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Quality Assurance for Specialized Clinical Services

Conducted Pursuant to HR 356 of 2003

April 2005

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Summary and Recommendations

House Resolution 356 of 2003 directed the Legislative Budget and Finance Committee, in consultation with health care experts and specialists, to study health care services requiring extraordinary expertise and resources, such as cardiac catheterization, open heart surgery, and organ transplants. The resolution also requires identification of standards for the safe and effective provision of such services, including volume proficiency standards, and information on how their quality has been assured since the sunset of Pennsylvania's Certificate of Need Program (CON) in December 1996. Pennsylvania was one of 14 states[1] without CON programs in 2004.

Quality of Care and Patient Safety for Highly Specialized Clinical Services

Certain medical procedures are associated with risks of known serious complications, including death, and have success and failure rates that are associated with operator skill and expertise. Highly specialized clinical services, such as those identified in HR 356, are among the medical procedures with higher risk of serious complications and success and failure rates associated with operator skill and expertise.

As higher risk procedures have been introduced, professionals and health care experts—those closest to the delivery system who see themselves as most responsible for health care quality and safety—have developed practice guidelines for the provision of such services. The American College of Cardiology and the American Heart Association (ACC/AHA), for example, have task forces that regularly gather information based on research findings and make recommendations for the safe and effective provision of therapeutic catheterizations and open heart surgery—the two most common interventional and invasive procedures used to treat heart disease. The ACC/AHA guidelines typically include a variety of standards, including operator and facility proficiency volume standards in view of research showing the relationship between procedural volumes and increased likelihood of patient survival.

Using New York state's mandatory, audited cardiac databases, which were developed and are overseen by a group of cardiologists and national health research experts, Hannon and colleagues found:[2]

- Patients undergoing therapeutic catheterizations (PCI) had higher risk adjusted rates of inpatient deaths and emergency open heart surgery compared to the statewide average when the procedure was performed by cardiologists with annual procedure volumes less than 75 procedures per year, at hospitals performing fewer than 400 procedures per year.
- Patients undergoing open heart surgery (Coronary Artery Bypass Graft, or CABG) performed by higher volume surgeons in higher volume hospitals have the lowest mortality rates. The lowest risk-adjusted CABG mortality occurred for patients undergoing surgery in hospitals with 600 or more CABGs per year and surgeons performing at least 125 procedures per year.

Also using New York's database, Babak and colleagues found:

- Patients receiving therapeutic catheterizations to treat "heart attacks" when procedures were performed by high-volume physicians at high volume hospitals had a 49 percent lower in-hospital mortality rate than those treated at low-volume hospitals. The benefit of procedures performed by high-volume physicians, moreover, was muted when the procedure was performed at a low-volume hospital.

The Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ)—the lead federal agency charged with supporting research designed to improve the quality of patient care and safety—has developed a series of inpatient quality of care indicators. Procedure volumes and mortality are among AHRQ's quality of care indicators. The following Exhibit displays the AHRQ procedure volume and mortality quality indicators for therapeutic catheterization and cardiac surgery along with relevant medical specialty society practice guidelines and reported mortality rates from national cardiology registries. Major health benefit managers involved in promoting health care quality have also developed proficiency volumes for certain highly specialized clinical services. These are also shown. The AHRQ recommends that facilities performing below its minimum procedure benchmarks or having mortality rates above its benchmarks should have their performance reviewed to assure the quality of their care.

[1]Other states without CON programs include: Arizona, California, Colorado, Idaho, Indiana, Kansas, Minnesota, New Mexico, North Dakota, South Dakota, Texas, Utah, and Wyoming.
[2]Citations for the peer reviewed journals in which the research was reported are found in the full report.

Quality of Care Indicators for Highly Specialized Cardiac Services

Therapeutic Catheterization (PCI)

	Procedural Volume	Mortality
AHRQ Quality Benchmark	*Recommended: Facility:* 400 procedures annually. *Minimum: Facility*: 200 procedures annually.	1.46%
ACC/AHA Guidelines	*Recommended:* *Facility*—400 procedures annually. *Operator*—75 procedures annually. *Minimums*: *Facility:* 200 procedures annually. Facilities performing fewer than 200 procedures should carefully consider whether to continue to offer service, unless in a geographically underserved area. *Operators* performing fewer than 75 procedures should develop a defined mentoring relationship with a highly experienced operator who performs greater than 150 procedures annually.	1.4[a]
Other	*Major Employer Group*: Employees should be directed to facilities performing 400 procedures annually.	

Open Heart Surgery (CABG)

	Procedural Volume	Mortality
AHRQ Quality Benchmark	100-200 procedures annually.	3.54%
ACC/AHA Guidelines	Ongoing outcome tracking with close monitoring of individuals and institutions performing fewer than 100 procedures annually.	3.5[b]
Other	*American College of Surgeons*: 100 to 125 cases annually to maintain quality programs, and 200 cases annually for the facility to function efficiently. *Major Employer Group*: 450 procedures annually.	

[a]American College of Cardiology National Cardiovascular Data Registry—Observed Mortality Rate.
[b]Society of Thoracic Surgeons National Cardiac Surgical Database—1994 risk adjusted rate.

Source: Developed by LB&FC staff.

AHRQ does not have quality indicators for organ transplant services. The federal Department of Health and Human Services' Center for Medicare and Medicaid Services (CMS), however, has established proficiency volumes and survival rates for such services, and the federal organ transplant network publishes national survival rates by center volume. The exhibit below provides CMS's proficiency volumes and survival rates.

Center for Medicare and Medicaid's Organ Transplant Quality Indicators

	Heart	Liver	Lung	Kidney[a]
Proficiency Volumes[b]	12 transplants/year	12 transplants/year	10 transplants/year	15 transplants/year
Survival Rates	73% survival after 1 year and 65% after 2 years.	77% survival after 1 year and 60% after 2 years	69% survival after 1 year and 62% after 2 years.	Expected rates vary by age and type of transplant

[a]Medicare's minimum utilization rate for unconditional designation as a renal transplant center. Conditional designation may be granted centers performing 7 to 14 transplants annually.
[b]On February 4, 2005, Medicare proposed revised volumes and survival rates for programs providing transplants to Medicare enrollees.
Source: Developed by LB&FC staff.

State Use of Practice Guidelines and Proficiency Volumes for Highly Specialized Clinical Services

Typically, states that regulate (either through certificate of need and/or licensure) highly specialized clinical services rely on national practice guidelines such as those of the ACC/AHA to assure quality of care. Several neighboring and large states that regulate cardiac services, for example, reference such guidelines and have established provider proficiency volumes as part of their efforts to assure quality of care. Maryland, Massachusetts, New Jersey, and Ohio require that therapeutic catheterization providers perform a minimum of 200 such procedures annually. Florida, Michigan, New York, and West Virginia require 300 or 400 procedures annually.[3] Massachusetts removes the license of diagnostic catheterization providers that do not perform 150 procedures annually.[4]

The Pennsylvania Department of Health previously incorporated nationally recognized practice guidelines, including proficiency volumes, in its State Health Services Plan. As part of the CON program, health care providers seeking to offer highly specialized clinical services in the Commonwealth had to meet the standards

[3]Massachusetts, Michigan, and New Jersey also have established minimum proficiency volumes for physicians performing such highly specialized clinical procedures.
[4]Florida, Maryland, Massachusetts, Michigan, Ohio, and West Virginia require 200 to 300 open heart procedures annually for facilities. New Jersey requires 350 procedures and New York 500. Massachusetts, Michigan, and West Virginia also have minimum physician proficiency volumes.

incorporated into the plan. With the sunset of the CON program in December 1996, Pennsylvania health care facilities were no longer required to comply with the plan's quality assurance standards.

In January 1997, therefore, the Department established work groups to review relevant plan parts to determine if it included quality assurance and patient safety criteria that should be added to existing licensure regulations. The work groups reported to the Secretary of Health that the state's licensure regulations did not include standards in national practice guidelines[5] and recommended revision of hospital licensure regulations to address cardiac catheterization, open heart surgery, and vital organ transplantation.

In 1998, the Department of Health issued regulations which incorporated many of the work groups' recommendations and some parts of national practice guideline standards. The final regulations issued by the Department, however, did not include specific proficiency volume or other quality performance benchmarks. They also did not provide for the cardiac oversight committee recommended by work groups to assist the Department with review of clinical performance data for certain services, which cardiac service providers routinely submitted to the Department.

The Department's 1998 regulations required hospitals performing highly specialized cardiac procedures to maintain and provide the Department on a quarterly basis data on:

- Patient mortality and morbidity.
- Infection and complications (such as rates of stroke, myocardial infarction, vascular complications, and emergency bypass surgery associated with therapeutic catheterizations).
- Patient risk factors.
- Volume of procedures performed.

The regulations also required hospitals to integrate such data into their quality assurance programs. In the preamble to its regulations, the Department indicated it would review the required data, and if its review raised quality of care concerns, the Department would undertake a review to determine if the concerns were valid.

In its proposed regulations for cardiac catheterization services, the Department indicated it would publish proposed values for the quality performance

[5]In 2003, when the Governor issued a comprehensive Medical Malpractice Liability Reform Plan to address state medical malpractice issues and improve patient safety, it provided for a series of reforms, including the drafting of new hospital regulations to replace current regulations that are basically 20 years old. The Governor's Office of Health Care Reform has been working with the Department to revise the state's hospital licensure regulations. The Department had not published such proposed regulations as of January 2005.

measure that might trigger further review by the Department. When issuing final regulations, the Department indicated it would not identify values that might trigger a performance review, noting that it did not think low procedure volume "proved" a quality of care problem. The preamble was silent on whether other quality performance indicators, such as patient death rates or higher than expected procedural complication rates, might trigger a quality assurance review by the Department.

In an effort to avoid duplicate data collection, the Department later advised hospitals they were no longer required to submit cardiac data they had been submitting to the Department, noting that the data hospitals submitted to the Pennsylvania Health Care Cost Containment Council (PHC4) would meet hospital licensure requirements. The data collected by the PHC4, [6] however, does not currently address all of the items previously reported to the Department and needed to address relevant patient risk factors and complications identified in DOH hospital regulations.

The Department also entered into an agreement with the Council for annual cardiac service reports that include proficiency volumes and other performance data. Since 1998, the PHC4 has provided such reports to the Department of Health for its use in identifying potential quality of care problems for highly specialized clinical services. The LB&FC staff reviewed the reports PHC4 prepares for the Department and other relevant data. We found:

- *Since 1996, the number of hospitals offering specialized cardiac services has substantially increased.* As of mid-2002, 38 of Pennsylvania's 67 counties had cardiac catheterization laboratories—seven more counties than in 1996, with an additional 15 counties having more laboratories than they did in 1996. Twenty-seven counties had open heart surgery programs—six more than in 1996, with nine counties having more programs than in 1996.

  In some areas, proliferation of cardiac services has occurred. Luzerne County, for example, went from having one open heart surgery program in 1996 to three in 2002, and Chester County went from having no program to three. The report lists the 107 facilities providing diagnostic catheterization (including the 21 post-CON programs), 68 providing therapeutic catheterizations (including 31 post-CON programs), and the 65 open heart surgery programs (including 23 post-CON programs) through December 2003.

[6]The Council's rich data set, does not include many of the items previously collected by the Department to take into account patient and procedure risk, such as the patient's New York Heart Association classification, or relevant patient outcomes such as rates of emergency bypass surgery and stroke associated with cardiac catheterizations. The Council's data for cardiovascular services, moreover, does not include 70 percent of the data reported to the American College of Cardiology National Cardiovascular Data Registry, and important elements required to adequately adjust for patient and procedural risk.

- *In 2002, one-third (7 of 21) of the cardiac catheterization programs with open heart surgery that started after the sunset of CON were not meeting the ACC/AHA's minimum proficiency volumes, though all adult cardiac catheterization facilities with open heart surgery programs approved under CON were meeting them.* The AHRQ recommends that when facilities do not meet its minimum procedural volume for therapeutic catheterizations, further review occur to assess the program's quality of care. The ACC/AHA suggests that programs not meeting its minimum proficiency volumes consider whether to continue their programs, unless they operate in an underserved geographic region.

- *The average number of catheterizations performed by programs without open heart surgery programs declined between 1996 and 2002, resulting in more of these diagnostic catheterization programs not meeting the volume proficiency standards that had been in place in the Department of Health's last State Health Service Plan (300 procedures annually).* Fourteen of the catheterization programs without open heart surgery performed fewer than 300 procedures annually in 1996, including two that performed fewer than 100 procedures. By 2002, the number of programs performing fewer than 300 procedures increased to 27, with 7 performing fewer than 100 procedures. Eleven of these programs would be "delicensed" if operating in Massachusetts, and the remainder be subjected to quality assurance review by the state licensure agency and its cardiac advisory committee.

- *Pennsylvania facilities are performing more therapeutic catheterizations than expected based on the federal AHRQ quality utilization indicator.* Utilization rates are also relevant quality of care indicators since rates for certain procedures vary widely with differences not accounted for by age or clinical factors. AHRQ reports the expected rate of therapeutic catheterizations is 528.16 procedures per 100,000 population at risk (i.e., those 40 years and older). Based on AHRQ's quality utilization indicator and state population data, Pennsylvania would expect to have had approximately 30,000 therapeutic catheterizations performed in 2000. Significantly more (over 40,000 annually), however were reported in the FY 1999-00 and FY 2000-01 Department of Health Annual Hospital Questionnaire Data.

- *Therapeutic catheterization mortality rates are higher at facilities that do not meet the ACC/AHA and AHRQ recommended proficiency procedural volumes.* Pennsylvania facilities' performance was consistent with the literature. Facilities performing more than 400 therapeutic catheterizations annually had average observed mortality rates of 1.35 percent, while those performing fewer than 100 procedures had a 1.78 percent average mortality rate. Eighty-seven percent of the approximately 155,000 catheterizations in our analysis were performed by high volume facilities. Nonetheless, 6 of the 18 facilities in our analysis performing fewer than 200 therapeutic catheterizations annually had mortality rates

greater than the AHRQ mortality benchmark (1.46 percent) that should trigger a quality assurance review.

- *New York's observed mortality rate for therapeutic catheterizations is roughly half that of Pennsylvania's.* In 2002, Pennsylvania's therapeutic catheterization providers had a 1.28 percent observed mortality rate compared with New York's rate of 0.70 percent for the same period. When multi-year data (2000 through 2002) are considered, Pennsylvania providers had a 1.45 percent mortality compared with New York's rate of 0.72 percent. New York providers performed an average number of procedures roughly twice that of Pennsylvania providers.

- *PHC4 reports prepared for the Department of Health identify deaths of patients receiving outpatient diagnostic and therapeutic catheterizations each year since 1998.* In 2003, nine facilities reported deaths of nine patients that received outpatient diagnostic catheterizations, and five reported deaths of five patients that received outpatient therapeutic catheterizations. The Department of Health's 1998 licensure regulations indicate outpatient catheterizations are only to be performed for low-risk patients. The Department, however, did not adopt the last State Health Services Plan definition of low risk patients, did not define "low risk" patients in its 1998 regulations, and did not form a cardiac advisory committee to assist with the development of "low risk" patient criteria, as recommended in 1998 by the Pennsylvania Chapter of the American College of Cardiology.

- *PHC4 reports prepared for the Department of Health show deaths of children receiving open heart surgery at adult open heart surgery program.* In 2003, two open heart surgery deaths for children were reported by adult open heart surgery programs. This is of concern because heart surgery programs for children have different requirements than programs for adults.

- *In late 2002, the Department of Health with limited public input started to issue exceptions to current hospital licensure regulations authorizing selected health care facilities to perform emergency and elective therapeutic catheterizations (PCI) without onsite open heart surgery backup, despite the ACC/AHA practice guidelines recommending most (i.e., elective) therapeutic catheterizations be performed at programs with onsite open heart surgery backup.* The committee of career professional (medical, nursing, legal) staff within the Department responsible for reviewing licensure exception requests denied selected hospitals' requests to perform therapeutic catheterizations without onsite open heart surgery, according to the documentation provided to the LB&FC. ACC/AHA guidelines (and the Pennsylvania Department of Health) recommend that all elective PCI be performed at hospitals with onsite open heart surgery. Subsequently, and without prior notice of the decision being published in the Pennsylvania Bulletin, the then Secretary of Health approved an exception to hospital licensure

regulations to allow certain hospitals without onsite cardiac surgery units to perform emergent and elective PCI as part of a state demonstration. All of the demonstration sites have programs providing therapeutic catheterizations with onsite open heart surgery within the county and/or in neighboring counties. Most (5 of 8) are in areas where not all existing programs are meeting ACC/AHA's minimum proficiency volume standards.

The licensure exceptions issued by the Department are controversial since medical researchers are not in agreement that the benefits to patients outweigh the increased risks associated with provision of PCI without onsite cardiac surgery backup. States that regulate cardiac services, moreover, typically do not permit such procedures.[7]

West Virginia is the only state regulating cardiac services that also has a state PCI demonstration project underway. Pennsylvania's demonstration sites, however, would not meet the criteria West Virginia established for its demonstration. Pennsylvania demonstration sites, for example, are not required to comply with ACC/AHA minimum proficiency guidelines for facilities and operators. Two of three Pennsylvania sites operating in 2003, performed an average of four therapeutic catheterizations monthly—far fewer than the monthly number required to perform a minimum of 200 procedures annually.

Pennsylvania sites do not have standard requirements, such as standardized informed patient consent forms. One site, for example, advises patients there is less than 0.1 percent risk of death associated with therapeutic catheterizations, even though the American College of Cardiology National Cardiovascular Data Registry's observed in-hospital mortality rates for emergent PCI on stable patients is 5.4 percent. In 2004, the Department of Health began requiring new demonstration projects to advise patients of nearby programs able to provide PCI with cardiac surgery backup and require the hospitals to notify their malpractice insurance carriers they are providing therapeutic PCI without onsite cardiac surgery; these steps, however, are not required of the existing demonstration projects.[8]

[7]LB&FC staff reviewed lists of hospitals that report providing elective PCI in states that regulate cardiac services. When we contacted relevant state officials in states such as Iowa, New Hampshire, North Carolina, Tennessee, and Washington, we were advised the state does not permit elective PCI at facilities without onsite open heart surgery programs. We were further advised the hospital "should not be doing it." In the case of a facility in New Hampshire, state officials indicated the hospital started its program prior to state regulation and, therefore, was exempt from the state regulation. Other states on the list are in western states that do not regulate cardiac services. Wharton reported in late 2000 that 68 sites in the United States performed PCI without onsite open heart surgery (out of a total of approximately 800 sites), but only 22 of the 68 performed elective PCI, and many of these sites had low volumes.

[8]Medical malpractice lawsuits are generally based on tort law, which includes both statutes and court decisions. A tort is a wrongful act or omission that causes harm. Typically, a malpractice tort would be based on the claim that the health care provider was negligent, had failed to meet the acceptable standard of care owed to the patient, and thus caused injury to the patient.

In June 2004, the Department for the first time received information for three demonstration sites to review their performance. The reports the Department received were designed by the selected hospitals. They do not identify the number of emergent and elective PCIs performed. They also do not demonstrate that relevant patient selection criteria are being followed, or that procedures were subject to peer review, including instances in which patient death or other adverse patient consequences occurred. They do show, however, that most emergent PCIs are not performed within 120 minutes of arrival at the hospital, as recommended by ACC/AHA guidelines (because of the importance of rapid restoration of blood flow to the heart) and required by the Department of Health as criteria for receipt of a hospital licensure exception.

- One of the three hospitals with licensure exceptions (operating in 2003) did not meet the criteria for any of its relevant patients.

- Two of the three hospitals did not meet the criteria for 60 percent or more of their relevant patients.

LB&FC staff also found discrepancies in the number of procedures and deaths reported by one of the facilities to a voluntary registry for submission to the Department and the data reported to the PHC4 as required by state law. The hospital had reported one death in the catheterization laboratory in the voluntary dataset, though two deaths were captured in the PHC4 dataset. The hospital subsequently advised us it had not reported all therapeutic catheterizations to the PHC4, and confirmed two patient deaths had occurred, as shown in the PHC4 data. Other differences in the reporting occurred because of differences in the way the hospital reported attempted and unsuccessful PCI.[9] Complete reporting to the PHC4 is mandatory in state law.

When the Department of Health initiated the PCI demonstration a national clinical trial was not available for interested hospitals. A national clinical trial is currently being developed. States that regulate cardiac services, including Maryland, New York, New Jersey, and Ohio may allow selected hospitals to participate in the national trial. Researchers from Johns Hopkins are interested in qualified Pennsylvania hospitals participating in the national trial.

- *Despite a 15 percent drop in the number of CABG surgeries from 1995 to 2002, 18 new cardiac surgery programs opened.* The two factors combined have resulted in the average volume of procedures performed in Pennsylvania going from 450 annually—the facility volume required in Pennsylvania's last State Health Services Plan—to 270 procedures. In 2000, New York and New Jersey cardiac service providers were performing over 50 percent more procedures on average than Pennsylvania providers.

[9]LB&FC staff have been advised that attempted and unsuccessful PCI should be rare occurrences.

- *Over one-half of Pennsylvania's transplant programs have lower than expected one year patient survival rates for adult patients receiving kidney, liver, heart, and lung transplants. For most programs, however, the differences between their actual and expected survival rates did not reach thresholds requiring further evaluation by the Organ Procurement and Transplant Network (OPTN)—the federally established organization responsible for the national list of patients waiting for organ transplants and matching organ donors and recipients.* Each transplant program in Pennsylvania has expected patient (and graft) survival rates established by the Scientific Registry of Transplant Recipients (SRTR) based on the characteristics of those served in their programs and the experience of programs nationwide serving similar types of patients during the same timeframe. The SRTR is federally required to post center specific survival and other data at its website twice each year. The SRTR website provides data for groups of transplant recipients at different periods of time, and as a result, a specific center's expected survival and actual survival rates continually change. The SRTR website notes that survival rates cannot be compared across programs. The Medicare program has reported that based on the Scientific Registry data posted in July 2004, 10 percent of the adult kidney, liver, heart and lung programs nationwide had lower than expected one-year patient and graft survival rates and met all of the criteria used by the OPTN to 'flag' possible poor performances. LB&FC staff reviewed similar scientific registry data from January 2005 and found that only 8.62 percent of Pennsylvania's programs had lower than expected one-year patient and graft survival that met all OPTN thresholds that would trigger a performance review. This suggests that Pennsylvania organ transplant programs as a group perform as well as programs nationwide. In addition to the OPTN provisions, the Department of Health regulations state that the Department is to review programs when actual survival rates are lower than their OPTN (i.e., SRTR) expected rates. In June 2004, the Department advised the LB&FC staff that information on all of its investigations and reviews of licensed facilities could be found at its website. We reviewed the information available at the website for all facilities with actual organ transplant patient survival rates lower than their expected rates, but were unable, however, to identify any reviews the Department had conducted of any of these programs.

