Chapter 3
Cardiac Surgery and Therapeutic Catheterization Services

Maryland Specialized Cardiac Care Services: Overview and Definition

The Commission has defined cardiovascular services as cardiac surgery and therapeutic cardiac catheterization. *Cardiac surgery* means surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery. *Open heart surgery* is a cardiac surgical procedure during which a heart-lung machine performs the functions of circulation. *Cardiac catheterization* means an invasive diagnostic procedure whereby a catheter is inserted into a blood vessel in the arm or leg and guided into the various chambers of the heart. *Therapeutic Catheterization* means percutaneous transluminal coronary angioplasty (PTCA).

Supply, Distribution, and Utilization of Cardiovascular Services

According to the first State Health Plan, adopted in 1980, open heart surgery services were available at four nonfederal hospitals in Maryland in 1978. The Plan noted that specialized cardiac facilities in adjoining jurisdictions, particularly metropolitan Washington and Wilmington, Delaware, provided services to residents of Maryland and were within an acceptable *travel time*. By December 1999, nine nonfederal hospitals in Maryland offered or had CON approval to begin offering open heart surgical services.

Table 3-1
Availability of Open Heart Surgery Services in Nonfederal Hospitals in Maryland, 1978

Hospital	Location
Washington Adventist Hospital	Montgomery County (Metro Washington)
Johns Hopkins Hospital	Baltimore City (Metropolitan Baltimore)
Sinai Hospital of Baltimore	Baltimore City (Metropolitan Baltimore)
University of Maryland Hospital	Baltimore City (Metropolitan Baltimore)

Source: Maryland Statewide Health Coordinating Council and Maryland Health Planning and Development Agency, *Maryland State Health Plan, 1979-1981, Volume 2: Analysis and Policies,* January 1980.

Table 3-2
Availability of Open Heart Surgery Services
in Nonfederal Hospitals in Maryland, 2000

Hospital	Location
Washington Adventist Hospital	Montgomery County (Metro Washington)
Prince George's Hospital Center	Prince George's County (Metro Washington)
Johns Hopkins Hospital	Baltimore City (Metropolitan Baltimore)
Sinai Hospital of Baltimore	Baltimore City (Metropolitan Baltimore)
St. Joseph Medical Center	Baltimore City (Metropolitan Baltimore)
Union Memorial Hospital	Baltimore City (Metropolitan Baltimore)
University of Maryland Medical Center	Baltimore City (Metropolitan Baltimore)
Peninsula Regional Medical Center	Wicomico County (Eastern Shore)
Sacred Heart Hospital	Allegany County (Western Maryland)

Source: Maryland Health Resources Planning Commission (MHRPC), July 2000.

Note: The program at Sacred Heart Hospital was approved in September 1999.

As part of comparative reviews conducted between 1982 and 1999, other hospitals submitted applications for open heart surgery programs. The applicants included the following:

1. Doctors Hospital
2. Francis Scott Key Medical Center (now Hopkins Bayview Medical Center)
3. Franklin Square Hospital
4. Holy Cross Hospital
5. Maryland General Hospital
6. Memorial Hospital and Medical Center of Cumberland (now part of Western Maryland Health System with Sacred Heart Hospital)
7. North Charles General Hospital (later closed as part of Hopkins Health System)
8. St. Agnes Hospital
9. Suburban Hospital

In a related action during that period, Washington County Hospital submitted a petition requesting that the Commission amend the State Health Plan to subdivide the region in which the facility is located so that the Plan might show a need for an open heart surgery program.

Trends in the number of adult open heart surgery cases over the six-year period, 1994-1999, are shown below. Data on the volume of coronary angioplasty procedures performed during the same period follow. As a rule, data on the most recent years of utilization are used to estimate the number of programs that should be available in a target year. Factors that may affect future use include demographic changes and technological advances.

Table 3-3
Adult Open Heart Surgery Cases by Hospital in Maryland and Washington, D.C., 1994-1999

Region/Hospital	Year					
	1994	**1995**	**1996**	**1997**	**1998**	**1999**
Metropolitan Washington Region						
Prince George's Hospital Center	59	81	90	61	91	120
Washington Adventist Hospital	925	723	839	899	817	817
Total Maryland	*984*	*804*	*929*	*960*	*908*	*937*
Georgetown University Hospital	542	444	451	328	301	140
George Washington University Hospital	148	150	118	65	85	----
Howard University Hospital	----	----	----	43	46	50
Washington Hospital Center	1,669	1,808	2,041	2,405	2,709	2,950
Total Washington, D.C.	*2,359*	*2,402*	*2,610*	*2,841*	*3,141*	*3,140*
Metropolitan Washington Total	**3,343**	**3,206**	**3,539**	**3,801**	**4,049**	**4,077**
Metropolitan Baltimore Region						
St. Josephs Hospital	842	1,008	1,269	1,388	1,411	1,308
Johns Hopkins Hospital	1,116	1,050	1,047	1,134	1,146	1,100
Sinai Hospital of Baltimore	473	444	577	416	477	541
Union Memorial Hospital	198	723	777	838	778	893
University of Maryland Hospital	785	713	818	775	553	596
Metropolitan Baltimore Total	**3,414**	**3,938**	**4,488**	**4,551**	**4,365**	**4,438**
Eastern Shore Region						
Peninsula Regional Medical Center	**360**	**448**	**475**	**482**	**536**	**561**
TOTAL	**7,117**	**7,592**	**8,502**	**8,834**	**8,950**	**9,076**

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base for calendar years 1994-1999; data reported for Washington, D.C. hospitals for 1994-1996 is from a Survey of Cardiac Surgery and PTCA Services conducted by the Health Resources Planning Commission; data reported for Washington, D.C. hospitals for 1997-1998 is from a discharge data base provided by the D.C. State Health Planning and Development Agency; and data reported for Washington, D.C. hospitals for 1999 is estimated based on the discharge data base for January-June 1999. Howard University Hospital did not report data for 1994-1996 and George Washington University Hospital did not report data for 1999.)

Table 3-4
Percutaneous Transluminal Coronary Angioplasty Cases by Hospital in Maryland and Washington, D.C., 1994-1999

Region/Hospital	Year					
	1994	**1995**	**1996**	**1997**	**1998**	**1999**
Metropolitan Washington Region						
Prince George's Hospital Center	155	222	232	252	302	318
Washington Adventist Hospital	1,833	1,952	1,806	1,933	1,996	1,836
Total Maryland	*1,988*	*2,174*	*2,038*	*2,185*	*2,298*	*2,154*
Georgetown University Hospital	346	401	354	173	141	80
George Washington University Hospital	----	----	----	295	259	----
Howard University Hospital	----	----	----	32	52	56
Washington Hospital Center	3,041	3,066	3,048	3,332	3,683	3,986
Total Washington, D.C.	*3,387*	*3,467*	*3,402*	*3,832*	*4,135*	*4,122*
Metropolitan Washington Total	**5,375**	**5,641**	**5,440**	**6,017**	**6,433**	**6,276**
Metropolitan Baltimore Region						
St. Josephs Hospital	1,269	1,528	1,664	1,592	1,820	1,775
Johns Hopkins Hospital	1,160	811	822	1,052	1,039	1,151
Sinai Hospital of Baltimore	652	740	757	778	764	848
Union Memorial Hospital	142	450	560	818	1,060	1,391
University of Maryland Hospital	571	541	579	591	588	538
Metropolitan Baltimore Total	**3,794**	**4,070**	**4,382**	**4,831**	**5,271**	**5,703**
Eastern Shore Region						
Peninsula Regional Medical Center	**776**	**909**	**1,098**	**1,246**	**1,153**	**1,386**
TOTAL	**9,945**	**10,620**	**10,920**	**12,094**	**12,857**	**13,365**

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base for calendar years 1994-1999; data reported for Washington, D.C. hospitals for 1994-1996 is from a Survey of Cardiac Surgery and PTCA Services conducted by the Health Resources Planning Commission; data reported for Washington, D.C. hospitals for 1997-1998 is from a discharge data base provided by the D.C. State Health Planning and Development Agency; and data reported for Washington, D.C. hospitals for 1999 is estimated based on the discharge data base for January-June 1999. Howard University Hospital did not report data for 1994-1996 and George Washington University Hospital did not report data for 1994-1996 and 1999.)

