

# POLICY PERSPECTIVE

By John Steen

## Angioplasty and CON.

One of the many controversial regulatory policies in the states is that of either permitting or prohibiting high-risk cardiac catheterization known as percutaneous coronary intervention (PCI), or angioplasty, without onsite open-heart surgical backup. Pennsylvania is among the states that have prohibited it out of concerns for safety, but also entertained the arguments of community hospitals in rural and medically underserved areas for increasing access in their areas, especially for minority populations. For three years now, the Pennsylvania Department of Health has been quietly conducting a pilot demonstration project of limited scope under which 11 such hospitals were approved through a waiver of Department regulations. Participating hospitals are required to adhere to certain operating conditions that are largely based on American College of Cardiology (ACC) guidelines. This includes a formal written agreement for immediate (within 1 hour) transfer of a patient to a cardiac surgical facility should the need arise. Furthermore, the hospitals' informed consent form must state that the PCI procedure is being done under a waiver from the Department's regulations and is not completely supported by the ACC guidelines. Patients considered for elective PCI must also undergo careful screening and risk stratification. Those who cannot meet the selection criteria and may be more likely to have an adverse outcome are transferred to a cardiac surgical facility for PCI. The project has allowed the hospitals to treat coronary artery blockages by inserting stents, a simpler, lower cost procedure than the CABG surgery performed at major medical centers.

As a specialized, high-risk procedure, stenting is subject to the now familiar volume-quality-cost proficiency/efficiency dynamic. The ACC and the American Heart Association (AHA) recommend that hospitals do 400 therapeutic catheterizations a year in order to achieve mortality rates of 1.35 percent or less. The highest volume cath labs in the largest medical centers commonly have rates under 1 percent. The hospitals in this pilot project have fallen far short of the recommended 400 procedures in their first and second years.

In April, the state's Legislative Budget and Finance Committee issued a report critical of the project. The report outlined serious patient safety concerns and lapses in hospital reporting of complications, and even of deaths ensuing from the procedures that were never reported to the Health Department. It also found that the hospitals don't have standardized informed patient consent forms, raising serious questions about whether patients having these procedures at the hospitals fully understand the risks. And it found that most cardiac cath were not done within two hours of patient arrival at the hospital as recommended by the ACC and the AHA and mandated by the state Department of Health. On May 23, the Health Department decided to suspend hospital enrollment in the project.

## **Specialty Hospitals.**

After consideration of the MedPAC report (described in my previous column), CMS delivered its own report to Congress on May 11. It outlines four essential steps CMS plans to take to correct system problems that may unfairly advantage physician-owned specialty hospitals:

- Reform payment rates for inpatient hospital services through changes to the DRG system. CMS wants to make the adjustments by the end of 2006.
- Reform payment rates for ambulatory surgical centers.
- Closer scrutiny of whether facilities meet the definition of a hospital. If a facility fails to meet that definition, then it could be classified as an ambulatory surgical center, which gets lower reimbursement rates than hospitals.
- Review of procedures for approval for participation in Medicare.

The last two recommendations may take as long as six months to accomplish. A copy of the full report to Congress is available on the CMS Web site:

<http://www.cms.hhs.gov/media/press/files/052005/RTC-StudyofPhysOwnedSpecHosp.pdf>.

Sen. Charles Grassley, R-Iowa, and Sen. Max Baucus, D-Mont., introduced a bill on May 11 that prohibits physicians from referring Medicare and Medicaid patients to new specialty hospitals in which they have an ownership interest, and set the effective date of the bill at June 8, 2005, when the current moratorium expires, regardless of when it is enacted. Though passage appears unlikely, there will be a de facto moratorium by CMS. Mark McClellan, the administrator of CMS, said his agency will stop processing specialty hospital applications - which are needed for Medicare reimbursement - while it considers changes to payment rules for the facilities. By the time such changes are made, they should govern the process through redrawn financial incentives, obviating the need for further process restrictions.

Sen. Tom Coburn (R-Okla.), chair of the Senate Homeland Security and Governmental Affairs Subcommittee on Federal Financial Management, Government Information and International Security, on May 24 held a hearing to address whether the federal government should regulate physician-owned specialty hospitals. Coburn said that the hearing is just the first on the issue, adding that he wants to establish a record to address the matter.

According to a Government Accountability Office report scheduled for release in the second week of June, an additional 37 specialty hospitals could open within the next one to two years without action by the federal government. The report, prepared for Grassley and Baucus, also found that CMS approval of the specialty hospitals under development would double the current number of facilities. Currently, there are about 130 specialty hospitals in the nation.

Meanwhile, a peer-reviewed research study concluded that “the lower unadjusted mortality rate after cardiac revascularization in specialty cardiac hospitals is accounted for by their healthier patients and higher procedural volumes,” and “our study provides no definitive evidence that cardiac specialty hospitals provide better or more efficient care than general hospitals with similar procedural volumes.” Cardiac Revascularization in Specialty and General Hospitals, Peter Cram, M.D., M.B.A., Gary E. Rosenthal, M.D., and Mary S. Vaughan-Sarrazin, Ph.D. *NEJM* 352: 1454-1462 (April 7, 2005), pp.1454, 1461. Accessible at <http://content.nejm.org/cgi/content/abstract/352/14/1454>.

### **Universal Health Care Revisited.**

That is the title of my article in the current newsletter of the Community Health Planning and Policy Development Section of the American Public Health Association. For APHA members, it may be accessed at <http://www.apha.org/newsletter/>. In it, I make the point that cost issues are the stumbling blocks that prove insurmountable for state initiatives, as well as a determinant of the feasibility of true reform on a national level:

Can there be any solution to this short of a federal takeover of the financing of health care? With its own rapidly growing costs for an expanded Medicare program and over half the costs of Medicaid, how else but by realizing the administrative efficiencies of a single-payer health care system can the federal government accomplish it? By consolidating federal, state, and private health insurance programs under one administration, the savings could be more than sufficient to fund a true universal health care program.

On May 23, 2005, the National Coalition on Health Care issued a press release, “New Projections From Nation's Largest Health Care Coalition Show Health Care Reform Would Produce Huge Savings,” accessible at [http://www.nchc.org/news/press\\_releases/2003/2005\\_05\\_23.pdf](http://www.nchc.org/news/press_releases/2003/2005_05_23.pdf). Its projections show that system-wide health care reform would save much more money than it would cost. In four scenarios for reform analyzed by Professor Kenneth Thorpe of Emory University, the investment needed to achieve universal health coverage would be more than offset by savings. In each case, the cost of a reformed system would be much less than the cost of continuing with the current “system.” Thorpe projected the total change in spending for years 2006 through 2015 under four scenarios (in comparison with the status quo):

Employer mandate supplemented by individual mandate: \$320 billion reduction.

Expand existing programs to expand coverage: \$320 billion reduction.

Develop new program modeled after the FEHB (federal employees' program): \$370 billion reduction.

Universal publicly financed program ("single payer"): \$1136 billion (\$1.136 trillion) reduction.