

POLICY PERSPECTIVE

By John Steen

In my column in the previous newsletter, I reported that a committee of the Pennsylvania state legislature had issued a report critical of the DOH's pilot two-year demonstration project in which 11 hospitals without open heart surgical capability had been granted a waiver from licensure requirements in order to permit them to perform non-emergent PCI (percutaneous coronary intervention). It found that in these hospitals, elective therapeutic cardiac catheterizations were being done contrary to national quality benchmarks and against American College of Cardiology (ACC) guidelines. Its criticisms have revived the question of how the state should be regulating health care in a post-certificate of need (CON) era. The state permitted its CON program to expire in 1996, and has been relying on its licensure process to regulate over the past nine years.

This report reflects a growing realization by legislators that the state has lost its ability to adequately regulate the proliferation of specialized, high-profit clinical procedures, chief among them CABG (23 new programs have been established since 1996) and PCI, and that it has lost its control of quality and cost issues in general. In its discussions preceding the report, consideration was given to restoring health facility performance standards, including proficiency volume, as conditions of licensure. Among the report's findings was that one-third of Pennsylvania's open heart surgery programs have volumes below proficiency standards being used by other states, and that some of them have mortality rates exceeding national benchmarks.

Its review of PCI outcomes reports the following relation between volume and mortality:

<u>Facility PCI Annual Volume</u>	<u>Observed Mortality Rate (in hospital)</u>
>400	1.35%
<400	1.41%
<200	1.46%
<100	1.73%

Legislation introduced in the Pennsylvania General Assembly would require the DOH to form a cardiac oversight committee working with the ACC's Pennsylvania Chapter, to develop clinical guidelines to inform hospital regulations, develop performance criteria – including complication rates and mortality and proficiency volumes – for highly specialized cardiac services, and develop guidelines for peer review. This is a process that New York State has been using effectively since the era of health planning in the 1960s. The DOH once had a Cardiac Catheterization Oversight Committee and as recently as 1995 when CON criteria applied to PCI volume, the DOH convened the

committee to review hospitals that were performing low volumes of diagnostic and therapeutic catheterizations. In undertaking its PCI initiative, the DOH failed to respond to offers from the ACC to provide its expert assistance in overseeing results. The legislature noted that New York also requires a minimum annual volume of 400 procedures, and it achieves a mortality rate that is only one-half that of Pennsylvania.

The American College of Cardiology and American Heart Association guidelines currently say elective angioplasty should not be performed in hospitals without the ability to perform cardiac surgery, but the Johns Hopkins School of Medicine has just launched a national three-year clinical trial study of more than 16,000 patients to better determine the safety and efficacy of angioplasty in non-emergency situations. About 40 community hospitals are expected to participate in the study. Special waivers from state authorities are required for participating community hospitals. In addition to the waiver from their state government, participating community hospitals must also have a combined emergency and elective angioplasty volume of at least 200 cases per year and a staff whose training meets national standards set by the American Heart Association and American College of Cardiology. States that have been asked to participate include Alabama, Georgia, Illinois, New Jersey, Ohio, Pennsylvania, Maryland, and Washington. Officials of the first six states listed have already granted the waivers. Funding for the study is provided by participating hospitals. For an account of this, see: http://www.bizjournals.com/industries/health_care/hospitals/2005/09/05/baltimore_story3.html.

Upon the legislature's recommendation, the DOH has agreed to make participation in a national clinical trial a condition of renewal for all waiver sites, and will seek to enter them in the Johns Hopkins national trial.

In its response to the legislature, the DOH noted the legislature's failure to restore CON in the state while using the CON model in criticism of DOH regulation, stating that **the validity of such a policy framework has been seriously questioned by the U.S. Department of Justice and the World Health Organization**. Calling CON "a set of non-marketplace supply restriction regulations and a highly complex quantitative analysis of outcome benchmarks," DOH stated that with the demise of CON, it had lost any statutory authority to establish or enforce quality benchmarks, and current regulations do not have explicit facility performance requirements. DOH is currently working under hospital licensure regulations that are over 20 years old. Though the legislature is no longer entertaining the restoration of CON in Pennsylvania, it is considering legislation to expand the DOH's authority to regulate using quality and safety standards for licensure. Under CON, criteria for quality were established legislatively, but it is now proposing the establishment of a clinical advisory committee that would develop the quality indicators and analyze performance data, conduct clinical peer review and recommend licensure actions against a hospital that failed to meet key quality indicators and correct deficiencies.

In August, DOH released a draft version of its health care facility regulations for comment, including

- A new licensure category, that of *outpatient ambulatory health care facility*, defined as providing emergency services, cardiac catheterization services, cancer treatment services involving radiation therapy, imaging services, pain management services, burn center services, and ambulatory surgery services.
- Minimum charity care levels and limitations on collection practices for hospitals and outpatient ambulatory care facilities.
- Minimum nurse staffing ratios for critical care, intensive care, coronary care, and neonatal intensive care units, and requirements to report nurse staffing ratios for each patient care unit of a hospital or outpatient ambulatory care facility.
- A requirement for any publicly-traded company to obtain DOH approval prior to operating a health care facility.

State regulators are properly concerned about maintaining the highest volumes feasible under the circumstances for all specialized medical procedures requiring special skills. Evidence of the efficacy of this continues to grow, and a new study reported in the September 1, 2005 issue of *Cancer*, the peer-reviewed journal of the American Cancer Society, indicates that post-operative mortality and complications for cystectomy -- the surgical removal of the urinary bladder -- were reduced by up to 75 percent in the best-case scenarios. Mortality was higher in low-volume hospitals compared with high-volume hospitals (3.1% vs. 0.7%; $P < 0.001$). Investigators led by Linda S. Elting, Dr.P.H. of the University of Texas M. D. Anderson Cancer Center in Houston, collected and analyzed data from 1302 bladder cancer patients who underwent cystectomy between January 1, 1999 and December 31, 2001 in all 133 Texas hospitals. They found about 12 percent had post-operative complications and about 2.2 percent died. But hospitals performing over 10 cystectomies per year had statistically significant lower mortality and morbidity rates. Mortality was reduced by almost 75 percent and complications were reduced by approximately 50 percent at the high-volume hospitals. **Interestingly, hospitals with a high registered nurse-to-patient ratio reduced post-operative mortality by more than 50 percent regardless of the hospital's cystectomy volume.**

To see the article, "Correlation between annual volume of cystectomy, professional staffing, and outcomes: A statewide, population-based study," go to:
<http://www3.interscience.wiley.com/cgi-bin/abstract/110552670/ABSTRACT>.