Access to Cardiovascular Services

Actual use of services is one indicator of the access to care by a population or group. The results of a national survey conducted by the Urban Institute in 1997 indicated that *uninsured low-income* adults were more likely to lack confidence in their ability to

access health care services than low-income adults who have health insurance.[34] Researchers have analyzed differences by *race* in the use of major cardiovascular procedures. The literature shows that black patients with acute myocardial infarction were less likely than white patients to have received coronary artery bypass graft surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA). Several factors may affect these findings, including differences in the severity of cardiovascular disease and the types of practitioners or facilities providing care.

Studies indicate that *health insurance* alone may not be sufficient for assuring equitable access to care. Insurance companies set different restrictions on use. Greater liability for deductibles and co-payments may result in a financial disincentive for some persons to use health services, especially more costly services.[35]

The decisions made by patients regarding treatment may also be affected by the *information available* to patients. Research indicates that, to be useful in making decisions about health care, the information must be relevant, comprehensible, and credible.[36]

Differences in *rates of referral* by practitioners also contribute to differences in use rates by race. The findings of a study that addressed the role of physicians in recommending cardiac catheterization suggested that decisions made by physicians may be an important factor in explaining differences in the treatment of cardiovascular disease with respect to both race and sex.[37]

The Federal law and regulations that established the certificate of need (CON) program set minimum standards to be included in each state's program. They required the agency administering the program to consider how a CON proposal would meet the needs of low-income persons, racial and ethnic minorities, women, handicapped persons, and other *underserved groups*. As a result, CON programs typically include requirements to address the issue of access by groups that have been shown to be or may be underserved. The Maryland CON program provides for awarding a preference in a comparative review to the applicant with a demonstrated record of reaching out to and serving minority and indigent persons with cardiovascular diseases.

Using a geographic information system, the Commission found that Maryland residents in

[34] John Holahan and Niall Brennan, *Who Are the Adult Uninsured?*, series B, no. B-14 (Washington, D.C.: The Urban Institute, March 2000).

[35] A. Marshall McBean and Marian Gornick, "Differences by Race in the Rates of Procedures Performed in Hospitals for Medicare Beneficiaries," *Health Care Financing Review* 15 (Summer 1994): 77-90. Janet B. Mitchell and Rezaul K. Khandker, "Black-White Treatment Differences in Acute Myocardial Infarction," *Health Care Financing Review* 17 (Winter 1995): 61-70.

[36] Judith A. Sangl and Linda F. Wolf, "Role of Consumer Information in Today's Health Care System," *Health Care Financing Review* 18 (Fall 1996): 1-8.

[37] Kevin A. Schulman et al., "The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization," *New England Journal of Medicine* 340 (February 25, 1999): 618-626.

certain areas of the state had *geographic access* within a 60-minute mid-day travel time to open heart surgery programs for adults in contiguous states. In addition to the hospitals in the District of Columbia, the programs included Christiana Hospital in Wilmington, Delaware; Arlington Hospital, Inova Alexandria Hospital, and Inova Fairfax Hospital in Northern Virginia; and Monongalia General Hospital and West Virginia University Hospitals (Ruby Memorial Hospital) in Morgantown, West Virginia. In 1997, before the program at Sacred Heart Hospital was approved, 92 percent of the adult population in Maryland resided within 60 minutes of one hospital with open heart surgery services, and 85 percent resided within 60 minutes of more than three such hospitals.

Another aspect of *temporal access* is the time spent by patients waiting for services at available facilities. As a rule, *waiting lists* are not standardized and monitored. Factors that may affect their use as a source of data on access to cardiovascular services include the preference of the referring physician or the patient.

Quality of Cardiovascular Services

In 1966, Donabedian proposed the sequence of structure, process, and outcome in describing quality of care. This conceptual framework continues to be useful for evaluating measures of quality. Each type of measure offers an opportunity to monitor and improve performance over time. Additionally, a system that includes measures of quality provides a structure for both incentives and sanctions.

Examples of *structural measures* include the facilities, equipment, and organizational and staffing capacities of hospitals. *Process measures* are used to assess the provision of care itself, for example, the use of certain diagnostic or therapeutic processes. *Outcome measures* often include rates of mortality or complications.

The *capacity* to provide cardiac surgical services depends on the availability of highly skilled *specialists* who function as a multidisciplinary team. Attributes that affect their performance, such as the training, experience, and specialization of physicians, may be used to assess and assure quality.[38]

Since 1963, the American Medical Association (AMA) has maintained a database on physicians in the United States and issued reports on their distribution. To update and verify the data on medical *specialization* and *certification*, the AMA sends an annual questionnaire to physicians and obtains information from the boards that comprise the American Board of Medical Specialties. Certification by a medical board is not required for a licensed physician to practice a medical specialty; however, hospitals or health plans may require certification for granting privileges to practice within their facilities.

The American Board of Pediatrics certifies physicians in the *subspecialty* area of Pediatric Cardiology. The Subspecialty Board on Cardiovascular Disease is part of the American Board of Internal Medicine, which also offers examinations for *certificates of*

[38] Avedis Donabedian, "The Epidemiology of Quality," *Inquiry* 22 (Fall 1985): 282-292.

added qualifications in Interventional Cardiology. The American Board of Surgery offers certifying examinations in Pediatric Surgery and Vascular Surgery. The American Board of Thoracic Surgery has established the requirements and offers examinations for certifying thoracic surgeons. In 1997, the specialties with the highest percentages of certified physicians included Pediatric Cardiology, Cardiovascular Disease, and Thoracic Surgery.

The AMA reports annual data on both self-designated and certified specialties of physicians. The data on self-designation are more detailed and numerous than the data on certification. For example, in addition to thoracic surgery, the questionnaire used by the AMA in 1997 listed cardiothoracic surgery and cardiovascular surgery. The vast majority of physicians selected cardiothoracic surgery (4,599) instead of thoracic surgery (270) or cardiovascular surgery (7). Changes in methods of coding and aggregation by specialty have made the examination of recent trends in distribution more difficult.

Urbanization, the composition of a population and its need for health care, and the regulatory requirements for offering health services are among the factors that affect the distribution of physicians. Specialists represent a larger percentage of physicians in metropolitan areas than non-metropolitan areas.[39]

In March 1978, the Federal government issued national guidelines that included standards regarding the supply, distribution, and organization of specific health resources. The standards for open heart surgery and cardiac catheterization were intended to promote the cost-effective use of resources, and maintain and strengthen the skills of the practitioners. The guidelines specified minimum *numbers of procedures* for both. In the case of open heart surgery, the guidelines recommended a minimum number of procedures by a team in any one institution.

The guidelines of professional associations comprised of specialists are often used in the granting of medical privileges. Based on a search of the literature since 1989, and expert opinion, a committee of the American College of Cardiology and the American Heart Association recently revised the joint guidelines for coronary artery bypass graft surgery. With regard to the competence of operators and institutions, the committee noted that risk-adjusted mortality rates in low-volume situations vary widely. The recommendations supported tracking outcomes and monitoring individuals or institutions that perform less than a specified number of cases annually.[40]

Outcome measures are receiving increased attention. The validity of structural and process measures is being examined based on evidence that they cause or have a strong

[39] *Physician Characteristics and Distribution in the United States, 1999 Edition*, Department of Data Survey and Planning, Division of Survey and Data Resources, American Medical Association, 1998.

