



MEMORANDUM

RE: Emergency Only PCI Programs: A Possible Stepping Stone to a Level I Adult Cardiovascular Services Program for New or Lower Volume Diagnostic Catheterization Labs

DATE: September 20, 2010

In 2004, the Florida Legislature dramatically changed the landscape for regulation of cardiovascular services in Florida. Gone are the days of CON review and protracted litigation over the right to implement an open heart surgery program, or an interventional cardiology program offering Percutaneous Coronary Interventions (PCI). Today, these programs are managed through the simple filing of an "Attestation" to meet either Level I requirements (adult cardiovascular and interventional PCI without onsite open heart surgery backup) or Level II requirements (adult cardiovascular and interventional PCI with onsite open heart surgery). In either instance, the hospital CEO simply attests that certain volume thresholds have been met to qualify for the license, and that the hospital will follow the applicable licensure and rule standards.

For Level I programs the volume thresholds are:

- a) 300 adult inpatient and outpatient diagnostic caths performed in past 12 months, or
- b) discharge or transfer of 300 inpatients with principal diagnosis of ischemic heart disease

For Level II programs the volume thresholds are:

- a) 1100 adult inpatient and outpatient diagnostic caths performed in past 12 months, or
- b) 800 patients with principal diagnosis of ischemic heart disease discharged in past 12 months

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While these volume thresholds are adequate for hospitals that have a well-established diagnostic cardiac cath lab program, there are some hospitals with new or lower volume diagnostic cardiac cath programs that do not meet the volume threshold for a Level I program.

A possible stepping stone for a diagnostic cardiac catheterization program that is new, or is seeking to increase its volume is to obtain approval for an “emergency only” PCI program under the CON exemption criteria contained in Section 408.036(3)(n), Florida Statutes. While this provision of law has not been utilized since the final adoption of new licensure rules, it remains a valid avenue that can result in increased utilization of a diagnostic cath lab. Many county EMS programs direct all patients suffering from ST segment elevated acute myocardial infarctions (STEMI) only to hospitals with approved PCI programs. The bypassing of hospitals without PCI programs can also be extended by cautious EMS programs to all types of chest pain or suspected cardiac patients. The approval of an “emergency only” PCI exemption allows the hospital to capture back some of the ambulance traffic that bypasses the hospital with only a diagnostic cath lab. This not only allows for the faster treatment of STEMI patients at a closer hospital, but also allows the hospital to increase its diagnostic cath volume as more patients use the ER as an access point for cardiac related emergencies.

While an “emergency only” approval can increase cath lab volumes, history has shown that such programs are expensive to operate, as hospitals must assure 24/7 call coverage with experienced and qualified staff in the cath lab. This added expense will need to be considered by the hospital in deciding whether to seek to use an “emergency only” program as a stepping stone to a full Level I PCI program that allows for performance of a full range of both emergency and elective PCI procedures. Once the volume of 300 diagnostic caths is reached for a rolling 12 month period, the hospital can “step up” to the Level I program. For some hospitals, the right choice may be to wait until the volume of diagnostic caths is sufficient to warrant a full Level I program. However, other hospitals may find that an emergency only PCI program will give the added volume that is needed to meet the volume threshold as a Level I program.

If you would like more information about how to apply for an emergency only PCI program, please call Geoff Smith at 850-297-2006.