Chapter 9:
State Regulation Impacting Acute Care Hospitals

Key Points

- **This chapter focuses on two general areas of regulation: Certificate of Need (CN) and licensure requirements of health care facilities. Action is needed in both areas to evenly apply certain requirements across different types of facilities.**
- **The current CN program places hospitals at a competitive disadvantage relative to free-standing facilities. A comprehensive review of the CN program is needed to ensure that the requirements do not place one type of a facility at a competitive disadvantage when similar services are being provided.**
- **CN requirements should be subject to a regular review process to respond to changes in the health care system.**
- **Current licensure exemptions for surgical practices with single operating rooms are not justified on either quality or safety grounds. Licensure should be required of all ambulatory surgery centers, including single operating room physician surgical practices.**
- **The limited focus of current data collection efforts on hospitals is too narrow for modern health system planning and evaluation. Enhanced data collection from ambulatory care facilities is needed and should be required.**

There are numerous State regulations that influence the hospital market in New Jersey. The Commission focused on three general areas: the CN program, licensure requirements for health care facilities, and the governance requirements for non-profit hospital boards. All three issues influence the economics and performance of hospitals in important ways. CN programs are intended to influence the supply of health care facilities and services in the State and thus cost and quality through an approval process for the opening or closing of facilities and/or certain clinical services. The licensure program helps ensure a certain level of quality for individual health care facilities. Governance requirements are intended to ensure that community assets are effectively managed in service of the community.

As part of the Commission's effort to examine the regulatory landscape in New Jersey, a subcommittee on Regulatory and Legal Reform was formed to provide guidance. A major theme that emerged from the subcommittee's deliberations was the need to ensure that regulatory requirements are evenly and appropriately applied. The unevenness arises when regulations or standards are differentially applied to facilities that are providing the same service. Another major area addressed in the subcommittee's deliberations was the governance of non-profit hospitals – the Commission wholeheartedly agreed with the critical importance of this issue and as such has devoted the subsequent chapter in this report to governance reforms (see Chapter 10).

I. Certificate of Need Programs – Challenges to Effective Health System Planning

Although national studies have shown that CN programs have failed to achieve some of their original goals[90], the program in New Jersey continues to play an important role in preventing over-proliferation of services where volume and quality are related. In addition, it continues to provide a process for the orderly closure of an existing facility. CN programs have been criticized for, in effect, granting existing facilities a "franchise" by limiting/precluding competition.[91] Thus, the success of CN in controlling costs is unclear. While some research suggests that the presence of a CN process lowers health care costs, other research finds the opposite.[92] In addition, the CN process is applied unevenly across services and providers, leading to unintended consequences. For example, many states' CN programs focus on hospitals' ability to increase bed capacity, but the same programs do not restrict purchase of new, expensive imaging technologies, or restrict the building of new ambulatory surgery centers. Research conducted in the late 1970s suggested that CN exacerbates hospitals' purchase of unneeded new technology, because hospitals race to be the first to offer a new technology before it becomes subject to the CN program.[93]

CN programs were originally designed to control capital expenditures by hospitals, which is understandable given the era in which these programs were developed. Advancements in technology, however, have enabled care that was once only provided in hospitals to be shifted to freestanding ambulatory settings, but in some states, including New Jersey, these settings have been exempted from CN programs. Regardless of the reason for these exemptions of certain provider types from CN requirements, the result is the creation of a competitive advantage for these providers relative to hospitals.

Some states believed these market-based economic forces obviated the need for their regulatory processes and discontinued their CN programs. Fifteen states have terminated their CN programs. New Jersey has not repealed its CN program, but in the 1990s the State began reviewing the CN process to allow more competition among health providers. The largest changes to New Jersey's CN program occurred in 1998 with the Certificate of Need Reform Act, which exempted ambulatory surgery centers, several technologies, basic obstetrics and pediatric services and residential substance abuse treatment programs.[94]

Recommendation

The Department of Health and Senior Services should conduct a comprehensive review of the CN and licensure programs to ensure that regulatory requirements do not place hospitals at a competitive disadvantage. CN requirements should be subject to a regular review process to respond to changes in the health care system.

While the evidence is mixed on the ability of CN programs to contain health care spending, proven relationships between volume and quality for certain clinical services argue for the continuation of the CN program for certain services. The State should ensure that CN programs particularly focus on clinical services where this relationship has been demonstrated. Licensure offers an additional policy tool to ensure minimum volume thresholds are reached to optimize quality.

[90] The Federal Trade Commission, Department of Justice, Improving Health Care: A Dose of Competition (Washington, D.C.: FTC, DOJ, 2004) Available online: http://www.justice.gov/atr/public/health_care/204694.pdf

[91] Havighurst, C.C., "Monopoly Is Not the Answer," *Health Affairs* Web Exclusive, (August 9, 2005). Available online: http://content.healthaffairs.org/cgi/content/citation/hlthaff.w5.373/DC1.

[92] Piper, T.M., "Certificate of Need: Protecting Consumers' Interests," (June 10, 2003). Available online: http://www.ftc.gov/ogc/healthcare-hearings/docs/030610piper.pdf.

[93] Salkever, D.S. and Bice, T.W., "The Impact of Certificate of Need Controls on Hospital Investment," *The Milbank Memorial Fund Quarterly, Health and Society,* Volume 54, Number 2, (Spring 1976).