[40] K. A. Eagle et al., "ACC/AHA Guidelines for Coronary Artery Bypass Graft Surgery: Executive Summary and Recommendations: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1991 Guidelines for Coronary Artery Bypass Graft Surgery)," *Circulation* 100 (1999): 1464-1480.

association with good outcomes. Outcome measures such as *mortality rates* are themselves being evaluated, particularly the extent to which differences in the measures reliably and consistently reflect true differences in the quality of care provided.

During the 1990s, the federal Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research) supported the emphasis on outcomes by funding studies conducted by Patient Outcome Research Teams. The large-scale PORT projects were designed to determine the most effective ways of preventing, diagnosing, or treating conditions. The Maryland Health Resources Planning Commission (MHRPC) approved a request to permit selected Maryland hospitals to participate in the first trial developed by the Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-PORT). With the exemption for research, the hospitals were able to perform primary angioplasty without on-site cardiac surgical backup. Recruitment of patients into the study ended in the summer of 1999. Results of the C-PORT trial will be important in the development of health care policy related to these services.

Table 3-5
Maryland Hospitals Participating in the
Primary Angioplasty Clinical Trial of the Atlantic C-PORT

Hospital	Location
Holy Cross Hospital	Montgomery County (Metro Washington)
Shady Grove Adventist Hospital	Montgomery County (Metro Washington)
Suburban Hospital	Montgomery County (Metro Washington)
Hopkins Bayview Medical Center	Baltimore City (Metropolitan Baltimore)
St. Agnes Hospital	Baltimore City (Metropolitan Baltimore)
Memorial Hospital of Easton	Talbot County (Eastern Shore)

Source: Maryland Health Care Commission, *Final Report of the Technical Advisory Committee on Cardiovascular Services*, December 1999.

In 1992, the federal Health Care Financing Administration (HCFA) initiated the Cooperative Cardiovascular Project (CCP), a national effort to improve the quality of care for Medicare beneficiaries with a diagnosis of acute myocardial infarction. The project included indicators of quality that were based on the guidelines of the American College of Cardiology and the American Heart Association. The work was performed as part of the contract between HCFA and the Peer Review Organizations (PROs) established by Federal legislation. Participating hospitals and PROs reviewed and analyzed data on the *use* and *timing* of *specific interventions*, including primary PTCA. The project helped physicians and hospitals to measure their performance and identify areas for improvement.

In 1997, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) introduced an initiative to integrate data on outcomes and other measures of performance into its process of *accrediting*

hospitals and other organizations. JCAHO has begun the process of selecting core measures for the five areas identified for hospitals. Acute myocardial infarction (including coronary artery disease) is among the five priorities, and JCAHO is coordinating its measures with those of the CCP. Hospitals can use the core measures for benchmarking or comparisons based on specific processes and actual outcomes of patient care.[41]

JCAHO also uses *on-site surveys* to assess the quality of care provided by accredited organizations. Generally, the Joint Commission conducts a full survey of a hospital every three years, and a random unannounced survey during the period of nine to 30 months after the full survey.

Accreditation by JCAHO is voluntary; however, Federal and State agencies use its accreditation to determine whether hospitals are complying with standards that are designed to assure quality of care. As a result, most hospitals seek accreditation by the Joint Commission. The Maryland Department of Health and Mental Hygiene uses the standards of JCAHO during the licensing process for any Maryland hospital that is not accredited by the Joint Commission.

[41] Mark A. Crafton, Director of State Relations for the Joint Commission on Accreditation of Healthcare Organizations, "Current and Future JCAHO Performance Measurement Requirements" (presentation at the meeting of the Hospital and Ambulatory Surgery Facility Report Card Steering Committee of the Maryland Health Care Commission, Baltimore, July 13, 2000).

Cost Efficiency of Cardiovascular Services

In addition to assuring the quality of care provided to Medicare patients, the Health Care Financing Administration has the responsibility of controlling the costs of the Medicare program. In 1991, HCFA initiated a demonstration project to pay a single, negotiated, global *price* for all inpatient care for heart bypass patients at four participating institutions; in 1993, the project was expanded to include three additional hospitals. The agency sought to encourage the performance of bypass procedures in higher-volume hospitals and to align the incentives of physicians with those of hospitals under prospective payment.

Researchers analyzed data from the project to assess the extent to which hospitals could reduce costs by changing the way they manage the care of patients. The findings included shorter stays in the hospital and reductions in *costs*, primarily for intensive care unit, routine nursing, pharmacy, and laboratory services. A finding of no reduction in quality was based on mortality rates adjusted for differences in severity of illness (for example, assignment by diagnosis related group, previous bypass, left ventricular cardiac function). The researchers found that the Medicare program had achieved significant discounts, and they concluded that the success of the demonstration had contributed to the spread of negotiated prices for bundled physician and hospital services across the nation.[42]

[42] Jerry Cromwell, Debra A. Dayhoff, and Armen H. Thoumaian, "Cost Savings and Physician Responses to Global Bundled Payments for Medicare Heart Bypass

Besides costs associated with *lengths of stay* that may be longer than necessary or hospitalizations that are potentially avoidable, the performance of a hospital may be measured by the percentage of expenses for *administrative costs*. The indicators of efficiency may exclude certain expenses that are incurred by a limited number of hospitals, and adjust for differences in the severity of the medical conditions of patients.

Data on *charges* may also be used to compare hospitals. An analysis of data from the Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project (HCUP) provides information on the charges of the most frequent diagnoses and procedures for patients hospitalized in the United States in 1996. The sample included about 900 hospitals in 19 states (including Maryland). This multi-state data system offers the largest all-payer inpatient database in the nation. The analysis uses administrative data included in a typical discharge abstract and does not control for severity of illness.[43]

Further, charges may not indicate what was actually paid. Payers may receive discounts on charges. The amount charged or paid may not cover the cost of care. As a result, one or more groups of patients may pay higher charges as unpaid charges or costs are shifted onto them. In Maryland, however, the rates of a hospital must be set so that its charges are related reasonably to the costs of providing the services. The HSCRC-approved rates for hospitals with cardiac catheterization laboratories are listed in Table 3-6.

Surgery," *Health Care Financing Review* 19 (Fall 1997): 41-57.

[43] Anne Elixhauser and Claudia A. Steiner, *Most Common Diagnoses and Procedures in U.S. Community Hospitals*, 1996 (Rockville, Maryland: Agency for Health Care Policy and Research, 1999).

Table 3-6
Rates Approved by the Maryland Health Services Cost Review Commission for Cardiac Catheterization Laboratory

Hospital	Effective Date	Charge Rates	Budget Volume
University of Maryland Medical System	January 2000	6.94	458,380
Peninsula Regional Medical Center	April 2000	7.40	585,761
Sinai Hospital of Baltimore	October 1999	7.82	448,184
St. Agnes Hospital	December 1998	8.99	159,940
Franklin Square Hospital	August 1999	9.49	114,748
Greater Baltimore Medical Center	May 1999	10.02	155,268
St. Joseph Hospital	July 1999	10.04	528,001
Washington Adventist Hospital	January 2000	10.26	825,797
Northwest Hospital Center	July 1999	10.64	83,242
Union Memorial Hospital	August 1999	10.68	434,012
Johns Hopkins Hospital	June 1999	10.97	1,122,175
Mercy Medical Center	November 1999	11.03	16,931
Hopkins Bayview Medical Center	November 1999	11.39	94,982
Shady Grove Adventist Hospital	January 2000	11.56	61,638
Bon Secours Hospital	November 1998	11.94	26,259
Howard County General Hospital	April 1999	11.94	15,243
North Arundel Hospital	May 1999	12.15	235,683
Memorial of Cumberland Hospital	April 2000	12.39	64,058
Good Samaritan Hospital	September 1999	12.44	96,230
Frederick Memorial Hospital	April 1999	12.79	27,396
Washington County Hospital	February 2000	12.83	54,073
Dorchester General Hospital	March 1997	12.84	39,923
Montgomery General Hospital	July 1999	13.12	3,380
Memorial Hospital at Easton	October 1999	13.57	42,793
Prince George's Hospital Center	October 1999	15.03	128,287
Sacred Heart Hospital	April 2000	15.80	49,421
Suburban Hospital	April 2000	15.81	70,687
Anne Arundel Medical Center	May 1999	19.26	68,566
Carroll County General Hospital	August 1999	19.68	37,066
Southern Maryland Hospital Center	January 1999	20.05	34,932
Laurel Regional Hospital	July 1999	20.69	16,062
Doctors Community Hospital	April 2000	21.32	22,568
Calvert Memorial Hospital	April 2000	22.95	804
Harbor Hospital	October 1999	23.48	36,216
Harford Memorial Hospital	April 2000	23.93	8,240
Holy Cross Hospital	June 1999	27.10	55,580
Maryland General Hospital	April 2000	61.07	13,100
All Hospitals		15.39	6,235,626

Source: Maryland Health Services Cost Review Commission, June 26, 2000.