Recommendations

1. **The Department of Health should routinely review the cardiac data hospitals submit as part of state licensure requirements.** The purpose of this review would be to identify programs that are not meeting Agency for Healthcare Research and Quality and other recognized performance benchmarks and to identify programs that may not be in compliance with existing licensure provisions related to performance of outpatient catheterizations and open heart surgery for children. To facilitate its review, the Department should work with the Pennsylvania Health Care Cost Containment Council to revise the current reports to incorporate the AHRQ quality benchmarks. Hospitals not meeting the relevant benchmarks, or hospital licensure requirements, should be requested to document steps they have taken or are taking to address quality concerns, and where necessary, submit a corrective action plan.

   The federal Medicare program and voluntary accreditation agencies are moving to incorporate evidenced-based performance measures in their processes for assuring quality care and patient safety. Recently, Congress required hospitals to start reporting on an initial set of quality performance indicators or have their Medicare payment levels reduced. The Department of Health currently serves as the designated state survey agency for the Medicare and Medicaid programs. Implementation of the quality performance reviews provided for in existing state licensure requirements for highly specialized clinical services, such as cardiac services, is consistent with Medicare and Medicaid programs efforts to assure quality of care.

2. **The Department of Health, working with the Pennsylvania Chapter of the American College of Cardiology, should take steps to form a cardiac oversight committee to assist the Department.** The cardiac clinical oversight committee (of state and national experts) should be used by the Department to:

   - develop clinical guidelines to inform hospital regulations, including guidelines for identification of low risk cardiac patients for whom outpatient catheterization procedures are appropriate and instances where cardiac surgery may be performed for children in adult programs;
   - develop performance criteria including rates of complications and mortality and proficiency volumes, for highly specialized cardiac services;
   - assist with the refinement of reporting requirements for such services since data currently reported to the PHC4 is not consistent with Department of Health regulations and does not lend itself to adjusting for relevant differences in patients and procedures;
   - review and interpret current and future data available to the Department and the Council;

- review plans of correction that are submitted to the Department; and
- develop guidelines and standards for peer review.

In 1996, the Legislative Budget and Finance Committee recommended the Department utilize a cardiac oversight committee for highly specialized cardiac services, and in 1998, the Pennsylvania Chapter of the American College of Cardiology recommended that such a committee be formed. More recently, legislation introduced in the House of Representatives directs the Department to establish clinical oversight committees to assist with quality assurance for highly specialized clinical services, including cardiac services.

3. **The Department of Health should institute a moratorium on approval of additional hospital licensure exceptions for provision of PCI without cardiac surgery onsite.** The ACC/AHA guidelines, and the Department of Health, recommend that patients undergo PCI at programs with cardiac surgery onsite. Medical researchers are not in agreement that PCI can routinely be provided without onsite cardiac surgery without further exposing patients to adverse consequences. PCI and cardiac surgery programs, moreover, are available throughout the state, PCI with onsite cardiac surgery would appear to be the current community standard of care in Pennsylvania, and existing PCI programs with cardiac surgery appear to have the ability to perform additional procedures based on their current procedure volumes.

4. **The Department of Health should require all current PCI demonstration sites to join a national clinical trial and comply with all requirements and protocols of the national clinical trial.** The Department of Health in late 2002 granted exceptions to hospital regulations to allow selected hospitals to perform primary and elective therapeutic catheterizations without onsite open heart surgery allowing them to conduct a two year demonstration. Such highly specialized clinical services present considerable risk to patients. At the time the Department provided two year approval for such projects to operate, a national trial was not available for interested hospitals. We recommend Pennsylvania hospitals that have received hospital licensure exceptions to perform PCI without onsite open heart surgery should be permitted to continue to do so only as part of a national clinical trial with well developed protocols and supervision provided by the trial principals.

   Hospitals whose licensure exception will expire in 2005 should be allowed until January 2006 to gain admission to the national trial. During this period, when oversight and responsibility for the quality of care and patient safety rests with the Department of Health, the Department should require demonstration sites to use a standard patient consent form reviewed and approved by a committee of interventional cardiologists and follow the requirements recently established by

the Department for new demonstration projects (regarding notification of nearby hospitals with cardiac surgery units and notification to malpractice insurers).

The Department should also utilize the cardiac advisory committee to develop reporting requirements and standards for programs that have received exceptions to hospital licensure regulations, and a system for peer review of procedures performed at such sites, including 100 percent review of all cases with adverse patient occurrences, and all attempted and unsuccessful procedures. Failure to accurately and fully report all procedures, including unsuccessful PCI, to the PHC4 and the Department of Health should have consequences, possibly even immediate revocation of the licensure exception.

5. **The Department of Health should routinely review survival data for individual transplant programs and follow-up with programs with lower than expected survival rates.** Such data are readily available to the Department of Health and the public. The Department should assure that a system of follow-up is in place as set forth in Pennsylvania hospital licensure regulations.

I. Introduction

House Resolution 356 of 2003 directed the Legislative Budget and Finance Committee, in consultation with health care experts and specialists, to study health care services requiring extraordinary expertise and resources and how their quality has been assured since the sunset of Pennsylvania's Certificate of Need (CON) in December 1996. The resolution specifically identified cardiac catheterization and open heart surgery and organ transplant as services requiring extraordinary expertise and resources. (Appendix A provides a copy of the resolution.)

Study Objectives

Specifically, the study sought to:

- Identify highly specialized clinical services requiring extraordinary expertise and proficiency for their safe and effective delivery.
- Identify Pennsylvania health care facilities providing such services.
- Identify recognized standards for provision of such service, including volume standards related to clinical proficiency, staff training and expertise, and resources required to effectively respond to clinical emergencies with provision of such specialized services.
- Assess the extent to which such standards are included in voluntary quality assurance programs and state health care facility regulations in Pennsylvania and other states.
- Identify ways to ensure that health care facilities are performing services requiring extraordinary clinical expertise and resources according to recognized standards.

Scope and Methodology

To identify highly specialized clinical services requiring extraordinary expertise and proficiency, we consulted with the Department of Health, the Pennsylvania Medical Society, and the Hospital & Healthsystem Association of Pennsylvania. We also examined peer reviewed and published health care research focusing on quality performance measures.

Our consultation and review confirmed the specific services identified in House Resolution 356 require specialized expertise and resources for their safe and effective provision. While experts have identified other services that also require specialized clinical expertise for their safe and effective provision, and we have

noted examples of such services within the report, our study's analysis focused specifically on the services identified within the resolution.

To identify health care facilities providing certain highly specialized clinical services in Pennsylvania, we analyzed Department of Health data from the Annual Hospital Questionnaire. We also relied on Pennsylvania Health Care Cost Containment Council data. While there are differences in the two data sets, together they provide the most complete overtime and current lists of specialized clinical service providers in Pennsylvania.

To identify standards for provision of highly specialized services, we consulted with health care experts, reviewed published guidelines of professional groups such as the American College of Cardiology and the American Heart Association, and reviewed health care research. We also reviewed the 2000, Institute of Medicine's report *Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality*, the July 2004, *Guide to Inpatient Quality Indicators: Quality of Care in Hospitals—Volume, Mortality, and Utilization* prepared by the Department of Health and Human Services, Agency for Healthcare Research and Quality, and relevant federal regulations for transplant centers.

To assess the extent to which such standards are included in voluntary quality assurance programs and state health care facility regulations in Pennsylvania and other states, we reviewed voluntary quality assurance program standards. We also reviewed Pennsylvania's regulatory requirements to assure quality of care for highly specialized services and those of selected states.

To identify ways to ensure that health care facilities are performing services requiring extraordinary clinical expertise and resources according to recognized standards, we reviewed the approaches taken in Pennsylvania and in other states. We also spoke with health care experts and specialists in Pennsylvania. As quality assurance standards for certain highly specialized services rely on review of performance data, we examined the available quality performance data for highly specialized clinical services provided in the Commonwealth.

Within the report when reporting cardiac services performance measures, we have typically reported observed hospital mortality rates for the state and groups of health care providers. The LB&FC would have preferred to utilize performance data that has been risk adjusted to take into account differences in patient and procedural risk factors. Such data, however, are not available for comparison to national and other state data.

In October 1998, the Department of Health published notice in the Pennsylvania Bulletin that hospitals were no longer required to submit data on cardiac services to the Department of Health for the Department to assess their compliance

with its cardiac service regulatory requirements and for quality assurance. The Department further advised hospitals they could fulfill their licensure regulatory requirement by providing information specified in the regulations to the Pennsylvania Health Care Cost Containment Council. The published notice indicates that the Council apprised the Department it would provide the information to the Department in quarterly reports for its use.

LB&FC staff has used the reports prepared by the Council for the Department using hospital discharge data from mid-1998 through calendar year 2003. We combined the quarterly data for individual facilities into single- and multi-calendar years for purposes of analysis and comparison with the Agency for Healthcare Research and Quality benchmarks and states such as New York, which have nationally recognized cardiac databases. The Council's reports are currently the only mandated source of information on volume of cardiac procedures and hospital patient mortality associated with such procedures.

Hospitals report significant data to the Pennsylvania Health Care Cost Containment Council, and the Council has a rich data set. Nonetheless, the data the Council gathers for cardiovascular services such as therapeutic catheterizations does not include 70 percent of the data reported to the American College of Cardiology National Cardiovascular Data Registry, including data elements required to adequately adjust for procedural risk. The Council's data (and the reports it provides to the Department of Health) do not include significant information on patient risk factors, such as the patient's New York Heart Association classification. The dataset, moreover, does not include information on adverse patient outcomes, such as rates of emergency bypass surgery, strokes, or heart attacks associated with the procedure, which are specifically referenced in the Department of Health regulations. In part for these reasons, we reviewed, but did not rely upon, the quarterly adjusted data provided by the Council to the Department of Health in our analysis.

Acknowledgments

We appreciate the cooperation we received from the Secretary and staff of the Pennsylvania Department of Health and the Pennsylvania Health Care Cost Containment Council. We also appreciate the assistance and support provided by the Hospital & Healthsystem Association of Pennsylvania, the Pennsylvania Medical Society, the American College of Cardiology staff, and physicians from the Pennsylvania Chapter of the American College of Cardiology who assisted our work.

Important Note

This report was developed by Legislative Budget and Finance Committee staff. The release of this report should not be construed as an indication that the Committee or its individual members necessarily concur with the report's findings and recommendations.

Any questions or comments regarding the contents of this report should be directed to Philip R. Durgin, Executive Director, Legislative Budget and Finance Committee, P.O. Box 8737, Harrisburg, Pennsylvania 17105-8737.

II. Findings and Conclusions

Quality of Care and Procedure Proficiency Volumes

A. Procedure proficiency volumes are recognized indicators of health care quality.

Certain medical procedures are associated with risks of known serious complications, including death, and have success and failure rates that are associated with operator skill and expertise. Highly specialized clinical services, such as cardiac catheterization,[1] open heart surgery, and organ transplant services identified in HR 356, are among the medical procedures with higher risk of serious complications and success and failure rates associated with operator skill and expertise.

Professional care providers, those closest to the delivery of health care, typically see themselves as most responsible for the quality of health care. Historically, such professionalism has resulted in self examination and the development of professional standards and guidelines for provision of care to which professional care providers voluntarily adhere.

In 1996, the American Board of Medical Specialties, for example, approved a New Certificate of Added Qualification (CAQ) in Interventional Cardiology to address the minimum training, experience, and cognitive and technical skills judged by the profession to be necessary for the competent performance of therapeutic catheterization. Such additional requirements are considered necessary because admission to one of the medical specialty boards is not intended to bestow a special license or particular credential, and ". . . it has never been a guarantee that an individual possesses specific technical or procedural skill."[2]

As increased numbers of patients are exposed to higher risk procedures, medical professionals and health care experts have also developed practice guidelines associated with their provision. The American College of Cardiology and the American Heart Association (ACC/AHA), for example, have task forces to gather information based on research findings and make recommendations about appropriate diagnosis and treatment of patients with cardiovascular disease. Such practice

[1]Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures.
[2]Topal, E., *Textbook of Interventional Cardiology*, Philadelphia: W.B.Saunders Company, p. 922.

guidelines are in place for interventional and invasive procedures such as PCI[3, 4] and Coronary Artery Bypass Graft Surgery.[5] The ACC/AHA's most recent guidelines for PCI, for example, address patient selection criteria, procedural complications, outcomes for various interventions, patient management including appropriate settings for provision of service, quality assurance, and operator and institutional competency, including proficiency volume standards.

Use of National Practice Guidelines and Efforts to Improve Quality of Care and Assure Patient Safety

The medical profession is not the only group concerned with healthcare quality and patient safety. State governments, voluntary accreditation organizations and health care providers, federal agencies, and major health care purchasers also focus on quality and ways to improve quality of care, including the quality of highly specialized clinical services.

State Governments: States often rely on the national practice guidelines to establish state standards for provision of specialized clinical services. As discussed below in Findings D and E, states often incorporate ACC/AHA practice guideline standards in their certificate of need requirements and/or licensure requirements.

Voluntary Accreditation Organizations: National voluntary accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), do not require that accredited healthcare organizations comply with national practice guidelines as a condition for accreditation. They do, however, suggest that national practice guidelines are excellent benchmarks for use by medical staff when granting clinical privileges to provide specific services.

JCAHO also encourages the use of performance data in quality assurance. The purpose of introducing such measures into the accreditation process is to accurately understand the basis for current performance so that better results can be achieved through focused improvement actions.

[3]Smith, SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. *ACC/AHA guidelines for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines* (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). J Am Coll Cardiol 2001; 37:2239 i.-lxvi.
[4]PCI (percutaneous coronary interventions) refers to the broad group of percutaneous techniques capable of relieving coronary narrowing. Such techniques include rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents and other devises for treating coronary atherosclerosis, including percutaneous transluminal coronary angioplasty (PTCA).
[5]Eagle KA, Guyton RA, Davidoff R, Ewy GA, Fonger J, Gardner TJ, Gott JP, Herrmann HC, Marlow RA, Nugent WC, O'Connor GT, Orszulak TA, Rieselbach RE, Winters WL, Yusuf S. *ACC/AHA guidelines for coronary artery bypass graft surgery: 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). J Am Coll Cardiol 1999; 34:1262-346.

JCAHO has introduced core performance measures into the accreditation process for acute myocardial infarction, heart failure, pneumonia and related conditions, and surgical infection prevention. Starting in 2004, JCAHO accredited hospitals with an average daily census greater than 10 must select core measure sets that meet JCAHO's requirements, and as part of the accreditation process, Commission surveyors will assess how health care organizations have integrated performance measures into their quality improvement activities.

Federal agencies: The federal Center for Medicare and Medicaid Services (CMS)[6] in the Department of Health and Human Services has been working with various organizations to identify clinical quality measures and promote public reporting of performance on such measures as part of its voluntary Hospital Quality Initiative. In 2003, Congress provided strong incentives for voluntary reporting on a "starter set" of 10 quality measures[7] when it enacted legislation stipulating that hospitals not voluntarily reporting data for 10 quality measures would have lower Medicare payment updates (0.4 percent lower) than hospitals reporting such data. In July 2004, the Department of Public Welfare reported to the Medical Assistance Advisory Committee it had initiated discussions with the hospital industry about including quality and performance standards as part of the state's Medicaid payment system.

CMS has also initiated a quality incentive demonstration as part of its Hospital Quality Initiative. This initiative involves voluntary reporting on an expanded set of quality measures.[8] Several Pennsylvania hospitals are participating in this CMS initiative.[9]

As part of its efforts to promote quality of care and public information on hospital care performance, the Department of Health and Human Services requested the National Quality Forum (NQF)[10] to begin work to develop national consensus standards for hospital care performance measures. NQF's initial set of quality measures include several involving specialized clinical services, including:

[6]Formerly referred to as the Health Care Financing Administration (HCFA).
[7]The starter set of 10 hospital quality measures for acute myocardial infarction/heart attack include aspirin at arrival, aspirin at discharge, beta-blocker at arrival, beta-blocker at discharge, ACE inhibitor for left ventricular systolic dysfunction; for heart failure include left ventricular functional assessment, ACE inhibitor for left ventricular systolic dysfunction; and for pneumonia include initial antibiotic timing, pneumococcal vaccination, and oxygenation assessment.
[8]Such measures include PCI received within 120 minutes of hospital arrival for AMI, AMI inpatient mortality rates, and CABG inpatient mortality rates.
[9]Pennsylvania hospitals participating in the Premier Hospital Quality Incentive demonstration include Albert Einstein Medical Center, Bon Secours Holy Family Regional Health System Altoona, Bryn Mawr Hospital, Frankford Hospital, Lankenau Hospital, Meadville Medical Center, Methodist Hospital Philadelphia, Paoli Memorial Hospital, South Hills Health System—Jefferson Hospital, St. Luke's Allentown, St. Luke's Hospital Bethlehem, St. Vincent Health Center Erie, and Thomas Jefferson University Hospital. Such hospitals may qualify for financial payments if they demonstrate provision of superior quality care.
[10]The National Quality Forum was established in 1999 to facilitate widespread healthcare quality improvements in part by endorsing national healthcare quality performance measurement and reporting systems.

- PCI volume
- PCI mortality
- PCI within 120 minutes of arrival for AMI/heart attack
- CABG volume
- CABG mortality

Within the federal Department of Health and Human Services, the Agency for Healthcare Research and Quality (AHRQ) is the lead agency charged with supporting research designed to improve the quality of health care and patient safety. AHRQ has developed a series of inpatient quality of care indicators that take advantage of available hospital discharge data. They include:

- *Volume*: These indicators are proxy, or indirect, measures of quality based on evidence suggesting that hospitals performing more of certain intensive, high-technology, or highly complex procedures may have better outcomes for such procedures.
- *Mortality*: These indicators include procedures and conditions where mortality has been shown to vary across institutions and for which there is evidence that higher mortality may be associated with deficiencies in the quality of care.
- *Utilization:* High or low rates for these indicators are likely to represent inappropriate or inefficient delivery of care.[11]

The AHRQ's most recent set of inpatient quality indicators include specific volume and mortality indicators for seven conditions and procedures, including two common procedures used to treat coronary artery disease: [12]

- Therapeutic cardiac catheterizations, i.e., Percutaneous Transluminal Coronary Angioplasty (PTCA/ PCI) and
- Coronary Artery Bypass Graft Volume (CABG), the major type of open heart surgery.

The AHRQ acknowledges its quality indicators rely on administrative data, and not direct clinical measures, but stresses that such administrative data can serve as a starting point for further investigation to assess potential quality-of-care problems and identify approaches to address such problems. Health care providers with poor outcomes on a particular indicator, for example, can initiate reviews of

[11]Department of Health and Human Services, Agency for Healthcare Research and Quality, *Guide to Inpatient Quality Indicators: Quality of Care in Hospitals—Volume, Mortality, and Utilization*, June 2002 AHRQ Pub. No. 02-RO204, Revision 3 (July 21, 2004).
[12]The other conditions include: Pediatric Heart Surgery, Esophageal Resection, Pancreatic Resection, Abdominal Aortic Aneurysm Repair, and Carotid Endarterectomy.

patient records to verify the reported outcomes and investigate potential quality of care problems.

Major Employers: Major employers are also involved in efforts to improve the quality of care and patient safety. The Leapfrog Group for Patient Safety, for example, is a group of Fortune 500 companies and other large private and public health benefit managers whose mission is to trigger giant leaps in safety, quality, and affordability of healthcare. The group as part of its evidence-based safety standards has developed proficiency volumes for highly specialized cardiac (and other) services that it encourages employers to use in referring employees for care.

B. Research shows procedure volumes are associated with quality of care for highly specialized clinical services.

Research has shown procedure volumes are associated with health care quality, including quality of care for highly specialized clinical services. In 2000, the Institute of Medicine (IOM)—a unit of the National Academy of Sciences—held a workshop to bring together health care experts to consider the evidence of the relationship between volume and quality. During the workshop, medical researchers summarized their systematic review of published research to assess the caliber of the research and what is known about how volume and quality of care are associated. Based on their review for eight medical conditions and procedures, including cardiac services such as PCI and CABG surgery,[13] they concluded:

> There can be little doubt that for a wide variety of surgical procedures and medical conditions higher volumes (whether assessed by hospital or by physician) is associated with better health outcomes. . . . the uniformity with which the published research documents or confirms the existence of the association is compelling. Fully 77 percent of the studies we reviewed found statistically significant associations between higher volume and better outcomes. The remaining 23 percent did not find statistically significant relationships. No study demonstrated a statistically significant association in the opposite direction. Finally, all 16 of the studies with the highest [methodology] quality scores found statistically significant associations.[14]

The medical researchers further noted, while the hypothesis that "practice makes perfect" is appealing, existing research has not been able to demonstrate what skills or practices improve as hospitals or physicians gain experience with

[13]The other procedures and conditions include acute myocardial infarction, pediatric cardiac surgery, carotid endarterectomy, abdominal aortic aneurysm repair, cancer surgery, and acquired immunodeficiency syndrome (AIDS).

[14]Halm, E., et al. "How is Volume Related to Quality in Health Care? A Systematic Review of the Research Literature," Appendix C, The Institute of Medicine's *Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality: Workshop Summary*, Washington, D.C. 2000.

particular kinds of patients and how these relate to volume. The researchers suggest that the relationship is complex and includes factors such as:

- patient selection,
- severity and comorbidity (i.e., other diseases such as diabetes),
- specific processes of care,
- physician skill,
- skill of other clinicians, and
- hospital skill.

