New State Rules for Catheter Procedures May Help Rural Patients, Hospitals

by George Lauer, California Healthline Features Editor
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A new California law that took effect this year changed state regulations to allow more California hospitals to perform catheter-based cardiac diagnostic and treatment procedures.

The policy shifts could cut miles and hours off cardiac patients’ drive time in rural parts of the state and could mean expanded services and revenues for regional and rural hospitals.

Last year’s bill calling for the new regulations—SB 906 by Lou Correa (D-Santa Ana)—came relatively late in the national trend toward allowing more hospitals to perform angioplasty and stent procedures.

Depending on the source, California is either the 45th or the 48th state to change the rules governing elective percutaneous coronary intervention, known as PCI—a nonsurgical technique to treat obstructive coronary artery disease. Procedures include coronary angioplasty, as well as the placement of arterial stents.

David Perrott, senior vice president and CMO of the California Hospital Association, said his organization estimates that 20 to 30 hospitals in the state will qualify under the new regulations.

“It will really help the hospitals way up in the northern part of the state—especially those that already have catheter labs,” Perrott said.

Patients also will benefit, said Lou Vadlamani, chief medical officer for CardioSolution, a national company specializing in helping rural and regional hospitals establish and run cardiac catheter units.

“We’ve been doing this for more than a decade in other states and we’re really glad to see it finally coming to California,” Vadlamani said. “It’s good for rural hospitals, certainly, but it’s the patients who really get the most out of it because they save time and money and hassle by not having to go the nearest cardiac surgery hospital, which could be hours away.”

California’s ‘Slow, Careful’ Road to New Rules

The new regulations allow general acute care hospitals that are licensed to provide cardiac catheterization laboratory service to be certified by the California Department of Public Health to perform scheduled, elective PCI procedures. Hospitals must demonstrate the ability to comply with recommendations of three organizations—the Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation and the American Heart Association.
Perrott said California health officials took a “slow, careful,” approach to formulating and then passing new PCI regulations.

“When ballooning and stenting started back in the ‘80s, there was a feeling that you had to have a cardiac surgery program on premises at the hospital to do that kind of procedure. But over the years, technology and techniques have improved, and it’s become evident and widely accepted that you don’t need to have cardiac surgery backup,” Perrott said.

“When California first looked at changing the regulations, the state arranged for a four-year study examining six hospitals,” Perrott said.

“For high-risk people, you’d probably still transfer them out, but for most people, regional and rural hospitals will be just fine. In fact, the California chapter of the American College of Cardiology found that in these facilities outcomes and mortality was equal to or better than hospitals with cardiac surgery backup,” Perrott said.

### 2009 Study Seen as Start of National Shift

Vadlamani said the national trend toward allowing more hospitals to perform PCI procedures began after a 2009 study showed no increased risk when hospitals without cardiac surgery units performed PCI procedures.

“The 2009 C-PORT study (cardiovascular patient outcomes research team) “was really the beginning for this,” Vadlamani said. “Since then, most states have done their own research, including California, and all have come to the same conclusion that you don’t have to have cardiac surgery onsite to offer high-quality PCI.”

California was the 48th state to rewrite PCI regulations, according to Vadlamani. Perrott said it was 45th. Either way, California is clearly one of the last states to change the rules.

“This is not reinventing the wheel,” Vadlamani said. “Now California hospitals have the opportunity to join the 21st century.”

### Details Still Being Hammered Out

Although the new law took effect Jan. 1, the actual regulations governing PCI at non-cardiac surgery facilities have yet to be worked out.

Once the three organizations – SCAI, ACCF and AHA – agree on the details, state officials will issue formal language.

“We hope the regulations will be finalized in the next few months,” Perrott said.