Collection, Analysis, and Dissemination of Statistical and Other Information

Hospitals submit data in *financial* reports, abstracts of medical records, institutional surveys, and other forms of documentation to a number of public and private organizations. In addition to administrative databases, hospitals may maintain detailed *clinical* databases. Both types of data have been used to publish information about the access, quality, and cost of cardiovascular services. The purposes and results of publicly disclosing comparative data on health care institutions and practitioners have varied.

A managed care organization may use the data to select a network of hospitals and monitor the performance of the hospitals with respect to quality and cost.[44] It has been suggested that, if the data are available, health plans should consider quality as well as price when contracting with hospitals; otherwise, they may be at risk of adverse publicity.[45] An agency may release data to generate peer pressure through public knowledge of poor performance and thereby promote competition.[46]

There are concerns, however, about whether the *methods of adjusting* for surgical risks, for example, are adequate. Because administrative data are frequently used to assess the quality of care, researchers have suggested that a limited number of clinical data elements should be added to those databases to improve the assessments.[47] More detailed methods of adjustment using data from registries have altered the rankings of individual hospitals in terms of mortality. Further, professional associations have questioned the role that *public release* of hospital- and physician-specific mortality rates has played in reducing mortality rates nationwide, effectively guiding consumers, or altering the referral patterns of physicians.[48] One survey indicated that such reports may impede access to care for severely ill patients.[49]

In 1998, the Institute of Medicine (IOM) initiated a project to improve the quality of health care in America. In a report on the safety of patients, the IOM committee overseeing the project recommended the

[44] P. L. Plogman et al., "Anthem Blue Cross and Blue Shield's Coronary Services Network: A Managed Care Organization's Approach to Improving the Quality of Cardiac Care for Its Members," *American Journal of Managed Care* 4 (December 1998): 1679-86.

[45] Lars C. Erickson et al., "The Relationship Between Managed Care Insurance and Use of Lower-Mortality Hospitals for CABG Surgery," *JAMA* 283 (April 19, 2000): 1976-1982.

[46] Mark R. Chassin, "Measuring and Improving Quality in Health Care," in *Health Care Policy and Regulation*, ed. Thomas A. Abbott, III (Boston: Kluwer Academic Publishers, 1995), 231-235.

[47] E L. Hannan et al., "Using Medicare Claims Data to Assess Provider Quality for CABG Surgery: Does It Work Well Enough?" *Health Services Research* 31 (February 1997): 659-78.

[48] Eagle et al., "ACC/AHA Guidelines for Coronary Artery Bypass Graft Surgery," 1464-1480.

[49] Eric C. Schneider and Arnold M. Epstein, "Influence of Cardiac-Surgery Performance Reports on Referral Practices and Access to Care: A Survey of Cardiovascular Specialists," *New England Journal of Medicine* 335 (July 25, 1996): 251-256.

following:

> A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. . . . Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; . . .

Recognizing the significant costs associated with reporting systems, the committee recommended a narrowly-defined focus.[50] Other organizations, however, have expressed the view that sanctions linked to *mandatory reporting* are likely to result in fewer events being reported.[51]

Government Oversight of Cardiac Surgery Services in Maryland

The Commission shares regulatory oversight of cardiovascular and other specialized services with several other State agencies, including the Department of Health and Mental Hygiene (DHMH), the Health Services Cost Review Commission (HSCRC), and the Maryland Institute for Emergency Medical Services Systems (MIEMSS). The related functions of each agency are described briefly.

Department of Health and Mental Hygiene. State law requires all hospitals in Maryland to be licensed by the Department of Health and Mental Hygiene. To qualify for a license under § 19-319(c)(1) of the Health-General Article, a hospital must have a certificate of need, as specified in the statute.

In carrying out their responsibilities, both the Commission and the Department of Health and Mental Hygiene are required to recognize but not duplicate standards or requirements related to quality that national accrediting authorities have adopted and enforced. Like most states, Maryland uses a deeming process for hospitals. Hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are deemed to have met the State's standards for licensure. In the mid-1980s, the State added the following requirements as a condition of licensure: a program for reviewing utilization, a process for granting privileges to physicians, and a program for managing risks. In the 1990s, the State amended the rules and regulations for licensure to require a protocol for the procurement of organs and tissues. Each hospital must submit an annual report to the Department.

The law provides for on-site inspections of accredited hospitals to investigate certain complaints and to review compliance with the added requirements for licensure or corrective actions related to certain findings of JCAHO. The sanctions under State law include

[50] Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy Press, 2000), 86-108.

[51] Crafton, "Current and Future JCAHO Requirements," July 13, 2000.

revocation of the license or imposition of a fine.

Accreditation by JCAHO is voluntary. For any Maryland hospital that is not accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Department will use the standards of review of the Joint Commission as well as standards adopted by the Department, as described previously.

The Department refers requests for public information to the hospital, which is required to release the information within 15 days. Any deficiencies resulting from the investigation of complaints are public information as soon as the Department informs the hospital about them.[52]

The Department has the authority to adopt guidelines governing the transfer of patients between hospitals. It is also authorized by law to establish standards related to the quality of care provided by health maintenance organizations.

With the enactment of Senate Bill 492 in 1985, a certificate of need was no longer required for the addition of a new hospital service if the new service was entirely associated with the operation of medical equipment. Under the authority of Health-General Article, § 19-1001 *et seq*., the Department adopted regulations to license major medical equipment. The regulations became effective in 1985 and covered stationary equipment necessary to perform cardiac catheterization. Acts 1995, chapter 499, section 4 repealed the subtitle on major medical equipment. In July 1999, the Department repealed its regulations and adopted new regulations under the authority of § 19-3B-01 *et seq*. The new regulations, which became effective on August 23, 1999, cover freestanding major medical equipment facilities.

Health Services Cost Review Commission. Like the Commission and the Department, the Health Services Cost Review Commission derives its authority to regulate the nonfederal hospitals in Maryland from Title 19 of the Health-General Article. The HSCRC reviews and approves the reasonableness of the rates of hospitals. It is responsible for assuring each purchaser of hospital services, and the public, that the total costs of all hospital services are reasonable, aggregate rates are related reasonably to aggregate costs, and rates are set equitably among all purchasers of services without undue discrimination.

The HSCRC requires each hospital to disclose publicly its financial position. It approves rates that will allow an effective, efficient hospital to remain solvent. In adopting standards regarding cost, efficiency, cost-effectiveness, or financial feasibility, the MHCC is required to take into account the relevant methodologies of the Health Services Cost Review Commission.

The HSCRC sets the rates each hospital is allowed to charge for a unit of service in the various departments of the hospital. A hospital's rates for cardiac surgery are determined based on the inclusion of various cost centers (for example, operating room and

[52] Carol Benner, Director of the Office of Health Care Quality in the Maryland Department of Health and Mental Hygiene, "Hospital and ASF Complaints Received" (presentation at the meeting of the Hospital and Ambulatory Surgery Facility Report Card Steering Committee of the Maryland Health Care Commission, Baltimore, May 1, 2000.)

coronary care unit). The rates for cardiac catheterization laboratories are based on Maryland relative value units (RVUs). This system of pricing assigns a number to various procedures based upon the relative amount of labor, supplies, and capital needed to perform the procedure. The unit value represents the costs of performing one service relative to another service, which is used as a base (that is, has a unit value of one).