Research on Volume and Quality of Specialized Cardiac Services

When discussing the impact of surgeon and hospital volumes on CABG mortality, the researchers gave high marks to the published work of Hannan and his colleagues. Unlike other published research that relies on administrative data or voluntarily reported clinical data, Hannan's research uses the state of New York's cardiac database.

New York's cardiac database includes all providers of cardiac services in the state, is independently audited to assure its accuracy and completeness, and contains not only administrative data, but also clinical data elements. Such data allowed Hannan and his colleagues to develop a risk adjustment model for use in their work, which over the years has shown statistically significant relationships between volume and quality of care for both physicians and hospitals.

In 2003, Hannan and colleagues[15] studied 57,150 CABG procedures from 1997 to 1999 to examine the individual and combined impact of annual hospital and surgeon volume on in-hospital mortality. The study found:

- Higher volume surgeons and hospitals continue to have lower risk-adjusted mortality rates.
- Patients undergoing surgery performed by higher volume surgeons in higher volume hospitals have the lowest mortality rates.
- The lowest risk-adjusted CABG mortality (1.89 percent) occurred for patients undergoing surgery in hospitals with 600 or more CABGs per year and surgeons performing at least 125 procedures per year. For patients undergoing surgery in hospitals with fewer than 600 CABG procedures

[15]Hannan, E., et al. *Circulation*. 2003; 108:795-801.

and surgeons performing fewer than 125 procedures, the risk adjusted mortality was 2.67 percent.

The study's findings remained the same when all types of open heart surgeries, not just CABG surgeries, were included.

Hannan and colleagues also examined over 62,000 procedures performed in New York in 1991 to 1994 using the New York State Department of Health Coronary Angioplasty Reporting System database, which contains clinical variables specifically identified by the New York State Cardiac Advisory Committee as necessary to account for risk factors associated with outcomes for such procedures. They reported that patients undergoing angioplasty had higher risk adjusted rates of inpatient deaths and emergency CABG surgery compared to the statewide average when the procedure was performed:

- By cardiologists with annual volumes less than 75 procedures per year.
- At hospitals that performed fewer than 400 angioplasties a year.

They further reported that both cardiologists' and hospitals' volumes independently contributed to clinical outcomes.[16]

Research on Volume and Quality of Organ Transplant Services

Medical research has shown relationships between volume and improved patient outcomes for other procedures. Such procedures include vital organ transplantation.

The Department of Health and Human Services reported a 1995 study found that the probability of death for patients receiving a heart transplant between 1986 and 1991 at Medicare-approved transplant centers, which must treat a high volume of transplant patients, was 7 percent within 30 days and 16.2 percent within one year compared with 9.2 percent within 30 days and 19.2 percent within one year at facilities not approved by Medicare. Such differences were not attributable to patient demographics or medical risk factors encountered in heart transplantation. Similarly, a study on liver transplant services found that liver transplant programs that perform 20 or fewer transplants per year have mortality rates significantly higher than those that perform more than 20 per year.[17]

[16]Hannan, E. et al. JAMA, March 19, 1997—Vol. 277, No. 11, pp. 892-898.
[17]Edwards, E. et al., New England Journal of Medicine, Vol. 341, Number 27: 2049-2053.

Possible Options in View of the Volume Quality Relationship

During the Institute of Medicine's 2000 workshop, medical researchers suggested in view of the evidence demonstrating a relationship between procedure volumes and mortality and other adverse patient outcomes several actions reasonably might be taken. These include the following:

- The public be provided data on health care provider procedural volumes.
- State governments take action to limit the number of hospitals permitted to perform certain procedures.
- Private purchasers require or provide incentives for managed care plans or employers to steer patients to high volume providers.
- Government (or other state or regional entities) use the data on volume and outcomes to promote improved performance.

C. Proficiency volumes have been identified for highly specialized clinical services, including cardiac and organ transplant services.

In view of the relationship between procedural volume and improved patient outcomes, medical specialty societies, federal agencies, and major employer groups have identified specific proficiency volumes for specialized cardiac and organ transplant services.

Proficiency Volumes for Specialize Cardiac Services

PCI Proficiency Volume: Current ACC/AHA practice guidelines for therapeutic cardiac catheterizations recommend that they be performed by:

- Operators that perform 75 or more procedures annually at facilities that perform more than 400 procedures annually.

They further recommend:

- Institutions with a PCI volume less than 200 procedures per year should carefully consider whether to continue to offer service, unless it operates in an underserved geographic region.

The federal AHRQ has incorporated such volume proficiency thresholds into its quality benchmarks. AHRQ's quality indicators for health care facilities provide for a minimum volume of 200 procedures per year and a suggested benchmark of 400 procedures per year. The Leapfrog Group for Patient Safety also recommends health care purchasers refer patients in need of therapeutic catheterizations to facilities that perform more than 400 procedures annually.

Proficiency Volumes for Specialized Organ Transplant Services

The Medicare program has recognized the relationship between volume and performance outcomes (such as one and two year patient survival rates) for major organ transplants.[18] It has established proficiency volumes in its requirements for facilities seeking to participate as organ transplantation centers and provide transplantation services to Medicare enrollees. Medicare requires that programs demonstrate proficiency for purposes of Medicare participation by annually performing:

- 15 kidney transplants.
- 12 heart transplants.
- 12 liver transplants.
- 10 lung transplants.

As discussed in Finding P, Medicare in February 2005 proposed modifications to its current requirements.

[18]See 52 *Federal Register* 10935, dated April 6, 1987, 56 *Federal Register* 15008, dated April 12, 1991, and 60 *Federal Register*, dated February 2, 1995, and 42 CFR 405.2130. The preamble to the federal regulations provides information on the basis for the federal standards.

Pennsylvania's Past and Current Standards

D. Prior to 1997, Pennsylvania assured quality of care for highly specialized clinical services through incorporation of national practice guidelines, including proficiency volumes and performance outcome monitoring, in its certificate of need (CON) standards.

Pennsylvania's certificate of need (CON) program was allowed to sunset in December 1996.[19] As part of the CON program, the Department of Health required health care providers seeking to offer clinically related health services, including cardiac catheterization, open heart surgery, and organ transplant services,[20] to meet standards specified in the Department of Health's State Health Services Plan. Pennsylvania's State Health Services Plan incorporated national practice guidelines for provision of clinically related health services, and included minimum proficiency volume standards and performance outcome measures for highly specialized clinical services with known risks of serious complications and where success and failure rates are known to be associated with operator skill and proficiency.[21]

Cardiac Catheterization Services – 1994 State Health Services Plan Requirements

Pennsylvania's last State Health Services Plan[22] required facilities that were awarded a certificate of need to provide cardiac catheterization services to:

- Perform a minimum of 300 adult angiography cases per year, with each angiographer performing 150 per year in not more than two institutions.[23]

Mirroring recognized practice guidelines, the State Health Services Plan also required.

[19]Pennsylvania is one of 14 states that do not currently have certificate of need (CON) programs. Other states without CON programs include: Arizona, California, Colorado, Idaho, Indiana, Kansas, Minnesota, New Mexico, North Dakota, South Dakota, Texas, Utah, and Wyoming, according to an early 2004 survey conducted on behalf of the Maryland Health Care Commission.

[20]Other clinically related services that required a CON included ambulatory surgery, neonatal intensive care, alcohol or other drug rehabilitation provided in hospital or non-hospital inpatient treatment programs lasting less than 60 days, inpatient comprehensive medical rehabilitation resonance imaging, inpatient medical surgical, positron emission tomography, inpatient psychiatric care, and inpatient surgery.

[21]Pennsylvania's Health Care Facilities Act specifically requires that in developing rules and regulations for licensure the Department shall take into consideration (i) federal certification standards, (ii) the standards of other third party payors for health care services, and (iii) such nationally recognized accrediting agencies as the department may find appropriate. 35 P.S. §§448.101-448.906, at §448.806.

[22]The Pennsylvania State Health Services Plan, approved June 17, 1994.

[23]The 1994 changes to the State Health Services Plan did not specify a minimum volume standard for quality assurance for pediatric facilities. Prior to 1994, the Plan called for pediatric facilities to perform 150 procedures within three years of opening.

- Cardiac catheterization services be provided in a licensed acute care hospital with inpatient medical/surgical services, a coronary care unit with 24-hour a day monitoring capability, a peripheral vascular surgery program, and the capacity to provide non-invasive cardiac diagnostic modalities.
- Therapeutic catheterizations services be performed in hospitals with open heart surgery programs and not in any other facilities.
- Cardiac catheterization services in hospitals without open heart surgery on site only perform diagnostic procedures on low risk patients.[24]
- Hospitals collect prospective data and monitor clinical outcomes related to service.

To assure hospitals were only performing appropriate cardiac catheterization procedures and help it assure quality of care, the Department of Health required submission of data on each diagnostic catheterization performed by hospitals. Exhibit 1 provides a list of the data hospitals reported to the Department of Health. The Department also formed a Cardiac Catheterization Oversight Committee to advise the Department concerning the data submitted since it had eliminated certain quality outcome performance standards[25] that had been in place since 1983 and replaced them with plans for a "peer monitoring" process.

The Department of Health's Cardiac Oversight Committee: When the Department first convened the Cardiac Catheterization Oversight Committee in July 1990, it directed the Committee to:

- Determine the expected occurrence of normal findings and set a threshold value for monitoring the possible "overuse" of cardiac catheterization procedures.
- Define "serious complications" and determine the expected incidence beyond which additional steps might be necessary for quality assurance.
- Evaluate the outcome data submitted by cardiac catheterization facilities and make recommendations for appropriate corrective action.

[24]The 1994 State Health Services Plan defined low risk patients to include adults with stable symptoms who have no active congestive heart failure, no significant arrhythmias, and no significant comorbid conditions (including no hypertension, diabetes, or renal insufficiency), and whose cardiac disease does not result in inability to carry on any physical activity without discomfort and whose symptoms of cardiac insufficiency or of angina may be present even at rest (New York Heart Association Class IV Patient). High risk patients included those with any one of the following pre-catheterization conditions: angina with unstable symptoms, clinical evidence suggestive of left main coronary artery disease, history of left main coronary artery disease, uncompensated congestive heart failure, hemodynamically significant stenotic valve disease, active, infective endocarditis or cyanotic congestive heart disease.

[25]The 1990 State Health Services Plan eliminated the requirement that mortality rates not exceed 0.3 percent and procedure repetition rates not exceed 2.0 percent.

The Department convened the Cardiac Oversight Committee three times in 1991. After the Department postponed a scheduled June 1991 meeting, it did not reconvene the Committee until four years later, when laboratories approved after the 1990-91 Plan revisions were having problems meeting the minimum procedural volume standards to assure quality of care. Data reports from 46 facilities that had started to perform catheterizations after the 1990 State Health Services Plan changes showed that 26 hospitals performed fewer than 300 catheterization procedures in 1994, with five performing fewer than 100. By comparison, only four hospitals performed fewer than 300 procedures in 1987.

When the Department reconvened the Committee in 1995, the Committee recommended that any laboratory performing fewer than 100 cases per year after two or more years of operations be required to undergo another CON review. Laboratories doing between 100 and 300 cases should be given an additional year to meet the minimum volume standard. Subsequently, the Department reported to the Committee that of the three hospitals that had completed fewer than 50 catheterizations, one had resubmitted a new CON application, another had relocated the lab to a different facility within the same health system, and the third had closed the laboratory.

In 1995, the Department also requested the Committee review the clinical outcome data catheterization labs submitted to the Department of Health. The data showed that nearly one-half of the catheterization laboratories performing fewer than 300 catheterizations annually were reporting more than 25 percent of their cases with normal findings, in other words, there was no finding of coronary blockage. The ACC/AHA guidelines at the time indicated that the current proportion of normal cases should not exceed 10 to 20 percent, and that 15 percent was an acceptable rate.

In December 1995, the Department indicated that it had not identified the additional steps it would take to ensure quality at cardiac catheterization laboratories doing fewer than 300 cases per year. In 1996, the Department did not reconvene the Cardiac Oversight Committee.

Open Heart Surgery – 1994 State Health Services Plan Requirements

The Department's last State Health Services Plan included a variety of standards for provision of open heart surgery based on national practice guidelines, and also included volume proficiency standards. The plan required that within three years of initiation, the open heart surgery program perform:

- 450 cases annually and each cardiac surgeon caring for patients with ischemic heart disease perform an annual minimum of 150 open heart operations.

Organ Transplant Services – 1994 State Health Services Plan Requirements

Organ transplant services typically have been available on a regional basis, in part because of the limited availability of vital organs and the national system in place for procuring and distributing organs for transplant.[26] The Department's last State Health Services Plan required facilities approved to provide transplant services to meet annual proficiency volumes after a three year start up period. Such volumes included:

- 30 kidney transplants per year.
- 15 heart transplants per year.
- 20 liver transplants per year.
- 15 lung or heart/lung transplants per year.
- 8 pancreas transplants per year.

E. In 1998, the Department of Health revised its hospital licensure regulations to include standards for certain specialized clinical services, but it did not include volume proficiency standards or specify other quality outcome standards as benchmarks to trigger quality assurance reviews.

Historically, the Department of Health relied on CON approval standards as set forth in the State Health Services Plan to assure quality of care for highly specialized clinical services since it did not routinely revise health care facility licensure standards to reflect changes in the practice of health care. In 2003, when the Governor issued a comprehensive Medical Malpractice Liability Reform Plan to address state medical malpractice liability issues and improve patient safety, it provided for a series of reforms, including the drafting of new hospital regulations, many of which are 20 years old. The Governor's Office of Health Care Reform has been working with the Department to revise the state's hospital licensure regulations. As of January 2005, the Department had not proposed revised regulations.

With the sunset of Pennsylvania's CON program in December 1996, health care facilities were no longer required to comply with the quality assurance standards in the State Health Services Plan. In January 1997, therefore, the Department of Health established work groups to review relevant parts of the plan sections to determine if it included quality assurance and patient safety criteria that

[26]In 1984, Congress passed the National Organ Transplant Act. Under the Act, the federal Department of Health and Human Services contracts for the operation of the Organ Procurement and Transplant Network (OPTN) that is responsible for the national list of patients waiting for organ transplants and the organ placement centers that matches donors and recipients, and for the Scientific Registry of Transplant Recipients (SRTR) that collects and analyzes data on all recipients of kidney, liver, heart, lung, and other organ transplants. The United Network for Organ Sharing (UNOS) operates the Organ Procurement and Transplant Network (OPTN). The University Renal Research and Education Association (URREA) operates the Scientific Registry of Transplant Recipients (SRTR).

should be added to existing health care facility licensure regulations. The work groups presented recommendations to the Secretary of Health concerning the need for facility licensure standards for six services, including cardiac catheterization, open heart surgery, and vital organ transplantation.[27]

Cardiac Catheterization – Pennsylvania's 1998 Hospital Licensure Standards and Standards in Other States

The Work Group on Cardiac Catheterization Services, after reviewing the Department's facility licensure regulations, stated that it:

> . . . found them insufficient to ensure the quality of cardiac catheterization services. In fact, the current licensure regulations do not address cardiac catheterization or contain any specific requirements for the provision of this service.

The Work Group went on to note:

> There are national guidelines for cardiac catheterization developed by the American College of Cardiology/American Heart Association (ACC/AHA), and the workgroup suggests that these be considered by all catheterization providers. Currently, there are no requirements [in Pennsylvania's health care facility licensure regulations] that these guidelines be followed.[28]

The Cardiac Catheterization Work Group recommended:

- Cardiac catheterization service be authorized under the overall license of the hospital, rather than separately.
- Diagnostic and therapeutic catheterizations be recognized as separate services.
- Adult and pediatric catheterizations be recognized as separate services.
- Freestanding and/or mobile catheterization laboratories not be permitted.
- High risk diagnostic and therapeutic catheterizations be limited to hospitals with onsite open heart surgery programs.
- The Cardiac Catheterization Oversight Committee be continued to advise and assist the Department in ensuring quality of care by reviewing outcome data gathered on cardiac catheterization procedures.

When in May 1997 the Department of Health published proposed regulations amending the standards a hospital needed to satisfy to secure authorization to perform cardiac catheterization services, the Department included most of the Work

[27]The other services included ambulatory surgical care, long-term care, and neonatal care.
[28]PA Department of Health, Quality Assurance '97, Draft Recommendations of the Work Group on Cardiac Catheterization Services, February 5, 1997.

Group's recommendations in its proposed regulations. While the proposed regulation provided for a quality assurance oversight mechanism, it did not provide for a Cardiac Catheterization Oversight Committee to advise and assist the Department.

The proposed regulations in part addressed quality assurance by requiring that hospitals providing cardiac catheterization services must maintain data on:

- patient mortality and morbidity,
- infections and complications (rates of stroke, myocardial infarction, vascular complications, emergency bypass surgery associated with PCI, etc.),
- patient risk factors, and
- volume of procedures performed (including separate volumes for diagnostic visualizations, PCI, and electrophysiology procedures).

They required hospitals to provide such information to the Department on a quarterly basis and integrate the data into the hospital's quality assurance program. The Department indicated in the proposed regulations it would review the data submitted by hospitals and other relevant information and publish values or standards, or both, for each of the factors reported to the Department. If the Department's review of such information raised concerns with the quality of care in a cardiac service program, the Department indicated it would undertake a review to determine if the concerns were valid.

In June 1998, when the Department published final regulations for cardiac catheterization service, the section on quality management retained many provisions in the proposed regulations, including the requirement that hospitals retain patient data on mortality/morbidity, infections and complications, and patient risk factors and that such information be provided to the Department. Subsequently, in an effort to avoid duplicate data collection, the Department modified its data submission requirements by allowing hospitals to submit only the data required by the PHC4, which does not include all data required by DOH regulation. (See Chapter I for additional information on currently reported data.)

The final regulations also deleted references to the Department publishing standards and values for catheterization procedures. The preamble to the Department's final regulation indicates that the Department decided not to issue proficiency volume standards for cardiac services as there is no definitive volume number that can "prove" that a program is providing substandard care. The preamble is silent on other performance outcomes such as patient death rates and higher than expected procedural complications or normal findings, which conceivably, alone or in combination with low procedure volume, might trigger a quality assurance review by the Department.

In the preamble to its final regulation, the Department of Health noted the representative of the state chapter of the American College of Cardiology recommended the Department:

> Seek ongoing professional input as the [cardiac catheterization service] regulations are implemented. Important issues which will have a direct effect on the practice of cardiac services in this state have yet to be defined, e.g., definition of 'high risk' cardiac catheterization and determination of acceptable complication rates for cardiac catheterization. During the deliberations of the work group on catheterization services, we discussed the possibility that DOH restructure and/or reconstitute the previous advisory committee. The State Chapter of the American College of Cardiology would welcome the opportunity to continue to be involved in this process.

In addition to Pennsylvania's Chapter of the American College of Cardiology, the Legislative Budget and Finance Committee's 1996 review of Pennsylvania's Certificate of Need Program [29] recommended the Department of Health:

- Convene the Cardiac Catheterization Oversight Committee in part to develop outcome standards for cardiac catheterization laboratories.
- Based on the Cardiac Catheterization Oversight Committee's review of the data submitted by cardiac catheterization laboratories share relevant information with the Department of Health licensure staff for appropriate follow-up.

The Department of Health has not formally convened a cardiac advisory committee. Recently, however, the Department did request to meet with representatives of the Pennsylvania Chapter of the American College of Cardiology.

During the course of this study, the Pennsylvania Medical Society convened a group of physicians to provide technical assistance to the Legislative Budget and Finance Committee, as called for in House Resolution 356. The Pennsylvania Chapter of the American College of Cardiology identified a group of members willing to assist the Commonwealth in reviewing technical clinical data associated with invasive and interventional cardiac procedures that is gathered by Commonwealth agencies. The Pennsylvania Chapter of the American College of Cardiology further volunteered members to assist the state should the Pennsylvania General Assembly enact legislation similar to that proposed in House Bill 2771. (Appendix B provides the Pennsylvania Chapter of the American College of Cardiology's correspondence identifying members willing to assist the Commonwealth.)

[29] The review was required by Act 1992-179 and a report issued in November 1996.

The General Assembly has provided the Department of Health with broad authority to establish health and safety standards for health care facilities. House Bill 2771 as introduced in 2004, in addition, specifically requires the Department of Health to promulgate regulations that include clinical quality indicators for specialized clinical services and a process for analyzing clinical quality indicator data, and to develop a system for clinical peer review and data-information analysis by state clinical advisory committees.

The state clinical advisory committees provided for in House Bill 2771 would further serve as an advisory board to the Secretary, conduct peer review consultations, and recommend licensure actions where there has been failure by a facility to meet key quality indicators and correct deficiencies. The proposed legislation further includes provisions for revocation-nonrenewal of a license, confidentiality and access to submitted materials and documents, and liability.

Other States' Cardiac Catheterization Requirements: Several major states similar to Pennsylvania currently rely on clinical advisory committees to assist in assuring patient safety and quality for specialized cardiac services. LB&FC staff reviewed requirements (licensure and/or CON) for cardiac catheterization service for eight comparison states (Florida, Maryland, Massachusetts, Michigan, New Jersey, New York, Ohio, West Virginia) selected because of their proximity to Pennsylvania and size. We found:

- Massachusetts and New York, and most recently Florida, have formally established ongoing cardiac service advisory committees to assist the state agency in establishing performance standards for cardiac service providers and other quality improvement matters. Other states, such as Maryland, New Jersey, and Ohio have formed ad hoc committees to provide the state agency with technical consultation.
- Massachusetts and New York cardiac service advisory committees are involved in provider performance reviews that are triggered when minimum volume proficiency standards are not met or when other relevant performance measures, such as mortality or complication rates, raise questions about quality of care.
- New Jersey utilizes an external organization approved by the state to conduct performance reviews and review plans of correction when minimum proficiency volumes are not met, and Michigan uses cardiologists for individual case reviews.
- Pennsylvania differs from the eight comparison states in that all eight states have established cardiac catheterization proficiency volume standards for health care facilities and/or physicians that are used to benchmark quality service provision. Such other state proficiency volumes are equal to or greater than the minimum facility proficiency standards in the ACC/AHA practice guidelines.

Exhibit 2 provides information on Pennsylvania's and the eight comparison states' cardiac catheterization service requirements.

