Amendment to Cardiac Services Section of Alabama State Health Plan Approved by SHCC January 29, 2013

5. Planning Policy

All cardiac catheterization services without open-heart surgical capability ("OSS") shall have written transfer agreements with an existing open-heart program located within 45 minutes by air or ground ambulance service door to door from the referring facility. Acute care hospitals providing diagnostic cardiac catheterization services may provide emergency interventional/therapeutic cardiac catheterization procedures. Notwithstanding anything in the State Health Plan to the contrary, an acute care hospital without on site openheart surgery capability may provide elective percutaneous coronary intervention (PCI) if the following criteria are met:

- 1. The hospital shall maintain twenty-four (24) hour, seven (7) day a week coverage by at least one interventional cardiologist and catheterization laboratory team for primary PCI treatment of ST elevation myocardial infarction.
- 2. The hospital shall participate in a recognized national registry for cardiac catheterizations and PCI procedures, such as the National Cardiovascular Data Registry (NCDR).
- 3. The hospital shall obtain informed patient consent for all elective PCI procedures, including an informed consent process in which it is clearly stated that the hospital does not offer OSS, and which clearly states that the patient may request at any time to be transferred to a hospital with OSS to undergo the PCI procedure.
- 4. The hospital shall conduct quarterly quality reviews of the elective PCI services under supervision of its serving interventional cardiologists.
- 5. The hospital shall demonstrate that applicable requirements in Planning Policy 2(ii) of this subsection (Ala. Code 410-2-3-.03(1)(b)(2)) will be met.
- 6. Hospitals shall use their best efforts to perform a minimum of 200 PCI cases per year. Any hospital performing less than 150 cases per year after the second full year of PCI operations must agree to an independent quality review of its program by an outside interventional cardiologist who is a member of the American College of Cardiology and to report a summary of such quality review confidentially to the Executive Director of SHPDA.

The CON Review Board shall also consider the most recent recommendations/guidelines for elective cardiac catheterizations adopted by the American College of Cardiology Foundation, the American Heart Association Task Force on Practice Guidelines, and the Society for Cardiovascular Angiography and Intervention as an informational resource in considering any CON application for elective PCI services.