The Federal government's Medicare program has instituted a prospective payment system for hospitals in every state except Maryland. Based on a Federal waiver, Medicare and Medicaid pay the HSCRC-approved rates. Hospital uncompensated care is financed through the system. Maryland law requires the HSCRC to assess the underlying causes of hospital uncompensated care and make recommendations to the General Assembly on the most appropriate alternatives to reduce uncompensated care and assure the integrity of the payment system. The HSCRC is in the process of implementing a redesign of its rate-setting system.

Maryland Institute for Emergency Medical Services Systems. An independent agency governed by the State Emergency Medical Services Board, MIEMSS is responsible for coordinating all emergency medical services in Maryland. Under the authority of the Education Article, §§ 13-509 and 13-510, MIEMSS establishes the criteria for designating trauma and specialty referral centers and coordinates the development of trauma and specialty referral centers. Specialty referral centers include Maryland hospitals that have been designated to provide care for a specific patient population with needs for special care (for example, burn or neonatal intensive care), and out-of-state hospitals that have entered into an agreement with MIEMSS to provide specialty care. MIEMSS has also established protocols for transferring critically ill or injured patients between facilities.

Maryland Board of Nursing. The Maryland Board of Nursing ensures that qualified individuals practice nursing in the state. The Board reviews the content of educational programs for nurse practitioners and approves or disapproves the programs based on the criteria established by the Board. The Board also provides staff support to the Statewide Commission on the Crisis in Nursing, created in 2000 by the Maryland General Assembly to determine the implications of the growing shortage of nurses in the state and report its findings and recommendations annually. All areas of practice appear to be affected by the shortage.

Clinical nurse specialists often provide care in specialized areas such as cardiac or neonatal nursing. Hospitals generally establish a process for reviewing the credentials of a registered nurse qualified for advanced practice by education, clinical training, and experience. That process is in addition to regulation by the Board of Nursing.

Board of Physician Quality Assurance. The Board of Physician Quality Assurance (BPQA) establishes and enforces standards for licensing physicians and allied health professionals. Effective October 1, 1999, BPQA creates a profile on each licensed physician and provides the profiles for access by consumers. In conjunction with BPQA's process and cycle for renewing medical licenses, the Maryland Health Care

Commission collects data on the practices of physicians. The data are used to support the planning functions of other agencies, including the designation of health professional shortage areas.

Maryland Health Care Commission. The Federal law that created certificate of need programs in 1974 emphasized the elimination of unnecessary duplication in facilities and equipment. Its requirements resulted in a uniform structure, operation, and performance of functions nationwide. State health plans and the criteria governing reviews under the CON program were to reflect national guidelines. The integration of planning at the state and local levels was designed to promote a comprehensive, rational approach to making regulatory decisions.

In the case of specialized services, national standards were established to support maintaining and strengthening the skills of costly, highly specialized personnel. In addition to helping to promote efficiency and restrain costs, the production of an adequate supply and distribution of health resources was intended to help make equal access to a high quality of care possible for everyone.

When the Federal law expired in 1986, eliminating the Federal funding for State CON programs in 1987, Maryland continued to support and operate the health planning and CON programs. The MHCC is responsible for developing the State health plan for licensed entities that are required to obtain a CON or a CON exemption, and administering the CON program. Additional responsibilities include, among others, the collection, management, and analysis of information on health care cost and utilization, and the development of quality and performance measures for health maintenance organizations, nursing homes, ambulatory surgery centers, and hospitals.

The Health-General Article of the Annotated Code of Maryland requires the MHCC to adopt a State health plan. The law also gives the Commission the authority to develop standards and policies consistent with the State health plan that relate to the CON program. The standards shall address the availability, accessibility, cost, and quality of health care.

The *State Health Plan: Specialized Health Care Services – Cardiac Surgery and Therapeutic Catheterization Services* (COMAR 10.24.17) includes a statement of principles for planning specialized health care services. The principles were also used to develop the regulations governing organ transplant and neonatal intensive care services. The key values represented by the principles emphasize matching the major health problems of the population to effective interventions; integrating levels of care within the regional delivery system; balancing optimal health outcomes and cost-efficiency; and achieving equity in terms of reasonable access to services and assurance of quality.

The *Plan* establishes minimum levels of utilization, a three-year horizon for projecting the need for services (shorter than previous plans), a policy requiring a merged hospital system to obtain a CON to relocate capacity to another hospital within the system (not addressed in previous plans), and a provision for exemptions for research proposals (also not in previous plans). It includes requirements for programs to review the quality of care. Based on the guidelines of

professional associations and the advice of clinical experts, the *Plan* retained the requirement that hospitals offering therapeutic catheterization services shall have on-site cardiac surgical backup.

In Maryland, a person is required by law to have a certificate of need issued by the Commission before developing, operating, or participating in any health care projects for which a CON is required. As of July 1, 1988, the establishment of a new open heart surgery, organ transplant surgery, burn or neonatal intensive care service requires a certificate of need, regardless of the amount of revenue generated. Prior to that date, the establishment of a new health care service was covered by CON if the service would generate more than the specified threshold for annual operating revenue.

The MHCC evaluates CON applications according to all relevant standards, policies, and criteria in the *State Health Plan*, as well as other criteria for review in the Commission's regulations governing CON determinations. The CON regulations specify that a CON is not required for a new health care service entirely associated with the use of medical equipment, including diagnostic cardiac catheterization. A new organ transplantation or open heart surgery program in which the use of medical equipment is merely incidental, however, is subject to CON review.

Maryland Certificate of Need Regulation Compared to Other States

As one response to the changing environment (including the elimination of Federal support in the 1980s), some States have eliminated their CON programs, while others have modified the programs and continue to use them in combination with other regulatory programs. Overall, 27 states and the District of Columbia (55 percent) regulate cardiovascular services through CON.

The activities of several states that responded to a survey conducted by the Commission are described briefly; their experiences may serve as a model for Maryland or other states. Among the major findings of the survey were that most States with specific standards included requirements to perform minimum volumes as one indicator of quality (93% of the 28), and most required facilities that perform therapeutic cardiac catheterization procedures to have on-site cardiac surgical backup (79%). A State CON program may have the authority to monitor or enforce standards after the issuance of a CON, but the available resources and other factors may limit its ability to do so.

Massachusetts. The Massachusetts Department of Public Health administers the Determination of Need Program, which evaluates DoN (CON) proposals. Massachusetts requires a DoN for open heart surgery services. In 1997, the State removed cardiac catheterization services from the list of services covered by DoN and added requirements for licensing cardiac catheterization services in hospitals. A hospital must reapply for licensure of the cardiac catheterization service when the hospital's license is renewed.

A multidisciplinary committee advises the Department on issues related to diagnostic and therapeutic catheterization services licensed by the Department. The committee

has the authority to recommend that a service performing within a certain range of volume continue to be licensed or be delicensed, or that a hospital may allow physicians performing within a certain range of volume to continue performing cardiac catheterization procedures at the hospital. The privileges of some physicians have been affected as part of a hospital's plan for correcting the deficiency.

To measure compliance with the licensing regulations, the Department developed an instrument for collecting data, now in its third year of use. The Department is developing a process to review those services performing within a certain range of volume, as specified in the regulations.

Five hospitals in Massachusetts participated in the Atlantic C-PORT trial. The Department has amended its licensing rules to include provisions for a special project allowing primary angioplasty at approved hospitals without cardiac surgery services. Requirements for continued operation include a minimum number of procedures annually. An Atlantic C-PORT investigator from Maryland will provide the required training for the hospitals. There are no limits on the number of hospitals that can apply for the waiver, or on the time frame for the project.