Exhibit 2

Cardiac Catheterization Requirements for Pennsylvania and Selected States

State	Annual Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
Pennsylvania	None	• Volume • Mortality/morbidity • Infection and complications • Patient risk factors	None
Florida	• Diagnostic: 300 • Level I Therapeutic: 300 • Level II Therapeutic: 1,100 with 400 therapeutic procedures	• Volume • Mortality • Infection rates • Nonfatal myocardial infarctions • Length of stay • Post operative bleeds • Same stay surgery • Others identified by a technical committee recently established in statute	Technical Advisory Committee: • Identifies standard data to be reported to the department • Identifies outcomes standards • Develops a risk adjustment methodology • Identifies specific steps to be taken by the department and individual hospitals that do not meet outcome standards within specified periods, including time periods for detailed case review and development and implementation of corrective action plans
Maryland	Therapeutic: 200	• Volume • Utilization • Access • Cost • Quality	Ad hoc committees formed.
Massachusetts	• Diagnostic: 300 (Performance of less than 150 results in delicensing) • Diagnostic and Therapeutic: 600, including 200 therapeutic • Physician minimum volumes also in place	• Mandatory National Cardiovascular Data Registry Reporting • Additional data submission to the state • Hospital quality assurance programs must perform assessments, including assessment of physician volumes, appropriateness of each procedure, all complications, any adverse outcomes, number of cases requiring transfer to tertiary facilities, and the technical quality of the catheterization studies, and provide a report of their findings and supporting data to the Department.	• The state has data collection and interpretation technical advisory committee. • The Invasive Cardiac Services Advisory Committee reviews the performance of diagnostic and diagnostic and therapeutic providers performing below established minimums (i.e., 300 and 600 procedures respectively), and the performance of physicians that do not meet minimum proficiency volumes. Based on the review of the Committee, the Department can permit a facility not meeting proficiency volumes to continue to offer service, and permit a hospital to continue to credential a physician.

Exhibit 2 (Continued)

State	Annual Minimum Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
Michigan	• 300 • Physician minimum volumes also in place.	• Procedure volume • Mortality and morbidity • Other procedure data requested by the state	Utilizes cardiologists in case reviews.
New Jersey	• Diagnostic: 350 • Diagnostic and selected therapeutic without cardiac surgery: 500 • Therapeutic with cardiac surgery center: 200 therapeutic • Physician volumes also in place.	• Audited procedure volumes • Mortality and complication rates • Normal study rates for specific laboratories and physicians • Percent of patients transferred to other facilities subsequent to diagnostic or therapeutic catheterizations • Number of right heart catheterization procedures	Independent external organization approved by the Department conducts a review and a plan of correction required when minimum proficiency volumes are not met.
New York	400	Coronary Angioplasty Reporting System includes: • demographic information; • patient, hospital, and cardiologist identifiers; • pre-procedural risk factors; post-PTCA complications; discharge date and disposition; • information on diseased vessels, including lesion location and type; • dilation attempt indicators; • pre-procedural and post procedural stenosis; and • bypass graft involvement in the angioplasty. State audits submitted data.	New York State Cardiac Advisory Committee developed the Coronary Angioplasty Reporting System. The committee also initiated efforts to measure risk-adjusted outcomes for CABG surgery in 1989 and has been in continuous operation ever since. In addition to reviewing state cardiac data, the committee has conducted site visits as part of departmental quality assurance efforts, and provided other assistance to the department.
Ohio	Diagnostic: 300 Therapeutic: 200	• Volume of procedures • Number of specific adverse outcomes identified in the National Cardiovascular Data Registry. • In hospital mortality • Mortality associated with reported adverse outcomes.	Ad hoc committees
West Virginia	300	• Requires Reporting to the National Cardiovascular Data Registry. • Certain providers must provide registry data reports to the state.	Utilizes an external quality assurance organization to review National Cardiovascular Data Registry data.

Source: Developed by LB&FC staff.

Open Heart Surgery – Pennsylvania's 1998 Health Care Facility Licensure Standards and Standards in Other States.

The Department of Health's Work Group on Cardiac Surgical Services, after reviewing the existing regulations, concluded in 1997 that they were insufficient to ensure the quality of open heart surgery services. The group, therefore, recommended a new chapter to existing hospital regulations be developed to address open heart surgery program personnel requirements, support services, physical plants, and monitoring and oversight.

The open heart surgery work group did not recommend specific volume proficiency requirements be included in the regulations. It did, however, support the concept of a cardiac oversight committee to develop quality performance outcome measures.

When the Department of Health published final regulations for open heart surgery programs in 1998, it included many of the work group's recommendations, but not a peer oversight committee. The regulations included an expanded section on quality management and improvement and required that hospitals with open heart surgery programs maintain patient data on:

- Mortality/morbidity.
- Infections and complications.
- Patient risk factors.
- Volume of procedures performed.

The Department of Health's final open heart surgery regulations require hospitals to submit the data to the Department of Health on a quarterly basis and integrate the data into the hospital's quality assurance program. Similar to the cardiac catheterization regulations, the Department indicated it would review the data on open heart surgery to assess the quality of each hospital program. If concerns were identified as a result of such reviews, the Department would undertake a review of the program to determine if the concerns were valid.

Other States' Open Heart Surgery Requirements: LB&FC staff reviewed the open heart requirements of the other states shown in Exhibit 3. We found:

- Florida, Maryland, Massachusetts, Michigan, New Jersey, New York, Ohio, and West Virginia all have proficiency volume standards that facilities must meet. Typically, these states require that facilities perform 300 open heart surgeries annually. New York with its requirement of 500 surgeries per year has the highest facility proficiency volume.

- Massachusetts, Michigan, New Jersey, and West Virginia also have proficiency volume standards for surgeons performing open heart surgery. Ohio does not impose minimum proficiency volume standards on surgeons, but provides for quality reviews of their performance when low volumes are combined with high mortality.

Exhibit 3 provides additional information on other states' requirements for open heart surgery providers.

Organ Transplant Services – Pennsylvania's 1998 Health Care Facility Licensure Standards and Standards in Other States.

The Work Group on Organ Transplant Services[30] similarly found there was a gap in quality assurance in organ transplant services after the sunset of CON. The group stated that the federal Organ Procurement and Transplant Network (OPTN) by-laws and standards be adopted as the Pennsylvania standard, but went on to note:

> Even with the adoption of OPTN by-laws and standards, there is still a gap in quality assurance as it relates to organ transplant services. For example, the OPTN bylaws and standards do not address the need for a Medical Director and a Transplantation Coordinator.

The Work Group recommended state hospital licensure regulations be revised. It recommended the revised regulation incorporate standards from OPTN and the Medicare and Medicaid programs. The proposed regulations issued by the Department included such standards, including the requirement that programs meet volume proficiency standards where they had been identified for particular transplant types.

In general, the final regulations governing organ transplantation are similar to the Work Group's recommendations. The regulations require each transplant program to be a participating member of the OPTN and comply with its bylaws and standards and require a medical director and transplantation coordinator. The regulations also include provisions for nursing staff and other health care personnel.

The final regulations, however, differ from the Work Group's recommendations and the proposed regulations in that they do not include Medicare's proficiency volumes. The Department of Health in the preamble to its final regulation indicated it modified the Work Group's recommendation because the Department was unable to find an explanation for the selection of Medicare's proficiency volumes for liver, heart, and lung transplants.

[30]The Work Group on Organ Transplant Services was not asked to address tissue, bone marrow, and eye transplants. Such organ transplants were not addressed in the last State Health Services Plan.

Exhibit 3

Open Heart Surgery Requirements for Pennsylvania and Selected States

State	Annual Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
Pennsylvania	None	• Volume • Mortality/morbidity • Infections and complications • Patient risk factors	None
Florida	300	• Specific data to be collected shall be developed with the assistance of technical advisory panels.	Technical Advisory Panel to develop procedures and standards for measuring of outcomes.
Maryland	200	• Volume • Utilization • Access • Cost • Quality	Ad hoc committees formed.
Massachusetts	300 Physician minimum volumes also in place.	• Data collection system for assessment of patient selection protocols. • Data sufficient for case-by-case analysis of cardiac procedures, peer review, performance measurement and feedback, and analysis of outcomes.	Cardiac Care Quality Advisory Commission
Michigan	300 Physician minimum volumes also in place.	• Volume and source of payment • Complications/mobility/mortality • Budget and cost information • Operating schedules • Demographic information • Diagnostic information	Requires consulting agreement with a high volume existing program to: • Receive and make recommendation of surgical and support areas, staff, and training. • Work with medical staff to develop process to measure outcomes.
New Jersey	350 Physician minimum volumes also in place.	• Patient characteristics • Patient outcomes • Service to medically underserved population • Data audited at hospital expense	An independent external organization approved by the Department conducts a review and a plan of correction is developed when minimum volumes and standards are not met.

Exhibit 3 (Continued)

State	Annual Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
New York	500	Cardiac Surgery Reporting System (CRCS) collects cardiac surgery data, including: • Outcomes • Patient risk factors • Complication • Outcomes	New York State Cardiac Advisory Committee
Ohio	250 Quality assurance reviews for surgeons with low procedure volume and high mortality.	• Volumes of CABG and other Open Heart procedures • Length of stay • Mortality	None
West Virginia	250 Minimum surgeon volumes also in place.	Provider must participate in a national cardiovascular registry or databank.	None

Source: Developed by LB&FC staff from information obtained from other states.

In place of Medicare's specified proficiency volumes, the Department's final regulation required that each program perform an "adequate number of procedures to maximize quality." It also required each transplantation program:

- Meet its expected survival rates as set forth by the national program.

When program survival rates are lower than expected, state regulations[31] provide for the Department:

- To review the program's performance to determine if the deviation can be accounted for by some unique aspect of the program, and
- Undertake a regulatory compliance review when the lower than expected patient survival rate cannot be explained.

Most of the comparison states we reviewed have some minimum volume standards for organ transplant providers. Of the eight states that we reviewed, only Pennsylvania has no proficiency volume standards, as shown in Table 1. Where states have not established minimum proficiency volumes, other restrictions may apply. West Virginia, for example, treats organ transplants as emerging technology and provides for imposition of a moratorium on their introduction. In New York, certain transplant programs without minimum proficiency volumes are limited to regional facilities involved in research.

Table 1

Minimum Volumes for Organ Transplants in Other States

	Liver	Heart	Kidney	Lung
Pennsylvania	0	0	0	0
Florida	5	12	15	2
Maryland	12	12	30	12
Massachusetts	15	12	NA	NA
Michigan	12	12	12	12
New Jersey	15	12	25	NA
New York	20	14	20	NA
Ohio	12	12	15	10
West Virginia	NA	NA	NA	NA

Source: Developed by LB&FC Staff from information provided by other states.

[31] 28 Pa. Code §158.19 (b) & (c).

F. After 1996, the number of Pennsylvania providers offering specialized cardiac services substantially increased.

As of mid-2002, as shown in Table2, 38 of Pennsylvania's 67 counties had health care providers with cardiac catheterization laboratories. As of June 2002,

- six more counties had labs than in 1996, and
- fifteen counties had more labs than they did in 1996.

Table 2 also shows 27 Pennsylvania counties had open heart surgery programs as of June 2002:

- Six more counties than had open heart surgery programs in 1996, and
- Nine counties with more open heart surgery programs than in 1996.

In some areas of the state, proliferation of cardiac services has occurred. Luzerne County, for example, went from having one open heart surgery program in 1996 to three by July 2002, and Chester County went from having no open heart program to three by July 2002.

Since the sunset of Pennsylvania's Certificate of Need Program in December 1996:

- 21 health care facilities established diagnostic cardiac catheterization programs,
- 31 health care facilities established therapeutic cardiac catheterization programs, and
- 23 health care facilities established open heart surgery programs.

Exhibits 4, 5, and 6 list programs that opened since CON sunset.

Table 2

Number of Facilities by County With Diagnostic and Therapeutic Cardiac Catheterization Labs and Open Heart Surgery Programs Pre and Post CON

County	Diagnostic Catheterization as of 6/30/96	Diagnostic Catheterization as of 6/30/02	Therapeutic Catheterization as of 6/30/96	Therapeutic Catheterization as of 6/30/02	Open Heart Surgery as of 6/30/96	Open Heart Surgery as of 6/30/02
Adams	0	1	0	0	0	0
Allegheny	18	18	9	11	9	11
Armstrong	1	0	0	0	0	0
Beaver	1	2	1	1	1	1
Berks	2	2	2	2	2	2
Blair	1	2	1	2	1	2
Bradford	1	1	1	1	1	1
Bucks	4	4	0	3	0	3
Butler	1	1	0	1	0	1
Cambria	2	2	1	2	1	2
Centre	0	1	0	0	0	0
Chester	4	4	0	3	0	3
Clearfield	2	2	0	1	0	1
Columbia	0	1	0	0	0	0
Cumberland	1	2	0	1	0	1
Dauphin	3	2	3	2	3	2
Delaware	5	3	1	2	1	2
Erie	2	3	2	2	2	2
Fayette	0	1	0	0	0	0
Franklin	1	1	0	0	0	0
Indiana	0	1	0	0	0	0
Lackawanna	2	2	1	2	1	2
Lancaster	3	3	2	2	2	2
Lawrence	1	1	0	0	0	0
Lebanon	1	1	0	0	0	0
Lehigh	5	4	3	4	3	4
Luzerne	1	3	1	3	1	3
Lycoming	1	1	1	1	1	1
McKean	0	1	0	1	0	0
Mercer	2	2	0	1	0	1
Montgomery	5	6	3	3	2	3
Montour	1	1	1	1	1	1
Northampton	1	1	1	1	1	1
Philadelphia	13	14	12	13	12	13
Schuylkill	0	1	0	0	0	0
Somerset	1	1	0	0	0	0
Washington	2	2	1	1	1	1
Westmoreland	4	3	1	1	1	1
York	1	3	1	1	1	1

Source: Developed by LB&FC staff from Department of Health Annual Hospital Questionnaire data.

Exhibit 4

Diagnostic Catheterization Programs Starting After 12/18/96

Year	Facility	Start Date
1997	Mercy Hospital/Wilkes-Barre	1/97
	Bon Secours Holy Family Regional Health System	8/97
	Uniontown Hospital	8/97
	Millcreek Community Hospital	10/97
1998	Frankford Hospital	3/98
	Canonsburg General Hospital	7/98
1999	Temple University Hospital	1/99
	Memorial Hospital York	6/99
2000	Mercy Providence Hospital	1/00
	Centre Community Hospital	4/00
	Chestnut Hill Hospital	4/00
	Bradford Regional Medical Center	12/00
	Warminster Hospital	12/00
2001	Hanover Hospital, Inc.	3/01
	Indiana Hospital	4/01
	Berwick Hospital Center	4/01
	Gettysburg Hospital	5/01
	Ohio Valley General Hospital	5/01
	Geisinger Wyoming Valley Medical Center	10/01
2002	Carlisle Regional Medical Center	1/02
2003	Meadville Medical Center	1/03

Source: Pennsylvania Health Care Cost Containment Council.

Exhibit 5

Therapeutic Catheterization Programs Starting After 12/18/96

Year	Facility	Start Date
1996	Abington Memorial Hospital	12/96
1997	Community Medical Center/Scranton	1/97
	Doylestown Hospital[a]	2/97
	St. Mary Medical Center	7/97
	Temple Lower Bucks Hospital	9/97
1998	Mercy Hospital/Wilkes-Barre	1/98
	Frankford Hospital	3/98
	St. Clair Memorial Hospital	4/98
	Butler Memorial Hospital	7/98
	Sacred Heart Hospital/Allentown	11/98
1999	UPMC Lee Regional Hospital	1/99
	Mercy Fitzgerald Hospital	6/99
2000	Bon Secours Holy Family Regional Health System	4/00
	Sharon Regional Health System	7/00
	Lehigh Valley Hospital/Muhlenberg	8/00
2001	DuBois Regional Medical Center	9/01
	Chester County Hospital	10/01
	Geisinger Wyoming Valley Medical Center	10/01
	Holy Spirit Hospital	10/01
2002	Main Line Hospital Paoli	1/02
	Jefferson Regional Medical Center	3/02
	Brandywine Hospital	7/02
2003	Somerset Hospital[a]	1/03
	Uniontown Hospital[b]	1/03
	Monongahela Valley Hospital[b]	2/03
	Phoenixville	7/03
	Chambersburg Hospital[b]	10/03
2004	Jameson Hospital[b]	2/04
	Montgomery Hospital[b]	7/04
	Jeannes[b]	7/04
	Holy Redeemer[b]	7/04

[a]Performed emergent PCI from 1997 through June 2000 as part of a national trial.

[b]Department of Health permits it to perform therapeutic catheterizations without onsite open-heart surgery.

Source: Developed by LB&FC staff from Pennsylvania Health Care Cost Containment Council data.

Exhibit 6

Open Heart Surgery Programs Starting After 12/18/96

Year	Facility	Start Date
1996	Abington Memorial Hospital	12/96
1997	Community Medical Center/Scranton	1/97
	Temple Lower Bucks Hospital	1/97
	St. Mary Medical Center	7/97
1998	Mercy Hospital/Wilkes-Barre	1/98
	Frankford Hospital	3/98
	St. Clair Memorial Hospital	4/98
	Butler Memorial Hospital	7/98
	Sacred Heart Hospital/Allentown	11/98
1999	UPMC Lee Regional Hospital	1/99
	Mercy Fitzgerald Hospital	5/99
2000	Bon Secours Holy Family Regional Health System	5/00
	Doylestown Hospital	7/00
	Sharon Regional Health System	7/00
2001	DuBois Regional Medical Center	4/01
	Chester County Hospital	9/01
	Geisinger Wyoming Valley Medical Center	10/01
	Holy Spirit Hospital	10/01
2002	Main Line Hospital Paoli	1/02
	Jefferson Regional Medical Center	3/02
	Lehigh Valley Hospital/Muhlenberg	6/02
	Brandywine Hospital	7/02
2003	Phoenixville	7/03

Source: Pennsylvania Health Care Cost Containment Council.

In the last half of 2003, Pennsylvania had 107 health care facilities providing diagnostic catheterization services, 68 providing therapeutic catheterizations, and 65 providing open heart surgery, according to data from the Pennsylvania Health Care Cost Containment Council. Appendices D and E provide lists of providers of cardiac catheterization services and open heart surgery during the period.

G. The number of hospitals offering organ transplants in Pennsylvania has remained relatively constant.

After the sunset of the CON program, one hospital (Pinnacle) established a kidney transplant program, though several hospitals approved to offer specific transplant programs under CON expanded their programs to cover additional types

of transplants. In 1997, Pennsylvania had 16 hospitals performing solid organ transplants—the same number as in 2004. The 16 hospitals[32] include 3 offering children transplant programs and 13 hospitals offering adult programs. As shown in Exhibit 7, the 13 hospitals offering adult transplant programs include:

- 13 kidney transplant programs,
- 7 liver transplant programs,
- 6 heart transplant programs, and
- 3 lung transplant programs.

Exhibit 7

Hospital Transplant Programs

Hospital	Kidney	Liver	Heart	Lung
Albert Einstein	✓	✓	N/A	N/A
Allegheny General	✓	N/A	✓	N/A
Geisinger	✓	N/A	N/A	N/A
Hershey Medical Center	✓	✓	✓	N/A
Pinnacle Health	✓	N/A	N/A	N/A
Hahnemann	✓	✓	✓	N/A
Lankenau	✓	N/A	N/A	N/A
Lehigh Valley Hospital	✓	N/A	N/A	N/A
UPMC	✓	✓	✓	✓
Oakland VA Medical Center	✓	✓	N/A	N/A
Thomas Jefferson	✓	✓	N/A	N/A
Temple University	✓	N/A	✓	✓
Hospital of the University of Pennsylvania	✓	✓	✓	✓

Source: Developed by LB&FC staff from the OPTN/UNOS database.

[32]VA hospitals were not subject to CON. Until recently the Oakland VA Medical Center program was part of the UPMC program. In 2003, the VA hospital transplant program separated from the UPMC program.

Cardiac Services and Quality Benchmarks

H. Proliferation of cardiac catheterization services in the Commonwealth has resulted in many recently established programs not meeting the volume proficiency standards of national practice guidelines.

LB&FC staff utilized available data to assess the extent to which Commonwealth cardiac catheterization services facilities are meeting ACC/AHA's quality proficiency standards and the extent to which providers offering cardiac catheterization services under CON have had their ability to meet minimum proficiency standards compromised as a result of cardiac service proliferation. We utilized data from the Department of Health's Annual Hospital Questionnaire for FY 1995-96 and FY 2001-02 to analyze volumes of cardiac procedures performed by three distinct groups of facilities, those with:

- catheterization laboratories and CON-approved cardiac surgery programs,
- catheterization laboratories with post-CON cardiac surgery programs, and
- catheterization laboratories but without cardiac surgery programs.

Table 3 shows facilities providing therapeutic catheterizations under CON typically continued to meet ACC/AHA's minimum proficiency volumes. All of the facilities providing cardiac catheterization and cardiac surgery under CON, with the exception of two children's hospitals, met the minimum facility proficiency volumes of ACC/AHA, performing at least 200 therapeutic catheterizations in FY 2001-02, and most of these facilities are performing the recommended number of procedures (i.e., 400).

Table 3 also shows a much higher proportion of the facilities that started cardiac surgery programs after the CON program sunset are not meeting minimum facility proficiency volumes (i.e., 200) identified in the ACC/AHA minimum guidelines for therapeutic cardiac catheterization services and the quality benchmark of the federal Agency for Healthcare Research and Quality (AHRQ). A relatively smaller proportion of such facilities are meeting recommended proficiency volumes (i.e., 400) for therapeutic catheterization services. Seven[33] such programs performed fewer than 200 therapeutic procedures, and an additional six performed fewer than 400 procedures in FY 2001-2002. In other words:

- 13 of 21 facilities in this group in 2001-02, would not have met Florida or New York's volume proficiency standards (see Exhibit 2), and
- 7 would not have met Massachusetts, Maryland, New Jersey, or Ohio's volume proficiency standards.

[33]These counts and the analysis do not include two facilities that started cardiac surgery programs in FY 2001-02, and that did not report performing therapeutic catheterizations for the period.

