



News Release

PO Box 360, Trenton, N.J. 08625-0360

Mary O'Dowd, M.P.H.,
Acting Commissioner

For Release:
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Department of Health and Senior Services Proposes Amendments to Establish Criteria for Continued Participation in the Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-Port-E) Trial.

The Office of Certificate of Need and Healthcare Facility Licensure in the Health Facilities Evaluation and Licensing Division of the Senior Services and Health Systems Branch of the Department of Health and Senior Services (Department) proposes amendments to allow continued participation by New Jersey hospitals, through a demonstration project, in the Atlantic C-Port-E trial as it transitions to a registry.

The Atlantic C-PORT-E trial is a multi-state randomized clinical trial of elective angioplasty or percutaneous coronary intervention (PCI) in hospital settings with and without on-site cardiac surgery. The original Department approvals required facilities to cease participation in the Atlantic C-PORT-E trial once enrollment concluded. The proposed amendments would allow qualified elective angioplasty demonstration projects to continue to provide elective PCI as participants in the Atlantic C-PORT-E registry, which will commence once the Atlantic C-PORT-E trial has reached its patient enrollment target of 18,360.

The notice of proposal appears in the April 4, 2011, issue of the New Jersey Register. LexisNexis® provides free on-line public access to the New Jersey Administrative Code and the New Jersey Register at <http://lexisnexis.com/njoal>.

The public has until June 3, 2011, to comment on the proposal. Persons wishing to comment on the proposal must submit their comments in writing to Devon L. Graf, Director, Office of Legal and Regulatory Compliance, New Jersey Department of Health and Senior Services, PO Box 360, Trenton, NJ 08625. Written comments on the proposal must be postmarked on or before June 3, 2011, which is the close of the 60-day public comment period for the proposal.