Massachusetts has 11 hospitals that provide open heart surgery services, and those facilities also provide therapeutic catheterization. Mergers have resulted in a number of community hospitals becoming part of the health systems of teaching hospitals. This development contributed to a change in the view that community hospitals should not perform open heart surgery. On July 28, 2000, the governor signed into law a bill to approve the development and operation of new open heart surgery pilot programs at seven community hospitals in the state. The criteria for approval include an affiliation agreement with an academic medical center that has an accredited primary thoracic surgery residency program; a cardiac catheterization laboratory that meets the standards of the Department; a potential to reach and maintain a minimum volume of open heart surgery procedures; and a demonstrated ability to finance any necessary capital improvements and operating expenses. The law also provides for the Department of Public Health to conduct an annual evaluation of all cardiac surgery programs, including an overall review of the quality of the service and the impact of the developing programs on the academic medical centers and community hospitals.

Massachusetts collects administrative data on patients undergoing cardiac surgery. The State is considering working with the Society of Thoracic Surgeons, which maintains a national database, to collect data on the outcomes of cardiac surgery performed in the state.[53]

Nevada. The Nevada Division of Health operates a CON Program, but does not require a certificate of need for cardiac surgery or catheterization services. The Division has had regulations governing the licensure of open heart surgery services since 1989. An approved hospital receives a special designation on its license.

[53] Massachusetts Department of Public Health, Joan Gorga, personal communication, July 19, 2000; Maureen Foley, personal communication, July 21, 2000.

In 1999, the State amended the licensing regulations to require a review and inspection each year instead of every five years. Each approved hospital must maintain a registry to record the results of open heart surgery for each patient. The on-site inspection includes a review of the registry. Nevada does not require approved hospitals to submit the data. The Division may deny, suspend, or revoke its approval if a hospital fails to comply with any provision in the regulations, which include requirements for a minimum number of operations to be performed and the adjusted rate of mortality to be reviewed.

Nevada has six hospitals with open heart surgery services. Because of significant growth in the population of Las Vegas (about 6,000 persons have moved to the area each month during the last five years), the Division expects the number of hospitals requesting approval for open heart surgery services to increase in that area of the state. Three new hospitals, each with 300 or more beds, have been built there in the last five years.[54]

New York. The New York State Department of Health has adopted rules to evaluate CON applications for cardiac catheterization and cardiac surgical services. The Department has also adopted rules for existing cardiac diagnostic and surgical centers, to which it issues operating certificates. The rules have been in effect since the early 1970s.

The Department has established an advisory committee; members of the committee serve four-year terms and include out-of-state specialists. Although the regulations provide for visits to existing and prospective new centers, the committee does not typically conduct such visits. The regulations also provide for waivers, but to waive a standard would be highly unusual. If an affiliation agreement is required, the outcomes of the affiliate are also examined to assure that the quality of service is adequate.

New York has 35 cardiac surgical centers and 75 cardiac diagnostic centers (including the surgical centers). The Department uses risk-adjusted mortality rates to review applications for certificates, and publishes the information by hospital and surgeon. Data are collected and reported annually. Hospitals have access to their data and can take corrective action (including voluntary suspension of the service) before the State intervenes.[55]

Ohio. The Ohio Department of Health operates a Certificate of Need Program, but does not require a CON for cardiac surgery or catheterization services. To monitor changes in the availability of cardiovascular services, the State requires hospitals that plan to offer the services to file notices of intent.

Ohio deregulated open heart surgery and cardiac catheterization services on March 1, 1998. The Department placed a moratorium on adult low-risk cardiac catheterization laboratories, which it lifted when new regulations were issued, effective in January 2000. Between March 1998 and June 1999, hospitals established eight new open heart programs. All of the new programs were in community hospitals. Ohio has about 40

[54] Nevada State Division of Health, Diane Allen, personal communication, July 25, 2000.

[55] New York State Department of Health, Donna Doran, personal communication, July 24, 2000.

hospitals that provide open heart surgery and therapeutic catheterization services.

Ohio does not have a program to license hospitals, but individual services are subject to review for quality of care. Existing institutional providers must register with the State and submit aggregate data on outcomes, as required by the rules governing the quality of cardiac services. In 1999, hospitals began submitting selected data elements for services provided during 1998. The aggregate data are available to the public.

Volume goals cannot be the sole indicator of service performance. The Department considers volumes of procedures in conjunction with data on outcomes and other indicators of quality; however, failure to meet a specified number of procedures for two consecutive years will trigger an extended review of a cardiac service. In one case requiring further review, the Department contracted with a physician to review the records of the facility. Penalties for noncompliance include the imposition of a fine and cessation of services.[56]

Pennsylvania. In 1998, the Pennsylvania Department of Health adopted rules and regulations for the licensure of open heart surgical services and cardiac catheterization services. When a sunset clause in the State's statutes resulted in the official end of the CON Program in December 1996, the Department amended its requirements for licensure to assure continued enforcement of certain aspects of quality of care previously addressed through the CON Program.

The Department requires hospitals providing cardiac services to report data on mortality and morbidity, infections and complications, patient risk factors, and the volume of procedures performed. To satisfy the reporting requirement for open heart surgical services, a hospital may submit information that its thoracic surgeons report to the Risk Stratification Program of the Society of Thoracic Surgeons.

If a review of the information leads to concerns about the quality of care, the Department will review the program to determine whether the concerns are valid. The Department's review is intended to identify trends of performance. The Department of Health shares data with the Pennsylvania Health Care Cost Containment Council (PHC4) and has begun to use the Council's data on outcomes to make decisions about licensure.[57]

The Pennsylvania Health Care Cost Containment Council is an independent State agency established in 1986 to address the rapid growth of health care costs. Its strategy to contain costs is to promote competition in the health care market by giving comparative information to consumers and payers. Providers of health care are expected to use the information to identify opportunities to contain costs and improve quality. The Council prepares an annual report on the financial status of hospitals in Pennsylvania.

[56] Ohio Department of Health, Christine Kenney, personal communication, July 19, 2000; Katherine Kimmet, personal communication, July 25, 2000.

[57] Pennsylvania, Title 28, Part IV, Subpart B, Chapter 136 and Chapter 138, *Pennsylvania Bulletin* 28 (June 6, 1998).

Recent trends have shown a reduction in the financial viability of hospitals in the state.

As part of its strategy, the Council publishes risk-adjusted mortality rates for coronary artery bypass graft (CABG) surgery by hospital and surgeon. Significant resources are used for data collection, verification, and processing; physician-specific information requires more resources than hospital-specific information. The Council asks each surgeon to examine the data and verify the assignment of the case.

The Council collects additional data on the severity of conditions treated by hospitals. The hospitals must pay a licensing fee for software that is used in abstracting the clinical data from medical records; initially, some institutions resisted the use of a particular product. The actual abstraction of the data represents most of the cost.

Hospitals have urged the Council to link its databases with those of the Department of Health, to include other adjustments related to risk (such as readmission), and to look beyond mortality and consider quality of care in a more comprehensive way. The Council does not examine institutional variables that might affect the quality of care.

The Council has the authority to impose penalties for noncompliance. To encourage compliance, it issues certificates of excellence for accurate and timely reporting, and publishes the names of hospitals that do not comply with reporting requirements. Collecting only needed data and educating individuals about methods and usefulness are important in this effort. Since deregulation, the Council has noted an increase in the number of Pennsylvania hospitals that provide cardiac surgery (from about 38 then to about 50 now). Many are smaller, community-based hospitals. The legislation that created PHC4 gave the Council the responsibility of studying, upon request, the issue of access to care for uninsured residents. The Council has not addressed the issue recently.[58]

Rhode Island. The Rhode Island Department of Health has adopted standards for designating coronary artery bypass graft surgical programs and coronary angioplasty programs at licensed hospitals in the state. The regulations became effective in June 2000. Rhode Island also requires a certificate of need for cardiac services.