Table 3

Comparison of Procedural Volumes for Selected Cardiac Catheterization Labs
(FY 1995-96 and FY 2001-02)

	Labs With Cardiac Surgery Programs Under CON		Labs With Cardiac Surgery Programs After CON		Labs Without Cardiac Surgery Programs	
	FY 1995-96	FY 2001-02	FY 1995-96	FY 2001-02	FY 1995-96	FY 2001-02
% of Facilities With at Least 400 PCI Procedures	73%	88%	NA	38%	NA	NA
% of Facilities With Fewer Than 200 PCI Procedures	7%	5%	NA	33%	NA	NA
Average Number of Therapeutic Procedures	767	949	NA	374	NA	NA
Average Number of Diagnostic & Therapeutic Procedures	2,852	3,357	386	1,524	315	250

Source: Developed by LB&FC staff from Department of Health Annual Hospital Questionnaire data.

In some states, such programs would be required to undergo state level quality assurance reviews.

As shown in Table 3, from FY 1995-96 through FY 2001-02, the average number of diagnostic and therapeutic catheterization procedures for facilities that started to offer cardiac surgery prior to and after the sunset of the CON program increased. The average number of catheterizations at facilities without surgery programs, however, declined.

In recent years, more cardiac catheterization providers without cardiac surgery programs are also encountering difficulty in meeting the minimum volume proficiency standards that were in effect in Pennsylvania's last State Health Services Plan. When we compared the individual facility volumes with the proficiency volumes in the state plan (i.e., 300 procedures annually), we found:

- Fourteen performed fewer than 300 procedures annually in FY 1995-96, including two performing fewer than 100.
- Twenty-seven performed fewer than 300 procedures annually in FY 2001-02, including seven performing fewer than 100.

In other words, in FY 2001-02,

- 75 percent (27 of 36) of the health care facilities in Pennsylvania providing cardiac catheterization services without cardiac surgery programs were not meeting the volume proficiency standards in place in the comparison states shown in Exhibit 2.
- Eleven of the 27 Pennsylvania providers would be "delicensed" if they were operating in Massachusetts and the remainder subject to quality assurance by the state licensure agency and its cardiac advisory committee.

I. Pennsylvania facilities are performing more therapeutic catheterizations than expected based on the federal Agency for Healthcare Research and Quality (AHRQ) quality utilization indicator.

While proficiency volume standards are important indicators of quality of care, they are not the only relevant indicators. The AHRQ has also identified other relevant quality of care indicators, such as area utilization rates. AHRQ has identified such an indicator for therapeutic catheterization services, noting that therapeutic catheterization is a potentially overused procedure, and rates vary widely with differences in procedure rates not accounted for by age or other clinical factors. More average procedure rates, therefore, represent better quality, according to AHRQ.

AHRQ reports that the expected rate of therapeutic catheterization is:

- 528.16 procedures per 100,000 population at risk (i.e., those 40 years and older).

Based on the AHRQ quality utilization indicator and state population data,[34] Pennsylvania would expect to have had approximately 30,000 therapeutic catheterizations performed in 2000. Significantly more (over 40,000 annually), however, were reported in the FY 1999-00 and FY 2000-01 Department of Health Annual Hospital Questionnaire Data.[35]

Such reported procedural volumes raise questions about the appropriateness of all therapeutic catheterization procedures performed in Pennsylvania. As noted in Finding D, in the past, the Department of Health has also raised questions about service appropriateness.

J. Pennsylvania facilities providing therapeutic catheterization services have observed mortality rates similar to reported national rates.

The federal Agency for Healthcare Research and Quality (AHRQ) has also identified procedural mortality rates as quality of care indicators. For therapeutic catheterization services, AHRQ has identified mortality greater than 1.46 percent as an indicator of a possible quality of care problem. The most recent observed mortality rate for the American College of Cardiology National Cardiovascular Data Registry (NCDR) is 1.4 percent, based on data from January 1998 through March 2001.[36]

LB&FC staff analyzed four years of data (calendar year 2000, 2001, 2002, and 2003) from patient discharges involving therapeutic catheterization procedures that hospitals report to the Pennsylvania Cost Containment Council. We found that Pennsylvania's average annual observed (in-hospital) mortality rate was 1.41 percent.

Pennsylvania facilities' performance was consistent with the literature--facilities with higher proficiency volumes had lower rates of mortality. Pennsylvania facilities with 400 or more therapeutic catheterization cases annually had an observed mortality rate of 1.35 percent. Eighty-seven percent of the approximately 155,000 therapeutic catheterizations in Pennsylvania from calendar years 2000 through 2003 were performed at health care facilities with more than 400 cases annually. Those with fewer than 400 had a 1.41 percent observed mortality rate, with

[34]2000 U.S. Census data for Pennsylvania.
[35]Higher than expected procedure volumes are also found in Pennsylvania Health Care Cost Containment data.
[36]The Journal of Invasive Cardiology 2003;15:578-580.

six facilities performing fewer than 200 procedures annually having rates greater than AHRQ's 1.46 percent benchmark. For facilities with fewer than 100 procedures annually, their observed mortality rate was 1.78 percent.

K. Pennsylvania's mortality rate for therapeutic catheterizations, though similar to the national rate, is much higher than New York's.

Pennsylvania's overall mortality rate for therapeutic catheterization is comparable to reported national rates, but there appear to be opportunities for improvement. For example, the New York State Department of Health has taken an active role in helping to improve the quality of cardiac services, including therapeutic cardiac catheterizations. As noted in Finding B, New York requires all providers to submit procedure data to its cardiac registry that is overseen by the state's Cardiac Advisory Committee, which includes state and nationally recognized cardiologists and healthcare analysts.

New York health care facilities and the state health department have responded in various ways when state registry data have suggested quality problems. Such approaches include analysis of the systems of care to identify what led to adverse outcomes for patients and changes to health care processes that are faulty. In some cases, hospitals have reported improved outcomes by altering the processes of care for select groups of patients with particularly poor outcomes (i.e., emergency cases). Some facilities have altered their referral patterns to physicians, referring the most difficult cases to physicians with superior results. Some facilities have reduced the number of physicians on staff performing below minimum proficiency procedure volumes; and in some cases have withdrawn credentialing privileges. Some also completely reorganized their programs.

LB&FC staff compared the most recent publicly reported[37] observed mortality rates for New York therapeutic catheterization facilities with data for the same period for Pennsylvania facilities from the Pennsylvania Health Care Cost Containment Council.[38] As shown in Table 4, New York's observed mortality rate is roughly half that of Pennsylvania, and multi-year variation in mortality across facilities is greater in Pennsylvania than in New York. New York providers, moreover, performed roughly double the average number of procedures performed in Pennsylvania.

[37]New York State Department of Health, *Percutaneous Coronary Interventions (PCI) in New York State*, October 2004.
[38]New York is the only state that currently publishes facility and provider performance data for therapeutic catheterization services. Other states are working to implement similar reporting.

Table 4

Pennsylvania and New York Therapeutic Catheterization Mortality Rates

	Number of Providers	Total Cases	Average Cases Per Provider	Observed Mortality Rate	Observed Mortality Range
Pennsylvania – 2002	66	39,490	598	1.28%	0.00—3.95%
Pennsylvania – 2000-2002	67	112,384	1,677	1.45%	0.51—5.48%
New York – 2002	41	46,090	1,124	0.70%	0.00—5.26%
New York – 2000-2002	41	128,230	3,128	0.72%	0.00—3.82%

Source: Developed by LB&FC staff from Pennsylvania Health Care Cost Containment data and published New York State Department of Health reports.

L. Other opportunities to improve the quality of Pennsylvania's cardiac catheterization services may be present.

Since 1998, the Pennsylvania Health Care Cost Containment Council, at the request of the Department of Health, has been providing the Department of Health with cardiac service reports to assist the Department in implementing hospital licensure regulations and assuring quality of care and patient safety. The requested data includes reports identifying in-hospital deaths of patients undergoing outpatient cardiac catheterizations and deaths of children receiving cardiac surgery at hospitals with adult cardiac surgery programs.

Outpatient Cardiac Catheterization Deaths

LB&FC staff reviewed all of the quarterly data provided to the Department of Health by the Council from the second half of calendar year 1998 through the fourth quarter of 2003. For each calendar year, we unduplicated the number of hospitals reporting deaths occurring for patients undergoing outpatient cardiac catheterization. As shown in Table 5, several hospitals have reported one or more deaths for patients undergoing outpatient cardiac diagnostic and therapeutic catheterizations. Some hospitals reported such deaths in multiple years. The reports do not identify if the outpatient catheterizations involved low or high risk patients.

Table 5

Number of Hospitals Reporting Deaths of Patients With Outpatient Catheterizations

Year	Number of Hospitals Performing Outpatient Diagnostic Catheterizations With Deaths (and Number of Reported Deaths)	Number of Hospitals Performing Outpatient Therapeutic Catheterizations With Deaths (and Number of Reported Deaths)
1998[a]	1 (1)	0 (0)
1999	8 (10)	5 (7)
2000	6 (12)	4 (4)
2001	8 (9)	4 (4)
2002	5 (5)	6 (6)
2003	9 (9)	5 (5)

[a]Partial year data.

Source: Developed by LB&FC staff from the Cardiovascular Reports prepared by the Pennsylvania Health Care Cost Containment Council for the Department of Health, and reporting data from July 1, 1998 through December 31, 2003.

The Department of Health's current hospital licensure regulations indicate outpatient catheterizations are only to be performed for low risk patients.[39] The Department of Health's last State Health Services Plan included a detailed definition of low risk patients for purposes of cardiac catheterization services. The Department of Health's 1998 licensure regulations, however, did not include a definition of a low risk patient for purposes of providing such services. When commenting on the Department's final regulations, the Pennsylvania Chapter of the American College of Cardiology noted the Department would need ongoing professional input to help define high risk catheterizations.

Adult Open Heart Surgery Programs With Child Deaths

The reports prepared by the Council and submitted to the Department of Health also highlight other possible opportunities for improvements. The Department of Health's licensure requirements recognize that cardiac services for children require specialized provisions. For this reason, the Council's report identifies all hospitals in which cardiac surgery is performed and a child's death occurs during such an admission. As shown in Table 6, Pennsylvania hospitals that do not have licensed pediatric cardiac surgery programs have reported child deaths during stays for open heart surgery.

[39]28 Pa. Code §138.14(b).

Table 6

Number of Adult Open Heart Surgery Programs Reporting In-Hospital Mortality for Children Following Open Heart Surgery

1998	3
1999	2
2000	2
2001	1
2002	0
2003	2

Source: Developed by LB&FC staff from the Cardiovascular Reports prepared by the Pennsylvania Health Care Cost Containment Council for the Department of Health and reporting data from July 1, 1998 through December 31, 2003.

In June 2004, the Department of Health advised the LB&FC staff that it had not used the cardiovascular reports prepared by the Council. It indicated that the reports "are not highly useful to survey process" as they cover previous year(s). The Pennsylvania Health Care Cost Containment Council advised the LB&FC that the Council prepares the reports based on the schedule requested by the Department in 1998.

In June 2004, the Department also advised the LB&FC staff that information concerning all of its investigations concerning cardiac (and other highly specialized clinical services) is found at the Department's website under Health Facility Locator and Survey Information. LB&FC staff reviewed the information at the website for all facilities reporting same stay deaths of patients that received catheterizations in an outpatient setting. We were unable to identify any report indicating the Department of Health had investigated such reported patient deaths.

M. In late 2002, the Department of Health officials started to waive key cardiac catheterization public health and safety licensure requirements with limited input and professional oversight.

Current Department of Health hospital licensure regulations require therapeutic catheterization services routinely be provided at hospitals with onsite open heart surgery programs. Similarly, the ACC/AHA guidelines recommend that such procedures be performed at hospitals with onsite open heart surgery.

The ACC/AHA guidelines allow an exception for some patients experiencing a "heart attack" and presenting at certain community hospital emergency rooms. Such therapeutic catheterization procedures are called "primary PCI," "primary angioplasty," or "emergent PCI."[40] Several important criteria for performance of

[40]"Emergent PCI" or "primary PCI" are PCIs (percutaneous coronary interventions) performed within 120 minutes for emergency acute myocardial infarction (AMI) patients seen in the emergency room with confirmed ST elevation or new left bundle branch block.

emergent or primary PCI are set forth in Tables 15 and 16 of the ACC/AHA's 2001 PCI guidelines. Exhibit 8 lists some of the key criteria.

As shown in Exhibit 8, the ACC/AHA criteria recognize the need for timely intervention to rapidly restore blood flow to the heart. The criteria, for example, indicate primary PCI procedures should be performed within 90 minutes (plus or minus 30 minutes) from arrival at the hospital. The ACC/AHA criteria also recognize operator and facility proficiency volumes are related to patient survival. They note practitioners should perform a minimum of 75 therapeutic catheterizations annually, and facilities should perform a minimum of 36 emergent PCIs annually.

Using New York's cardiac database, Babak and colleagues found low-volume physicians had a 7.1 percent observed mortality rate for primary angioplasty for acute myocardial infarction compared to a 3.8 percent rate for high volume physicians. Low volume hospitals had a 5.8 percent observed mortality rate compared to a 4.0 percent rate for high volume hospitals. Those patients treated by high volume physicians at high volume hospitals had a 49 percent lower in-hospital mortality rate than those treated at low volume hospitals. The researchers also noted the benefit of procedures performed by high volume physicians is muted when the procedure is performed at a low volume hospital.[41]

[41]*Circulation*, 2001;104:2171-2176.

Exhibit 8

Criteria for the Performance of Primary Angioplasty at Hospitals Without Onsite Cardiac Surgery

Primary PCI procedures performed at facilities without onsite cardiac surgery must be performed:

- Within 90 ± 30 (i.e., not more than 120) minutes of admission,
- By a practitioner who performs 75 or more therapeutic catheterizations annually,
- At a facility that performs a minimum of 36 emergent PCIs annually,
- At a facility with a proven plan for appropriate hemodynamic[a] support capability for transfer with access within one hour to an open heart surgery operating room,
- At a facility with trained nursing and technical catheterization laboratory staff that participate in a 24 hour 365 day call schedule, and
- At a facility with rigorous case selection criteria.

Patient selected for such procedures should not include:

- Hemodynamically stable patients with:
  - Significant (greater than or equal to 60 percent) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.
  - Extremely long or angulated infarct-related lesions with TIMI grade 3 flow.
  - Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease.
  - Infarct-related lesions of small or secondary vessels.
  - Lesions in other than the infarct artery.

Facilities should transfer for emergency by-pass surgery patients with:

- High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability
  - After angioplasty or occluded vessels,
  - Preferably with intraaortic balloon pump support.

[a]Movement involved in the circulation of the blood.

Source: Developed by LB&FC staff from the *ACC/AHA Percutaneous Coronary Intervention Guidelines*, JACC Vol. 37, No. 8, 2001, June 15, 2001:2239xxi.

The ACC/AHA guidelines specifically recommend non-emergent therapeutic catheterizations (also known as "elective PCI") be performed at facilities with onsite open heart surgery. Most therapeutic catheterizations are non-emergent/elective PCIs. Ninety percent of all therapeutic catheterizations performed in New York from 2000 through 2002 were non-emergent.

Starting in December 2002, the Department of Health granted exceptions to hospital licensure regulations and authorized eight hospitals to provide both emergent and elective therapeutic catheterization at facilities without onsite open heart surgery backup. Table 7 lists hospitals that received licensure exceptions. The Department advised the LB&FC that several more hospitals had submitted requests to provide emergent and elective therapeutic catheterization at facilities without onsite open heart surgery and that their requests were under review.

Table 7

Hospitals With DOH "Waivers" to Perform Emergent and Elective Therapeutic Catheterizations Without Onsite Open Heart Surgery Backup

Hospital	Date "Waiver" Authorized	Annual Number of Diagnostic Catheterizations Performed in FY 2001-02
Somerset	December 2002	28
Uniontown	January 2003	210
Monongahela Valley	February 2003	199
Jameson	February 2004	253
Chambersburg	January 2004	238
Montgomery	July 2004	251
Jeanes	July 2004	0
Holy Redeemer	July 2004	415

Source: Developed by LB&FC staff.

Department of Health Process for awarding cardiac service "waivers": The Department of Health utilized a committee of its career professional (medical, nursing, legal) staff to review requests for exceptions to hospital licensure regulations. Based on their review, the committee recommended denial[42] of the hospitals' requests to provide emergent and elective therapeutic catheterizations without onsite open heart surgery.[43] However, the then Secretary of Health subsequently determined[44] the Commonwealth would grant selected hospitals' requests to provide both emergent and elective therapeutic cardiac catheterization without onsite open heart surgery.[45] The Department did not in all cases publish notices of its subsequent reversal of its denials in the Pennsylvania Bulletin, even though its regulations require it to publish notice of its exception decisions.[46]

In June 2002, the Department first advised selected hospitals it would grant them waivers to perform:

[42]The Department advised the LB&FC the committee meetings are not open to the public and meeting notes are not prepared and maintained. The Department did, however, provide the LB&FC with copies of project denial notices issued following committee reviews.

[43]The Department of Health publishes notices of its receipt of exception requests and its approval or denial of such requests in the Pennsylvania Bulletin. From the data provided to the LB&FC, one acute care hospital listed in Table 7 did not specifically submit a formal waiver request to the Department, and notice of the hospital's request was not published in the Pennsylvania Bulletin. The Department of Health advised the LB&FC that a notice was not published in the Pennsylvania Bulletin as the Department considered the hospital as one of the "other hospitals" referred to in a related application.

[44]In some instances, such determinations occurred after providers appealed their exception denials. In other instances, the decisions were reached through discussions and development of agreements.

[45]In 1998, the Department of Health required a hospital that started performing emergency therapeutic catheterizations as part of a national clinical trial to cease performing the procedures. Subsequently, this hospital developed an open heart surgery program.

[46]28 Pa. Code §51.33(d).

- Emergent therapeutic catheterizations (emergent/primary PCI) by authorizing an exception to Pennsylvania hospital licensure regulations.[47]
- Non-emergent or elective therapeutic catheterizations (non-emergent/elective PCI) by granting an exception to hospital licensure regulations to conduct a two year "demonstration, or pilot, project" during which time such procedures could be performed without onsite open heart surgery backup.

The Department stated the demonstration would allow participants:

> . . . to provide better access to vital health services to members of their communities while establishing appropriate monitoring mechanisms to ensure that patient safety and quality assurance issues are identified and addressed.[48]

Current hospital regulations for cardiac services allow hospitals without onsite open heart surgery to perform therapeutic catheterization in emergency situations without obtaining an exception from the Department as long as the hospital reports the circumstances to the Department in writing within 72 hours.[49] By granting a hospital licensure exception for emergent or primary PCI, the Department, in effect, no longer required the hospital to promptly document the need for provision of an emergent PCI without onsite open heart surgery backup or to immediately alert the Department of the procedure for purposes of its quality assurance monitoring.

Earlier in 2002, Aversano and colleagues published results from the first randomized clinical trial highlighting the benefits of emergent or primary PCI for certain patients in certain hospitals without onsite open heart surgery backup. The researchers, however, stressed their result did not apply to all patients at all facilities. They also stressed their results did not apply to elective PCI. Specifically, they noted:

> . . . our results apply only to primary PCI for patients with acute MI with ST-segment elevation or left bundle-branch block on presenting ECG. They do not apply to rescue PCI after failed thrombolysis, to

[47]The Department may grant exceptions to licensure regulations when the policy and objectives contained therein are otherwise met, or when compliance would create an unreasonable hardship and an exception would not impair or endanger the health, safety or welfare of a patient or resident. No exceptions or departures from licensure regulations will be granted if compliance with the requirement is provided for by statute. 28 Pa. Code §51.31.

[48]Department of Health correspondence June 7, 2002.

[49]See 28 Pa. Code §138.15 (restricting a hospital from performing high-risk cardiac catheterizations only if it has an open heart surgical program onsite); see also, 28 Pa. Code §138.2 (defining "high risk cardiac catheterization" to include PTCA procedures. 28 Pa. Code §138.17(c) provides that if a hospital that does not have an open heart surgery program onsite performs an emergent PTCA, the hospital shall report the circumstances to the Department in writing within 72 hours.

> other unstable coronary syndromes such as unstable angina or MI associated with a nondiagnostic ECG, or to elective PCI.[50]

All medical researchers are not in agreement with the conclusion drawn from Aversano's research about the patient benefits to be gained from treating certain acute MI patients with primary PCI (rather than other available therapy) without onsite surgery backup. The randomized trial's findings have been questioned because the trial enrolled only 18 percent of the number of patients needed for statistical proof, and concerns about possible sample bias. Many initially randomized patients in the study sample were subsequently judged ineligible for the treatment to which they were assigned and were treated outside of the study's protocol. The ability of community emergency medical transport systems and community hospitals to routinely replicate the practices of the clinical trial have also been questioned.[51]

More recently, Wennberg and colleagues[52] utilized Medicare hospital data (from January 1, 1999, and December 1, 2001) to compare patient outcomes following PCI at facilities without and with onsite cardiac surgery. They found that mortality for patients with primary/rescue PCI was similar for facilities without (11.3 percent) and with (12.2 percent) cardiac surgery. For the larger non-primary/rescue PCI population, however, mortality was much higher at facilities without onsite cardiac surgery (4.6 percent vs. 2.8 percent). The odds of mortality at facilities without cardiac surgery were 38 percent higher, with increased mortality primarily confined to hospitals performing 50 or fewer Medicare PCIs per year. Wennberg and colleagues concluded:

> If PCI programs are allowed to develop in centers without on-site cardiac surgery, patients being treated by primary/rescue PCI will likely benefit. However, 78% of PCIs at institutions without cardiac surgery programs [in the study] were not primary/rescue PCIs and these patient outcomes were poorer than those in hospitals that had on-site cardiac surgery. Given that the absolute risk reduction in short-term mortality for primary PCI over thrombolysis (about 2%) is comparable with the increase in mortality for the non-primary/rescue PCI populations in hospitals without cardiac surgery, PCI performed at hospitals without cardiac surgery may be doing more harm than good.

The Wennberg study has also been critiqued. The Medicare database used in the study is limited to patients who are Medicare beneficiaries, and therefore does represent patients of all ages. The available Medicare data, moreover, has several more important limitations. It does not allow for researchers to statistically control for important patient and procedural risk factors, such as MI location, heart rate,

[50]Aversano, T. et al, JAMA, April 17, 2002, Vol 287, No 15, p. 1950.