[94] Sagness, J., "Certificate of Need Laws: Analysis and Recommendations for the Commission on Rationalizing New Jersey's Health Care Resources," (January 12, 2007). Available online: http://nj.gov/health/rhc/documents/con_laws.pdf.

The Commission grappled with the rapid proliferation of ambulatory surgery centers and their economic impact on hospitals. However, at this time, it is impossible to roll back the clock and CN does not appear to be a useful policy tool to address this issue. Relying on it would simply grant existing ambulatory surgery centers enhanced market power.

II. The Licensure of Health Care Facilities

A. Ambulatory Care Facility Resources in New Jersey

The New Jersey Department of Health and Senior Services (DHSS) licenses several types of ambulatory care centers. Based on analysis of information on ambulatory care centers data provided by DHSS, below is a description of the kinds of services provided in each type of ambulatory care center:

- Hospital-based centers – includes centers that provide substance abuse services and a variety of other facilities such as sleep centers, dialysis units and clinics;
- Free-standing centers – includes ambulatory surgery centers and imaging centers;
- Federally Qualified Health Centers (FQHCs) – public and private non-profit organizations that provide primary care to federally-designated medically underserved areas and populations and are important sources of primary care for uninsured Medicaid patients;
- Other centers – includes Planned Parenthood centers and other clinics.

Table 9.1 presents the number of these ambulatory care centers in each of the eight market areas used by the Commission for its analyses.

Table 9.1:
Number of Ambulatory Care Centers by Market Area and Type

Market Area	Hospital-based Ambulatory Care Centers	Free-Standing Ambulatory Care Centers	Federally Qualified Health Centers	Other Ambulatory Care Centers
Atlantic City	12	49	15	4
Camden	31	69	6	2
Hackensack, Ridgewood and Paterson	23	101	10	5
Morristown	14	56	6	3
New Brunswick	7	72	4	2
Newark/Jersey City	30	93	16	6
Toms River	10	66	8	2
Trenton	10	16	3	-
Total	137	522	68	24

As Table 9.1 shows, the vast majority of the ambulatory care centers are in the freestanding care center category that comprises ambulatory surgery centers and imaging centers.

The Commission noted two major areas where licensure requirements are not evenly applied with respect to ambulatory care centers. Currently, free-standing ambulatory surgery centers are not required to report clinical data on volume, costs, and quality in ways that hospitals are. In addition, ambulatory surgery centers (i.e. surgical practices) with single operating rooms are completely exempt from licensure requirements. In both cases, quality improvement and health system planning processes are hindered by these uneven requirements.

Recommendations

The Department of Health and Senior Services should require licensure for all ambulatory surgery centers and surgical practices with operating rooms.

Patient safety and quality goals require monitoring of all facilities. Although the Board of Medical Examiners has oversight over physician practices, the current exemption of physician offices with single operating rooms from DHSS licensure requirements is not justified. Elimination of this exemption would bring more uniform requirements to facilities providing similar services. In addition, it will make the data collected comprehensive and thus more meaningful with respect to health system planning.

The Department of Health and Senior Services should compile and maintain an inventory of non-hospital health care resources and a database to assess their use.

A necessary component of health services planning is data to assess the needs of the population and compare them with the supply of health care services. However, New Jersey, like many states, does not have a comprehensive data collection process to support needs assessment of many non-hospital health care services. Instead, existing data collection efforts focus on inpatient services. However, inpatient hospital services comprise less than half of total health care spending, and for the remaining facilities-based health care services, there is a dearth of data in general, and in particular, in New Jersey. Some states require freestanding ambulatory surgery centers to provide patient volume information by surgical specialty, payer source, patient age, etc. New Jersey does not collect similar information, although the State requires ambulatory surgery centers and other freestanding ambulatory care centers to report data for the assessment that helps funds charity care subsidies to hospitals.

Given the number of ambulatory surgery centers in New Jersey and the debate about whether they and other freestanding ambulatory centers are a factor in the troubled financial condition of the State's acute care hospitals, New Jersey should begin its expanded data collection with ambulatory surgery centers. The State should consider requiring all ambulatory surgery centers to submit billing claims data similar to the data hospitals currently submit to the State. The DHSS has been collecting outpatient same day surgery data from hospitals for several years, but in an inpatient bill format. However, in January 2008, the Department is planning to switch to collecting hospital outpatient same-day surgery data in an outpatient bill format and to group the data into ambulatory patient classifications that the Medicare Program uses, so it will be positioned to expand data collection to freestanding ambulatory surgery centers. This would allow the Department to analyze hospital outpatient surgery data and freestanding ambulatory surgery utilization data together to understand the entire market for these services. In addition, the State should maintain a database of the number of operating rooms in hospitals and freestanding ambulatory centers.

III. Conclusion

The Commission strongly endorses the view that regulation and licensure requirements ought to be more evenly applied across health care facilities. The current focus on hospitals has not kept pace with changes in the health care system and has contributed to an uneven playing field with respect to the CN program, requirements for licensure, and data reporting. A consistent theme of the Commission's discussion was the need for consistency based on clinical services, not facility type. The Commission recommends a review of CN requirements and expanded licensure and data reporting requirements with this underlying principle in mind.