State law authorizes the Department to adopt licensing standards for specific tertiary health care services where peer-reviewed medical and health literature establishes significant relationships between desired quality-related outcomes and the volume of services provided. The regulations include minimum standards for volume and survival rates. Hospitals with approved programs must maintain a database that is sufficient to analyze outcomes; each fiscal year, they must report aggregate data to the Department. Rhode Island is considering using the national database of the Society of Thoracic Surgeons in its assessment of the survival rates of surgical programs. The State operated a

[58] Joe Martin, Director of Communications and Education for the Pennsylvania Health Care Cost Containment Council, "Pennsylvania Health Care Cost Containment Council" (presentation at the meeting of the Hospital and Ambulatory Surgery Facility Report Card Steering Committee of the Maryland Health Care Commission, Baltimore, June 5, 2000.)

Cardiac Services Registry, but found it to be very expensive.

Each hospital must renew the designation of its program annually. A hospital's failure to maintain compliance with the standards may result in revocation or suspension of the designation of its program, with possible cessation of the program's activities. Public information includes any final action taken by the Department as well as the statistics reported to the Department.

Two hospitals in Rhode Island offer open heart surgery services. A third hospital has submitted a CON application to establish a coronary artery bypass graft surgical program.[59]

Minnesota. In 1984, Minnesota repealed its CON program and enacted a moratorium on hospital construction or modification. Still in effect, the moratorium covers projects that establish a new hospital, increase the bed capacity of a hospital, relocate hospital beds from one physical facility, complex, or site to another, or otherwise result in an increase or redistribution of hospital beds within the state. The law identifies categories of projects that are not covered, such as construction or relocation within a county by a national referral center that receives more than 40 percent of its patients from outside the state. The legislature has granted exemptions to three projects.

Generally, hospitals have chosen not to delicense beds. One hospital that is interested in establishing a new suburban hospital has requested that the Minnesota Department of Health, within its health planning authority, conduct an administrative review to determine if the moratorium is leading to problems related to access. The proposed hospital would provide open heart surgery services in an area where there is an existing program. Examination of that issue has been limited by the data-sharing agreement of the hospital association, which collects the data needed for the analysis.

Minnesota also enacted legislation that requires a provider making a major spending commitment after April 1, 1992, to notify the Department of Health and report relevant information to the Department. The requirement covers expenditures over $500,000 for such projects as the acquisition of a unit of medical equipment or the offering of a new specialized service, including open heart surgery services and cardiac catheterization services for high-risk patients.

The Department conducts a retrospective review of the information, which must include statements about the availability of equivalent services to the actual and potential patient population. The Department is required to determine whether the expenditure was appropriate and notify the provider of the results of the review. The law does not provide for the Department to prevent or prohibit a major spending commitment that is subject to retrospective review; however, prospective review and approval may be the penalty for failing a retrospective review or not complying with the reporting requirements. To date, the Department has made one provider's major expenditures subject to prospective review for a five-year period. The Department has not required

[59] Rhode Island Department of Health, Michael Dexter, personal communication, July 19, 2000; Wayne Farrington, personal communication, July 21, 2000.

prospective review for any open heart surgery program. Most of the process has involved gathering information.[60]

Arizona. In March 1985, the rules for the Arizona Certificate of Need Program expired. During the initial period of deregulation, from 1985 to 1987, the number of hospitals performing coronary bypass procedures on adult patients increased from six to 16 facilities (excluding a federal hospital).[61] By 1998, there were 23 nonfederal hospitals (excluding a pediatric hospital) that reported discharges of patients who had received coronary bypass procedures. The Arizona Department of Health Services makes available to the public information about the number of discharges, average length of stay, and average charge by diagnosis related group for each hospital.[62]

Other findings of the survey were:

- Most states continue to operate certificate of need (CON) programs. Most states with CON programs regulate cardiovascular health care services.
- The laws, rules, regulations, plans, and guidelines used by state CON programs show that they have retained the broad, sometimes competing, goals of the Federal legislation that created the health planning and resources development program: equal access to quality health care at a reasonable cost.
- States that repealed or allowed the CON program to sunset did not systematically study the effects after the expiration of the program. This finding also holds for examining the effects of deregulating cardiovascular services beyond reporting any changes in the supply of cardiovascular programs.
- States reported using various mechanisms to finance uncompensated care in general. Only one financed hospital uncompensated care through a state rate-setting system that covers private and public payers, including Medicare.
- States have shared a wide range of data and information on the use of cardiovascular services with physicians, hospitals, and the general public, to the extent that state laws and rules permit.

Alternative Regulatory Strategies: An Examination of Certificate of Need Policy Options

Several policy options considered by the Commission in conducting this study of CON

[60] Minnesota Department of Health, Stefan Gildemeister, personal communication, July 25, 2000; Cathy Malave, personal communication, July 25, 2000.

[61] Jeremy Voas, ed., "Special Report: Open market, open heart," *The Phoenix Gazette*, August 26, 1987.

[62] Arizona Department of Health Services, *Discharges by Hospital and DRG for 7-1-1998 through 12-31-1998*; available from www.hs.state.az.us/plan/hosp.htm; Internet; accessed April 11, 2000.

regulation of cardiac surgery services are presented and discussed below.

Option 1-Maintain Existing Certificate of Need Regulation

Under this option, the Commission would continue to require a certificate of need for the establishment of a new open heart surgery service. A certificate of need would not be required for a new diagnostic cardiac catheterization service. The regulation of therapeutic cardiac catheterization would result from the requirement for on-site open heart surgery backup. The Commission would continue to develop a statewide plan establishing the number and distribution of open heart surgery programs needed in Maryland, and would adopt the plan as a regulation. Before approving an application for a new open heart surgery program, the Commission would evaluate the CON application according to the plan and the CON criteria for review, also adopted as a regulation. The Commission may withdraw a CON for failure to comply with the conditions of approval.

Option 2-Expand CON Regulation

Under this option, provisions in the law for the CON program to regulate services provided by cardiac catheterization laboratories in hospitals would be restored. The Commission's current regulations specify that a CON is not required for a new health care service entirely associated with the use of medical equipment, including diagnostic cardiac catheterization. In 1985, the Maryland General Assembly deregulated major medical equipment from CON review, and the Department of Health and Mental Hygiene adopted regulations to license major medical equipment, including stationary equipment necessary to perform cardiac catheterization. Chapter 499 of the Acts of 1995 repealed the authority of the Department to regulate major medical equipment under Health-General Article, § 19-1001 *et seq*., Annotated Code of Maryland. The bill defined facilities that use major medical equipment as freestanding ambulatory care facilities to be licensed and regulated under a new statute.

The Health Services Cost Review Commission has approved rates for cardiac catheterization laboratories at 37 hospitals. Technological advances have helped increase the use of therapeutic procedures in cardiac catheterization laboratories; however, it is not recommended that angioplasty be performed at every hospital with a cardiac catheterization laboratory. The joint guidelines of the American College of Cardiology and the American Heart Association continue to recommend, without exception, that angioplasty should be limited to institutions with cardiovascular surgical backup. Under this option, the establishment of therapeutic cardiac catheterization services would be regulated directly under the CON program.

Provide additional sanctions for failure to comply with CON conditions. Provisions for the Commission to withdraw the affected CON and consider a provider's noncompliance during the evaluation of any future CON applications would continue. If a health care facility failed to provide information required by regulation, the Commission would continue to have the authority to impose a monetary penalty during the period of the violation, issue an

administrative order requiring the information, or apply to the court for legal relief. Other sanctions may include imposing a civil fine in the amount of the charges for the services provided in violation of the CON, publicizing the violation or enforcement, prohibiting the provider from recovering costs for services provided in violation of the CON, or requiring the provider to refund charges, upon request, to the person or persons from whom the charges were collected.

Option 3-Retain but Restrict CON Regulation

Under this option, the authority of the CON program would be limited to projections of need, and issues related to geographic access and the distribution of services. Projections of need have helped to identify geographic areas of the state that are underserved. The unmet needs of a population would be the focus of the plan and CON review. Standards would address the availability and accessibility of services, but not the cost or quality of the services.