[51]See for example, *Mayo Clin Proc.* 2004;79:731-732.

[52]*JAMA*, October 27, 2004—Vol 292, No 16, 1961—1968.

blood pressure, and volume of patients presenting with shock. Without such important control data, it is not possible to determine if the reported observed differences in patient outcome are the result of patient differences or procedural and health system differences. Such differences among medical researchers highlight the need for a well designed national clinical trial with sufficient sample size from which to draw conclusions. As discussed below, such a study is currently being developed by nationally recognized medical researchers to provide the type of evidence-based research used by ACC/AHA committees in refining existing practice guidelines.

Department of Health Requirements for PCI without onsite open heart surgery: The Department of Health established certain requirements for the hospitals receiving exceptions to licensure regulations to perform primary and elective PCI without onsite open heart surgery backup, and indicated its Division of Acute and Ambulatory Care would monitor hospitals performance to ensure compliance with ACC/AHA guidelines. Exhibit 9 identifies requirements established by the Department of Health for hospitals providing therapeutic catheterizations without onsite open heart surgery.

Exhibit 9

Pennsylvania Department of Health Requirements for Selected Sites' Provision of Primary and Elective PCI Without Onsite Open Heart Surgery

Requirements for an Exception to Provide Emergent PCI

- Each hospital must comply with the standards and criteria set forth in the 2001 ACC Guidelines at Table 15 and 16. (See Exhibit 8.)

Requirements for an Exception to Provide Elective PCI as Part of a Pilot Project.

- Each hospital must identify and adopt standards and criteria that will be used in implementing non-emergent PCI. Such standards and criteria must address all relevant issues, including patient selection criteria, the criteria in Tables 15 and 16 of the ACC/AHA 2001 Guidelines, and other clinical issues raised in the guidelines (i.e., timely management of ischemic[a] complications, adequacy of specialized post-interventional care, logistics for managing cardiac surgical or vascular complications, and operator/laboratory volumes and accreditation).
- Each hospital must enlist a facility with expertise in the field to assist in the establishment of the standards and criteria, and provide required project monitoring.
- Each hospital must submit the proposed standards and criteria to the hospital institutional review board (IRB) for approval and, after the IRB has given its approval, to the Department of Health for review and approval.
- Each hospital must submit data as directed by the Department.
- Each hospital must provide evidence of how the project improves patient access to non-emergent PCI.

[a]Ischemia is a deficiency of blood in a part, usually due to functional constriction or actual obstruction of a blood vessel.

Source: Developed by LB&FC staff from correspondence signed by the Secretary of Health dated June 7, 2002.

As shown in Exhibit 9, the Department of Health did not:

- Establish minimum procedural volumes for both primary and elective PCIs for participating facilities,
- Require documentation of staff training and demonstrated ability for timely transfer of patients for emergency surgery, or
- Require 100 percent peer review of all procedures.

As a result, the Department of Health's criteria do not provide important patient safeguards used in other states.

Requirements in Other States: Several states that regulate cardiac services provide pathways for certain hospitals without onsite open heart surgery to perform emergent/ primary (but not elective) PCI for certain patients. Three of the states shown in Exhibit 2, Florida, Michigan, and New Jersey, have processes in place to allow hospitals without onsite open heart surgery backup that meet certain criteria to obtain permission to regularly perform emergent PCI for selected patients. Exhibit 10 provides key requirements used in such states.

Exhibit 10

Selected State Requirements for Emergent/Primary PCI Waivers

Florida

- Requires compliance with ACC/AHA guidelines, including operator and facility proficiency volumes.
- Revokes its exemption for facilities failing to comply (within 18 months) with ACC/AHA proficiency volumes.
- Prohibits programs with revoked exemptions from reapplying for two years.
- Requires programs to review and test transfer and transport agreements.
- Requires facilities to document such transfer and transport agreements at least every three months.
- Requires compliance with the state's therapeutic catheterization reporting requirements.

Michigan

- Requires demonstrated performance of at least 400 diagnostic procedures annually.
- Requires documentation that at least 48 primary PCI will be performed annually based on submission of actual case records for patients transferred to other facilities, with the records reviewed by state staff and state-designated cardiologist to determine if primary PCI was appropriate for the patient.
- Assures compliance with ACC/AHA guidelines by requiring facilities seeking waivers to:
    - Have at least two interventional cardiologists performing primary PCI who have each performed 75 interventions annually as a primary operator at a facility with open heart surgery during the proceeding two years.
    - Have two interventional cardiologists who commit to functioning as a group willing and able to provide primary PCI at the community hospital 24/7, 365 days a year per a call schedule, and have the ability to be onsite and available to operate within 30 minutes of identifying the need for primary PCI.
    - Immediately report any changes in the interventional cardiologists who perform PCI to the state.
- Requires written agreements between a community hospital and an open heart surgery center before it will consider an application. The written agreement must include:
    - Involvement of the open heart surgery facility in the development of credentialing criteria and recommending physicians approved to perform primary PCI.
    - Provision for ongoing cross-training for professional and technical staff involved in the provision of primary PCI, along with annual documentation of competency.
    - Provision for ongoing cross training for emergency department, catheterization laboratory and critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient candidates, along with annual documentation of competency.
    - Regularly held joint cardiology/cardiac surgery conferences to review all primary PCI cases.
    - Development and ongoing review of patient selection criteria for primary PCI patients, and implementation of those criteria.
    - A mechanism to provide for appropriate transfer between facilities and an agreed plan for prompt care.
    - Written protocols, signed by the community hospital and the open heart surgery facility, for provision for immediate and efficient transfer.
    - Quarterly review and testing of written protocols for patient transfer and transport.
    - Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.
    - A written protocol for case selection for the performance of primary PCI consistent with ACC/AHA guidelines.
    - A written protocol to ensure primary PCI is provided within 120 minutes of the patient presenting at the community hospital emergency room.
- Requires participation in a data registry, with the hospital requesting state permission to perform primary PCI liable for the cost of data submission and of onsite reviews required for the state to verify and monitor volumes and assure quality.

New Jersey

- Requires documentation of performance of 500 diagnostic catheterizations per year and transfer of 36 primary PCI cases per year based on actual AMI cases from the prior two years.
- Requires documentation that physicians performing primary PCI have performed at least 75 interventions annually and continue to do so.
- Requires compliance with ACC/AHA guidelines.
- Requires compliance with reporting requirements.

Source: Developed by LB&FC staff.

In addition, several of the states listed in Exhibit 2, have authorized selected hospitals to perform emergent/primary PCI as part of national research trials. New York, Maryland, Massachusetts, and Ohio authorized selected hospitals to perform emergent PCI as part of national research trials conducted by Aversano and other Johns Hopkins Medical Institution researchers. In addition to the criteria established by the national trial, New York developed additional criteria for facilities receiving waivers to provide primary PCI without onsite surgery. For example, waiver applicants were required to have performed a minimum of 400 diagnostic catheterization cases a year for the previous three years, and have had good results as judged by their mortality and major complication rates. New York, moreover, required facilities with waivers to report data to its cardiac registries and it includes data for such facilities and participating physicians in its published PCI performance reports.

Typically, states that regulate cardiac services do not authorize provision of elective PCI at hospitals without onsite open heart surgery.[53] Pennsylvania and West Virginia are the only states in Exhibit 2 that have authorized certain hospitals to perform emergent and elective PCI without onsite open heart surgery.

In West Virginia, the state's certificate of need program is conducting a demonstration pilot project. West Virginia published the criteria facilities had to meet to qualify to participate in the demonstration pilot project and selected three hospitals for its demonstration. Exhibit 11 provides West Virginia's selection criteria.

[53] LB&FC staff reviewed lists of hospitals that report providing elective PCI in states that regulate cardiac services. When we contacted relevant state officials in states such as Iowa, New Hampshire, North Carolina, Tennessee, and Washington, we were advised the state does not permit elective PCI at facilities without onsite open heart surgery programs. We were further advised the hospital "should not be doing it." In the case of a facility in New Hampshire, state officials indicated the hospital started its program prior to state regulation and, therefore, was exempt from the state regulation. Other hospitals on the lists are in western states that do not regulate cardiac services. Dr. Wharton from New Hampshire reported in late 2000 that 68 sites in the United States performed PCI without onsite open heart surgery (out of a total of approximately 800 sites), but only 22 of the 68 sites performed elective PCI, and many of these sites had low volumes.

Exhibit 11

West Virginia's Requirements to Participate in a Pilot Project to Provide Emergent and Non-Emergent/Elective PCI Without Onsite Open Heart Surgery

Pilot demonstration applicant must:

- Have provided diagnostic cardiac catheterization services for a period of not less than three years.
- Have performed a minimum of 600 diagnostic catheterization procedures annually for the most recent three year period.
- Have capacity to perform a minimum of 200 therapeutic catheterizations annually within 24 months of initiating services.
- Have at least two Board certified physicians who will actively participate in the Demonstration Pilot Project.
- Demonstrate each participating physician has performed a minimum of 75 therapeutic cardiac catheterizations annually for each of the most recent three years.
- Document patients have been informed that cardiac surgery is not available onsite, are aware of the associated risks, and have consented to have the procedure performed.
- Document provisions for joint quality review, to include 100 percent peer review of all procedures.
- Document proposed unit staffing meets ACC/AHA guidelines.
- Document staff has training in advanced life-saving procedures, including but not limited to, Intra-Aortic Balloon Pump Assist and sealing of perforated vessels using Stents.
- Document services will be available 24 hours a day, seven days a week.
- Provide a current copy of a collaborative agreement with one or more tertiary facility(ies) within 30 minutes air travel time of the demonstration facility and must possess the ability to transfer patients by air. The cooperative agreement must include:
    - Guidelines for selection of patients.
    - Provisions for emergency and routine transfer of patients, including transfer of patient information, and for agreed-upon cardiac catheterization imaging standards to avoid redundant catheterizations.
    - Provisions that specify cardiac surgery staff and facilities shall be immediately available to the patient upon notification of an emergency.
    - Explicit description of the responsibilities of each party.
- Participate in a national cardiovascular registry or databank, and report outcome results to the state.

Source: West Virginia Health Care Authority.

The LB&FC staff analyzed available data to assess the extent to which Pennsylvania hospitals providing primary and elective PCI without onsite open heart surgery meet West Virginia's criteria to participate in its demonstration. We found:

- None of the eight facilities selected by the Department performed at least 600 diagnostic catheterizations annually (see Table 7).
- Two of the eight facilities did not have the experience of performing diagnostic catheterizations for three years prior to receiving the waiver.
- None of the eight facilities documented that all physicians performing emergent PCI at demonstration sites had performed at least 75 interventions annually.
- None of the eight facilities documented call schedules showing availability of primary PCI 24/7, 365 days a year.
- Two of the three facilities operating in 2002 and 2003, including one that advised the Department it would perform over 300 PCI procedures annually (i.e., 25 per month), performed only four therapeutic catheterizations monthly during that period, based on data reported to the PHC4.
- Only one of the three facilities performing emergent and elective PCI in 2002 and 2003 performed an average of 15 procedures monthly and was on path to meet West Virginia's standard of at least 200 therapeutic catheterizations annually after 24 months of operations.

Both West Virginia and Pennsylvania require patients provide informed consent to participate in the state's demonstration or pilot projects. LB&FC staff reviewed the available patient consent forms approved for use at Pennsylvania's demonstration sites and provided to us by the Department.[54] We found patient consent forms are not standard across the demonstration sites, and Pennsylvania patients in the demonstration are not given important information about the risk associated with their participation. Exhibit 12 provides selected language from patient consent forms used in the Department of Health's demonstration.

As shown in Exhibit 12, Hospital 1 advises the patient there is less than 0.1 percent risk of death associated with therapeutic catheterizations. The American College of Cardiology National Cardiovascular Data Registry's observed in-hospital mortality rates for emergent PCI on stable patients is 5.4 percent, and for emergent salvage PCI 42.6 percent.[55] The New York cardiac data reports an observed mortality rate of 3.73 percent for "emergency cases" for 2000 through 2002 PCI discharges, and 0.37 percent for non-emergency cases.

[54]Consent forms were not included in the information provided by the Department of Health for all projects.
[55]Observed mortality rates also differ by age groups. The NCDR observed mortality rate for those less than 50 is 0.6 percent, and for those greater than 80, it is 3.8 percent.

The language in Hospital 1 and Hospital 2's informed consent forms acknowledges complications associated with the procedure can trigger the need for emergency open heart surgery. Hospital 2 advises the patient there is "minimal risk" the patient might need to be transferred to a hospital for open heart surgery if certain complications arise during the procedure. Hospital 1 advises that there is less than a 2 percent risk of blood vessel damage, closure, or severe bleeding associated with the procedure. Neither consent form, however, explicitly advises the patient about differences in the likelihood of survival related to time to surgery should the patient experience serious complications (i.e., the shorter the time to surgery, the greater the likelihood of patient survival). Hospital 1 only implies such differences by noting on the consent form that if transferred, "emergency surgery . . . might be performed more quickly and thus possibly more safely. . . ."

As shown in Exhibit 12, several of the consent forms approved by the Department do not advise the patient that the American College of Cardiology recommends against elective PCI at facilities without open heart surgery onsite. The language in some forms, moreover, could be interpreted by a patient to mean that the Pennsylvania Department of Health endorses the quality and the safety of the procedure being performed at a hospital without onsite open heart surgery backup. Such an interpretation could easily be drawn by laypersons since several of the hospitals were reported by local newspapers as having "received state approval to perform the life-saving procedure."[56]

Starting in 2004, the Department of Health has required facilities with licensure exceptions to include specific language in their informed consent forms indicating the Pennsylvania Department of Health and the American College of Cardiology recommend that patients undergo non-emergent therapeutic catheterizations in a hospital with open heart surgery onsite (see Exhibit 12, Hospital 4). The Department, however, has not required hospitals that received exceptions in 2002 and 2003 to modify their patient consent forms to include similar language.

In 2004, the Department of Health also started to require hospitals participating in its demonstration to advise their medical malpractice insurers they were providing therapeutic catheterizations as part of a demonstration without onsite open heart surgery backup and required documentation of such notice to the medical malpractice insurer.[57] To date, the Department has not required similar notice and submission of documentation from previously approved facilities.

[56]See, for example, Herald-Standard, 2/14/03.

[57]Medical malpractice lawsuits are generally based on tort law, which includes both statutes and court decisions. A tort is a wrongful act or omission that causes harm. Typically, a malpractice tort would be based on the claim that the health care provider was negligent, had failed to meet the acceptable standard of care owed to the patient, and thus caused injury to the patient.

Exhibit 12

Selected Excerpts From Informed Consent Forms Used in Programs Performing Emergent and Elective Therapeutic Cardiac Catheterization Without Onsite Open Heart Surgery Backup

Hospital 1: For catheterization/angiography, there is less than 1% risk of heart attack or stroke, and less than 0.1% risk of death or major allergic reaction. Blood vessel damage, closure, or severe bleeding occurs in less than 2%. For balloon PTCA/stenting there is generally less than 3% risk of major heart attack and less than 1% risk of death or need for emergency transfer for coronary bypass surgery. There is less than 2% risk of major blood vessel problems requiring blood transfusion or surgery. . . . Other treatment options include bypass surgery, or transfer to a cardiac surgical hospital before balloon PTCA/stenting. If I am transferred first, emergency surgery (in the rare event that I need it after the PTCA/stenting) might be performed more quickly and thus possibly more safely, but I will need a second procedure and often a longer hospital stay with this option.

Hospital 2: My doctor has explained to me what these procedures are and the possible risks of these procedures. These risks include: (a) heart attack, (b) major vascular damage (puncture or injury of a blood vessel), (c) allergy to the contrast (or dye) that is injected into the vessel, (d) death, and (e) arrhythmia. . . . My doctor has explained that . . . hospital does not have an open heart surgery service. It also has been explained that angioplasty procedures have usually been performed in a hospital with open heart surgery, but that . . . hospital has been approved by the Pennsylvania Department of Health to offer this service at . . . as part of a demonstration project. The demonstration project is intended to make angioplasty procedures more accessible in community hospitals qualified to provide the service. My doctor has explained that there is minimal risk that I might need to be transferred to a hospital with an open heart surgery service if certain complications arise during the procedure. If that happens, I have been told that I would be transferred immediately to a hospital with open heart surgery. I also understand that as part of the demonstration project, [the] hospital may be reporting data about my case to the Department of Health and to another teaching hospital.

Hospital 3: My doctor has explained that . . . hospital does not have an open heart surgery service. My doctor also has explained that in Pennsylvania angioplasty procedures have usually been performed in a hospital with open heart surgery, but that . . . hospital has been granted an exception to this requirement by the Pennsylvania Department of Health to participate in a demonstration project. The demonstration project is intended to make angioplasty procedures more accessible in community hospitals that qualify to provide the service. My doctor has explained that there is a minimal risk that I might need to be transferred to a hospital with an open heart surgery service if certain complications arise during the procedure. If that happens, I have been told that I would be transferred urgently using strict policies and procedures already developed to a hospital with open heart surgery. Guidelines of the American College of Cardiology recommend that elective angioplasty be performed in hospitals with open heart surgery on site.

Hospital 4: In Pennsylvania, angioplasty and stenting procedures have usually been performed in hospitals offering open heart surgical services. The Pennsylvania Department of Health and the American College of Cardiology recommend that patients undergo elective angioplasty procedures in a hospital with onsite open heart surgery services. A list of hospitals in the . . . area with open heart surgery services is attached to this consent form. The Department has granted an exception to certain community hospitals in order to make angioplasty procedures more available to patients located in areas served by those community hospitals.

Source: Developed by LB&FC staff from documents provided by the Department of Health.

In 2004, the Department of Health also started to require new demonstration projects to identify nearby facilities that provide therapeutic catheterizations with onsite open heart surgery backup. As shown in Table 8, four of the eight facilities in the Department's pilot projects are in counties that did not have open heart surgery programs. All demonstration sites, however, had hospitals providing therapeutic catheterization with onsite open heart surgery backup in at least one county. Neighboring programs[58] providing therapeutic catheterization with onsite open heart surgery backup appear to have capacity to serve additional patients given the number of available programs. Five of the eight pilot programs operate in areas where not all of the existing programs are meeting ACC/AHA's minimum proficiency volume standards.

Table 8

Waiver Facilities and Number of Nearby Hospitals With Open Heart Surgery Programs

Hospital	Number of Open Heart Surgery Programs Within County	Number of Open Heart Surgery Programs in Surrounding Counties
Somerset	None	3
Uniontown	None	2
Monongahela Valley	1	13
Jameson	None	3
Chambersburg	None	1
Montgomery	3	24
Jeanes	10	8
Holy Redeemer	3	24

Source: Developed by LB&FC staff from Department of Health data.

Department of Health Monitoring of Waiver Sites: The Department of Health advised hospitals that received exceptions to hospital licensure regulations to provide PCI without onsite open heart surgery that it would monitor their performance for compliance with the ACC/AHA guidelines. LB&FC staff met with Department of Health staff to become familiar with their monitoring procedures. They advised us projects are monitored using American College of Cardiology National Cardiovascular Data Registry reports for individual sites and that Department staff first received such reports for calendar year 2003 in June 2004.

LB&FC staff reviewed the data (for the three demonstration sites operating in 2003) available to the Department of Health through the national registry. The national registry lends itself to a variety of reports. The reports presented to the Department have been designed by the sites themselves, according to national registry officials with whom we spoke.

[58]All but one of the demonstration programs have neighboring programs within one hour or less travel time, and the one program where the neighboring program is over one hour relies on physicians from the neighboring program to provide coverage.

The national registry reports provided to the Department do not provide the Department with information required to assess compliance with the ACC/AHA requirements adopted by the Department (see Exhibit 8). They, for example, do not provide information on:

- number of primary PCI performed at the facility during the year, and
- number of such therapeutic catheterizations performed by each physician during the year.

The reports submitted to the Department also do not:

- Demonstrate relevant patient selection criteria are being followed.
- Demonstrate the procedures were subject to peer review, including procedures involving patient death.

One area where information relevant to the ACC/AHA guidelines is provided is the time from when a patient arrives at the hospitals to the time of the emergent PCI. ACC/AHA guidelines indicate emergent PCI should be performed within 120 minutes of arrival at the hospital.

- One of the three hospitals (operating in 2003) did not meet the criteria for any of its patients.
- Two of the three hospitals did not meet the criteria for 60 percent or more of their patients.

In addition, LB&FC staff identified certain key discrepancies in the procedure volumes reported voluntarily to the national registry and those reported to the Pennsylvania Health Care Cost Containment Council for one of the three hospitals. The facility reported performing 47 PCI to the national registry (and the Department of Health) with one patient death in the catheterization laboratory, and 35 therapeutic catheterizations to the Council with no patient deaths.

We contacted the hospital, and after researching the data, the hospital informed us that they had conducted 52 PCI in calendar year 2003, including nine unsuccessful attempts, and had two patient deaths. Based on our discussions with other states, we understand attempted and unsuccessful PCI and associated patient outcomes are to be reported to the national registry. It is also our understanding that attempted and unsuccessful PCI should be rare events.

Differences in the number of reported procedures were due to the way in which unsuccessful PCI were recorded in the different data systems, and the

hospital failing to report outpatient procedures to the PHC4. In the case of the PHC4 data, the unsuccessful PCIs, including two in which patient deaths occurred, were not reported as therapeutic catheterizations. Instead, they were captured as inpatient deaths with diagnostic catheterizations.

The problems with the data for one demonstration site highlight the significant challenge facing the Department of Health staff and the staff of tertiary care hospitals working with the demonstration sites to assure quality of care and patient safety. They have no way of assuring all procedures relevant to quality of care and patient safety in the demonstration come to their attention. To begin to assure that all procedures with adverse patient outcomes are identified, they would need to review all diagnostic and therapeutic catheterizations billed and reported to the PHC4.

