

## Report Highlights

### Quality Assurance for Specialized Clinical Services

House Resolution 356 directed the LB&FC to identify health care facilities providing specialized clinical services such as cardiac catheterization, open heart surgery, and organ transplantation; standards for their safe and effective provision; and how their quality is ensured in Pennsylvania and other states.

#### Findings:

- **National medical and health associations establish standards for services with high risks of serious complications.** Standards, including proficiency volumes and expected survival rates, have been developed by the American College of Cardiology and the American Heart Association (ACC/AHA) for cardiac services, and the Organ Procurement and Transplant Network (OPTN) for organ transplants. The federal Agency for Healthcare Research and Quality (AHRQ) recognizes such measures and recommends those performing below minimum procedure volumes and having mortality rates above its benchmarks engage in quality assurance reviews.

- **States often include volume standards in licensure and/or certificate of need (CON) requirements.** Maryland, Massachusetts, New Jersey, and Ohio, for example, require therapeutic catheterization providers perform at least 200 procedures annually (the ACC/AHA minimum). Florida, Michigan, New York, and West Virginia require 300 to 400 procedures (ACC/AHA recommended). Florida, Maryland, Massachusetts, Michigan, Ohio, and West Virginia require 200 to 300 open heart procedures, New Jersey 350, and New York 500.

As a result of PA's CON program sunseting in 1996, PA no longer has such minimum volume requirements. Instead, in 1998 DOH issued regulations incorporating some ACC/AHA standards (e.g., elective therapeutic catheterization only be performed at facilities with open heart surgery) and requiring cardiac providers submit data on procedure volume, complications (e.g. strokes), mortality, and risk factors for DOH review and quality assurance follow-up if indicated. Transplant programs that do not meet OPTN's expected survival rates are to be reviewed by DOH. We found little evidence, however, that DOH was using such data to target programs for review.

- **Cardiac programs started under CON met ACC/AHA minimum proficiency volume for therapeutic catheterizations in 2002, but one-third of those that started after did not.** Most (87%) such catheterizations from 2000 through

2003 were performed at programs meeting the ACC's recommended volumes with mortality rates lower than the national rate (1.35% vs. 1.46%), though programs performing less than 100 procedures had higher mortality (1.78%). New York, assisted by a cardiac advisory committee, has improved its cardiac care and reduced its mortality to one-half that of PA providers.

- **PA CABG surgeries declined 15% from 1995 to 2002, while 18 new programs opened.** In 2000, New York and New Jersey providers performed 50% more procedures than PA's. Mortality has declined for all PA CABG surgeons, but high volume surgeons (200 per year) have mortality rates 34% lower than the average statewide.

- **DOH has granted exceptions to its regulations to allow certain facilities without open heart surgery to perform elective therapeutic catheterizations.** All such hospitals have not had experience performing diagnostic catheterizations, and typically programs with open heart surgery are available within one hour's travel time. New Jersey and Maryland may start to permit such practices, but only at facilities that are part of a national clinical trial.

- **Although over one-half of PA adult transplant programs have lower than expected one-year patient survival rates, the differences are not significant for most programs.** The number of transplant programs in PA has remained stable since 1996. Nationwide, 10% of adult kidney, liver, heart, and lung programs had lower than expected one-year patient and graft survival rates that met all of the criteria used by the OPTN to "flag" possible poor performance. In PA, 8.6% meet all such criteria.

#### Recommendations:

DOH should:

- Use the data cardiac and transplant programs submit to assure quality of care.
- Form a cardiac oversight committee.
- Require elective therapeutic catheterizations be performed at programs with open heart surgery, except for providers participating in a national clinical trial.