Transfer full authority for the regulation of quality of care and financial access to other State agencies. Require continued coordination among State agencies. The primary indicator of quality of care in the *State Health Plan* is the volume of procedures performed. The literature cautions against the use of data or measures that do not include adjustments for risk factors related to quality of care.

The American College of Surgeons has developed guidelines for minimum volumes of procedures from the standpoint of promoting quality. When the number of open heart operations does not meet the established guidelines, the College recommends the use of peer review.[63]

The *State Health Plan* that was adopted in 1990 required a CON applicant to document that the proposed program would achieve a minimum operating volume within three years. The *Plan* also included policies that required a hospital whose cardiac surgery program had not performed a minimum number of cases to conduct a review of the quality of care and provide the Commission with specific information. According to the policies, a low-volume program whose rates of mortality and morbidity were found to be excessive should terminate its services.

The establishment of the policies and standards in regulation, and the availability of data from discharge abstracts, enabled the Commission, as well as existing and potential providers, to monitor compliance. When a program that was approved in 1990 and initiated in 1992 failed to achieve the projected volumes, the Commission received a report from the hospital itself and an independent evaluation of the review at the request of the hospital.

Consistent with a revised policy in the present *Plan*, a CON issued by the Commission for the establishment of a new cardiac surgery program will require as a condition of issuance that the program achieve minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent

[63] American College of Surgeons, "College Guidelines: Guidelines for Standards in Cardiac Surgery," *Bulletin of the American College of Surgeons* 82 (February 1997): 27-29.

year of operation. If an applicant does not voluntarily terminate a noncompliant program or service, the Commission has developed, by regulation, sanctions, including the cessation of a noncompliant program where appropriate.

The American College of Surgeons has noted that the number of procedures necessary for a program to function efficiently is likely to be considerably higher than the number determined to be sufficient for quality. The HSCRC advises the Commission on the financial feasibility of a hospital's proposal and its impact on the Medicare waiver. Its review of a hospital's proposal is a major determinant of the facility's operating efficiency. Hospital uncompensated care is financed through the rate-setting system. Any imposition of requirements to provide charity care would be enforced by the State agency that is responsible for the system by which hospital uncompensated care is financed.

Several agencies would continue to share oversight of the hospitals that provide cardiovascular services. The Maryland Health Care Commission would continue to coordinate its activities with appropriate planning and regulatory entities.

Option 4-Eliminate CON Regulation

Under this option, cardiac surgery services would be deregulated from CON review. The Commission would retain the planning function to assess geographic access to services and identify any areas of the state that have a substantial deficiency in services. The Commission would establish minimum standards related to geographic access, and examine the patterns of use of available cardiovascular services. Working with public and private entities, the Commission would develop and publish a statewide plan on a periodic basis. The Plan would address the availability and accessibility of cardiac surgery and therapeutic catheterization services to residents of Maryland, and identify possible barriers to access. It would serve as a reference for a variety of persons interested in issues of access, and facilitate the exchange of information.

Require certain data to be reported to assess and improve the performance of providers. Maryland law authorizes the Commission to collect and analyze certain data. The Commission would work with other entities, including national associations that have established cardiovascular data registries, to specify the minimum data needed.

Develop and enforce specific standards for reviewing the quality of cardiovascular services. Creating specific standards for cardiovascular services may increase the effective use of information about facilities that provide the services. The Commission would continue to recognize but not duplicate standards or requirements related to quality that national accrediting or State licensing authorities have adopted and enforced. Licensure could be structured to provide appropriate oversight. This option could include consideration of a moratorium until a system to address quality-related issues is in place. The system could include on-site inspections of the cardiovascular services.

Chapter 657 of the Acts of 1999 provides for the Maryland Health Care Commission, on or before July 1, 2001, to develop and implement a system to comparatively

evaluate the outcomes and performance of hospitals on an objective basis, and annually publish the summary findings of the evaluation. The purpose of establishing such a system of measurement is to improve the quality of care through the use of a common set of measures and the dissemination of the findings to the facilities, consumers, and interested parties. Before adopting the regulations to implement the system, the Commission is required to consider the performance measurements of appropriate accrediting organizations, State licensure regulations, Medicare certification regulations, the quality indicator project of the Association of Maryland Hospitals and Health Systems, and any other relevant performance measurements.

Table 3-7 summarizes the policy options for regulating specialized cardiac care services discussed in this chapter.

Table 3-7
Summary of Regulatory Options for Cardiac Surgery Services

Options	Level of Government Oversight	Description	Administrative Tool
Option 1 Maintain Existing CON Regulation	No Change in Government Oversight	•Market Entry for Cardiac Surgery Regulated by CON •CON Withdrawal for Failure to Comply with Conditions of Approval	Commission Decision (CON)
Option 2 Expand CON Regulation	Increase Government Oversight	•Market Entry Regulated by CON for Cardiac Surgery; New Diagnostic and Therapeutic Cardiac Catheterization Services •CON Withdrawal for Failure to Comply with Conditions of Approval	Commission Decision (CON)
Option 3 Retain but Restrict CON Regulation	Change Government Oversight	•Eliminate CON Authority to Regulate Quality or Financial Access	Commission Decision (CON)
Option 4 Deregulate from CON Review	Change Government Oversight	•No Barrier to Market Entry by CON •Market Exit for Non-Compliance with Licensure Standards	Licensure Standards

Commission Recommendations

Recommendation 2.0

The Commission should continue its regulatory oversight of open heart surgery services through the Certificate of Need program.

Recommendation 2.1

The Commission should establish an Advisory Committee on Outcome Assessment in Cardiovascular Care.

Recommendation 2.2

The Commission should use a well-designed research project to investigate cardiac surgical support for specific groups of patients receiving elective angioplasty.

Recommendation 2.3

The Commission will continue to coordinate its planning and regulatory activities with other entities for the purpose of promoting affordable, accessible, high quality care for all residents of the state. The Maryland Health Care Commission and Health Services Cost Review Commission should monitor changes in market demand and referral patterns as a result of new or expanded open heart surgery services that may affect Maryland's Medicare waiver.

Recommendation 2.4

The Commission should have the authority to revoke its certification if an operating service fails to meet the standards adopted by the Commission. The Commission should conduct a study before seeking the required statutory change.

The Commission recommends that the General Assembly maintain existing Certificate of Need regulation for cardiac surgery services. The Certificate of Need program protects against the establishment of cardiac surgery programs with low volumes and ensures that highly specialized resources and personnel are allocated to appropriately meet community needs. Evidence of an inverse relationship between volume and quality presents a compelling reason for the State to promote high volume cardiac surgery and therapeutic catheterization programs. To review available models of measuring outcomes, develop an agenda on researching the organization of services to improve outcomes, and develop recommendations for an on-going process to assess outcomes of cardiovascular care, the Commission recommends the establishment of an Advisory Committee on Outcome Assessment in Cardiovascular Care. As a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care, the Commission should work to develop a well-designed research project to investigate cardiac surgical support for specific group of patients receiving elective angioplasty. The limited exemption for primary angioplasty performed in hospitals participating in the on-going C-PORT project should be continued.

The Commission also believes that providing financial and geographic access to quality health care services at a reasonable cost for all residents of Maryland will require the efforts of multiple organizations and individuals.

When applying for a CON, an applicant makes a representation to the Commission that the service will meet certain standards when it becomes operational. If a service fails to meet the standards, the service should be given a period of time to remedy the failure. If the noncompliance continues after the period for remedy, the Commission should have the ability to withdraw its certification and the authority to operate the service. Before seeking the necessary change in its statute, the Commission should examine the effectiveness of existing monitoring systems, assess the extent of noncompliance, review past remedial action or enforcement of sanctions, and address other issues, such as shared responsibilities and workload. This study should begin after completion of the current two-year study of the Certificate of Need program and include all services covered by the Certificate of Need program.