AIDS care.

[8]Nursing homes, home health agencies, intermediate care facilities for the mentally retarded, and hospitals, nursing home quality reports, and MDS public use files are included.

[9]These health care organizations include, but are not limited to, hospitals, nursing facilities, home health agencies and hospices.

[10]July 13, 2000 AHA Statement paper on OSHA's proposed ergonomic standard.

[11]September 2000 report, *HIPAA: Wake up call for Health Care Providers*, by the international rating agency Fitch.

[12]State of Connecticut Office of Health Care Access Hospital Budget Reporting System.

[13]July 13, 2000 AHA Statement paper on OSHA's proposed ergonomic standard.