In 2003, the Pennsylvania Chapter of the American College of Cardiology advised the Department of Health of its concerns for patient safety with the demonstration pilot project. The Chapter noted:

> . . . the recent waivers granted to hospitals to perform elective [PCI] without onsite cardiac surgical back-up are potentially hazardous. All angioplasty procedures carry a small and unpredictable risk for major complications, including death. Recent data available from the NCDR database would suggest that urgent bypass surgery is needed in 1 of 300 patients undergoing elective PCI. For this reason, the expert committee of cardiologists that revised the guidelines for PTCA stated: 'at this time, the Committee, therefore continues to support the recommendation that elective PCI should not be performed in facilities without onsite cardiac surgery (Table 17 [in the ACC/AHA guidelines]).' (J Am Coll Cardiol 2001;37:2239xxi)[59]

In December 2004, the Department of Health requested to meet with representatives from the Pennsylvania Chapter. It sought Chapter input as the two year demonstration period for the initial sites is coming to a close.

Proposed National Elective PCI Clinical Trial: When the Department of Health initiated its demonstration program allowing performance of elective PCI, a national clinical trial was not available to hospitals interested in evaluating the safety and efficacy of elective PCI provision without onsite open heart surgery backup to improve the availability of cardiac services in their communities. Currently, medical researchers at Johns Hopkins Medical Institutions are in the process of finalizing the design for an elective angioplasty study. This national trial requires random of assignment of 12,000 patients to PCI at a facility with onsite open heart surgery or a facility without such surgical backup.

[59]May 5, 2003 correspondence.

Hospitals seeking to participate in the proposed national trial must meet certain criteria. They must:

- have the capability to perform 200 therapeutic catheterizations in an existing laboratory;
- agree to complete a primary and elective PCI development program, abide by the trial's physician, patient, and devise selection criteria; collect and transmit study data in a timely manner; perform certain therapeutic catheterizations via a defined study protocol;
- develop and maintain a quality and error management program, including a weekly interventional conference and monthly QE review;
- perform PCI 24/7; and
- report outcomes to a clinical trial registry.

The national trial physician inclusion criteria require that physicians:

- meet the ACC/AHA standards for competency (minimum of 75 cases per year),
- agree to practice in accordance with defined study device and patient selection criteria,
- obtain necessary informed consent from patient participants,
- complete necessary data forms, and
- participate in required QE programs and competency review and training.

The principal researcher for the proposed national trial advised the LB&FC that several states that regulate cardiac services and have requirements for onsite open heart surgery backup for therapeutic catheterizations (e.g., Massachusetts, New Jersey, Michigan, and Maryland) are considering granting waivers to their regulations to allow selected facilities to participate in the proposed national trial. We were also advised that Pennsylvania facilities that meet project selection criteria would be welcomed to participate in the national trial.

N. The volume of open heart procedures performed has been declining at the same time as many new programs opened.

In 1995, Pennsylvania providers performed over 19,000 CABG procedures—the primary type of open heart surgery—according to published reports from the Pennsylvania Health Care Cost Containment Council (PHC4). By 2002 just over 16,000 procedures were performed. Despite the 15 percent drop in reported CABG

cases, 18 new open heart surgery programs were included in the Council's 2002 published report.[60]

The decline in procedure volume and the increase in the number of open heart surgery programs have resulted in a sharp drop in the average volume of procedures performed by Pennsylvania open heart surgery programs. In 1995, they averaged about 450 procedures annually—the facility volume required in Pennsylvania's last State Health Services Plan. By 2002, Pennsylvania programs had dropped to just under 270 procedures.

When we compared Pennsylvania cardiac surgery providers' average volume of procedures with surrounding states for whom data were available, we found Pennsylvania providers perform fewer CABG procedures on average than providers in New York and New Jersey. As shown in Table 9, the average number of procedures performed by providers in New York and New Jersey is over 50 percent greater than the average for Pennsylvania's providers.

Table 9

Calendar Year 2000 CABG Volumes for Pennsylvania and Selected States

State	Total Providers	Total Procedures	Average Procedures Per Provider
Pennsylvania	55	19,281	350
New York	34	18,121	533
New Jersey	15	8,220	548

Source: Developed by LB&FC staff from published CABG reports.

In 2003, many Pennsylvania cardiac surgery programs were not meeting facility proficiency volumes that are in place in other states. Table 10 provides the cardiac service facility proficiency volumes used in selected states.[61] Failure to meet proficiency volumes in many of the states triggers a quality assurance review to assure patient safety.

[60]PHC4 published CABG reports do not include all programs that are in operation at a particular point in time. From December 1996 through December 2003, Pennsylvania had 23 new open heart surgery programs.

[61]Massachusetts, Michigan, and West Virginia also have minimum proficiency volumes for physicians.

Table 10

Cardiac Surgery Annual Proficiency Volumes for Selected States

State	Annual Proficiency Volumes
Pennsylvania	None
Florida	300
Maryland	200
Massachusetts	300
Michigan	300
New Jersey	350
New York	500
Ohio	250
West Virginia	250

Source: Developed by LB&FC staff from relevant state regulations and policies.

In calendar year 2003,

- 19 of Pennsylvania's 63 adult open heart surgery programs did not meet facility volume proficiency standards of any of the other states listed in Table 10.
- 14 met New York's facility proficiency volume standard.
- 28 met New Jersey's standard.
- 34 met Florida's, Massachusetts', and Michigan's standard.
- 39 met Ohio's and West Virginia's standard.
- 44 met Maryland's standard.

Five of the 19 programs that did not meet the volume proficiency standards of the other states had observed mortality rates greater than the AHRQ's quality benchmark for CABG.

O. More open heart surgeons were performing fewer than 100 CABG in 2002 than in 1995, and such surgeons have mortality rates 30 percent higher than the statewide average.

Over time the number of open heart surgeons in Pennsylvania has remained fairly stable. An increasing number and proportion of such surgeons, however, performed fewer than 100 surgeries, as shown in Table 11.

Table 11

Surgeons Performing Fewer Than 100 CABG Procedures
(In 1995 and 2002)

Year	Total Surgeons	Surgeons Performing Fewer Than 100 CABG Procedures
1995	189	88 (47%)
2002	190	102 (54%)

Source: Pennsylvania Health Care Cost Containment.

The PHC4's CABG-procedure-only mortality rate declined for all surgeons from 1995 to 2002, as shown in Table 12. Surgeons performing more than 200 cases had the lowest CABG mortality rates in 1995 and 2002. They also had the most improvement over the period. As a result, by 2002, surgeons performing more than 200 cases had CABG mortality rates in 2002 that were 34 percent less than the rate for all CABG surgeons in the state.

The mortality rates for surgeons performing fewer than 100 cases also improved from 1995 to 2002. Nonetheless, their CABG mortality rates remained roughly 30 percent higher than the average for all surgeons over the period.

Table 12

Surgeon CABG Mortality Rates by Procedure Volume
(1995 and 2002)

Year	CABG Mortality-All Surgeons	CABG Mortality-Surgeons Performing Fewer Than 100 Procedures	CABG Mortality-Surgeons Performing 200 or More Procedures
1995	3.3%	4.4%	2.7%
2002	2.4	3.1	1.6

Source: Pennsylvania Health Care Cost Containment Council.

Organ Transplant Services and Quality Benchmarks

P. Some Pennsylvania transplant programs have not met Medicare's proficiency volumes.

Several Pennsylvania transplant programs have not met Medicare's volume standards in recent years.[62] As shown in Table 13:

- One (Oakland VA Medical Center) of the 13 adult kidney transplant programs did not met Medicare's standard.
- Two (Hershey Medical Center and Hahnemann) of the seven liver transplant programs did not meet Medicare's standard.
- One (Allegheny General Hospital) of the six heart transplant programs did not meet Medicare's standard.
- One (Temple University) of the three lung transplant programs did not meet Medicare's standard.

Table 13

Average Annual Transplant Volumes

Hospital	Kidney	Liver	Heart	Lung
Albert Einstein	45.2	41.6	N/A	N/A
Allegheny General	72.8	N/A	5.2	N/A
Geisinger	36.0	N/A	N/A	N/A
Hershey Medical Center	62.0	6.8	13.2	N/A
Pinnacle Health	58.8	N/A	N/A	N/A
Hahnemann	92.8	6.0	17.2	N/A
Lankenau	18.0	N/A	N/A	N/A
Lehigh Valley Hospital	29.6	N/A	N/A	N/A
UPMC	126.0	157.2	33.6	48.0
Oakland VA Medical Center	2.0	18.8	N/A	N/A
Thomas Jefferson	95.2	30.0	N/A	N/A
Temple University	17.2	N/A	41.6	7.6
Hospital of the University of Pennsylvania	130.4	94.4	46.0	28.8

Note: Annualized volumes for kidney and liver transplants are based on data for the period 1/1/01 to 6/30/03. Annualized volumes for heart and lung transplants are based on data for the period 7/1/00 to 12/31/02.
Source: Developed by LB&FC staff from the Scientific Registry of Transplant Recipients database.

[62]Transplant programs are not required to participate in the Medicare program; 93 percent of programs nationwide, however, do participate.

In part, the problems providers experience in meeting Medicare's volume standards for heart and lung transplants may be due to the decline in available organs for such transplants in Pennsylvania from 1995 through 2003. In 1995, there were 211 heart transplants in Pennsylvania, according to the database of the Scientific Registry of Transplant Recipients. By 2003, there were only 169. In 1995, there were 118 lung transplants in Pennsylvania. By 2003, they were just 93.

Only kidney and liver transplants increased during the period—mirroring the recent increase in such transplants nationwide. Kidney transplants in Pennsylvania increased from just over 700 in 1995 to over 1,000 in 2003, with the number of liver transplants increasing from 400 to over 500.

On February 4, 2005, moreover, the federal Department of Health and Human Services published proposed changes to its Medicare conditions of participation for transplant hospitals. The proposal would replace Medicare's current standards of 12 transplants over a 12-month period for heart, and liver transplant programs, and 10 transplants for lung transplant programs. In their place, Medicare would require centers to achieve specified one-year patient and graft survival rates over a 2.5 year period based on a minimum of 9 patients. Medicare's proposed outcome measures for centers seeking initial approval and subsequent re-approval mirror the current approach taken by the National Organ Procurement Transplant Network (OPTN) discussed below.

Q. Over one-half of Pennsylvania transplant programs have one-year patient survival rates lower than their expected rates, though the difference is not significantly lower for most programs.

In addition to volume, patient survival rates[63] historically have been considered indicators of quality of care for transplant programs. In the case of major organ transplants, Medicare has established initial patient survival rates, which it currently considers too low since medical technology and pharmacology have significantly increased transplant patient and graft survival. In early February 2005, therefore, Medicare proposed to adopt center-specific outcome standards based on those of the Organ Procurement and Transplant Network (OPTN).

The national Organ Procurement and Transplant Network (OPTN),[64] in conjunction with the Scientific Registry of Transplant Recipients (SRTR), establishes survival rates for individual programs based on the characteristics (such as age, disease, blood type, and relevant clinical data) of those served and the experience of similar patients nationwide during specific periods of time. According to

[63]These rates represent patients and may include patients whose transplants have failed, but the patient continues to survive though such means as a subsequent transplant, or in the case of kidney patients through dialysis.
[64]See, 42 C.F.R. §§121.1-121.12.

Pennsylvania Department of Health licensure regulations and as discussed below, quality assurance reviews are to be conducted when transplant programs are not meeting their Organ Procurement and Transplant Network (OPTN) expected survival rates.[65]

Federal OPTN regulations require ongoing and periodic review and evaluation of transplant programs that are part of OPTN.[66] They also require transplant centers to submit significant data, including clinical data, to the Scientific Registry for all patients receiving organ transplants in the United States.[67] In the United States, transplant programs are required to participate in the OPTN in order to match patients in need of organ transplants with organs available for transplant.

The OPTN bylaws state:

> Survival rates. In the distribution of survival rates of all OPTN members a center with a low (as defined below) survival rate would be subject to evaluation to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question.
>
> Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed . . .
>
> While the precise numerical criteria may be selected by the MPSC (Membership and Professional Standards Committee), the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that the observed events minus expected events is greater than 3 and the observed event divided by the expected events is greater than 1.5; and there exists an one sided p value of less than 0.05.
>
> Observed events[68] represent deaths or graft loss as reported in the OPTN database. Expected events represent deaths or grafts as calculated utilizing organ specific transplant models. Incomplete follow-up data will be treated as a graft loss or patient death in the context of this analysis.

[65]§158.19
[66]42 C.F.R. §121.10 (b) (iii).
[67]See, 42 C.F.R. §121.11 (b) (2).
[68]Observed and expected events are referring to numbers of patient deaths and numbers of graft failures. Observed events are the actual numbers reported by the program to the Registry, and expected events are the numbers expected based on the model used by the Scientific Registry of Transplant Recipients to arrive at a center specific survival rate.

> If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, it will be considered for appropriate action in accordance with Appendix A of [the OPTN] bylaws.[69]

On February 4, 2005, Medicare proposed one-year patient (and also graft) survival rates over a 2.5 year period based on OPTN's three thresholds.

The OPTN/UNOS[70] board of directors had designated responsibility for monitoring transplant programs to its membership and professional standards committee. The OPTN/UNOS staff regularly provide the committee with various reports to help identify if relevant criteria[71] established for transplant centers are being followed.

Such reports include quarterly reports of risk-adjusted center specific patient mortality using statistical models developed by the Scientific Registry. The committee uses these reports (without the names of centers identified) to identify transplant programs that should be reviewed because of possible poor performance. The reports, which focus on one-year survival rates adjusted for patient characteristics, are used to flag programs that fall below the thresholds specified in the bylaws.

Transplant programs that are "flagged" by the OPTN/UNOS membership and professional standards committee are regularly monitored to see if their performance improves. They are also engaged in a quality assurance process. The process involves:

- Requesting programs to verify the data they reported to the Scientific Registry and providing complete data when all required data has not been submitted. Programs that may not have reported complete data to the Registry may have different survival results based on more complete reporting.

- Assessing to determine if the program's expected survival rate is accurate, or if the program includes patients or performs procedures that are not accounted for in the model the Scientific Registry uses to identify each program's expected survival rate. Based on the additional information provided by the program, the committee may decide that the lower than expected survival for the program is due to its serving patients who have characteristics that are not included in the statistical model.

[69]OPTN bylaws, Appendix B-2 at www.optn.org. The exact same language can be found in the UNOS bylaws Appendix B Attachment 1-designated transplant program criteria, xii transplant programs.
[70]OPTN bylaws state: The OPTN board of directors shall be elected in parallel with and using the same processes as the OPTN contractor's board of directors, resulting in identical membership, if the OPTN contract provides for such an arrangement." The bylaws go on to state: "this will enable the OPTN contractor to perform tasks required by the OPTN contract under the governance of the OPTN board of directors.
[71]The reader should note that survival rates are not the only criteria that are monitored.

- Requesting and reviewing information from the program based on its own self-assessment and on the steps the program is taking to improve performance.

- Reviewing independent consulting reports and recommended plans for improvement that have been initiated by the program itself.

- Contracting with transplant experts to conduct onsite reviews and offer consultation when requested or where indicated.

Ultimately, the committee may recommend to the OPTN board that a process begin to declare the program not to be a member in good standing. Remaining a member in good standing is important to programs since such membership is required to receive donor organs for transplant. If the committee should recommend and the board concur that the program's designated transplant program status be changed, the program has rights to appeal to the Secretary of the Department of Health and Human Services. OPTN staff with whom we spoke, however, advised that programs "flagged" for monitoring typically have identified relevant program issues and are taking steps to implement improvements. In some cases, they decide to voluntarily change their program status and make their program inactive. In other words, they stop performing transplants.

In addition to supporting the work of OPTN and its board, the Scientific Registry of Transplant Recipients (SRTR) is required by federal regulations[72] and its federal contract to post on the Internet center-specific outcome data for every transplant center in the United States. Twice a year, the SRTR website posts significant performance outcome data at its website including one month, one year, and three-year expected and actual survival rates for specific cohorts of patients served by each center.

The SRTR website (and the OPTN membership and standards committee's) reported survival data are based on a specific group of transplant patients served during specific timeframes. The time frames and characteristics of the patients served by the center continually change. A particular program's expected survival rate, therefore, is not constant and continually changes.

The Scientific Registry's website notes that because of differences in patients served across programs, individual program survival rates cannot be compared. It also notes that specific circumstances at each center may affect many of the measures included in the report and advises the public to contact the program for further information.

[72]42 C.F.R. §121.11 (b) (1) (iv).

The reports posted by the Scientific Registry at its website are based on the same patient and center database used by the OPTN membership and professional standards committee to review and evaluate programs. The website semi-annual reports are similar, though not the same, as the committee's quarterly reports. The Scientific Registry's website reports, however, can be used to "flag" programs with possible performance issues and monitor their performance over time for quality assurance follow up, or to determine if the program is involved with the OPTN in quality assurance processes.

LB&FC staff reviewed the Scientific Registry's website (www.ustranplant.org) reports for Pennsylvania transplant programs. Specifically, we reviewed the one-year patient expected and actual survival rates for kidney, liver, heart and lung transplant programs for each center for two groups (or cohorts) of patients:

- patients receiving kidney and liver transplants from January 1, 2001 through June 30, 2003, and patients receiving heart and lung transplants from July 1, 2000 through December 31, 2002, and
- patients receiving kidney and liver transplants from July 1, 2001 through December 31, 2003, and patients receiving heart and lung transplants from January 1, 2001 through June 30, 2003.

We found:

For kidney transplant patients:

- From January 1, 2001 through June 30, 2003, 6 of the 13 kidney transplant programs had actual one-year patient survival below their expected rates. For 1 of the 6 programs, the lower than expected rate was significantly different.

- From July 1, 2001 through December 31, 2003, 7 of the 13 kidney transplant programs had actual one-year patient survival below their expected rates. For 1 of the 7 programs, the lower than expected rate was significantly different.

For liver transplant patients:

- From January 1, 2001 through June 30, 2003, 5 of the 7 liver transplant programs had actual one-year patient survival below their expected rates. For 1 of the 5 programs the lower than expected rate was significantly different.

- From July 1, 2001 through December 31, 2003, 5 of the 7 liver transplant programs had actual one-year patient survival below their expected rates. For 2 of the 5 programs, the lower than expected rate was significantly different.

For heart transplant patients:

- From July 1, 2000 through December 31, 2002, 4 of the 6 heart transplant programs had actual one-year patient survival below their expected rates, though none of the 4 programs had rates that were significantly different from their expected rates.

- From January 1, 2001 through June 30, 2003, 4 of the 6 heart transplant programs had actual one-year patient survival below their expected rates, though none of the 4 programs had rates that were significantly different from their expected rates.

For lung transplant patients

- From July 1, 2000 through December 31, 2002, 3 of the 3 lung transplant programs had actual one year patient survival below their expected rates, though none of the 3 programs had rates that were significantly different from their expected rates.

- From January 1, 2001 through June 30, 2003, 3 of the 3 lung transplant programs had actual one year patient survival below their expected rates, though none of the 3 programs had rates that were significantly different from their expected rates.

Those programs with actual one-year patient survival rates significantly lower than their expected rates appear[73] to meet the two additional criteria in OPTN bylaws that would "flag" them for OPTN monitoring of performance trends and quality assurance efforts on the part of the programs to address problems that may be identified.

The federal Department of Health and Human Services, in the February 4, 2005, proposed Medicare regulations, stated that based on the Scientific Registry data from July 2004, nationwide 10 percent of all adult kidney, liver, heart and lung programs had lower than expected one-year patient and graft survival and met all three OPTN thresholds that would "flag" their performance. LB&FC staff reviewed

[73]The Scientific Registry's website does not list the actual number of deaths to determine if the difference in observed events versus expected events is greater than 3. The number, however, can be inferred from the reported data (i.e., the actual number of transplant patients and the difference between the actual and expected survival rates), according to staff from the Scientific Registry with whom we spoke.

Pennsylvania adult patient programs' patient and graft one-year survival rates, using the Scientific Registry data from January 2005. We found:

- Only 8.62 percent of Pennsylvania's adult kidney, liver, heart, and lung programs had lower than expected one-year patient and graft survival rates that met all three OPTN thresholds that would trigger performance review.

This suggests that Pennsylvania organ transplant programs as a group perform as well, possibly somewhat better, than programs nationally.

In addition to the OPTN review, the Pennsylvania Department of Health is also to monitor the performance of Commonwealth transplant programs. The Department of Health's vital organ transplant regulations at §158.19 state as follows:

> (a) Each transplantation program shall perform an adequate number of procedures to maximize quality.
>
> (b) Each transplantation program shall meet the expected survival rate as set forth by the Organ Procurement and Transplantation Network in its bylaws. Those programs whose actual survival rates fall below their expected survival rates will be reviewed by the Department to determine if this deviation can be accounted for by patient mix or some other unique clinical aspect of the transplantation program.
>
> (c) If the transplantation program is unable to provide an explanation for its failure to meet the expected survival rate, the Department will undertake a review of that program to determine if it is in compliance with the criteria in this chapter. The hospital shall cooperate with the Department in this review.

In June 2004, the Department advised the LB&FC staff that information on all of its investigations and reviews of licensed facilities could be found at its website. We reviewed the information available at its website for all facilities with actual organ transplant survival rates lower than their expected rates, including those where the difference is lower and significant. We were unable to identify any such reviews having been undertaken by the Department of Health.

III. Appendices

APPENDIX A

House Resolution 356 of 2003

PRINTER'S NO. 2400

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 356 Session of 2003

INTRODUCED BY MUNDY, DAILEY, BIANCUCCI, DeLUCA, D. EVANS, BEBKO-JONES, BROWNE, COY, CRUZ, CURRY, EACHUS, FRANKEL, FREEMAN, GEORGE, GERGELY, GOODMAN, GRUCELA, HARHAI, HERSHEY, LEACH, LEDERER, LEVDANSKY, MANDERINO, PETRI, READSHAW, ROONEY, SURRA, TANGRETTI, TIGUE, WASHINGTON, WHEATLEY, YOUNGBLOOD AND VANCE, JULY 8, 2003

REFERRED TO COMMITTEE ON AGING AND OLDER ADULT SERVICES, JULY 8, 2003

A RESOLUTION

Directing the Legislative Budget and Finance Committee to study certain issues related to health care facilities.

WHEREAS, The House of Representatives recognizes the need for quality assurance in providing health care services which involve specialized technical medical procedures and require extraordinary expertise and resources to be effective, including, but not limited to, organ transplant, cardiac catheterization and open-heart surgery; and

WHEREAS, The Department of Health currently licenses health care facilities in this Commonwealth and focuses primarily on basic safety standards for facility structures; and

WHEREAS, Since the sunset of the certificate of need program in the mid-1990s, there has been no statutory authority that requires health care facilities to prove they are providing needed services to the communities in which they operate; and

WHEREAS, The result has been an increase in the number of ambulatory surgical facilities and similar nonhospital health care facilities in this Commonwealth; and

WHEREAS, The quality of health care declines when fewer procedures and treatments are performed at each facility; and

WHEREAS, The cost of health care rises as duplicate medical equipment and staff are needed at each facility; therefore be it

RESOLVED, That the House of Representatives direct the Legislative Budget and Finance Committee, in consultation with health care experts and specialists, to conduct a study to examine and identify:

(1) Health care services that require extraordinary expertise and resources, such as organ transplant, cardiac catheterization and open-heart surgery.

(2) Types of health care facilities that provide these health care services.

(3) Standards for clinically effective care developed by national accreditation and specialty organizations for health care facilities that offer these services, including volume standards on the minimum number of cases a health care facility must treat in order to ensure clinical proficiency.

(4) Ways to ensure that health care facilities performing these services have sufficient volume to meet recognized professional standards for clinically effective care.

(5) Ways to ensure that health care facilities performing these services have appropriate staff and backup resources that deal with emergency circumstances to meet recognized professional standards for clinically effective care.

Appendix A (Continued)

(6) Standards for clinically effective care and licensing procedures for health care facilities in other states;

and be it further

RESOLVED, That the Legislative Budget and Finance Committee make a report of its findings and recommendations to the Speaker of the House of Representatives, the Aging and Older Adult Services Committee and the Health and Human Services Committee within one year of adoption of this resolution.

APPENDIX B

Correspondence From the Pennsylvania Chapter of the American College of Cardiology

Pennsylvania
CHAPTER

Chapter Administrative Office
Maria B. Elias
777 East Park Drive
PO Box 8820
Harrisburg, PA 17105-8820
(888) 633-5184
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Executive Council
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Governor, Western PA
A.J. Conrad Smith, MD, FACC

Vice President
Governor, Eastern PA
Steven M. Ettinger, MD, FACC

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Michael D. Eschowitz, MD, FACC

Immediate Past Governor, Eastern PA
Howard C. Herrmann, MD, FACC

Immediate Past Governor, Western PA
Joseph G. Cacchione, MD, FACC

Councilors
District I
John Doherty, MD, FACC
Philadelphia

District II
Michael A. Rossi, MD, FACC
Allentown

District III
Jack E. Smith, MD, FACC
Erie

District IV
David Lasorda, DO, FACC
Sewickley

October 7, 2004

Mrs. Mary Anne Nardone
Legislative Budget and Finance Committee
Finance Building
Room 400A
PO Box 8737
Harrisburg, PA 17105

Dear Mrs. Nardone:

Enclosed is a list of practicing physicians who are members of the Pennsylvania Chapter of the American College of Cardiology. Each cardiologist has expressed a willingness and commitment to volunteer his service in working with the state as it relates to HB2771.

As per our telephone conversation, our state chapter is very interested in working with you and the legislature in reviewing data submitted to PHC4 and NCDR as it pertains to the practice of invasive and interventional cardiology in Pennsylvania.

The physicians listed below are in good standing in the PaACC and possess the clinical expertise necessary to critically review the practice records submitted to these monitoring agencies.

If we can be of any further assistance please do not hesitate to contact us individually or our Chapter administrator, Maria Elias [telephone: 558-7850 ext.1475; fax: 717-558-7841; e-mail: melias@pamedsoc.org].

Again, thank you for your time.

Steven M. Ettinger

Steven Ettinger
ACC Governorship Eastern Pennsylvania

Dr. Donald C. Durbeck
Dr. Howard C. Herrmann
Dr. Ancil A. Jones
Dr. Steven M. Ettinger
Dr. Paul N. Casale
Dr. A.J. Conrad Smith
Dr. Joseph G. Cacchione
Dr. David M. Lasorda
Dr. Michael A. Rossi

Copy: Dr. A.J. Conrad Smith
Chapter File

Source: American College of Cardiology, Eastern Pennsylvania Governorship.

APPENDIX C

Hospitals Providing Diagnostic Catheterizations
(As of 12/31/03)

Alle-Kiski
Berwick
Bradford Regional
Brookville
Canonsburg General
Carlisle Regional
Chambersburg
Chestnut Hill
Clearfield
Community Lancaster
Ellwood City
Ephrata Community
Forbes Regional
Frick
Gettysburg
Good Samaritan/Lebanon
Grant View
Hanover
Holy Redeemer
Indiana Regional
Jameson Memorial
Latrobe Area
Meadville
Memorial York
Mercy Philadelphia
Mercy Providence
Millcreek Community
Montgomery
Moses Taylor
Mount Nittany
Ohio Valley General
Pottstown Memorial
Riddle Memorial
Sewickley Valley
Suburban General/Pittsburgh
UPMC Horizon
UPMC McKeesport
UPMC Passavant Cranberry
UPMC St. Margaret
Warminster

Source: PA Health Care Cost Containment Council.

APPENDIX D

Hospitals Providing Diagnostic and Therapeutic Catheterizations
(As of 12/31/03)

Abington Memorial
Albert Einstein
Allegheny General
Altoona
Bon Secours Holy Family
Brandywine
Butler Memorial
Chester County
Children's Hosp Pgh
Children's Hosp Phila
Community/Scranton
Conemaugh Valley Memorial
Crozer-Chester
Doylestown
DuBois Regional
Easton
Frankford
Geisinger Wyoming Valley
Geisinger/Danville
Graduate
Hahnemann University
Hamot
Holy Spirit
Hospital University PA
Jefferson Regional
Lancaster General
Lancaster Regional
Lehigh Valley
Lehigh Valley/Muhlenberg
Main Line Bryn Mawr
Main Line Lankenau
Main Line Paoli
Medical Center Beaver
Medical College PA
Mercy Fitzgerald
Mercy Pittsburgh
Mercy/Scranton
Mercy/Wilkes-Barre
Milton S Hershey
Monongahela Valley
Pennsylvania
Phoenixville
Pinnacle Health
Reading
Robert Packer
Sacred Heart/Allentown
Saint Vincent Health
Sharon Regional
Somerset Center Health
St Christopher's Children
St Clair Memorial
St Francis Central
St Joseph/Reading
St Luke's/Bethlehem
St Mary
Temple Lower Bucks
Temple University
Thomas Jefferson Univ
Uniontown
Univ PA/Presbyterian
UPMC Lee Regional
UPMC Passavant
UPMC Presby Shadyside
Washington
Western Pennsylvania
Westmoreland Regional
Williamsport
WVHCS
York

Source: PA Health Care Cost Containment Council.

APPENDIX E

Hospitals Providing Open Heart Surgery
(As of 12/31/03)

Abington Memorial
Albert Einstein
Allegheny General
Altoona
Bon Secours Holy Family
Brandywine
Butler Memorial
Chester County
Children's Hosp Pgh
Children's Hosp Phila
Community Medical Center/Scranton
Conemaugh Valley Memorial
Crozer-Chester
Doylestown
DuBois Regional
Easton
Frankford
Geisinger Wyoming Valley
Geisinger/Danville
Graduate
Hahnemann University
Hamot
Holy Spirit
Hospital University PA
Jefferson Regional
Lancaster General
Lancaster Regional
Lehigh Valley
Lehigh Valley/Muhlenberg
Main Line Bryn Mawr
Main Line Lankenau
Main Line Paoli
Medical Center Beaver
Medical College PA
Mercy Fitzgerald
Mercy Pittsburgh
Mercy/Scranton
Mercy/Wilkes-Barre
Milton S Hershey
Pennsylvania
Phoenixville
Pinnacle Health
Presbyterian (U of PA)
Reading
Robert Packer
Sacred Heart/Allentown
St Christopher's Children
St Clair Memorial
St Joseph/Reading
St Luke's/Bethlehem
St Mary
St Vincent Health
Sharon Regional
Temple University
Temple Lower Bucks
Thomas Jefferson Univ
Uniontown
UPMC Presbyterian
UPMC Lee Regional
UPMC Passavant
UPMC Shadyside
Washington
Western Pennsylvania
Westmoreland Regional
Williamsport
WVHCS
York

Source: PA Health Care Cost Containment Council.

APPENDIX F

Hospitals Providing Major Organ Transplants
(As of June 2004)

Albert Einstein Medical Center
Allegheny General
Children's Hosp Pgh
Children's Hosp Phila
Geisinger Medical Center/Danville
Hahnemann University
Hamot
Hospital University PA
Lehigh Valley
Main Line Lankenau
Milton S Hershey
Pennsylvania
Pinnacle Health
St Christopher's Children
Temple University
Thomas Jefferson University Hospital
UPMC Presbyterian/Shadyside
Western Pennsylvania

Source: PA Health Care Cost Containment Council.

APPENDIX G

Response to This Report

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

THE SECRETARY

HARRISBURG

April 8, 2005

Mr. Philip R. Durgin, Executive Director
Legislative Budget and Finance Committee
Room 400, Finance Building
Harrisburg, Pennsylvania 17107

Dear Mr. Durgin:

Thank you for the opportunity to comment on the draft report entitled Quality Assurance for Specialized Clinical Services.

Our comments fall into four general categories: Recommendations, Process, General, and Specific.

RECOMMENDATIONS:
The Department's comments on the report recommendations follow:

1. The Department of Health should routinely review the cardiac data hospitals submit as part of state licensure requirements. The Department agrees. We currently use the hospital data provided to us by PHC4 in two ways. The detailed cardiac catheterization reports that we receive periodically are used as a resource for our regular survey process if we find a problem at a facility. We also obtain quarterly sample reports that are used to structure our patient chart sample. Since much of our clinical work is based on individual patient chart review, this tool allows us to focus our attention on the services offered at a particular hospital.

2. The Department of Health, working with the Pennsylvania Chapter of the American College of Cardiology, should take steps to form a cardiac oversight committee to assist the Department. The Department agrees. We have had several discussions with the PA chapter of the ACC regarding their recommendations and advice. The Deputy Secretary for Quality Assurance was invited to present to their annual conference. Most recently, we asked the ACC to make recommendations to us regarding the use of exceptions, and methods of evaluation. We are currently waiting to receive these recommendations.

POST OFFICE BOX 90, HARRISBURG, PA 17108 717 787 6436

3. The Department of Health should institute a moratorium on approval of additional hospital licensure exceptions for provision of PCI without cardiac surgery on site. The Department agrees, and we will cease approvals once all outstanding litigation is resolved.

4. The Department of Health should require all current PCI demonstration sites to join a national clinical trial and comply with all requirements and protocols of the national clinical trial. The Department agrees, and we will make it a condition of exception renewal after the initial two-year exception is completed. We also require this as a condition of any new exceptions that result from litigation.

5. The Department of Health should routinely review survival data for individual transplant programs and follow-up with programs with lower than expected survival rates. The Department agrees. We currently use the organ transplant web site data in cases where the survey identifies problems with the transplant program.

PROCESS:
As we expressed to you at our transmittal meeting on January 24, 2005, the Department believes that the process LB&FC uses for obtaining agency feedback does not provide a good opportunity to incorporate all subjects' observations into the final report.

The Department requested (copy attached) that we be permitted to share copies of the confidential report with the entities that were the focus of the report. As of the date of this letter, we have not received a response from you, so we have honored your request to keep the report confidential. However, several entities that are the subject of specific recommendations have not had an opportunity to comment. By issuing a confidential document that is not sent to all the parties being studied, we believe that the accuracy and depth of the report is compromised. The entities in question include the hospitals that are currently providing percutaneous coronary intervention (PCI) services under the demonstration project.

The Department also requested a listing of the facilities that your staff believes provide care that does not meet benchmark standards. As of the date of this letter, we have not received this list and as a result, have not been able to evaluate your findings as accurately as we would like.

GENERAL:
Our general observations focus on three areas: Policy Analysis, PCI Exceptions, and Regulation Enforcement.

Policy Analysis
The issue of how to control and improve quality in health care facilities is very complex. Legislators, regulators and policy analysts have not yet developed a national consensus on the best policy framework to use. There are three generally accepted policy approaches:

1. CERTIFICATE OF NEED (CON) MODEL: This model uses a set of non-marketplace supply restriction regulations and a highly complex quantitative analysis of outcome benchmarks.
2. REGULATORY MODEL: This model relies on rigorous compliance regulations and a robust consumer complaint system.
3. LEARNING MODEL: This model adopts a facility self-reporting and education model in which the reported data are analyzed for quality problem patterns, and the results are fed back to the reporting facilities, so they may implement policies and protocols that will prevent recurrence of these problems.

The Pennsylvania General Assembly has explicitly changed Commonwealth policy away from the CON model toward the regulatory and learning models. The Department has made every effort to comply with the changes required by the General Assembly.

The CERTIFICATE OF NEED statute sunset in 1996. That statutory sunset removed any legal authority that the Department had for establishing or enforcing quality benchmarks or limiting facility growth before a hospital could commence the provision of a service. The Department, under a prior administration, adopted compromise regulations that retained some very limited ability to use service data as one of the regulatory tools that could be incorporated into our traditional licensing survey. These regulations did not have explicit facility performance requirements, so even though the Department enforced these standards, the outcomes are not as effective as originally hoped.

The REGULATORY MODEL is embodied in the Health Care Facility Act (HCFA) and Department regulations. These requirements spell out in considerable detail the expectations the General Assembly and the Department have for facility performance, and the methods that the Department may use in enforcing those expectations in health care facilities. The legislation and regulation combine to establish minimum acceptable quality standards with which all facilities must comply. During the last several years the Department has improved our survey activity to substantially increase the amount of oversight in health care facilities. At the same time the Department has substantially increased our capacity to receive and manage consumer complaints.

The LEARNING MODEL is represented in the MCARE Act (Act 13 of 2002). This forward-looking statute moved Pennsylvania (PA) substantially ahead of other states by forming the Patient Safety Authority (PSA), along with very detailed requirements for reporting. There are three types of things that facilities must report to the Commonwealth: incidents, serious events, and infrastructure failures. The Department is now beginning to collect enough data to begin evaluating problem areas. In addition to reporting, Act 13 requires facilities to develop patient safety plans, establish patient safety committees, and designate patient safety officers.

The interplay of these three policy approaches and an analysis of the PA legislative history should be the foundation for any serious discussion of health care quality in the Commonwealth. Unfortunately, the report, Quality Assurance for Specialized Clinical Services, devotes all its attention to the CON model.

Even if this was the intended focus, the Department believes that your report would have been well served by a more balanced review of the literature and analysis of the consequences of the various policy options. For example, several notable organizations such as the U.S. Department of Justice and the World Health Organization have raised serious questions about the validity of the supply restriction, or CON model. Given the stature of these organizations, their position certainly warrants consideration. We believe that it is legitimate to periodically debate how best to control and monitor the operation of health care facilities in the Commonwealth. However, the issues incumbent to licensing health care facilities are complex and certainly warrant a more thorough debate.

PCI Exceptions

In looking at the issue of the appropriateness of hospitals without open-heart surgical services providing PCI services, the report notes the recommendation of the ACC on this issue. While it is correct that the ACC Guidelines of 2001 recommend that elective PCI be provided only in hospitals with open-heart surgical services, the report does not recognize that there are other studies and literature that have found that PCI services can be safely provided in hospitals without open-heart surgical services. Any comprehensive study of this issue should show that there is ongoing discussion in this area and that it is far from settled. The Department's discussions with hospital representatives, cardiac surgeons and cardiologists confirm that there is a wide variance of opinion on this matter. When Department representatives participated in a discussion of this issue at a meeting last year of the Pennsylvania Chapter of the American College of Cardiology, there was an acknowledgement that the issue of PCI services is unsettled and that data can be reviewed which suggest that the provision of certain PCI services in hospitals without open heart surgery is feasible.

In grappling with this issue and recognizing that this is an ever developing and changing area of medicine, the Department determined that it would balance the potential risk of providing PCI in a hospital without open heart surgical services with the benefits of making this service available to more Pennsylvania citizens. Those hospitals that are participating in the demonstration projects were able to show that they would be providing PCI services to individuals who otherwise would have to travel substantial additional distances to access this service. In the case of elective PCI services, the geographical distances involved could mean that the patient would not receive this vital service at all.

All of the above is not to suggest that the Department agrees that all hospitals should be permitted to provide PCI services. However, this Committee must realize that this is a complex issue with many diverse viewpoints and the subject of ongoing research and discussion. In being responsive to the direction of the General Assembly "to encourage innovation and continuous

development of improved methods of health care" (35 P.S. §448.102) the Department must consider these viewpoints and accommodate them where possible.

Regulation Enforcement
The Department is particularly concerned that the report implies that we failed to properly implement our regulations. We disagree with that implication and question whether the research examined how the survey process uses Pennsylvania Health Care Cost Containment Council (PHC4) data as part of that process.

A summary of that process follows:

The Department conducts full license surveys in each hospital at least every two years. In addition, we investigate any complaints received, and any serious events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) system. Our survey method is based on two techniques.

First, we walk through the facility to identify any obvious regulatory non-compliance. Second, we obtain a sample of patient care charts that will be investigated in detail for compliance with our regulations. To the extent that organ transplant, cardiac catheterization and open-heart surgery services are provided at the facility, we include those services as part of the patient chart review. We routinely receive reports from PHC4 that are used to select our sample of patient charts. We believe that this approach satisfies the requirements of our regulations, without being unduly burdensome to providers, or consume inordinate amounts of staff time trying to evaluate complex data reports. If either our walk through, or chart review indicates a quality problem in organ transplant, cardiac catheterization and open-heart surgery services, we expand the number of charts reviewed, and look at facility clinical procedures for these services. If we need additional information, we look at national benchmark data such as the national organ transplant database.

SPECIFIC:

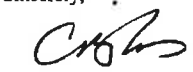
The Department would also like to call your attention to several specific concerns regarding the accuracy of portions of the report. The comments are arranged by page number.

1. **Page S-1** The statement that PA is one of 14 states without CON is inaccurate and misleading to the reader. For example, since much of the discussion relates to Percutaneous Coronary Intervention it should be noted that, according to 2004 data from the American Health Planning Association, an additional 14 states (including Virginia, Ohio, Delaware, Oregon) have limited CON programs. Of these, only 3 regulate PCI, and only 3 regulate open-heart. Thus 25, not 14 states do not regulate PCI through CON, and 24 do not regulate open heart, at least through CON.

2. **Page S-5** This section overstates the pre-CON sunset "after-the-fact" evaluation authority of the Department. After the initial volume projections were reviewed during the application process; no further monitoring or remediation was conducted. Therefore, suggestions that CON somehow provided a tighter monitoring process are inaccurate.
3. **Page S-6** First bullet. There is no normative data presented regarding the number of hospitals offering specialized services. For example, is the number of Pennsylvania programs per 100,000 population high or low compared to the U.S.?
4. **Page S-7** First bullet. The statistic as stated distorts the dimension of the issue. For example, when compared to the total number of cardiac catheterization programs not in compliance, it should be noted that those seven hospitals represent only 6.5% of the total number of programs.
5. **Page S-7** Third bullet. To be meaningful, the data should be normalized for acuity. For example, PA also has the third-largest population over the age of 65. Additionally, according to the Bureau of Health Statistics and Research, PA has a significantly higher age-adjusted rate of cardiovascular disease and coronary heart disease per 100,000 population than the U.S. Therefore, a higher rate of PCI may be explainable.
6. **Page S-8** First bullet. Is this an age-adjusted mortality rate? What is the statistical significance of this comparison? Why was New York selected as the baseline comparison as opposed to U.S. data?
7. **Page 14** The 1994 State Health Services Plan is 11 years old, and is based on data several years older than that. It is invalid to compare these data to the 2005 health services market place. The authority and basis for the plan sunset in1996 and it no longer reflects Commonwealth policy.
8. **Page 24-25** The report includes charts comparing PA standards to other states. According to the report, states were selected according to populations and proximity to Pennsylvania. Only 8 states are included in the comparison. This leaves this reviewer wondering if any bias crept into the selection of the comparison states.
9. **Page 38** The tables are presented in a manner that may possibly distort the magnitude of the problems. Without providing the Department with the names of the facilities, it is impossible to evaluate the allegations.

Thank you for the opportunity to review and provide comments on the draft report, Quality Assurance for Specialized Clinical Services. If we can be any further assistance, please feel free to contact me.

Sincerely,



Calvin B. Johnson, M.D., M.P.H
Secretary of Health

Enclosure

Commonwealth of Pennsylvania **CORRECTED COPY**

DEPARTMENT OF HEALTH
P. O. BOX 90
HARRISBURG 17108-0090

January 27, 2005

DEPUTY SECRETARY FOR
QUALITY ASSURANCE

(717) 783-1078

Mr. Philip R. Durgin, Executive Director
Legislative Budget and Finance Committee
Room 400, Finance Building
Harrisburg, Pennsylvania 17105

Dear Mr. Durgin:

Thank you for sharing a draft copy of your study entitled Quality Assurance for Specialized Clinical Services. We have begun our review, and we believe that we can improve the quality of our response by obtaining thoughts directly from several of the organizations you mention in your confidential draft.

First, the recommendations in the report specifically address a variety of hospital issues. In order to provide a thorough review of the document, we respectfully request permission to share the draft report with the Hospital and Health Systems Association of PA (HAP). We believe that they may have useful observations to suggest regarding your findings.

Second, you make two specific recommendations regarding the PCI demonstration sites. We would like your permission to share your draft with those sites so that we could incorporate their opinions into our response. We believe that they may be in a better position to directly comment on your recommendations.

Third, I would like to formally restate the written request that I gave you at the meeting. Your staff made specific reference to hospitals that provide care that does not meet benchmark standards. Please provide us with a list of those facilities so that we can review our files to determine whether we concur with your findings. It is my understanding that there is no data confidentiality restriction on sharing your detailed analysis since we are the ones that originally provided the data to your staff.

Thank you for your consideration of these three requests.

Sincerely,

Richard H. Lee

cc: Dr. Johnson
Ms. Matio
Ms. Wolf
bcc: Mr. Lee
File